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2020
Medical Device Approval Report

2021 July

Ministry of Food and Drug Safety

Director for Novel Products Approval

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Overview of Approval, Certification, and Notification of Medical

Ⅰ. Overview of Approval, Certification, and Notification of Medical Devices

The 2020 Approval Report compiles and analyzes the status of the approval, certification, and notification of medical devices in continuation of the 2019 Approval Report. Moreover, the document shares the data to support the establishment and execution of the relevant policies; improve the systematicity and efficiency of approval, certification, and notification; and support companies in developing new products.

Ⅰ-1. Approvals, Certifications, and Notifications by Year

A review of approvals, certifications, and notifications over the last 5 years shows that the total number of approval/certification/notification cases was 8,183 in 2020, 8,269 in 2019, 7,745 in 2018, 8,308 in 2017, and 8,236 in 2016.

According to an overview of notifications by year, although importation was relied on about twice as much, the percentage of manufactured products relative to imported products was higher in certification and approval, where technical documentation has to be reviewed, and high potential risk is involved. The total number of approvals, certifications, notifications decreased temporarily in 2018 and has been exhibiting a sideways trend since 2019. The number of manufacturing approvals was found to be 1,132, which was 40.8% larger than the previous year due to the increase in development of diagnostic reagents for COVID-19.

[Table 1] Overview of Approvals, Certifications, and Notifications by Year (2016-2020)

(Unit: Number of products)

Category	Notification		Certification		Approval		Total
	Manufactured	Imported	Manufactured	Imported	Manufactured	Imported	
2016	1,538	3,482	941	705	988	582	8,236
2017	1,462	3,654	982	795	924	491	8,308
2018	1,740	2,966	1,049	852	811	327	7,745
2019	1,763	3,448	1,038	859	804	357	8,269
2020	1,963	2,906	1,127	825	1,132	230	8,183
Total	**8,466**	**16,456**	**5,137**	**4,036**	**4,659**	**1,987**	**40,741**
	24,922		**9,173**		**6,646**		

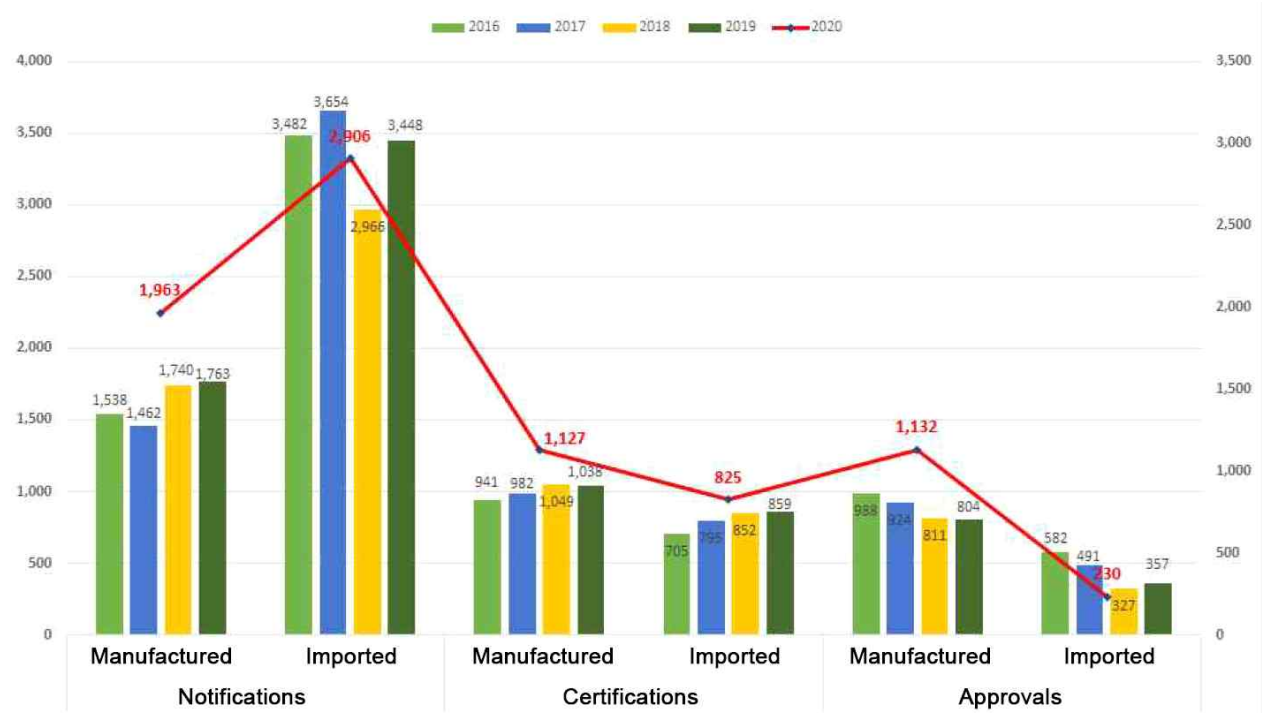


Figure 1. Overview of Approvals, Certifications, and Notifications by Year (2016-2020)

The total number of approvals, certifications, and notifications over the last 5 years was 40,741, which consists of 6,646 approvals (16.3%), 9,173 certifications (22.5%), and 24,922 notifications (61.2%). In 2020, the number of approvals and notifications increased compared to the previous year (approvals by 201 (17.3%) and notifications by 55 (2.9%)).

Meanwhile, the number of approvals, certifications, and notifications over the last 5 years (2016-2020) was 6,646 (16.3%), 9,173 (22.5%), and 24,922 (61.2%), respectively, after the introduction of technical document review by private entities (2015.7.29). Since 2016, it has been found that certification-related affairs increased more compared to approval-related affairs after the full-scale implementation of the review.

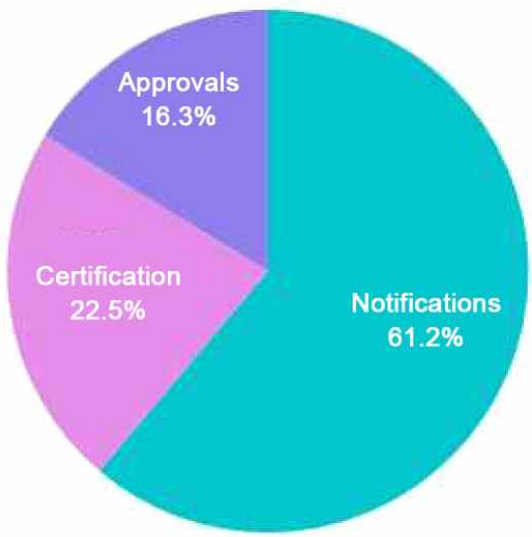


Figure 2. Percentages of Approved, Certified, and Notified Items Over the Last Five Years (2016-2020)

Figure 3. Approvals, Certifications, and Notifications by Year (2016-2020)

Among the approved, certified, and notified medical devices, the percentages of manufactured and imported devices were, respectively, 51.6% and 48.4% in 2020, 43.6% and 56.4% in 2019, 46.5% and 53.5% in 2018, 40.5% and 59.5% in 2017, and 42.1% and 57.9% in 2016. The ratio between manufactured and imported devices remained at approximately 4:6 from 2016 to 2019, and in 2020, the percentage of manufactured devices, which rose 8% compared to the previous year, exceeded that of imported devices for the first time after 2016.

[Table 2] Approval, Certification, and Notification of Manufactured/Imported Devices by Year (2016-2020)

(Unit: Number of products)

Category	2016	2017	2018	2019	2020
Imported	4,769 (57.9%)	4,940 (59.5%)	4,145 (53.5%)	4,664 (56.4%)	3,961 (48.4%)
Manufactured	3,467 (42.1%)	3,368 (40.5%)	3,600 (46.5%)	3,605 (43.6%)	4,222 (51.6%)
Total	**8,236**	**8,308**	**7,745**	**8,269**	**8,183**

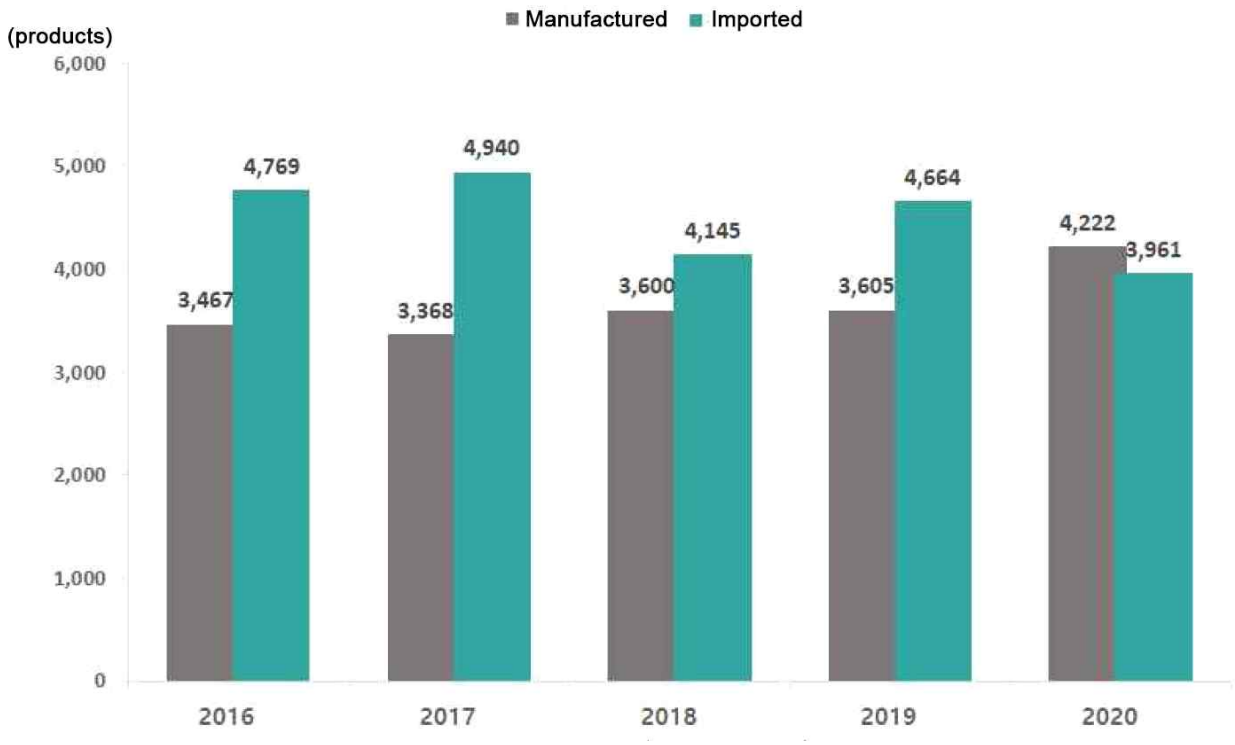


Figure 4. Approval, Certification, and Notification of Manufactured/Imported Devices by Year (2016-2020)

The number of revised approvals and certifications over the last 5 years decreased rapidly in 2017 and increased by 20.8% compared to the previous year to 8,348 in 2018. As of 2020, it is maintaining a growing tendency. The rapid decrease in 2016 and 2017 is considered to be attributed largely to the difficulties associated with the application of the Common Standard Specifications on Electric and Mechanic Safety of Medical Devices, which has been effective since 2015 when it was revised.

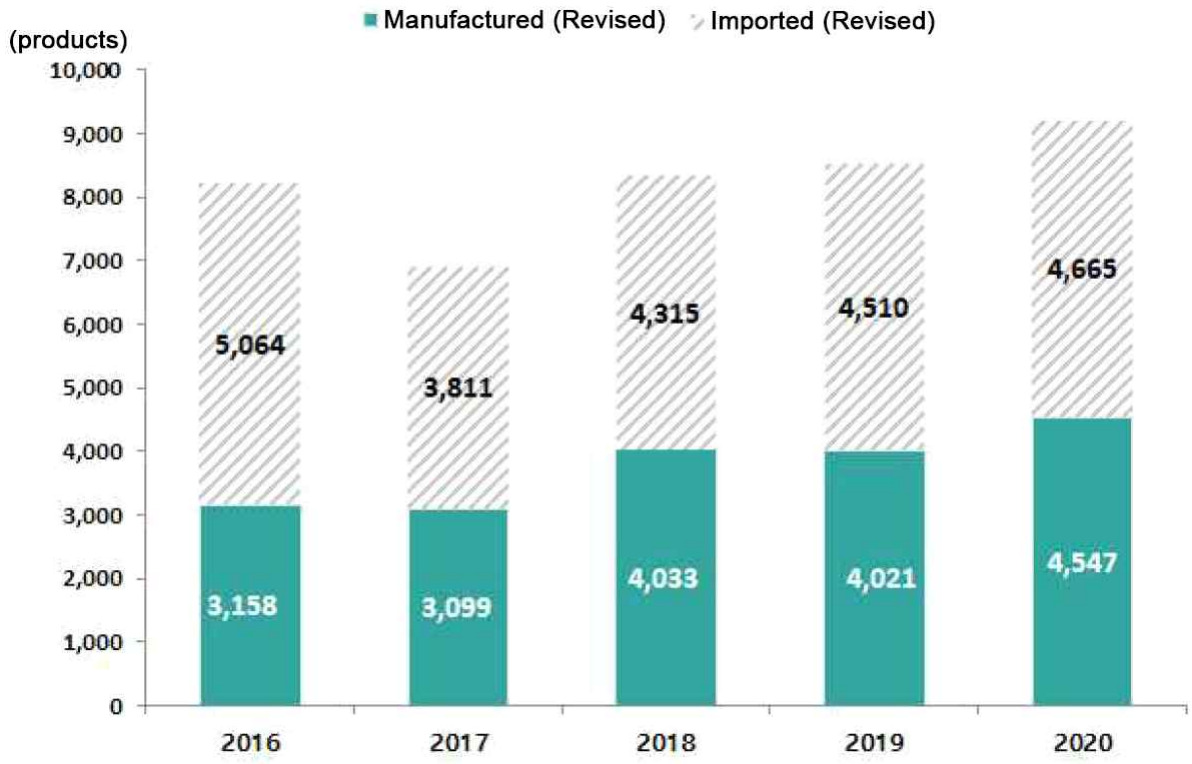
Moreover, the Ministry of Food and Drug Safety (MFDS) has been helping the industry utilize the standard specifications since 2016 through various measures including the distribution of practical guides. As a result, the numbers of both new and revised approvals and certifications (Table 1 and Table 3, respectively) returned to the levels before the application of the standard specifications mentioned above.

[Table 3] Revised Approval and Certification of Manufactured/Imported Devices by Year (2016-2020)

(Unit: Number of products)

Category	2016	2017	2018	2019	2020
Manufactured	3,158	3,099	4,033	4,021	4,547
[Year-on-year (%)]	(-)	(△1.9%)	(30.1%)	(△0.3%)	(13.1%)
Imported	5,064	3,811	4,315	4,510	4,665
[Year-on-year (%)]	(-)	(△24.8%)	(13.2%)	(4.5%)	(3.4%)

Figure 5. Revised Approval and Certification of Manufactured/Imported Devices by Year (2016-2020)



Revised approvals and certifications can be classified into two categories: revised approvals and certifications requiring technical document reviews, and revised approvals and certifications not requiring technical document reviews.

According to a review of revised approvals and certifications by evaluation type from the last 5 years, the number of revised approvals and certifications requiring document reviews is showing a sideways trend, whereas the number of revised approvals and certifications not requiring document reviews increased by 1032 (16.1%) in 2020 relative to 2016, decreased in 2017, and is exhibiting a rising trend from 2020.

These findings are considered due to the fact that revised approvals and certifications requiring document reviews are now handled immediately in the same manner as revised approvals and certifications not requiring document reviews because minor changes such as “reflection (negative regulation) of significant changes in in vitro diagnostic medical devices” were

subjected to extended enforcement to improve the regulations regarding the approval system. In particular, it is believed that the number of manufactured devices not requiring document reviews increased significantly after the "addition of model names within the approved dimensions" such as "Orthopedic Materials" and "Orthodontic Materials" was included in the scope of minor changes not requiring document reviews.

[Table 4] Revised Approvals and Certifications by Evaluation Type and Year (2016-2020)

(Unit: Number of products)

Category		2016	2017	2018	2019	2020
Manufactured	Review required	736	718	780	702	837
	Review not required	2,422	2,381	3,253	3,319	3,710
Imported	Review required	1,076	890	937	1,021	933
	Review not required	3,988	2,921	3,378	3,489	3,732
Total		**8,222***	**6,910****	**8,348*****	**8,531******	**9,212*******

* Revised certifications in 2016 (3,811), ** Revised certifications in 2017 (3,302) *** Revised certifications in 2018 (4,932) **** Revised certifications in 2019 (4,981) ***** Revised certifications in 2020 (5,040)

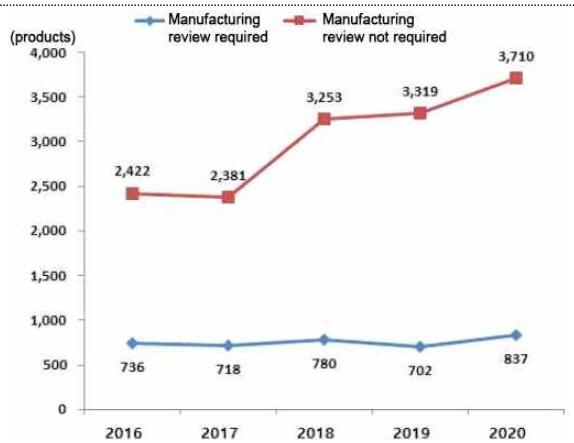


Figure 6. Revised Approval and Certification of Manufactured Devices by Year (2016-2020)

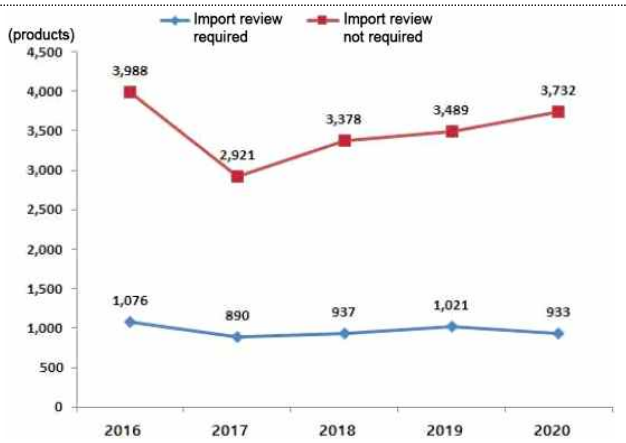


Figure 7. Revised Approval and Certification of Imported Devices by Year (2016-2020)

Ⅰ-2. Approvals, Certifications, and Notifications by Class

Over the last five years, the numbers of approvals, certifications, and notifications were higher in the lower classes. In particular, Class I, II, III, and IV accounted for 61.2%, 24.8%, 10.1%, and 3.9%, respectively, of the total number of approvals, certifications, and notifications.

In 2020, the percentages of Class I, II, III and IV were 59.6%, 25.3%, 11.7%, and 3.4%, respectively, which are similar to the overall percentages over the last 5 years. Moreover, the number of approvals and notifications of Class II and Class III medical devices slightly increased compared to the previous year.

[Table 5] Approvals, Certifications, and Notifications by Class and Year (2016-2020)

(Unit: Number of products)

Category	Class of Medical Devices				Total by Year
	Class I	Class II	Class III	Class IV	
2016	5,022 (61.0%)	2,051 (24.9%)	827 (10.0%)	336 (4.1%)	**8,236**
2017	5,117 (61.6%)	1,957 (23.6%)	838 (10.0%)	396 (4.8%)	**8,308**
2018	4,706 (60.8%)	2,021 (26.1%)	760 (9.8%)	258 (3.3%)	**7,745**
2019	5,212 (63.0%)	1,993 (24.1%)	720 (8.7%)	344 (4.2%)	**8,269**
2020	4,874 (59.6%)	2,068 (25.3%)	959 (11.7%)	282 (3.4%)	**8,183**
Total by Class	**24,931 (61.2%)**	**10,090 (24.8%)**	**4,104 (10.1%)**	**1,616 (3.9%)**	**40,741**

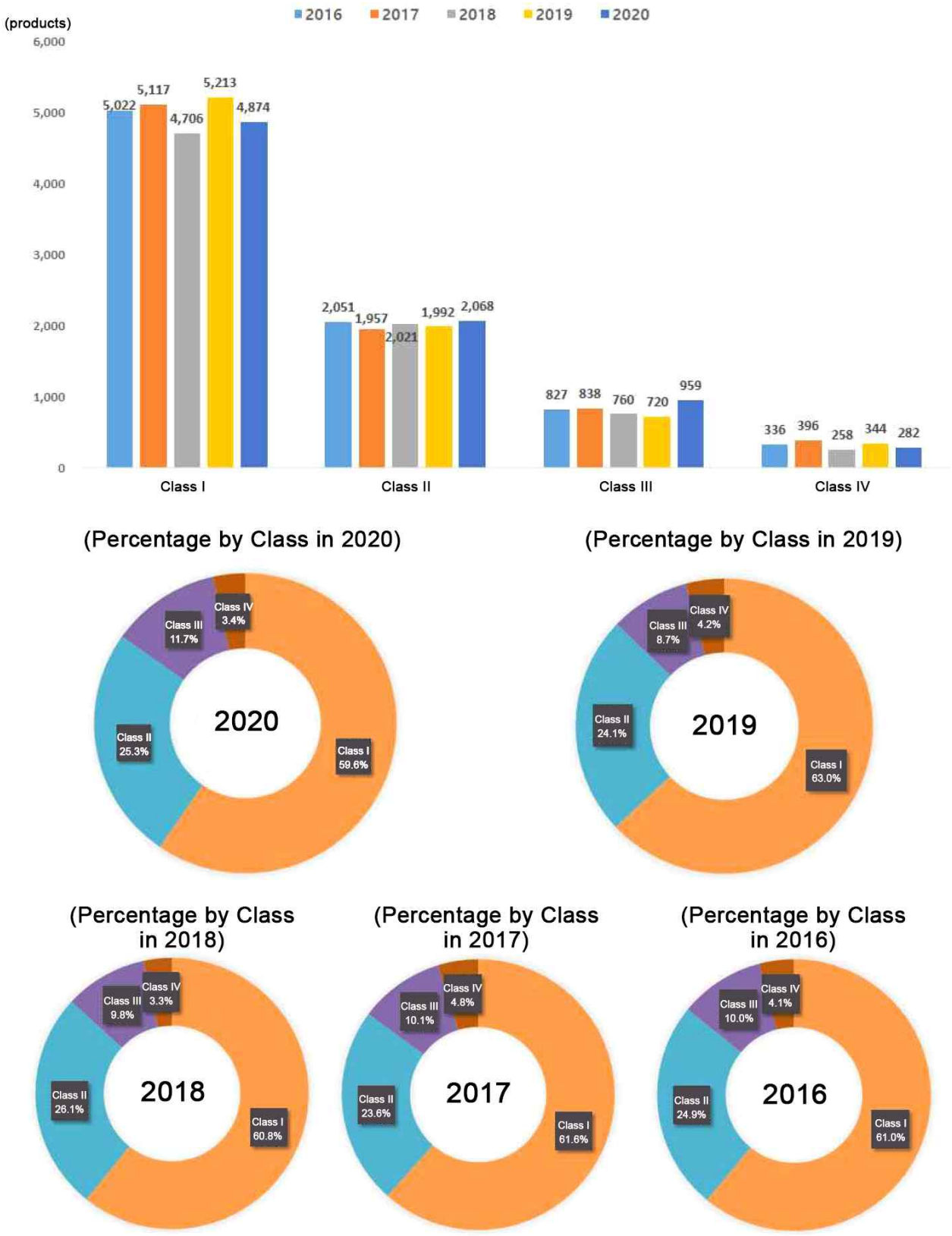


Figure 8. Approvals, Certifications, and Notifications by Class and Year (2016-2020)

When approvals, certifications, and notifications were divided into those of manufactured devices and those of imported devices, the number of approvals, certifications, and notifications still grew higher in an increasing order of class. However, the percentages of the respective classes were different between manufactured devices and imported devices. In particular, the percentage of imported medical devices was relatively higher with Class I than the other classes, and the percentage of Class II through IV was higher with manufactured devices relative to imported devices.

[Table 6] Approvals, Certifications, and Notifications of Manufactured/Imported Devices by Class and Year (2016-2020)

(Unit: Number of products)

Category	Manufactured					Imported					Total by Year
	Class I	Class II	Class III	Class IV	Subtotal	Class I	Class II	Class III	Class IV	Subtotal	
2016	1,540 (44.4%)	1,139 (32.9%)	542 (15.6%)	246 (7.1%)	3,467	3,482 (73.0%)	912 (19.1%)	285 (6.0%)	90 (1.9%)	4,769	**8,236**
2017	1,462 (43.4%)	1,062 (31.5%)	551 (16.4%)	293 (8.7%)	3,368	3,655 (74.0%)	895 (18.1%)	287 (5.8%)	103 (2.1%)	4,940	**8,308**
2018	1,740 (48.3%)	1,123 (31.2%)	539 (15.0%)	198 (5.5%)	3,600	2,966 (71.6%)	898 (21.7%)	221 (5.3%)	60 (1.4%)	4,145	**7,745**
2019	1,763 (48.9%)	1,095 (30.3%)	480 (13.3%)	267 (7.4%)	3,605	3,449 (73.9%)	898 (19.3%)	240 (5.1%)	77 (1.7%)	4,664	**8,269**
2020	1,965 (46.5%)	1,197 (28.4%)	846 (20.0%)	214 (5.1%)	4,222	2,909 (73.4%)	871 (22.0%)	113 (2.9%)	68 (1.7%)	3,961	**8,183**
Total by Class	**8,470 (46.4%)**	**5,616 (30.7%)**	**2,958 (16.2%)**	**1,218 (6.7%)**	**18,262**	**16,461 (73.2%)**	**4,474 (19.9%)**	**1,146 (5.1%)**	**398 (1.8%)**	**22,479**	**40,741**

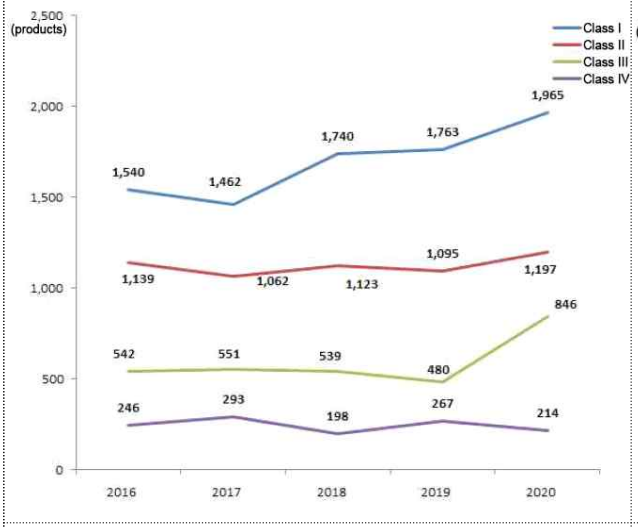


Figure 9. Approval, Certification, and Notification of Manufactured Devices by Class and Year (2016-2020)

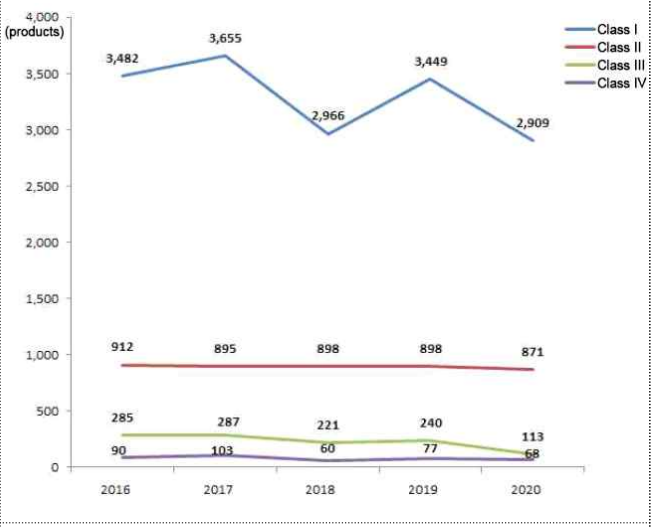


Figure 10. Approval, Certification, and Notification of Imported Devices by Class and Year (2016-2020)

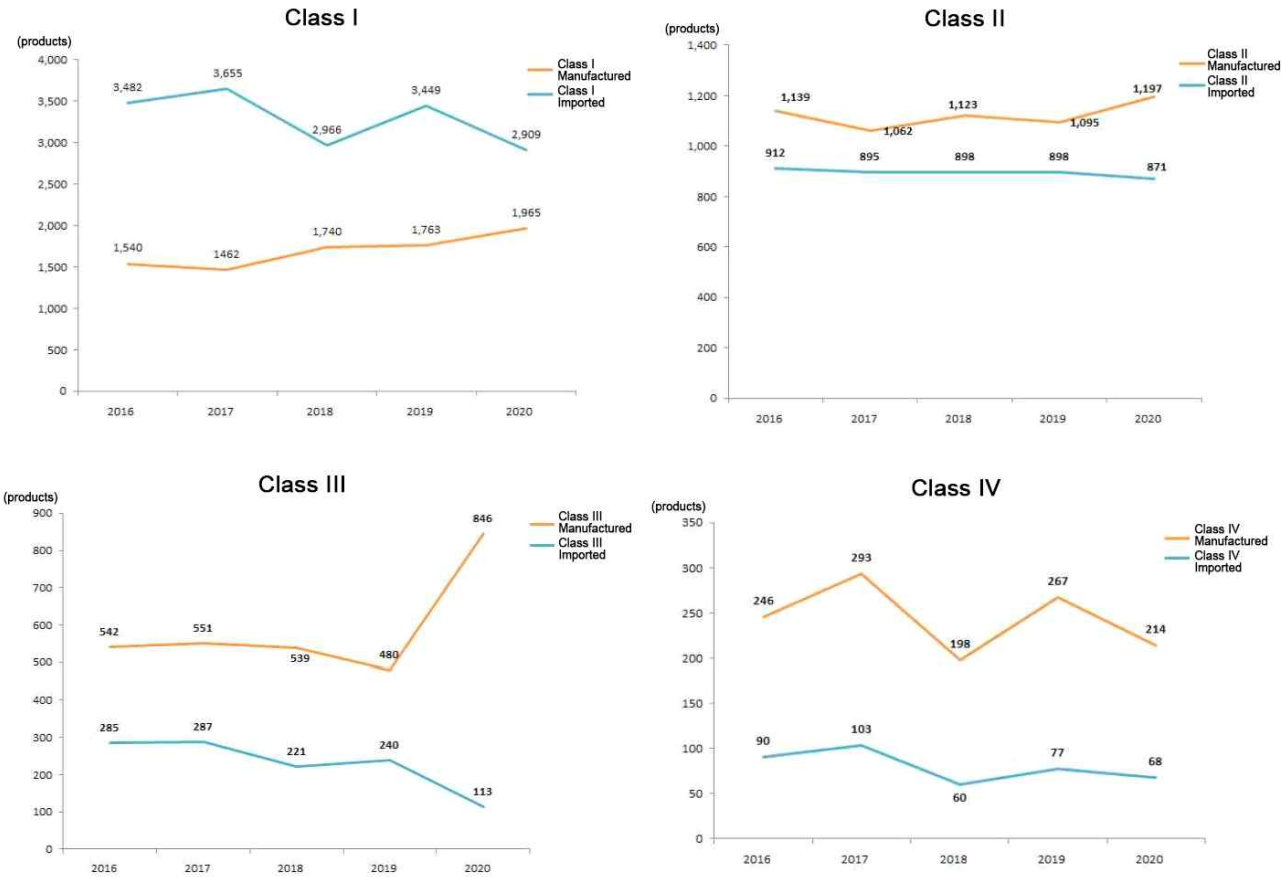


Figure 11. Approved, Certified, and notified Items Over the Last Five Years (2016-2020) by Class

'In 2020, among 8,183 manufactured and imported items, notified products (4,869) accounted for 59.5% of the total, while approved/certified products accounted for 40.5% of the total. In particular, similar to the case for the last five years, the number of approvals and certifications of manufactured high-risk products exceeded that of imported high-risk items in 2020. This suggests that Korean manufacturers are gradually focusing on high-value-added products because of advancements in medical device development technologies.

[Table 7] Approval, Certification, and Notification of Manufactured/Imported Items in 2020

(Unit: Number of products)

Category	Manufactured	Imported	Total by Civil Affairs
Notification	1,963 (40.3%)	2,906 (59.7%)	4,869
Certification	1,127 (57.7%)	825 (42.3%)	1,952
Approval	1,132 (83.1%)	230 (16.9%)	1,362
Total by Manufactured/ Imported Items	**4,222 (51.6%)**	**3,961 (48.4%)**	**8,183**

Figure 12. Percentages of Approvals, Certifications, and Notifications in 2020

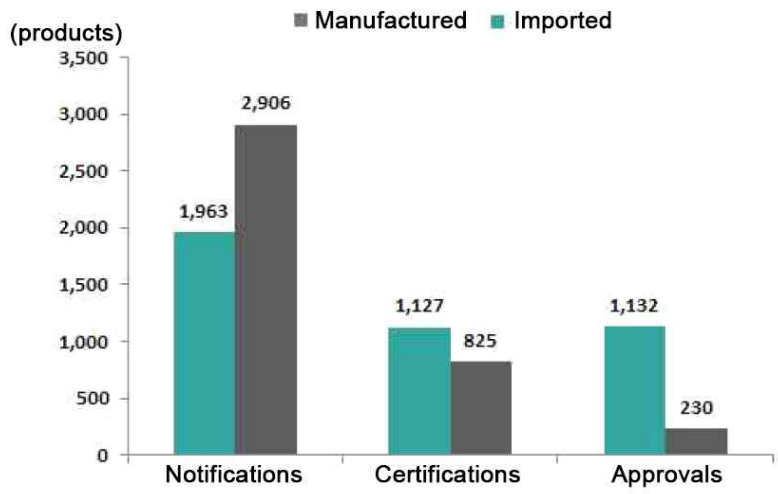


Figure 13. Percentages of Approvals, Certifications, and Notifications of Manufactured/Imported Devices in 2020

Ⅰ-3. Approvals, Certifications, and Notifications by Section

Over the last 5 years, among all approved, certified, and notified devices, "(A) Medical Instruments" accounted for 69.6%, followed by "(B) Medical Supplies (13.6%)," "(D) IVD Reagents (9.5%)," "(C) Dental Materials (7.2%)," and "(E) Software (0.1%)." As shown by the figures, "(A) Medical Instruments" accounted for the vast majority.

[Table 8] Items by Section and Year (2016-2020)

(Unit: Number of products)

Category	(A) Medical Instruments	(B) Medical Supplies	(C) Dental Materials	(D) IVD Reagents	(E) Software	Total by Year
2016	5,623 (68.3%)	1,076 (13.1%)	498 (6.0%)	1,039 (12.6%)		**8,236**
2017	5,744 (69.1%)	1,092 (13.1%)	503 (6.1%)	969 (11.7%)		**8,308**
2018	5,184 (67.0%)	1,033 (13.3%)	583 (7.5%)	945 (12.2%)		**7,745**
2019	5,767 (69.7%)	1,080 (13.1%)	662 (8.0%)	760 (9.2%)		**8,269**
2020	4,987 (74.6%)	1,070 (16.0%)	591 (8.9%)		35 (0.5%)	**6,683**
Total by Section	**27,305 (69.6%)**	**5,351 (13.6%)**	**2,837 (7.2%)**	**3,713 (9.5%)**	**35 (0.1%)**	**39,241**

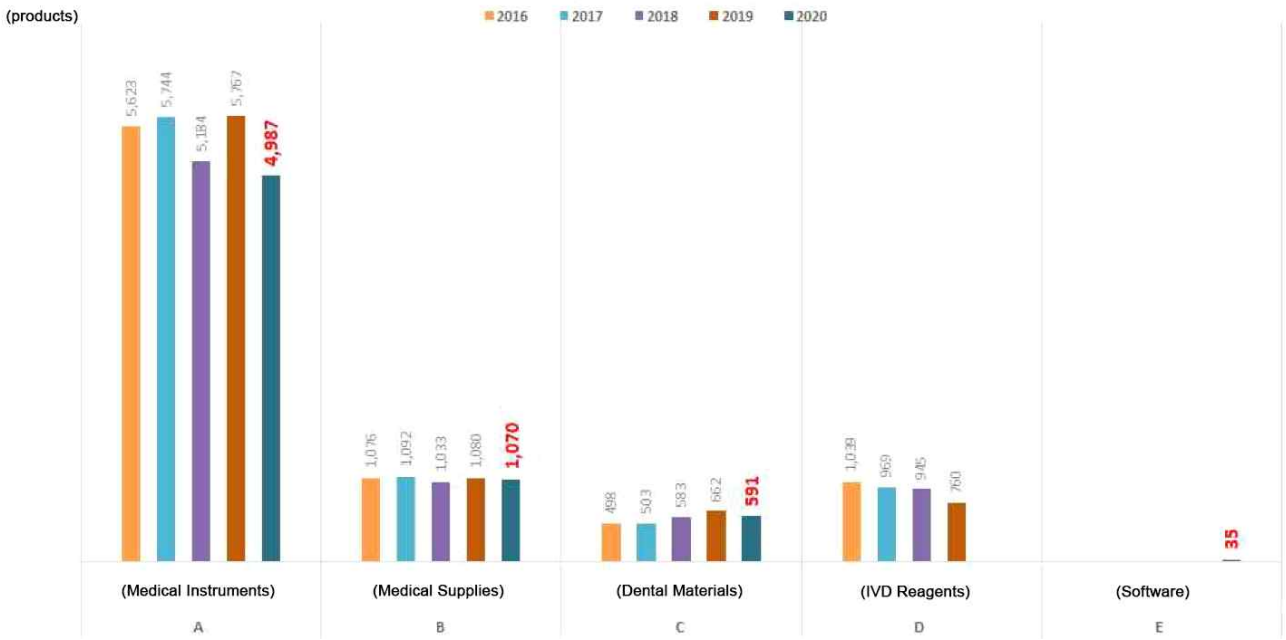


Figure 14. Items by Section and Year (2016-2020)

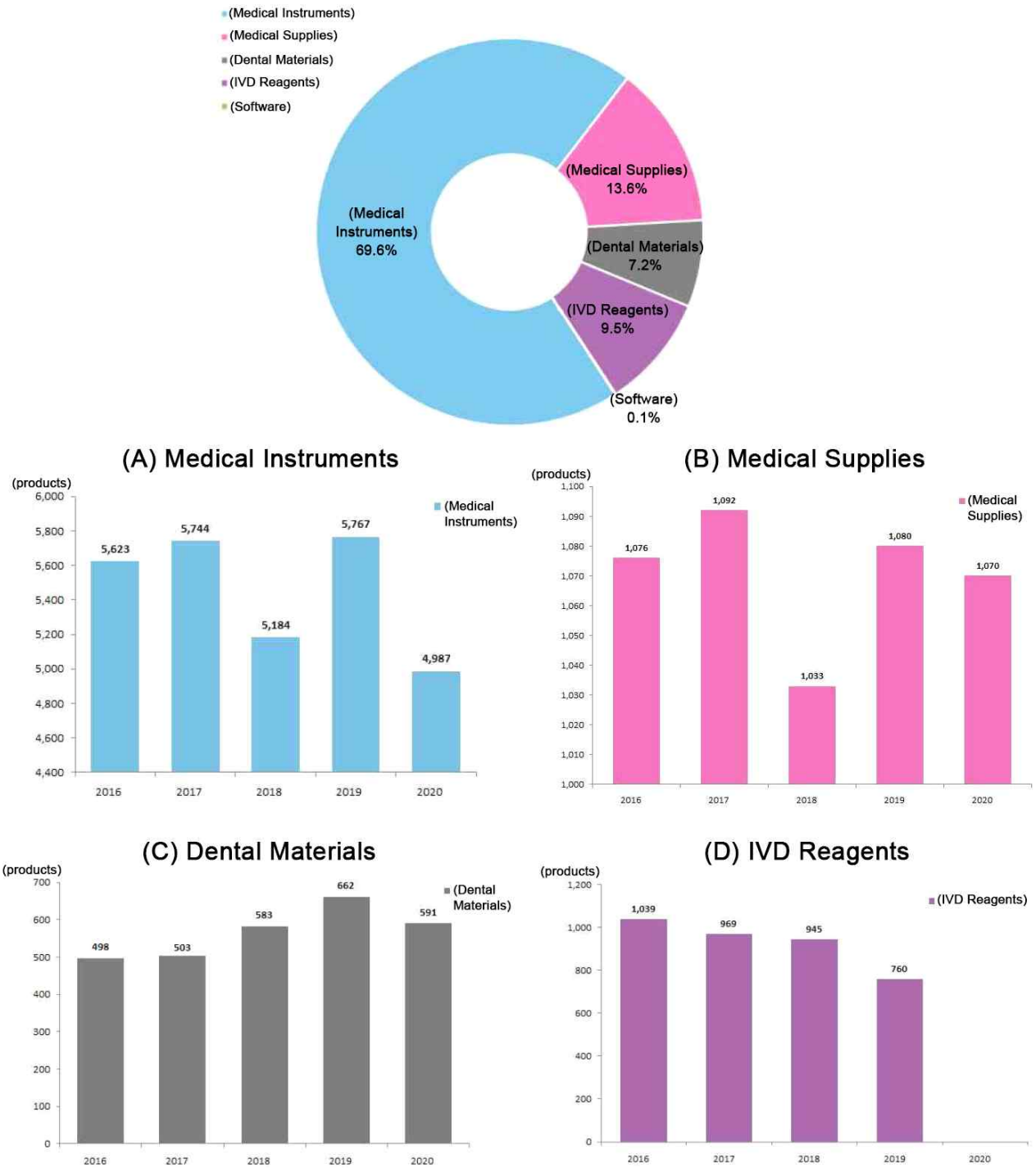


Figure 15. Approved, Certified, and Notified Items over the Last Five Years (2016-2020) by Section

In 2020, the percentage of notifications was relatively high with both manufactured and imported devices in the "(A) Medical Instruments" section, while the percentage of approvals was higher with manufactured devices than imported devices in the "(B) Medical Supplies" section. The percentages of certified and notified products were higher than that of approved products with both manufactured and imported devices in the "(C) Dental Materials" Section.

[Table 9] Approval, Certification, and Notification of Manufactured/Imported Devices in 2020 by Section

(Unit: Number of products)

Category	Manufactured				Imported			
	(A) Medical Instruments	(B) Medical Supplies	(C) Dental Materials	(E) Software	(A) Medical Instruments	(B) Medical Supplies	(C) Dental Materials	(E) Software
Notification	1,142 (56.1%)	287 (44.8%)	203 (40.0%)	2 (11.1%)	2,256 (76.5%)	360 (83.9%)	41 (48.8%)	3 (17.6%)
Certification	664 (32.6%)	68 (10.6%)	226 (44.6%)	12 (66.7%)	553 (18.7%)	18 (4.2%)	42 (50.0%)	14 (82.4%)
Approval	231 (11.3%)	286 (44.6%)	78 (15.4%)	4 (22.2%)	141 (4.8%)	51 (11.9%)	1 (1.2%)	-
Total	**2,037**	**641**	**507**	**18**	**2,950**	**429**	**84**	**17**

In 2020, the "(A) Medical Instruments" section and the "(B) Medical Supplies" section did not report any notable year-on-year changes in the percentages of approvals, certifications, and Notifications. On the other hand, in the imported items of the "(C) Dental Materials" section, the percentages of notifications, certifications, and approvals decreased from 2019 (74 cases → 41 cases, 81 cases → 42 cases, and 7 cases → 1 case, respectively).

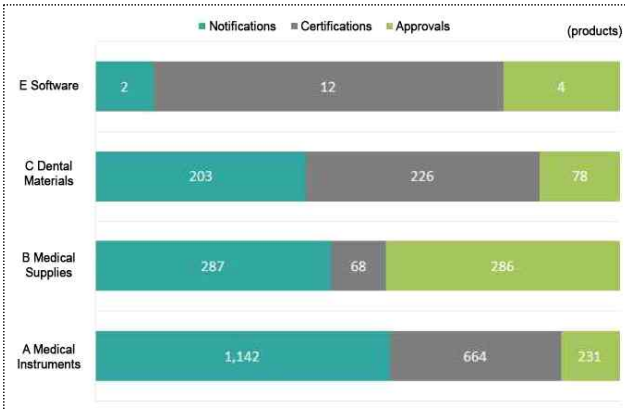


Figure 16. Approval, Certification, and Notification of Manufactured Devices in 2020 by Section

Figure 17. Approval, Certification, and Notification of Imported Devices in 2020 by Section

After the enactment of the Act on In Vitro Diagnostic Medical Devices on 2020.5.1, the percentages of approvals, certifications, and notifications were the highest in "(K) Devices for Clinical Immunity (35.1%)," followed by "(I) Devices for Sample Preparation (22.0%)," "(J) Devices for Clinical Chemistry (20.5%)," "(N) Devices for Molecular Diagnostics (14.0%)," "(M) Devices for Clinical Microbiology (5.8%)," "(O) Devices for Immuno Cyto/Histo Chemistry (2.3%)," and "(P) IVD Software (0.3%)." As shown by the figures, "(K) Devices for Clinical Immunity" accounted for the vast majority.

[Table 10] In Vitro Diagnostic Devices by Section in 2020

(Unit: Number of products)

Category	(I) Devices for Sample Preparation	(J) Devices for Clinical Chemistry	(K) Devices for Clinical Immunity	(L) Devices for Blood Transfusion	(M) Devices for Clinical Microbiology	(N) Devices for Molecular Diagnostics	(O) Devices for Immuno Cyto/Histo Chemistry	(P) IVD Software	Total by Year
2020	328 (22.0%)	308 (20.5%)	527 (35.1%)	-	87 (5.8%)	210 (14.0%)	35 (2.3%)	5 (0.3%)	**1,500**
Total by Section	**328 (22.0%)**	**308 (20.5%)**	**527 (35.1%)**		**87 (5.8%)**	**210 (14.0%)**	**35 (2.3%)**	**5 (0.3%)**	**1,500**

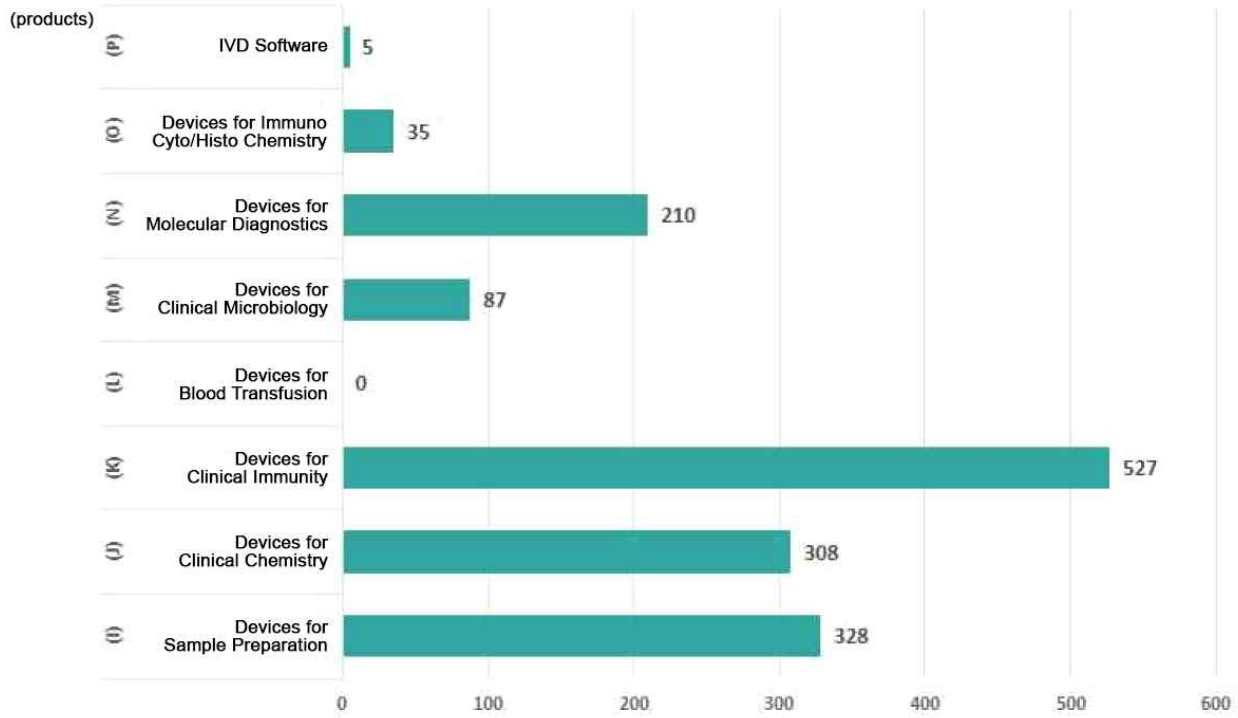


Figure 18. Approved, Certified, and Notified In Vitro Diagnostic Devices by Section in 2020

[Table 11] Approval, Certification, and Notification of Manufactured/Imported In Vitro Diagnostic Devices by Section in 2020

(Unit: Number of products)

Category	Manufactured								Imported							
	(I) Devices for Sample Preparation	(J) Devices for Clinical Chemistry	(K) Devices for Clinical Immunity	(L) Devices for Blood Transfusion	(M) Devices for Clinical Microbiology	(N) Devices for Molecular Diagnostics	(O) Devices for Immuno Cyto/Histo Chemistry	(P) IVD Software	(I) Devices for Sample Preparation	(J) Devices for Clinical Chemistry	(K) Devices for Clinical Immunity	(L) Devices for Blood Transfusion	(M) Devices for Clinical Microbiology	(N) Devices for Molecular Diagnostics	(O) Devices for Immuno Cyto/Histo Chemistry	(P) IVD Software
Notification	241 (99.6%)	31 (26.5%)	22 (5.0%)	-	26 (81.2%	5 (2.7%)	4 (66.6%)	-	82 (95.3%)	82 (42.9%)	15 (16.5%)	-	29 (52.7%)	14 (51.9%)	24 (82.8%)	-
Certification	-	56 (47.9%)	84 (19.3%)	-	6 (18.8%)	9 (4.9%)	1 (16.7%)	1 (33.3%)	4 (4.7%)	100 (52.4%)	61 (67.0%)	-	25 (45.5%)	6 (22.2%)	2 (6.9%)	-
Approval	1 (0.4%)	30 (25.6%)	330 (75.7%)	-	-	169 (92.4%)	1 (16.7%)	2 (66.7%)	-	9 (4.7%)	15 (16.5%)	-	1 (1.8%)	7 (25.9%)	3 (10.3%)	2 (100%)
Total	**242**	**117**	**436**	**0**	**32**	**183**	**6**	**3**	**86**	**191**	**91**	**0**	**55**	**27**	**29**	**2**

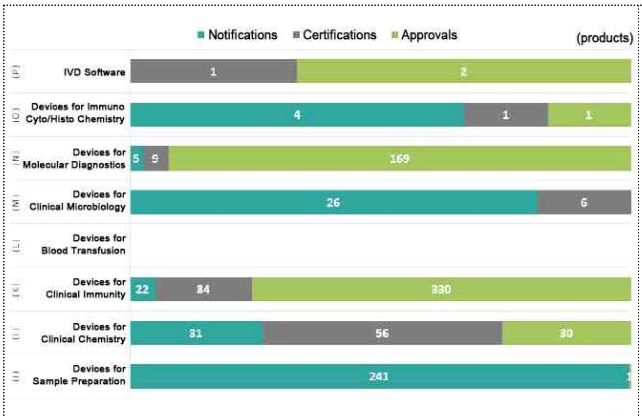


Figure 19. Approval, Certification, and Notification of Manufactured In Vitro Diagnostic Devices by Section in 2020

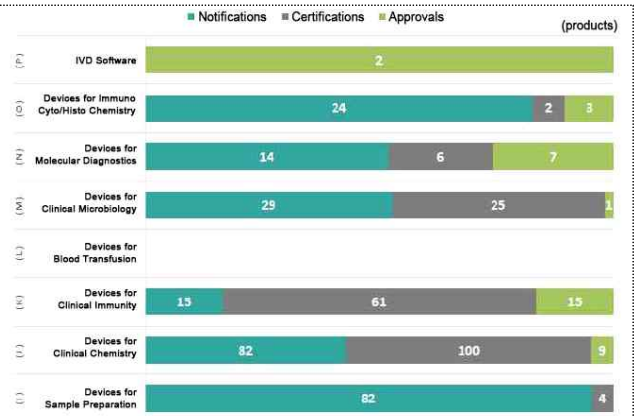


Figure 20. Approval, Certification, and Notification of Imported In Vitro Diagnostic Devices by Section in 2020

Ⅰ-4. Approvals, Certifications, and Notifications by Division

A review of approvals, certifications, and notifications of manufactured/imported devices in each division in 2020 reveals that the most frequently approved/certified/notified product was "B07000 Surgical Supplies (525)," followed by "A77000 Ophthalmic Lens (440)," "A38000 Instruments for Ligature and Suture (282)," and "A64000 Measuring and Introducing Instrument (263)."

In particular, the number of approvals, certifications, and notifications of "B07000 Surgical Supplies" significantly increased compared to the previous year (461 in 2019 (2nd) → 525 in 2020 (1st)), while noteworthy changes were not observed among the other top 10 divisions.

The 10 divisions with the highest number of approvals in 2020 are listed in the table below.

[Table 12] (Top 10) Divisions Including High-Frequency Items in 2020

(Unit: Number of products)

Rank	Division No.	Division Name	Manufactured	Imported	Total	Rank in 2019
1	B07000	Surgical Supplies	238	287	525	2
2	A77000	Ophthalmic Lens	127	313	440	1
3	A38000	Instruments for Ligature and Suture	152	130	282	8
4	A64000	Measuring and Introducing Instrument	90	173	263	4
5	K05000	IVD Reagent for Infectious Disease, Immunological Method	246	10	256	-
6	A57000	Tube and Catheter for Medical Use	106	137	243	6
7	A55000	Puncturing, Abrasion, and Perforating Instrument for Medical Use	55	167	222	9
8	A67000	Medical Devices for Orthopedics and Restoration	96	118	214	-
9	A31000	Speculums for Medical Use	48	163	211	5
10	B05000	Splints	123	86	209	10

According to an analysis of the frequently approved/certified/notified divisions in each section, the most frequently approved/certified/notified division in the "(A) Medical Instruments" section was "A77000 Ophthalmic Lens (440)," followed by "A38000 Instruments for Ligature and Suture (282)," and "A64000 Measuring and Introducing Instrument (263)." Although The number of approvals, certifications, and notifications of "A77000 Ophthalmic Lens" decreased from the previous year, it was still the highest in the division like it was the previous year (772 in 2019 (1st) → 440 in 2020 (1st)).

[Table 13] Approved, Certified, and Notified Items in 2020 by Division ((A) Medical Instruments)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	A77000	Ophthalmic Lens	127	313	440
2	A38000	Instruments for Ligature and Suture	152	130	282
3	A64000	Measuring and Introducing Instrument	90	173	263
4	A57000	Tube and Catheter for Medical Use	106	137	243
5	A55000	Puncturing, Abrasion, and Perforating Instrument for Medical Use	55	167	222
6	A67000	Medical Devices for Orthopedics and Restoration	96	118	214
7	A31000	Speculums for Medical Use	48	163	211
8	A26000	Visceral Function Testing Instruments	112	74	186
9	A66000	Blood donor or Transfusion and Biopsy Set	91	87	178
10	A45000	Forceps for Medical Use	36	138	174
11	A19000	Patient Transport	39	123	162
12	A58000	Probe and Sound for Medical Use	49	106	155
13	A56000	Wound Retractors and Speculums	30	114	144
14	A78000	Hearing Aid	41	90	131
15	A53000	Needles for Syringe and Puncture	52	77	129
16	A79000	Infusion Instruments	70	52	122
17	A35000	Electrosurgical and Other Surgical Devices	62	31	93
18	A21000	Clinical Thermometric System	81	9	90
19	A01000	Operating and Treatment Table	41	41	82
20	A28000	Eye Testing Instruments	14	65	79
21	A16000	Physical Devices For Medical Use	66	12	78
22	A44000	Clamp for Medical Use	8	61	69
23	A02000	Bed for Medical Use	54	14	68
24	A07000	Respiratory Apparatus	26	42	68
25	A42000	Scissors for Medical Use	7	53	60
26	A11000	Diagnostic X-ray System	29	28	57
27	A17000	Cardiovascular Devices	27	28	55
28	A48000	Raspatories for Medical Use	8	45	53

No.	Division No.	Division Name	Manufactured	Imported	Total
29	A37000	Laser Apparatus for Medical Use	38	13	51
30	A59000	Dilator and Expander for Medical Use	19	32	51
31	A39000	Aspirators for Medical Use	32	15	47
32	A85000	Magnetic Induction Apparatus for Medical Use	43	4	47
33	A03000	Medical Light and Lamp	16	27	43
34	A41000	Knives for Medical Use	6	29	35
35	A23000	Sphygmomanometers and Sphygmographs	4	30	34
36	A43000	Curetts for Medical Use	5	28	33
37	A83000	Electric Simulator for Medical Use by Personal	27	6	33
38	A15000	Radiation protective device	17	13	30
39	A30000	Perception and Organs Diagnostic Devices	12	16	28
40	A47000	Chisel for Medical Use	7	19	26
41	A09000	Artificial Internal Organ Apparatus	6	19	25
42	A34000	Thermostats for Medical Use	9	15	24
43	A04000	Medical Sterilizing Apparatus	15	7	22
44	A62000	Filling Instruments for Medical Use	12	9	21
45	A73000	Impression Taking and Articulating Instruments	11	10	21
46	A65000	Douche Instruments for Medical Use	13	7	20
47	A76000	Sight Corrective Spectacles	11	8	19
48	A54000	Syringes	9	9	18
49	A61000	Dispensers and Mixing Instrument	15	3	18
50	A49000	Mallet for Medical Use	5	12	17
51	A63000	Depressors for Medical Use	6	11	17
52	A90000	U-Healthcare Medical Device	16	1	17
53	A15500	Laser Protective Device	1	15	16
54	A50000	File for Medical Use	3	12	15
55	A84000	Acupuncture and Moxibustion Apparatus	13	1	14
56	A60000	Applicator for Medical Use	1	11	12
57	A14000	Film Developer for Medical Use	7	4	11
58	A27000	Respiratory Function Testing Apparatus	2	7	9
59	A72000	Moisture-Excluding Instruments for Dental Use	-	9	9
60	A12000	Non-Ionization Diagnostic Device	-	8	8
61	A08000	Medical Chamber	7	-	7
62	A18000	Urology Devices	2	5	7
63	A29000	Hearing Testing Instruments	-	7	7
64	A74000	Vulcanizers and Curing Units for Dental Use	2	5	7
65	A81000	Inhalators for Medical Use	2	5	7
66	A86000	Medicinal Substance-Producing Equipment	6	1	7
67	A91000	Cell and Tissue Processing Apparatus for Medical Use	6	1	7
68	A69000	Dental Engine	3	3	6
69	A46000	Saw for Medical Use	-	5	5
70	A71000	Explorers for Dental Use	3	2	5
71	A13000	Radiologic Device	-	4	4
72	A20000	Stethoscope	1	2	3

No.	Division No.	Division Name	Manufactured	Imported	Total
73	A82000	Vibrators	3	-	3
74	A36000	Cryosurgery Device	-	2	2
75	A40000	Pneumothorax and Pneumoperitoneum Apparatus	-	2	2
76	A51000	Lever for Medical Use	-	2	2
77	A88000	Treatment Table for Ear, Nose, and Throat	2	-	2
78	A89000	Ophthalmic Instrument Table and Chair	1	1	2
79	A25000	Body Fluid Testing Apparatus	1	-	1
80	A33000	Tissue Processing Device	-	1	1
81	A70000	Broaches for Dental Use	-	1	1
Total			**2,037**	**2,950**	**4,987**

In the "(B) Medical Supplies" section, the most frequently approved/certified/notified division was "B07000 Surgical Supplies (525)," followed by "B05000 Splints (209)" and "B03000 Orthopedic Materials (139)." No notable changes were observed compared to 2019.

[Table 14] Approved, Certified, and Notified Items in 2020 by Division ((B) Medical Supplies)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	B07000	Surgical Supplies	238	287	525
2	B05000	Splints	123	86	209
3	B03000	Orthopedic Materials	112	27	139
4	B04000	Human Tissue and Organ Substitute	94	18	112
5	B02000	Suture and Ligature	74	1	75
6	B06000	Test Chart for Visual Acuity and Color Blindness	-	7	7
7	B01000	Radiographic Supplies	-	2	2
8	B08000	Condom	-	1	1
Total			**641**	**429**	**1,070**

In the "(C) Dental Materials" section, the most frequently approved/certified/notified division was "C21000 Implant Instrument for Dental Use (203)," followed by "C20000 Endosseous Implant System (161)" and "C17000 Orthodontic Material (43)." Generally, the findings were similar to those of 2019. However, the number of approvals, certifications, and notifications of "C20000 Endosseous Implant System" increased slightly (94 in 2019 → 161 in 2020).

[Table 15] Approved, Certified, and Notified Items in 2020 by Division ((C) Dental Materials)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	C21000	Implant Instrument for Dental Use	192	11	203
2	C20000	Endosseous Implant System	153	8	161
3	C17000	Orthodontic Material	27	16	43
4	C07000	Crown & Bridge Material for Dental Use	27	8	35
5	C13000	Impression Material for Dental Use	20	7	27
6	C26000	Material for Prosthesis	22	3	25
7	C23000	Intra Oral Tissue Regeneration Barrier	18	-	18
8	C10000	Endodontic Material for Root Canal	9	4	13
9	C16000	Protection Material for Dental Use	3	8	11
10	C12000	Adhesive for Dental Use	5	5	10
11	C11000	Cement for Dental Use	3	5	8
12	C22000	Bone Graft Material	8	-	8
13	C18000	Maxillofacial Implant	6	-	6
14	C06000	Filling Material for Dental Use	3	2	5
15	C09000	Denture Material	4	1	5
16	C03000	Alloy, Metal-Ceramic	2	1	3
17	C27000	Retentive Material for Dental Use	-	3	3
18	C01000	Alloy, Foil	-	2	2
19	C14000	Wax for Dental Use	2	-	2
20	C02000	Alloy, Casting	1	-	1
21	C08000	Artificial Teeth Material	1	-	1
22	C25000	Separating Material for Prothesis	1	-	1
Total			**507**	**84**	**591**

In the "(E) Software for Cardiovascular" section, the most frequently approved/certified/notified division was "E11000 Software for Radiation Oncology and Diagnostic Radiology (17)," followed by "E02000 Software for Dental (10)," and "E05000 Software for General Hospital (4)."

[Table 16] Approved, Certified, and Notified Items in 2020 by Division ((E) Software for Cardiovascular)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	E11000	Software for Radiation Oncology and Diagnostic Radiology	12	5	17
2	E02000	Software for Dental	3	7	10
3	E05000	Software for General Hospital	1	3	4
4	E01000	Software for Cardiovascular	-	2	2
5	E06000	Software for Neurology	1	-	1
6	E08000	Software for Ophthalmology	1	-	1
Total			**18**	**17**	**35**

In the "(I) Devices for Sample Preparation" section, the most frequently approved/certified/notified division was "I20000 Other Devices for Sample Preparation (145)," followed by "I03000 Concentration/Extraction Devices (122)," and "I01000 Centrifuge for Medical Use (34)."

[Table 17] Approved, Certified, and Notified Items in 2020 by Division ((I) Devices for Sample Preparation)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	I20000	Other Devices for Sample Preparation	130	15	145
2	I03000	Concentration/Extraction Devices	89	33	122
3	I01000	Centrifuge for Medical Use	11	23	34
4	I02000	Cell/Tissue Preparation Instruments for IHC	8	10	18
5	I04000	Cell/Tissue Culture Device	4	5	9
Total			**242**	**86**	**328**

In the "(J) Devices for Clinical Chemistry" section, the most frequently approved/certified/notified division was "J08000 IVD Reagent for Clinical Chemistry (117)," followed by "J11000 IVD Reagents for Endocrine Test (37)," and "J03000 Blood Component Analyzer (32)."

[Table 18] Approved, Certified, and Notified Items in 2020 by Division ((J) Devices for Clinical Chemistry)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	J08000	IVD Reagent for Clinical Chemistry	38	79	117
2	J11000	IVD Reagents for Endocrine Test	14	23	37
3	J03000	Blood Component Analyzer	9	23	32
4	J01000	Clinical Chemistry Analyzer	9	14	23
5	J09000	IVD Reagent for Blood Cell Test	2	21	23
6	J14000	IVD Strip for Self Test	13	6	19
7	J22000	IVD Devices for Other Clinical Chemistry	5	8	13
8	J07000	Clinical Urinary and Stool Analyzer	6	3	9
9	J04000	IVD Analyzer for Self Test	8	-	8
10	J12000	IVD Reagent for Clinical Urinary and Stool Test	7	1	8
11	J05000	Blood Coagulant Analyzer	-	6	6
12	J10000	IVD Reagent for Hemostasis and Thrombosis	1	5	6
13	J13000	IVD Strip for Clinical Chemistry, Non-Self	4	1	5
14	J06000	Body Fluid Analyzer	1	1	2
Total			**117**	**191**	**308**

In the "(K) Devices for Clinical Immunity" section, the most frequently approved/certified/notified division was "K05000 IVD Reagent for Infectious Disease, Immunological Method (256)," followed by "K02000 IVD Reagent for Immune Related Protein Test (206)," and "K01000 Clinical Immune Response Analyzer (30)."

[Table 19] Approved, Certified, and Notified Items in 2020 by Division ((K) Devices for Clinical Immunity)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	K05000	IVD Reagent for Infectious Disease, Immunological Method	246	10	256
2	K02000	IVD Reagent for Immune Related Protein Test	150	56	206
3	K01000	Clinical Immune Response Analyzer	19	11	30
4	K03000	IVE Reagents for Autoimmune Disease	16	5	21
5	K06000	IVD Reagent for Drug Monitoring Test	4	7	11
6	K04000	IVD Reagents for Histocompatibility	-	2	2
7	K20000	IVD Devices for Other Clinical Immunology	1	-	1
Total			**436**	**91**	**527**

In the "(M) Devices for Clinical Microbiology" section, the most frequently approved/certified/notified division was "M02000 Cultural Reagent for Clinical Microbiology (75)," followed by "M01000 Clinical Microbiology Analyzer (9)," and "M20000 IVD Devices for Other Clinical Microbiology (3)."

[Table 20] Approved, Certified, and Notified Items in 2020 by Division ((M) Devices for Clinical Microbiology)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	M02000	Cultural Reagent for Clinical Microbiology	30	45	75
2	M01000	Clinical Microbiology Analyzer	-	9	9
3	M20000	IVD Devices for Other Clinical Microbiology	2	1	3
Total			**32**	**55**	**87**

In the "(N) Devices for Molecular Diagnostics" section, the most frequently approved/certified/notified division was "N05000 IVD Reagents for Infectious Molecular Diagnostic Test (164)," followed by "N01000 Molecular Diagnostic Analyzer (28)," and "N02000 IVD Reagents for Molecular Diagnostic Test (11)."

[Table 21] Approved, Certified, and Notified Items in 2020 by Division ((N) Devices for Molecular Diagnostics)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	N05000	IVD Reagents for Infectious Molecular Diagnostic Test	157	7	164
2	N01000	Molecular Diagnostic Analyzer	12	16	28
3	N02000	IVD Reagents for Molecular Diagnostic Test	11	-	11
4	N20000	IVD Devices for Other Molecular Diagnostics	-	4	4
5	N04000	IVD Reagents for Blood Cell Antigen Genetic Test	2	-	2
6	N03000	IVD Reagents for Pharmacogenetic Test	1	-	1
Total			**183**	**27**	**210**

In the "(O) Devices for Immuno Cyto/Histo Chemistry" section, the most frequently approved/certified/notified division was "O02000 IVD Reagents for Cell/Histopathology (24)," followed by "O01000 Cell/Histopathology Test Analyzer (9)," and "O03000 IVD Reagents for Nucleic Acid In Situ Hybridization (1)."

[Table 22] Approved, Certified, and Notified Items in 2020 by Division ((O) Pathology Devices for Others)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	O02000	IVD Reagents for Cell/Histopathology	2	22	24
2	O01000	Cell/Histopathology Test Analyzer	4	5	9
3	O03000	IVD Reagents for Nucleic Acid In Situ Hybridization	-	1	1
4	O04000	IVD Reagent for Pathology Companion Diagnostic	-	1	1
Total			**6**	**29**	**35**

In the "(P) IVD Software" section, the most frequently approved/certified/notified division was "P04000 Pathological Image Processing Software (2)," followed by "P20000 Other Software for IVD (2)," and "P01000 IVD Software for Diagnosis (1)."

[Table 23] Approved, Certified, and Notified Items in 2020 by Division ((P) IVD Software)

(Unit: Number of products)

No.	Division No.	Division Name	Manufactured	Imported	Total
1	P04000	Pathological Image Processing Software	2	-	2
2	P20000	Other Software for IVD	-	2	2
3	P01000	IVD Software for Diagnosis	1	-	1
Total			**3**	**2**	**5**

The following is a summary of the details regarding the approved, certified, and notified devices in the top 10 divisions in [Table 10].

○ Surgical Supplies (B07000)

- The “Surgical Supplies (B07000)” division includes a total of 38 items consisting of 9 Class I items, 17 Class II items, 6 Class III items, and 6 Class IV items. The number of items in the division increased by 1 compared to 2019.

  * New Item (1): Respirator, Medical (B07160.01, Class II)

- In 2020, products under 31 items including divisions were approved, certified, and notified (525). The numbers of manufactured devices and imported devices were 238 (45.3%) and 287 (54.7%), respectively.
- Among the 30 items, “Bandage, Compression (B07090.02)” accounted for the largest proportion with 231 products (44.0%), followed by “Glove, Patient Examination (B07010.02)” with 104 products (19.8%), and “Dressing, Fluid-Impermeable Film (B07070.01)” with 35 products (6.7%).
- The following table shows the details of “Surgical Supplies (B07000)” approved, certified, and notified in 2020.

[Table 24] “Surgical Supplies (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Bandage, Compression	B07090.02	1	107	124	231
2	Glove, Patient Examination	B07010.02	1	4	100	104
3	Dressing, Fluid-Impermeable Film	B07070.01	2	33	2	35
4	Gel for Medical Use, Non-Sterilized	B07140.01	1	14	20	34
5	Pressure Alleviation Pad, Skin	B07080.01	1	22	9	31
6	Dressing, Occlusive, Hydrogel	B07070.03	2	11	2	13
7	Surgical Supplies	B07000	1	10	3	13
8	Dressing, High-Absorbent, Foam/Sheet/Liquid/Powder	B07070.11	2	5	4	9
9	Dressing, Topical Homeostasis, External	B07100.01	2	6	1	7
10	Drape, Surgical, General Purpose, Non-Contact Type	B07050.01	1	5	2	7

11	Glove, Surgical	B07010.01	2		7	7
12	Bag, Ostomy	B07030.01	1	1	2	3
13	Drape Adhesive, Aerosol	B07060.01	1		3	3
14	Drape, Surgical, General Purpose, Non-Contact Type, Single-Use	B07050.04	2	3		3
15	Intraoperative Procedure Bag	B07040.01	2	3		3
16	Dressing, Secondary Treatment, High-Absorbent, Foam/Sheet/Liquid/Powder	B07070.12	3		2	2
17	Dressing, Non-Adhesive	B07070.02	2	2		2
18	Lubricant for Medical Use	B07150.01	2	1	1	2
19	Drape, Surgical, General Purpose, Contact Type, Single-Use	B07050.02	2	1	1	2
20	Dressing, Collagen, Wound	B07070.10	3	1	1	2
21	Hemostat, Internal, Absorbable	B07120.02	4	2		2
22	Dressing, Secondary Treatment, Occlusive, Hydrogel	B07070.04	3		1	1
23	Hemostat, Internal, Non-Absorbable	B07125.01	3	1		1
24	Sterile Saline, Wound Irrigation	B07070.05	2	1		1
25	Dressing, Absorbable, Wound, Biological Origin	B07070.07	4	1		1
26	Dressing, Deep-Cavity Wound	B07070.14	3	1		1
27	Surgical Supplies	B07000	2		1	1
28	Surgical Supplies	B07000	3		1	1
29	Dressing, Adhesion Barrier	B07070.14	3	1		1
30	Respirator, Medical	B07160.01	2	1		1
31	Sizer, Breast Prothesis	B07110.01	2	1		1
Total				**238**	**287**	**525**

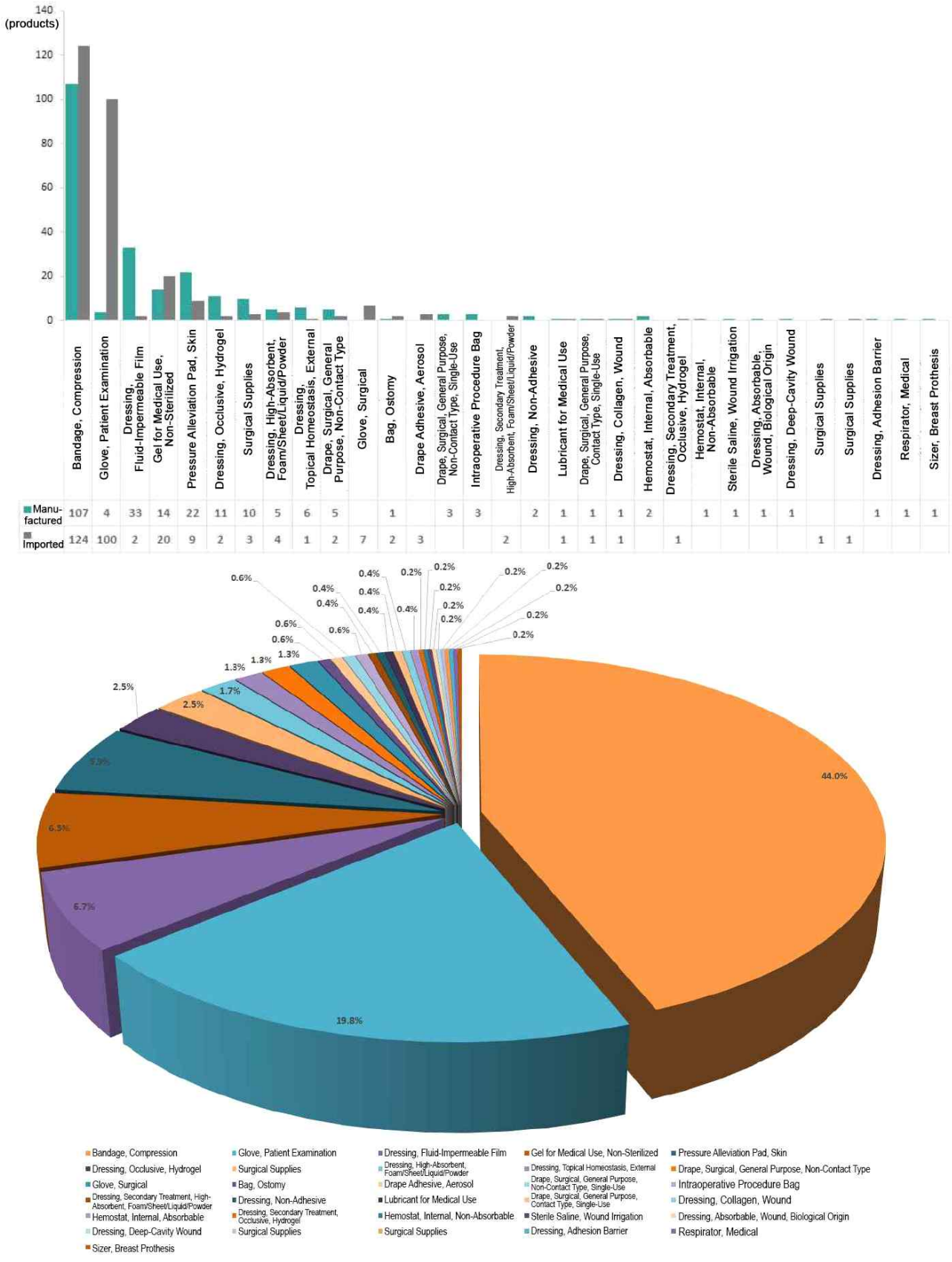


Figure 21. “Surgical Supplies (Division)” Items in 2020

○ Ophthalmic Lens **(A77000)**

- The “Ophthalmic Lens (A77000)” division includes a total of 10 items consisting of 2 Class I items, 3 Class II items, 4 Class III items, and 1 Class IV item.
- In 2020, products under 4 items were approved, certified, and notified (440). The numbers of manufactured devices and imported devices were 127 (28.9%) and 313 (71.1%), respectively. Imported products were still more dominant than manufactured products as in 2019 (In 2019, there was a total of 772 devices, 186 (24.1%) of which were manufactured, and 586 (75.9%) were imported).
- Among 10 items, “Sight Corrective Ophthalmic Lens (A77010.01)” accounted for the largest proportion with 231 products (89.3%), and the number of approvals, certifications, and notifications decreased drastically relative to 2019 (736 in 2019 → 393 in 2020).
- The following table shows the details of “Ophthalmic Lens (A77000)” approved and notified in 2020.

[Table 25] “Ophthalmic Lens (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Sight Corrective Ophthalmic Lens	A77010.01	1	91	302	393
2	Soft Contact Lens, Daily-Wear	A77030.01	2	34	9	43
3	Soft Contact Lens, Extended-Wear	A77030.02	3		2	2
4	Hard Contact Lens, Extended-Wear	A77020.02	3	2		2
Total				**127**	**313**	**440**

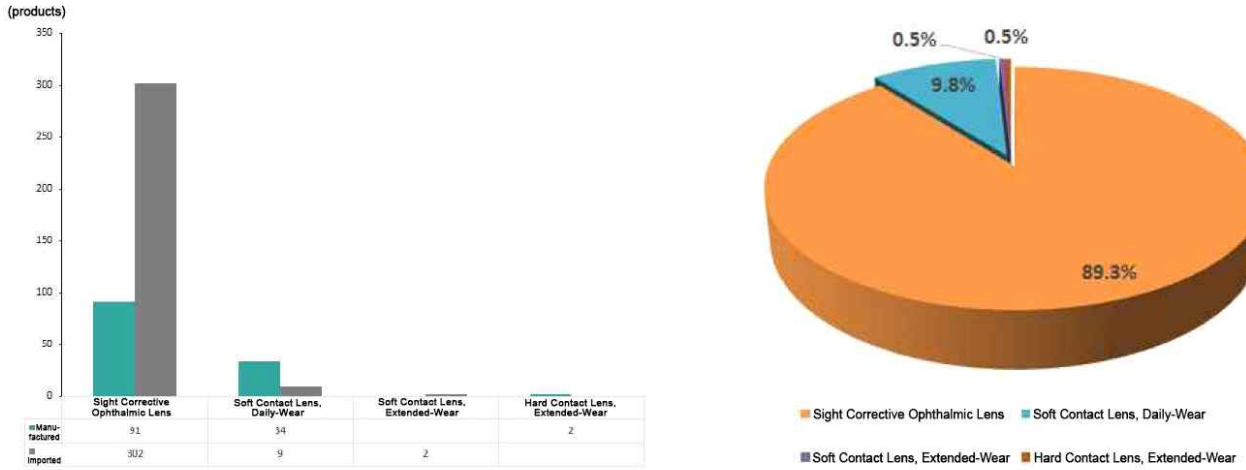


Figure 22. “Ophthalmic Lens (Division)” Items in 2020

○ Instruments for Ligature and Suture **(A38000)**

- The “Instruments for Ligature and Suture (A38000)” division includes a total of 45 items consisting of 16 Class I items, 17 Class II items, 5 Class III items, and 7 Class IV items.
- In 2020, products under 14 items including divisions were approved, certified, and notified (282). The numbers of manufactured devices and imported devices were 152(53.9%) and 130 (46.1%), respectively.
- Among the 14 items, “Clip, Surgical, External (A38090.05)” accounted for the largest proportion with 202 products (71.6.%), followed by “Suture Instrument Only, Reusable (A38010.01)” with 34 products (12.1%), and “Suture Retention Device (A38040.01)” with 11 products (3.9%).
- Among the 14 items, “Clip, Surgical, External (A38090.05)” accounted for the largest proportion (71.6%), and the number of approvals, certifications, and notifications increased significantly relative to 2019 (158 in 2019 → 202 in 2020).
- The following table shows the details of “Instruments for Ligature and Suture (A38000)” approved, certified, and notified in 2020.

[Table 26] “Instruments for Ligature and Suture (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Clip, Surgical, External	A38090.05	1	136	66	202
2	Suture Instrument Only, Reusable	A38010.01	1	6	28	34
3	Suture Retention Device	A38040.01	1	6	5	11
4	Surgical Staple Remover, Reusable	A38200.04	1		5	5
5	Surgical Clip Remover for Blood Vessel, Reusable	A38190.01	1		5	5
6	Ligature Implanting Instrumentation, Endoscopic	A38020.01	1		4	4
7	Clip, Implantable, Haemostatic	A38090.07	2	1	3	4
8	Wire/Ligature Passer	A38070.01	1	1	2	3
9	Applier, Surgical Staple, Cutting, Single-Use	A38200.03	2		3	3
10	Surgical Clip Applier, Haemostatic, Reusable	A38190.02	1		3	3
11	Haemorrhoid Ligator	A38030.01	2		3	3
12	Surgical Staple, Non-Biodegradable	A38170.02	3	1	1	2
13	Suture Instrument, Single-Use	A38010.02	2	1	1	2
14	Clip, Surgical, Non-Biodegradable	A38090.12	3		1	1
Total				**152**	**130**	**282**

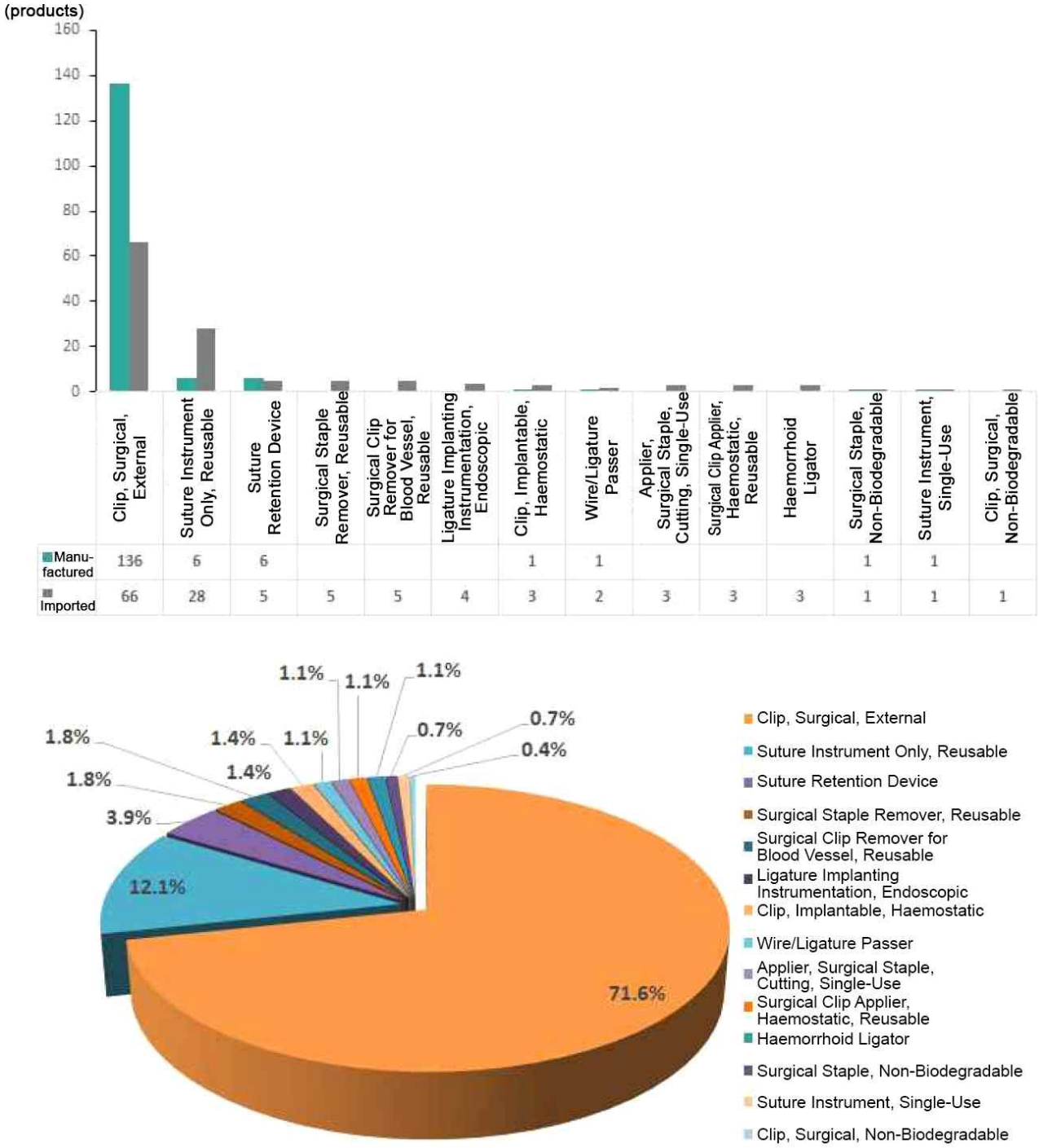


Figure 23. “Instruments for Ligature and Suture (Division)” Items in 2020

○ Measuring and Introducing Instrument (A64000)

- The “Measuring and Introducing Instrument (A64000)” division includes a total of 50 items consisting of 26 Class I items, 19 Class II items, and 5 Class IV items.
- In 2020, products under 28 items were approved, certified, and notified (263). The numbers of manufactured devices and imported devices were 90 (34.2%) and 173 (65.8%), respectively. The percentage of imported products decreased compared to the previous year (A total of 331 in 2019, 84 (25.4%) of which were manufactured, and 247 (74.6%) were imported).
- Among the 28 items, “Guide for Medical Use (AA64050.01)” accounted for the largest proportion with 52 products (19.8%), followed by “Sizer for Medical or Dental Use (A64070.01)” with 48 products (18.3%), and “Guard for the Prevention of Bruxism (A64060.02)” with 31 products (11.8%).
- The following table shows the details of “Measuring and Introducing Instrument (A64000)” approved, certified, and notified in 2020.

[Table 27] “Measuring and Introducing Instrument (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Guide for Medical Use	A64050.01	1	21	31	52
2	Sizer for Medical or Dental Use	A64070.01	1	11	37	48
3	Guard for the Prevention of Bruxism	A64060.02	1	13	18	31
4	Measuring Instrument, General-Purpose	A64020.01	1	13	11	24
5	Marker, Surgical, External	A64040.01	1	2	16	18
6	Guard for Medical Use	A64060.01	1	5	7	12
7	Body Fluid Volume Measuring Apparatus	A64210.01	1	5	7	12
8	Endoscopic Dilator, Cavity	A64200.01	1	2	6	8
9	Caliper, General-Purpose	A64030.01	1		6	6
10	Implantation Assistant, Inserter	A64240.01	1	1	5	6
11	Catheter Guidewire, Vascular	A64160.01	2	2	4	6
12	Catheter Introducer, Central Vein	A64170.03	4		5	5

No.	Item	Classification No.	Class	Manufactured	Imported	Total
13	Guide for Medical Use, Invasive, Single Use	A64050.02	2	3	2	5
14	Marker, Surgical, Internal	A64040.02	2	3	1	4
15	Ophthalmodiastimeter	A64150.01	1		3	3
16	Clinical Goniometer, Manually-Operated	A64010.01	1	1	2	3
17	Tracheal Tube Stylet, Reusable	A64180.03	1	1	2	3
18	Endoscopic Dilator, Subcutaneous	A64200.02	2	2		2
19	Stereotaxic Unit, Navigation	A64110.03	2	1	1	2
20	Catheter Guidewire, Urological	A64160.05	2		2	2
21	Stereotaxic Unit, Non-Frame	A64110.01	1	1	1	2
22	Catheter Guidewire, Enteral	A64160.04	2	1	1	2
23	Catheter Introducer	A64170.01	2	1	1	2
24	Exophthalmometer	A64130.01	1		1	1
25	Tracheal Tube Stylet, Single-Use	A64180.04	2	1		1
26	Template for Clinical Use	A64090.01	1		1	1
27	Catheter Introducer, Haemostasis Valve, Not for Central Vein	A64170.08	2		1	1
28	Stereotaxic Unit, Frame	A64110.02	2		1	1
Total				**90**	**173**	**263**

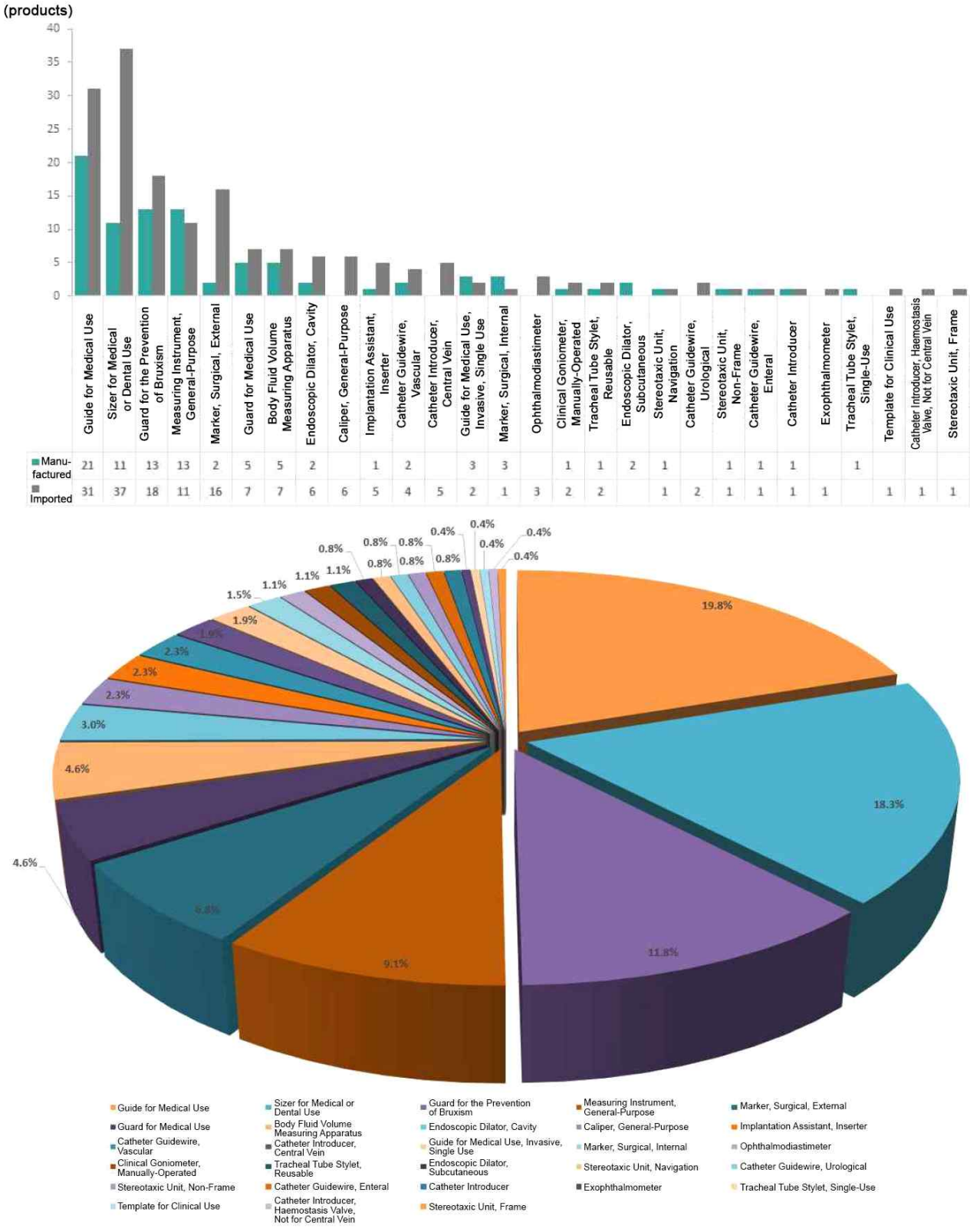


Figure 24. “Measuring and Introducing Instrument (Division)” Items in 2020

○ IVD Reagent for Infectious Disease, Immunological Method **(K05000)**

- The "IVD Reagent for Infectious Disease, Immunological Method (K05000)" division includes a total of 5 items consisting of 2 Class II items, 2 Class III items, and 1 Class IV item.
- In 2020, products under 5 items were approved, certified, and notified (440). The numbers of manufactured products and imported products were 246 (96.1%) and 10 (3.9%), respectively. Generally, manufactured products were more dominant than imported products in this division.
- Among the 5 items, "IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01)" accounted for the largest proportion with 229 products (89.5%), followed by "IVD Reagents for Diagnosis of HIV, HBV, HCV, HTLV (K05010.01)" with 11 products (4.3%).
- The following table shows the details of "IVD Reagent for Infectious Disease, Immunological Method (K05000)" approved, certified, and notified in 2020.

[Table 28] "IVD Reagent for Infectious Disease, Immunological Method (Division)" Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	IVD Reagents for Infectious Disease Marker (Immunological Method)	K05030.01	3	228	1	229
2	IVD Reagents for Diagnosis of HIV, HBV, HCV, HTLV, Immunological Method	K05010.01	4	7	4	11
3	IVD Reagents for Infectious Disease Marker (Detection of Low Infectivity Pathogen)	K05040.01	2	6	2	8
4	IVD Reagents for Infectious Inflammatory Test	K05050.01	2	3	3	6
5	IVD Reagents for Serotyping for Patient Monitoring of HIV, HBV, HCV, HTLV, Immunological Method	K05020.01	3	2		2
Total				**246**	**10**	**256**

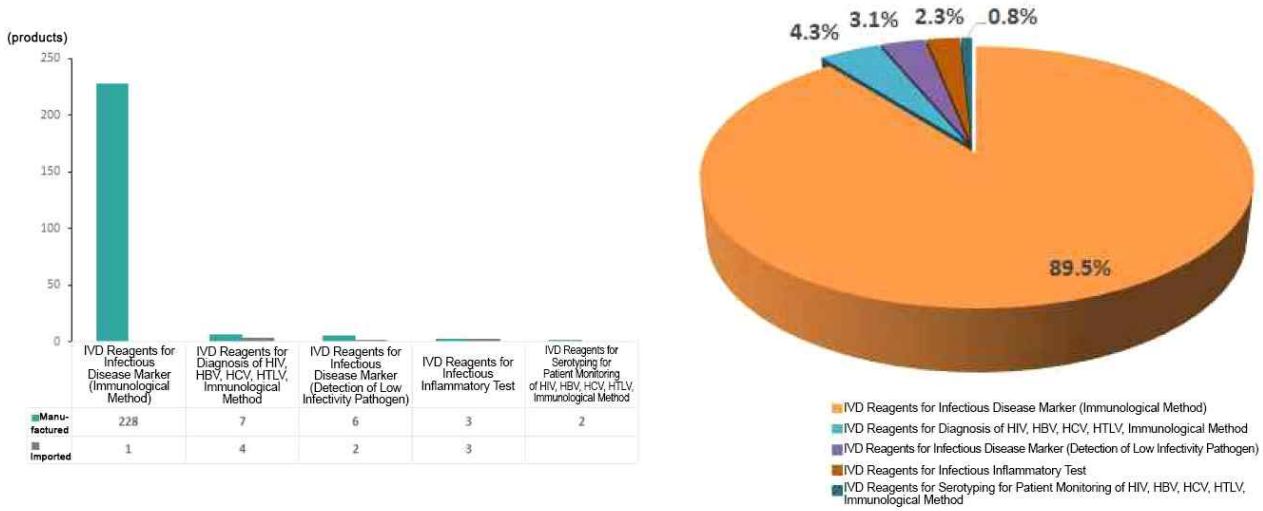


Figure 25. “IVD Reagent for Infectious Disease, Immunological Method (Division)” Items in 2020

○ Tube and Catheter for Medical Use (A57000)

- The “Tube and Catheter for Medical Use (A57000)” division includes a total of 178 items consisting of 7 Class I items, 84 Class II items, 24 Class III items, and 63 Class IV items.
- In 2020, products under 39 items were approved, certified, and notified (243). The numbers of manufactured products and imported products were 106 (43.6%) and 137 (56.4%), respectively. The percentage of manufactured products increased significantly compared to the previous year (A total of 266 in 2019, 62 (23.3%) of which were manufactured, and 204 (76.7%) were imported).
- Among the 39 items, “Catheter, Evacuator ” accounted for the largest proportion with 93 products (38.3%), followed by “Oxygen Tube and Catheter, Single-Use (A57070.01)” with 32 products (13.2%), and “Catheter, Urological (A57060.01)” with 10 products (4.1%).
- The following table shows the details of “Tube and Catheter for Medical Use (A57000)” approved, certified, and notified in 2020.

[Table 29] “Tube and Catheter for Medical Use (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Catheter, Evacuator	A57090.01	1	38	55	93
2	Oxygen Tube and Catheter, Single-Use	A57070.01	1	8	24	32
3	Catheter, Urological	A57060.01	2	1	9	10
4	Catheterization Kit, Haemodialysis	A57250.01	2	6	4	10
5	Catheter, Epidural	A57220.17	3	9		9
6	Angioplasty Catheter, Balloon Dilatation, Coronary, Perfusing	A57130.21	4	2	7	9
7	Catheter, Bronchus, Short-Term Use	A57030.01	2	1	6	7
8	Catheter, Infusion, Drainage	A57220.01	2	4	3	7
9	Cannula, General-Purpose	A57140.01	2	6		6
10	Catheter, General-Purpose, Balloon	A57275.01	2	5	1	6
11	Catheter, Micro	A57130.27	3	1	3	4
12	Catheter, Cardiac,	A57190.01	2	2	2	4

No.	Item	Classification No.	Class	Manufactured	Imported	Total
	Electrophysiological Mapping					
13	Intravascular Catheter, Short-Term	A57130.01	2	2	2	4
14	Catheter, Percutaneous	A57260.01	2	3		3
15	Cholangiopancreatography Catheter, Single-Use	A57040.03	2	2	1	3
16	Circulatory Assist System, Intra-Aortic Balloon	A57130.33	4		3	3
17	Intravascular Guiding Catheter	A57130.04	2	3		3
18	Catheter, Bileduct, Short-Term Use	A57040.01	2	2		2
19	Catheter, Ventilatory, Short-Term Use	A57030.02	2		2	2
20	Catheter, Bileduct, Balloon	A57040.06	2	1	1	2
21	Ureteral Catheter	A57060.03	2		2	2
22	Tube and Catheter for Medical Use	A57000	3	1	1	2
23	Catheter, Intravascular, Embolectomy/Thrombectomy, Central Circulation	A57130.17	4		2	2
24	Catheter Balloon, Kyphoplasty	A57275.04	2	2		2
25	Catheter, Nasal, Haemostatic	A57290.01	1	1	1	2
26	Oximeter Catheter, Fibreoptic	A57270.01	2		1	1
27	Catheter, Gastrointestinal	A57020.01	2		1	1
28	Catheter, Bileduct, Dilator	A57040.04	2	1		1
29	Catheter, Intravascular, Embolectomy/Thrombectomy, Non-Central Circulation	A57130.16	2		1	1
30	Catheter, Supraenteral	A57020.13	2		1	1
31	Catheter Snare	A57130.22	2	1		1
32	Gastric Appetite-Suppressing Balloon	A57020.08	2	1		1
33	Tube and Catheter for Medical Use	A57000	4	1		1
34	Catheter Balloon, Intrauterine	A57275.05	2		1	1
35	Liposuction System Cannula, Single-Use	A57090.02	2	1		1
36	Tube, Rectal	A57020.17	2		1	1
37	Angioplasty Catheter, Balloon Dilatation, Non-Coronary	A57130.18	4		1	1
38	Catheter, Intravascular, Angiography	A57130.05	2		1	1
39	Disposable Sucker	A57080.01	1	1		1
Total				**106**	**137**	**243**

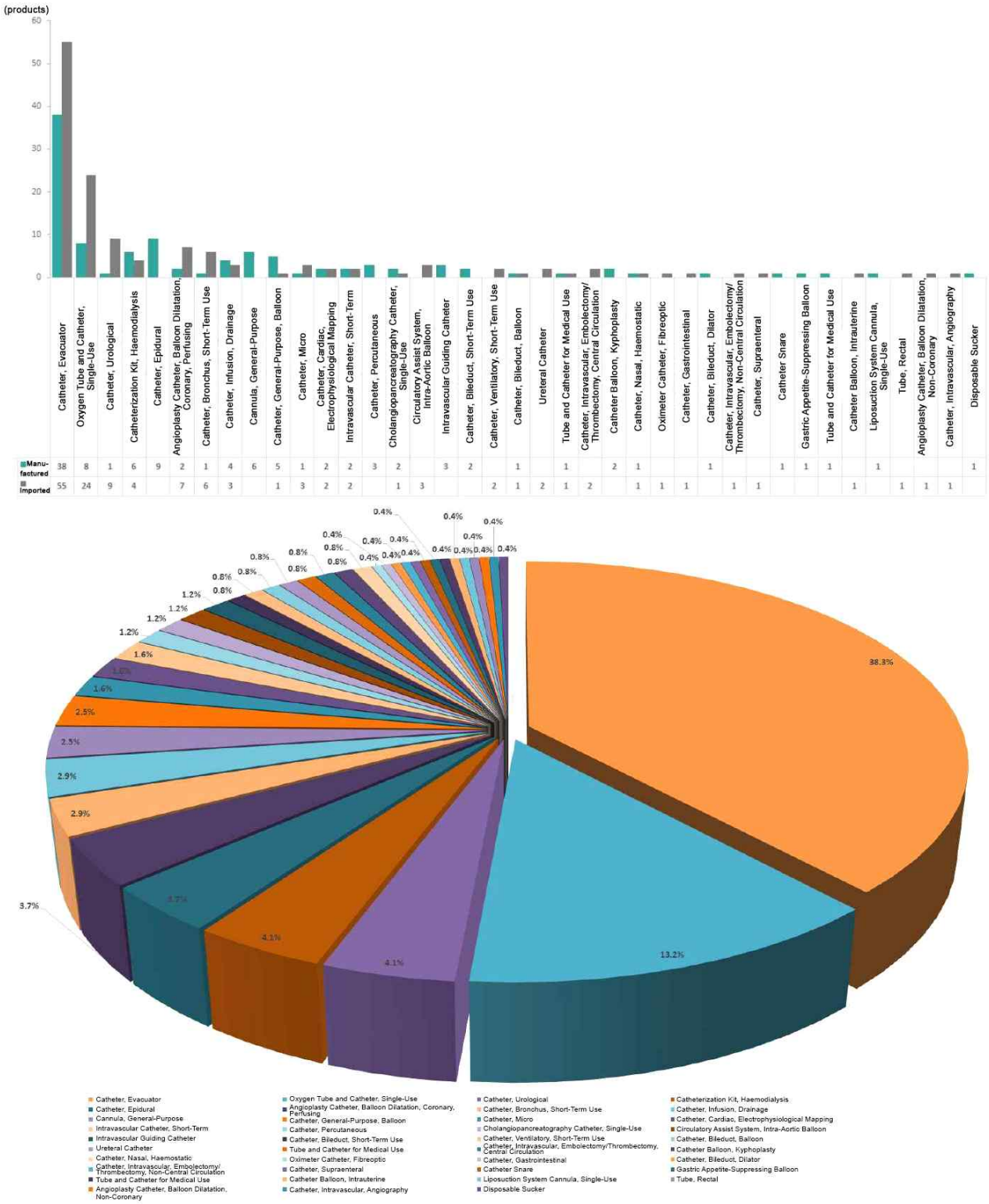


Figure 26. “Tube and Catheter for Medical Use (Division)” Items in 2020

○ **Puncturing, Abrasion, and Perforating Instrument for Medical Use (A55000)**

- The “Puncturing, Abrasion, and Perforating Instrument for Medical Use (A55000)” division includes a total of 32 items consisting of 13 Class I items, 17 Class II items, and 2 Class III items.
- In 2020, products under 22 items were approved, certified, and notified (222). The numbers of manufactured devices and imported devices were 55 (24.8%) andv167 (75.2%), respectively. The percentage of manufactured products decreased compared to the previous year (The total number was 223 in 2019 with 81 (36.3%) manufactured and 142 (63.7%) imported products).
- Among the 22 items, “Abrasive Device (A55050.01)” accounted for the largest proportion with 81 products (36.5.%), followed by “Puncture Instrument, Surgical, Manually-Operated, Reusable (A55010.01)” with 33 products (14.9%).
- The following table shows the details of “Puncturing, Abrasion, and Perforating Instrument for Medical Use (A55000)” approved, certified, and notified in 2020.

[Table 30] “Puncturing, Abrasion, and Perforating Instrument for Medical Use (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Abrasive Device	A55050.01	1	22	59	81
2	Puncture Instrument, Surgical, Manually-Operated, Reusable	A55010.01	1	8	25	33
3	Surgical Drill Handpiece, Manual	A55030.01	1	5	14	19
4	Central Drill System Handpiece, Pneumatically-Powered	A55030.05	2	2	10	12
5	Dental Scaler, Manual, Reusable	A55040.01	1	2	8	10
6	Trephine Instrument, Manually-Operated, Reusable	A55020.01	1	3	7	10
7	Drill Handpiece, Surgical, Electrically-Powered	A55030.03	2	2	6	8
8	Scaler System Tip, Ultrasonic	A55040.04	1	2	6	8
9	Puncture Instrument, Surgical, Manually-Operated, Single-Use	A55010.02	2	4	2	6
10	Dental Abrasive Device	A55050.05	1		5	5
11	Instrument for Medical Handpiece, Surgical, Power Delivery	A55090.01	1	1	4	5
12	Teeth Cleaning Brush, Dental-Professional	A55050.02	1		4	4
13	Dental Abrasive Disk	A55050.03	1		4	4
14	Dental Abrasive Strip	A55050.04	1		3	3
15	Drill Handpiece, Dental, Surgical	A55030.06	2		3	3
16	Central Drill System Handpiece, Surgical, Pneumatically-Powered	A55030.09	2		2	2
17	Drill Handpiece, Surgical, Electrically-Powered, Single-Use	A55030.10	2	2		2
18	Dental Drill System Handpiece, Line-Powered	A55030.04	2	1	1	2
19	Ultrasonic Dental Scaling System	A55040.03	2		2	2
20	Trephine Instrument, Manually-Operated, Single-Use	A55020.02	2		1	1
21	Abrasive Device, Ophthalmic, Single-Use	A55050.08	2	1		1
22	Prophylaxis Cup	A55050.06	1		1	1
Total				**55**	**167**	**222**

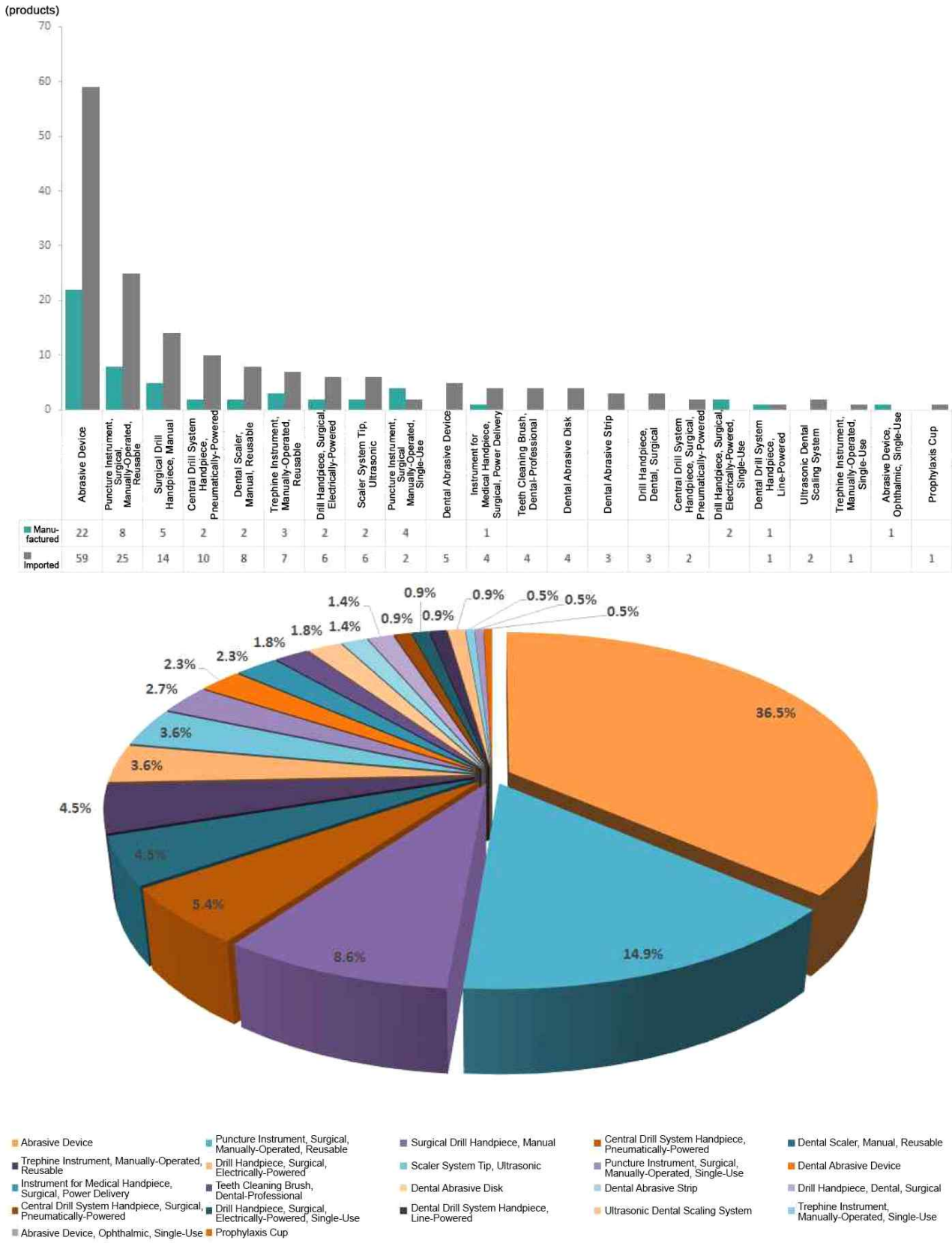


Figure 27. “Puncturing, Abrasion, and Perforating Instrument for Medical Use (Division)” Items in 2020

○ Medical Devices for Orthopedics and Restoration **(A67000)**

- The “Medical Devices for Orthopedics and Restoration (A67000)” division includes a total of 19 items consisting of 7 Class I items, 9 Class II items, and 3 Class III items.
- In 2020, products under 15 items were approved, certified, and notified (214). The numbers of manufactured devices and imported devices were 96 (44.9%) and 118 (55.1%), respectively.
- Among the 15 items, “Instruments, Bone, Surgical, Manually-Operated (A67050.01)” accounted for the largest proportion with 110 products (51.4%), followed by “Traction Unit, Air-Powered, Manually-Operated (A67010.04)” with 24 products (11.2%), while the other items remained similar to each other.
- The following table shows the details of “Medical Devices for Orthopedics and Restoration (A67000)” approved, certified, and notified in 2020.

[Table 31] “Medical Devices for Orthopedics and Restoration (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Instruments, Bone, Surgical, Manually-Operated	A67050.01	1	37	73	110
2	Traction Unit, Air-Powered, Manually-Operated	A67010.04	1	5	19	24
3	Exerciser, Orthopaedic, Manually-Operated	A67020.01	1	14	8	22
4	Manually-Operated Rehabilitation Exerciser	A67070.01	1	9	6	15
5	Exerciser, Orthopaedic, Electrically-Powered	A67020.02	2	13	1	14
6	Traction Unit, Manually-Operated	A67010.01	1	3	5	8
7	Robotic Surgical System, Navigation	A67050.04	3	4		4
8	Orthopedics Appliance	A67030.01	2	4		4
9	Percussor, Chest, Manually-Operated	A67040.01	1	1	2	3
10	Percussor, Chest, Electrically-Powered	A67040.02	1	1	2	3
11	Robotic-Guidance Rehabilitation System	A67080.01	3	1	1	2
12	Hair Implant System	A67060.01	2	2		2
13	Traction Unit, Electrically-Powered	A67010.03	2	1		1
14	Instruments, Bone, Surgical, Battery-Powered	A67050.03	2		1	1
15	Powered Orthopedic Device	A67025.01	2	1		1
Total				**96**	**118**	**214**

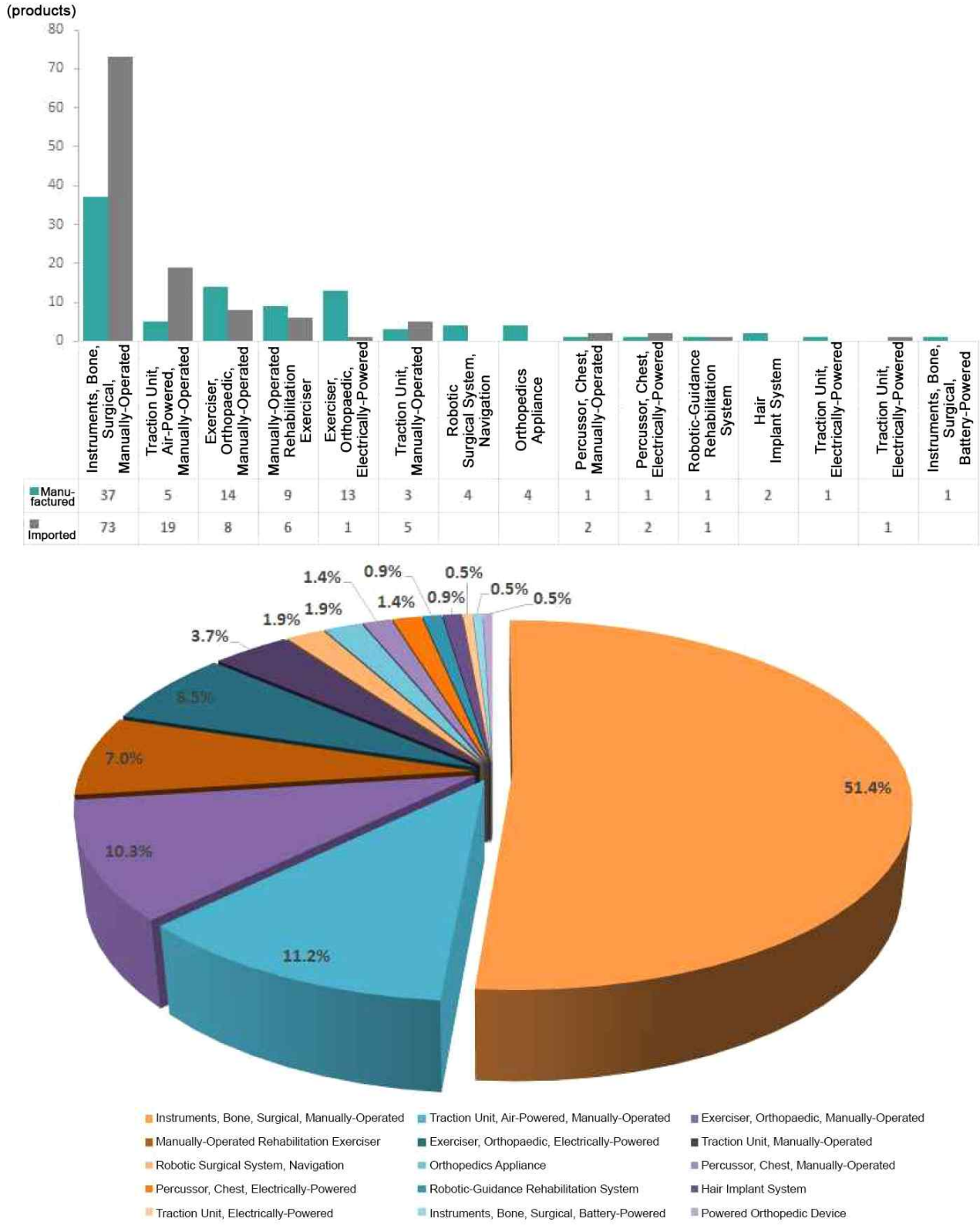


Figure 28. “Medical Devices for Orthopedics and Restoration (Division)” Items in 2020

○ Speculums for Medical Use (A31000)

- The “Speculums for Medical Use (A31000)” division includes a total of 200 items consisting of 37 Class I items, 144 Class II items, and 19 Class IV items.
- In 2020, products under 57 items were approved, certified, and notified (211). The numbers of manufactured products and imported products were 48 (22.7%) and 163 (77.3%), respectively. Generally, imported products were more dominant than manufactured products in this division.
- Among the 57 items, “Stomatoscope, Flexible, Fibreoptic (A31020.04)” accounted for the largest proportion with 20 products (9.5%), followed by “Dental Mirror (A31060.01)” with 16 products (7.6%).
- The following table shows the details of “Speculums for Medical Use (A31000)” approved, certified, and notified in 2020.

[Table 32] “Speculums for Medical Use (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Stomatoscope, Flexible, Fibreoptic	A31020.04	2	2	18	20
2	Dental Mirror	A31060.01	1	5	11	16
3	Laryngoscope, Rigid	A31100.01	1	1	11	12
4	Adaptor, Endoscope Element	A31010.01	1	3	9	12
5	Camera Head for Medical Use	A31020.03	1	5	7	12
6	Microscope, Surgical, General-Purpose	A31030.01	1		12	12
7	Endotherapy Forceps, Reusable	A31010.29	1	2	8	10
8	Camera, Still, Surgical	A31020.01	1	6	1	7
9	Otoscope, Rigid	A31360.01	1		6	6
10	Duodenoscope, Video	A31190.05	2		6	6
11	Scraper, Cytology, Single-Use	A31010.17	2		5	5
12	Endoscopic Trocar, Single Use	A31010.39	2	4	1	5
13	Endotherapy Cannula, Reusable	A31010.22	1	3	2	5
14	Endoscopic Trocar, Reusable	A31010.38	1		5	5
15	Intubation Laryngoscope, Rigid, Sing-Use	A31100.08	2		4	4
16	Endotherapy Needle, General-Purpose, Single-Use	A31010.37	2	1	3	4

17	Scraper, Cytology, Reusable	A31010.16	1		4	4
18	Endotherapy Device, General-Purpose, Reusable	A31010.32	1	2	2	4
19	Colonoscope, Fibreoptic	A31170.01	2		3	3
20	Stomatoscope, Video	A31020.05	1	3		3
21	Colonoscope, Video	A31170.03	2		3	3
22	Endotherapy Device, General-Purpose, Single-Use	A31010.33	2	1	2	3
23	Endotherapy Scissors, Reusable	A31010.26	1	1	2	3
24	Endoscopic Lithotomy, Resectoscope, Reusable	A31010.06	1		3	3
25	Ultrasonic Endoscope	A31090.01	2		3	3
26	Arthroscope, Rigid	A31140.01	2	1	1	2
27	Nasopharyngo-Laryngoscope, Fibreoptic	A31310.07	2		2	2
28	Spinoscope, Rigid	A31090.26	4	1	1	2
29	Endotherapy Device, Elevator	A31010.09	1		2	2
30	Laryngoscope, Intubation, Rigid, Video	A31100.09	2		2	2
31	Bronchoscope, Flexible, Video	A31110.03	2		2	2
32	Small Intestinoscope, Fibreoptic, Video	A31190.08	2		2	2
33	Capsule Endoscope for Medical Use	A31090.44	2	2		2
34	Endoscopic Lithotomy, Resectoscope, Single-Use	A31010.07	2		2	2
35	Cystourethroscope, Rigid	A31200.01	2		1	1
36	Laparoscope, Rigid, Optical	A31290.01	2		1	1
37	Sinoscope, Rigid	A31090.05	2		1	1
38	Neuroscope, Rigid, Reusable	A31350.01	4		1	1
39	Thracoscope, Rigid	A31370.01	1		1	1
40	Electrosurgical Endotherapy Electrode, Single-Use	A31010.11	2		1	1
41	Endoscopic Forceps, Biopsy, Electrically-Powered, Flexible	A31010.18	2	1		1
42	Cystourethroscope, Flexible, Video	A31200.03	2		1	1
43	Oesophagoscope, Flexible, Video	A31120.03	2		1	1
44	Gastroscope, Video	A31190.03	2		1	1
45	Endoscopic Knife, Manually-Operated	A31010.21	1		1	1
46	Esophagogastroduodenoscope	A31320.01	2		1	1
47	Endoscope for Medical Use	A31090.42	2	1		1
48	Endotherapy Forceps, Single-Use	A31010.30	2		1	1
49	Snare, Endoscopy	A31010.15	2	1		1
50	Endotherapy Cannula, Single-Use	A31010.23	2		1	1
51	Endotherapy Cytology Brush, Flexible, Reusable	A31010.12	1		1	1
52	Polypectomy Snare, Rigid, Reusable	A31010.14	1		1	1
53	Endoscopic Evacuator, Reusable	A31010.02	1		1	1

54	Intubation Laryngoscope, Rigid, Reusable	A31100.10	1		1	1
55	Camera, Still, Endoscopic	A31020.02	2	1		1
56	Colposcope	A31040.01	1		1	1
57	Laryngostroboscope System	A31100.04	2	1		1
Total				**48**	**163**	**211**

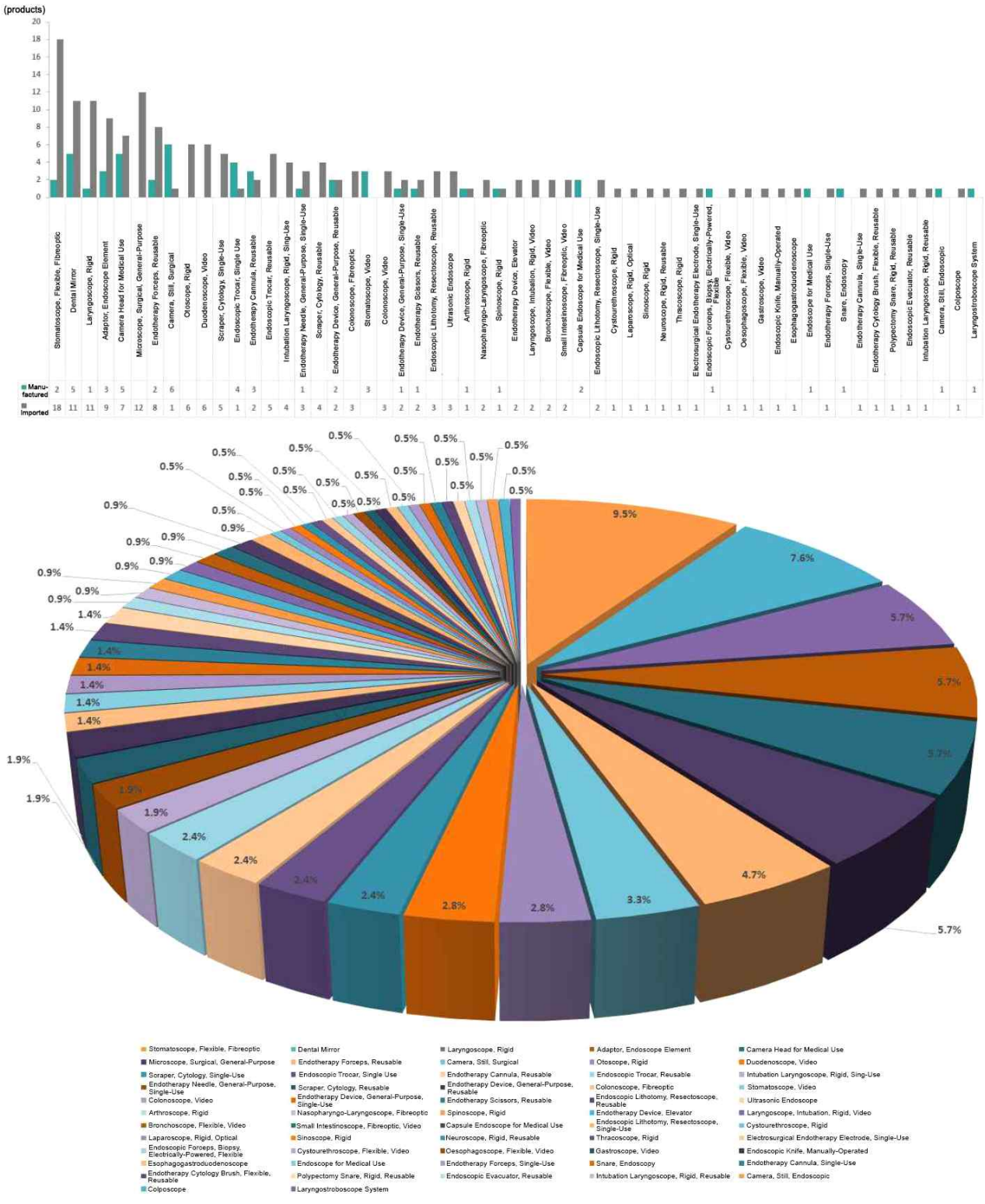


Figure 29. “Speculums for Medical Use (Division)” Items in 2020

○ **Splints (B05000)**

- The “Splints (B05000)” division only includes 11 Class I items.
- In 2020, products under 10 items were approved, certified, and notified (209). The numbers of manufactured products and imported products were 123 (58.9%) and 86 (41.1%), respectively.
- In addition, among the 10 items, “Splints (B05010.01)” reported the highest number of products at 120 (57.4%).
- The following table shows the details of “Splints (B05000)” approved, certified, and notified in 2020.

[Table 33] “Splints (Division)” Items in 2020

(Unit: Number of products)

No.	Item	Classification No.	Class	Manufactured	Imported	Total
1	Splints	B05010.01	1	62	58	120
2	Splints, Mouldable	B05040.03	1	26	2	28
3	Hand/Finger Splint	B05010.02	1	9	13	22
4	Splint, Hallux Valgus	B05030.02	1	6	7	13
5	Splint, Extremity, Inflatable	B05020.01	1	3	5	8
6	Splint, Padded Stays	B05040.05	1	6	1	7
7	Nasal Splint, External	B05040.02	1	5		5
8	Nasal Splint, Internal	B05040.01	1	3		3
9	Splint, Cogenital Hip Dislocation Abduction	B05050.01	1	2		2
10	Splint, Denis Brown	B05030.01	1	1		1
Total				**123**	**86**	**209**

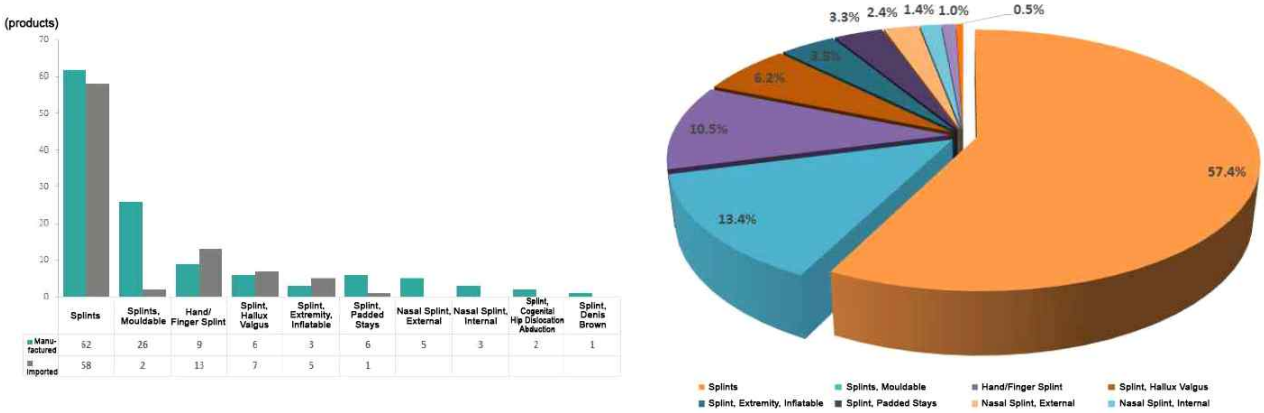


Figure 30. “Splints (Division)” Items in 2020

Ⅰ-5. Frequently Approved, Certified, and Notified Items

A total of 1,362 items consisting of 1,132 manufactured devices (83.1%) and 230 imported devices (16.9%) were approved in 2020. In particular, the most frequently approved manufactured item was “IVD Reagents for Infectious Disease Marker (Immunological Method) (228),” followed by “IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (157),” and “General Calibrators, Controls or Standards, Class III, For Clinical Immunology, Not a Component of Specific Kit, Wide Use (62).” Meanwhile, the most frequently approved imported item was “Soft Contact Lens, Daily-Wear (9),” followed by “Angioplasty Catheter, Balloon Dilatation, Coronary, Perfusing (7),” and “Intraocular Lens (6).”

The 10 items with the highest number of approvals in 2020 are listed in the table below. In comparison to imported items, there were more manufactured items including approved items for export. In particular, as a result of increases in the development of COVID-19 diagnostic reagents due to the spread of the COVID-19 virus, “IVD Reagents for Infectious Disease Marker (Immunological Method)” and “IVD Reagents for Infectious Disease Marker (Molecular Diagnostics)” were the 1st and 2nd most frequently approved items.

[Table 34] Frequently Approved Manufactured/Imported Items in 2020

(Unit: Number of products)

Rank	Manufactured			Imported		
	Item	No. of Products	Rank in 2019	Item	No. of Products	Rank in 2019
1	IVD Reagents for Infectious Disease Marker (Immunological Method)	228	3	Soft Contact Lens, Daily-Wear	9	3
2	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics)	157	1	Angioplasty Catheter, Balloon Dilatation, Coronary, Perfusing	7	-
3	General Calibrators, Controls or Standards, Class III, For Clinical Immunology, Not a	62	-	Intraocular Lens	6	-

	Component of Specific Kit, Wide Use					
4	Graft/Prothesis, Biomaterial	54	5	Fluoroscopic X-ray System, General-Purpose, Mobile, Digital	5	-
5	Soft Contact Lens, Daily-Wear	34	7	Defibrillator, Implantable	5	-
6	Polydioxanone Suture	30	6	Catheter Introducer, Central Vein	5	-
7	Graft/Prothesis	29	-	IVD Reagent for Hemostasis and Thrombosis	5	-
8	Implant, Endosseous, Fixture	29	10	IVD Reagents for Diagnosis of HIV, HBV, HCV, HTLV, Immunological Method	4	-
9	Suture, Absorbable	22	4	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics)	4	-
10	Spinal Cage	18	9	Hip Prothesis, Internal, Total	4	-

A total of 1,952 items consisting of 1,127 manufactured devices (57.7%) and 825 imported devices (42.3%) were certified in 2020. The most frequently certified manufactured item was “Implant, Endosseous, Superstructure (115),” followed by “General Calibrators, Controls or Standards, Class II, For Clinical Immunology, Not a Component of Specific Kit, Wide Use (43),” and “Hearing Aid, Air-Conduction (41).” Meanwhile, the most frequently certified imported item was “Hearing Aid, Air-Conduction (89),” followed by “General Calibrators, Controls or Standards, Class II, For Clinical Chemistry (29),” and “General Calibrators, Controls or Standards, Class II, For Clinical Immunology, Not a Component of Specific Kit, Wide Use (27).”

The 10 items with the highest number of certifications in 2020 are listed in the table below. Although “Hearing Aid, Air-Conduction” and “IVD Medical Devices” accounted for high percentages in the imported devices as was the case with the previous year, in the manufactured devices, “Implant, Endosseous, Superstructure” accounted for a high percentage unlike the previous year when “Hearing Aid, Air-Conduction” was the dominant item. In addition, “Thermometer, Electronic, Infrared, Skin” was added to the list of frequently certified items due to the COVID-19 virus.

[Table 35] Frequently Certified Manufactured/Imported Items in 2020

(Unit: Number of products)

No.	Manufactured		Imported	
1	Implant, Endosseous, Superstructure	115	Hearing Aid, Air-Conduction	89
2	General Calibrators, Controls or Standards, Class II, For Clinical Immunology, Not a Component of Specific Kit, Wide Use	43	General Calibrators, Controls or Standards, Class II, For Clinical Chemistry	29
3	Hearing Aid, Air-Conduction	41	General Calibrators, Controls or Standards, Class II, For Clinical Immunology, Not a Component of Specific Kit, Wide Use	27
4	Thermometer, Electronic, Infrared, Skin	40	IVD Reagents and Media for Antibiotic Susceptibility	25
5	Magnetic Induction Apparatus	38	Stomatoscope, Flexible,	18

	for Medical Use		Fibreoptic	
6	Dressing, Fluid-Impermeable Film	33	IVD Reagents for General Immune Test	15
7	Medical Image, Analog to Digital Transform, DR, CR	25	IVD Reagents for Flow Cytometric Test	14
8	Analyser, Medical Image, Software	24	CT System, Full-Body	12
9	Ceramic, Milling	19	Light Source, Endoscope	11
10	Attachment, Precision	16	Central Drill System Handpiece, Pneumatically-Powered	10
			Probe, Ultrasonic, Hand-Held, External	10
	Implant, Surgical, Guide for Medical Use	16	Direct Infusion Device	10
			Electrosurgical System Electrode, Foot-Controlled, Single-Use	10

A total of 4,869 items consisting of 1,963 manufactured devices (40.3%) and 2,906 imported devices (59.7%) were notified in 2020. The most frequently notified manufactured item was “Clip, Surgical, External (135),” followed by “Specimen Transport Media (122),” and “Implant, Endosseous, Hand Instrument (110).” Meanwhile, the most frequently notified imported item was “Sight Corrective Ophthalmic Lens (302),” followed by “Bandage, Compression (124),” and “Glove, Patient Examination (100).”

The 10 items with the highest number of notifications in 2020 are listed in the table below. Particularly, “Tool for Specimen” which includes tools, swabs, etc. used to collect body fluids, secretions, etc. for testing of diseases, etc. entered the ranks unlike the previous year, and that is considered due to the increases in development as a result of the spread of the COVID-19 virus.

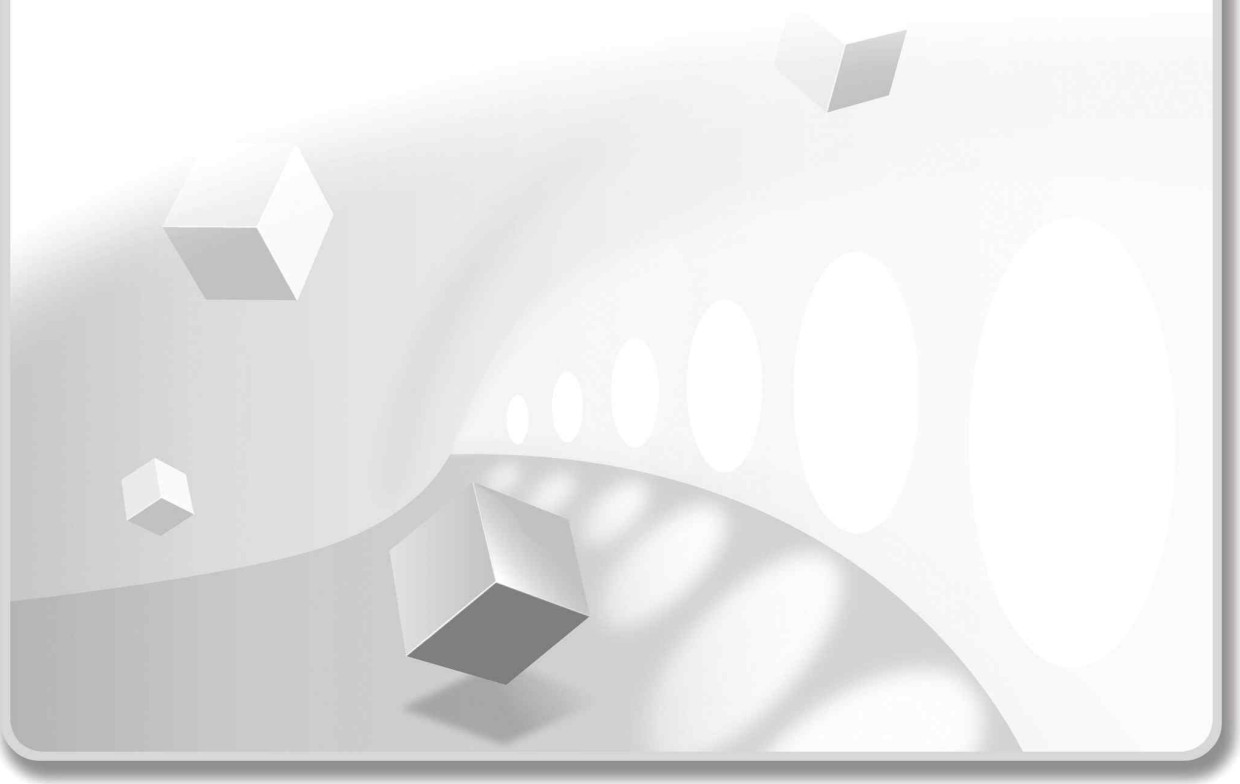
[Table 36] Frequently Notified Manufactured/Imported Items in 2020

(Unit: Number of products)

No.	Manufactured		Imported	
1	Clip, Surgical, External	135	Sight Corrective Ophthalmic Lens	302
2	Specimen Transport Media	122	Bandage, Compression	124
3	Implant, Endosseous, Hand Instrument	110	Glove, Patient Examination	100
4	Bandage, Compression	107	Retractor, Surgical, Manually-Operated	81
5	Sight Corrective Ophthalmic Lens	91	Forceps, Reusable	76
6	IVD Reagents for Extracting Nucleic Acids	77	Instruments, Bone, Surgical, Manually-Operated	73
7	Tool for Specimens	69	Clip, Surgical, External	66
8	Splints	62	Tool for Specimens	61
9	Implant, Endosseous, Drill/Handpiece	43	Abrasive Device	59
10	Bed, General-Purpose, Electrically-Powered	38	Splints	58
	Catheter, Evacuator	38	Wheelchair, Manually-Operated	58

Ⅱ

Approvals, Certifications, and Notifications by Type



Ⅱ. Approvals, Certifications, and Notifications by Type

Ⅱ-1. Approval of Medical Devices Subject to Re-evaluation

The lack of clinical use cases and other factors prevent sufficient evaluation of the safety and effectiveness of novel or orphan medical devices. Given this, these medical devices are monitored for adverse events for a certain post-market period. During this period, the data collected are used for the re-evaluation of the products' safety and effectiveness.

In particular, one medical device item was added to the list of products subject to re-evaluation in 2020, making the list 24 items consisting of 13 (54.2%) novel medical devices and 11 (45.8%) orphan medical devices.

The novel medical device approved in 2019 is "Circulatory Assist System, Artificial Heart (A09150.02)". The HeartMate 3TM Left Ventricular Assist System is a medical device used to provide patients suffering from progressive refractory left-sided heart failure with short-term and long-term circulatory support.

[Table 37] Medical Devices Subject to Re-evaluation (All)[1)]

No.	Company	Item (Class)	Approval No. (Date	Category
1	St. Jude Medical Korea Co., Ltd.	Circulatory Assist System, Artificial Heart (4)	Import Approval No. 12-1670 (2012.11.29)	Novel
2	REMED, Inc	Electromagnetic Therapy Stimulator (2)	Manufacturing Approval No. 13-820 (2013.5.9)	Novel
3	Medtronic Korea Co., Ltd.	Circulatory Assist System, Artificial Heart (4)	Import Approval No. 13-3075 (2013.12.6)	Novel
4	UNI, Inc	Orthopaedic Bone Screw, Biodegradable (4)	Manufacturing Approval No. 15-594 (2015.4.20)	Novel
5	UNI, Inc	Orthopaedic Fixation Plate Kit, Biodegradable (4)	Manufacturing Approval No. 16-166 (2016.3.4)	Novel
6	Gencurix, Inc	IVD Reagents for Cancer	Manufacturing Approval	Novel

1) Excluding conditional approvals

No.	Company	Item (Class)	Approval No. (Date	Category
		Related Gene (3)	No. 16-800 (2016.11.2)	
7	CG Bio, Inc	Bone Graft, Composite (4)	Manufacturing Approval No. 17-451 (2017.6.29)	Novel
8	Abbott Korea, Inc	Instruments for Ligature and Suture (4)	Import Approval No. 17-406 (2017.8.30)	Novel
9	Aptamer Sciences, Inc	IVD Reagents for Tumor Marker, Immunological Test (3)	Manufacturing Approval No. 17-748 (2017.9.26)	Novel
10	NovoMix, Inc	IVD Reagents for Cancer Related Gene (3)	Manufacturing Approval No. 17-865 (2017.11.10)	Novel
11	Genomictree, Inc	IVD Reagents for Cancer Related Gene (3)	Manufacturing Approval No. 18-593 (2018.8.28)	Novel
12	Bertis, Inc	IVD Software(3)	Manufacturing Approval No. 19-5 (2019.01.03)	Novel
13	Abbott Medical Korea, Inc	Circulatory Assist System, Artificial Heart (4)	Import Approval No. 20-124 (2020.6.3)	Novel
14	Medtronic Korea Co., Ltd.	Prosthesis, Valve, Cardiac, Biological (4)	Import Approval No. 11-1145 (2011.10.4)	Orphan
15	Edwards Lifesciences Korea, Inc		Import Approval No. 12-531 (2012.4.6)	Orphan
16	Edwards Lifesciences Korea, Inc		Import Approval No. 12-532 (2012.4.6)	Orphan
17	Boston Scientific Korea, Inc		Import Approval No. 14-2158 (2014.6.27)	Orphan
18	Honex Korea, Inc	Pleuroperitoneal Shunt (3)	Import Approval No. 14-3186 (2014.11.14)	Orphan
19	St. Jude Medical Korea Co., Ltd.	Prosthesis, Valve, Cardiac, Biological (4)	Import Approval No. 15-471 (2015.2.13)	Orphan
20	Vasocare, Inc	Cardiovascular Devices (4)	Import Approval No. 15-520 (2015.3.2)	Orphan
21	Kisan Tech, Inc	Physical Devices for Medical Use (4)	Import Approval No. 17-179 (2017.4.14)	Orphan
22	Global Damon Pharma, Inc	Diaphragm/Phrenic Nerve Electrical Stimulation System (4)	Import Approval No. 17-478 (2017.10.20)	Orphan
23	TaeWoong Medical, Inc	Prosthesis, Valve, Cardiac, Biological (4)	Manufacturing Approval No. 18-658 (2018.10.1)	Orphan
24	Biotronik Korea, Inc	Coronary Artery Stent (4)	Import Approval No. 19-207 (2019.07.05)	Orphan

The percentage of manufactured products is relatively high among novel medical devices. This can be attributed to Korea's advanced development/production capabilities as well as the enhanced national support for the entire bio industry including R&D. In particular, the MFDS has been actively supporting the development of novel medical devices through programs like "Approval Helper for Novel Medical Devices, Etc."

* Approval Helper for Novel Medical Devices, Etc.: a program in which the MFDS works with various entities to provide technical and administrative support for a novel medical device throughout its life cycle

In 2020, 13 novel medical devices have been approved. The details are as follows.

[Table 38] Approved Novel Medical Devices (All)

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Rationale for New Development	Re-evaluation
1	Circulatory Assist System, Artificial Heart (A09150.02(4))	HeartMate II Left Ventricular Assist System (LVAS))	St. Jude Medical Korea Co., Ltd.	Import Approval No.12-1670 (2012.11.29)	Used as a bridge to transplantation in candidates for a heart transplant due to left ventricular failure, or as a destination therapy in patients with terminal left ventricular failure	Approved for the first time	Re-evaluation required
2	Electromagnetic Therapy Stimulator (A85020.01(2))	ALTMS	REMED, Inc	Manufacturing Approval No.13-820 (2013.5.9)	An apparatus that creates an electromagnetic field for the treatment of depression in adult patients	The operating principles and intended use, etc. are not essentially equivalent to those of previously approved items	Re-evaluation required
3	Circulatory Assist System, Artificial Heart (A09150.02(4))	Heartware ⓡ Ventricular Assist System	Rapamed Co., Ltd.	Import Approval No.13-3075 (2013.12.6)	This is used in patients at risk of death caused by terminal heart failure (left and	Approved for the first time	Re-evaluation required

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Rationale for New Development	Re-evaluation
					right ventricles). Patients can be discharged and return to normal life after the procedure.		
4	Orthopaedic Bone Screw, Biodegradable (B03100.02(4))	resomet™ Bioresorbable Bone Screw(BS2006 Bone Screw Ø2.0 X 6mm and 133 others)	UNI, Inc	Manufacturing Approval No.15-594 (2015.4.20)	A biodegradable screw used to fix fractured bones	The operating principles and raw materials, etc. are not essentially equivalent to those of previously approved items	Re-evaluation required
5	Orthopaedic Fixation Plate Kit, Biodegradable (B03140.03(4))	resomet™ Bioresorbable K-wire and Pin(KW0907 KIRSCHNER WIRE Ø0.9 X 70MM and 192 others)	UNI, Inc	Manufacturing Approval No.16-166 (2016.3.4)	A biodegradable orthopaedic fixation plate kit used to hold or tighten fractured bones	The raw materials, etc. are not essentially equivalent to those of previously approved items	Re-evaluation required
6	IVD Reagents for Cancer Related Gene (D06020.01(3))	GenesWell™ BCT	Gencurix, Inc	Manufacturing Approval No.16-800 (2016.11.2)	This is an in vitro diagnostic device that puts data about the expression of the 9 genes, the size of breast carcinoma, and the status of auxiliary lymph node metastasis in formalin-fixed, paraffin-embedded (FFPE) breast cancer tissues from early breast cancer patients (those who have ER and/or PR positive hormone receptors, are HER2 protein negative, and have 3 or fewer	Approved for the first time	Re-evaluation required

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Rationale for New Development	Re-evaluation
					axillary lymph nodes that have been metastasized) into an algorithm to provide information regarding the risk of metastasis to other organs within 10 years (low-risk group or high risk group) (However, the current status of the breast cancer, the prediction or confirmation of reaction to treatment, or the treatment method cannot be determined based solely on the test result).		
7	Bone Graft, Composite (B04220.03(4))	Novosis (BMPGM025 OS and 11 others)	CG Bio, Inc	Manufacturing Approval No.17-451 (2017.6.29)	This device is used for the short posterolateral fusion of the lumbar spine (L1–S1) after posterior lumbar interbody fusion. Furthermore, it is used with internal/external fixation devices in cases of insufficient autogenous bone graft transplants at bone defects measuring 5 cm or smaller caused by an acute traumatic upper/lower extremity fracture or at the risk of complications.	The raw materials, operating principles, and intended use are not essentially equivalent to those of previously approved items	Re-evaluation required
8	Instruments for Ligature and Suture (A38000(4))	MitraClip NT (CDS0502 and 1 other)	Abbott Korea, Inc	Import Approval No.17-406 (2017.8.30)	MitraCilp NT System is used to reduce symptoms of degenerative mitral valve insufficiency (MR	The operating principles and intended use, etc. are not essentially equivalent to	Re-evaluation required

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Rationale for New Development	Re-evaluation
					≥3+) percutaneously in patients for whom a mitral valve surgery is dangerous, as determined by a physician experienced in mitral valve surgery.	those of previously approved items	
9	IVD Reagents for Tumor Marker, Immunological Test (D04060.01(3))	AptoDetectTM -Lung	Aptamer Sciences, Inc	Manufacturing Approval No.17-748 (2017.9.26)	This in vitro diagnosis device measures proteins (C9, CA6, EGFR1, MMP7, SERPINA3, Kit, CRP) in the serum of a patient with a solitary pulmonary nodule using the aptamer-based liquid-bead microarray method and applies the data to an algorithm to provide information on the risk of non-small-cell lung cancer (low-risk group or high-risk group).	The operating principles, performance, and intended use, etc. are not essentially equivalent to those of previously approved items	Re-evaluation required
10	IVD Reagents for Tumor Marker, Immunological Test (D04060.01(3))	nProfiler I stomach cancer assay	NovoMix, Inc	Manufacturing Approval No.17-865 (2017.11.10)	This in vitro diagnosis device uses RT-qPCR to measure the expression of nine genes (WARS, GZMB, CDX1, SFRP4, ACTB, ATP5E, HPRT1, GPX1, UBB) in formalin-fixed, paraffin-embedded (FFPE) tissue samples from a progressive stage 2 or 3 stomach cancer patient who received surgery. Afterward, it applies the data to an algorithm to provide	Approved for the first time	Re-evaluation required

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Rationale for New Development	Re-evaluation
					prognosis information on the patient's five-year survival rate.		
11	IVD Reagents for Cancer Related Gene (D06020.01(3))	GT-CRC-1	Genomictree, Inc	Manufacturing Approval No.18-593 (2018.8.28)	This in vitro diagnosis device uses real-time polymerase chain reaction (PCR) to measure the methylation of syndecan-2 (SDC-2) gene in the DNA extracted from a person's feces to assist with colon cancer diagnosis (However, the type of colon cancer and the need for colonoscopy cannot be determined only with this product).	Approved for the first time	Re-evaluation required
12	IVD Software (A24500(3))	Masto Check (BM_1BCM program)	Bertis, Inc	Manufacturing Approval No.19-5 (2019.01.03)	This in vitro diagnosis device uses a mass spectrometer (LC-MS/MS) to quantify the 3 proteins (APOC1, NCHL1, and CAH1) in human blood plasma and applies the values to a breast cancer diagnosis algorithm to assist with the diagnosis of stage 0, 1, and 2 breast cancer. * Stage 0, 1, or 2 breast cancer diagnosis or treatment methods cannot be determined based solely on the test result obtained with this product. Different clinical diagnostic tests are required	Approved for the first time	Re-evaluation required

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Rationale for New Development	Re-evaluation
					for stage 3 or 4 breast cancer diagnosis.		
13	Circulatory Assist System, Artificial Heart(4)	HeartMate 3™ Left Ventricular Assist System (HeartMate 3™ LVAS)	Abbott Medical Korea, Inc	Import Approval No. 20-124 (2020.6.3)	HeartMate 3™ Left Ventricular Assist System is used to provide patients suffering from progressive refractory left-sided heart failure with short-term and long-term circulatory support.	The performance is not essentially equivalent to those of previously approved items	Re-evaluation required

The MFDS is supplying the relevant medical devices domestically via import, etc. and providing rare disease patients with the relevant information to offer them more treatment opportunities and help them manage their diseases.

Medical devices for diseases that are rare in Korea and medical devices with special values are designated as orphan medical devices. The following table shows the details of the 11 orphan devices approved in Korea.

[Table 39] Approved Orphan Medical Devices (All)

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Re-evaluation
1	Prosthesis, Valve, Cardiac, Biological (B04030.02(4))	MCS-P3-640 and 14 others	Medtronic Korea Co., Ltd.	Import Approval No.11-1145 (2011.10.4)	Used for valve replacement surgery in case of a combined surgical bioprosthetic valve failure accompanied by aortic valve stenosis and/or dysfunction	Re-evaluation required
2	Prosthesis, Valve, Cardiac, Biological (B04030.02(4))	S3TF123 and 3 others	Edwards Lifesciences Korea, Inc	Import Approval No.12-531 (2012.4.6)	Replaces the valves of a patient experiencing severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic valve	Re-evaluation required
3	Prosthesis, Valve, Cardiac, Biological (B04030.02(4))	S3TA120 and 3 others	Edwards Lifesciences Korea, Inc	Import Approval No.12-532 (2012.4.6)	Replaces the valves of a patient experiencing severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic valve	Re-evaluation required
4	Prosthesis, Valve, Cardiac, Biological	H749LTV230	Boston Scientific Korea, Inc	Import Approval No.14-2158 (2014.6.27)	Improves the aortic valve function in a patient with severe calcific aortic stenosis	Re-evaluation required

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Approval No. (Date of Approval)	Intended Use	Re-evaluation
	(B04030.02(4))				or a patient for whom standard surgical valve replacement involves high risk	
5	Pleuroperitoneal Shunt (A57330.01(3))	22112540 and 1 other	Honex Korea, Inc	Import Approval No.14-3186 (2014.11.14)	Drains pleural effusion fluid to the amniotic cavity when thoracentesis is not effective for fetal pleural effusion	Re-evaluation required
6	Prosthesis, Valve, Cardiac, Biological (B04030.02(4))	PRT-23 and 3 others	St. Jude Medical Korea, Inc	Import Approval No.15-471 (2015.2.13)	Used in transcatheter aortic valve implantation (TAVI) for aortic valve stenosis treatment	Re-evaluation required
7	Cardiovascular Devices (A17000(4))	PCG35, 14Fr and 15 others	Vasocare, Inc	Import Approval No.15-520(2015.3.2)	An apparatus that separates the damaged part of the left ventricle from the remaining part in a patient experiencing ischemic heart failure caused by a left ventricular aneurysm and the expansion of the left ventricle after a myocardial infarction	Re-evaluation required
8	Physical Devices for Medical Use (A16000(4))	Argus II Retinal Prosthesis System	Kisan Tech, Inc	Import Approval No.17-179 (2017.4.14)	Used to induce visual recognition in a visually impaired person by stimulating the retina electrically	Re-evaluation required
9	Diaphragm/Phrenic Nerve Electrical Stimulation System (A16180.20(4))	NeuRx Diaphragm Pacing System	Global Damon Pharma, Inc	Import Approval No.17-478 (2017.10.20)	A device used to assist with the respiration of a patient with Lou Gehrig's disease or a spinal cord injury, who is also experiencing diaphragm dysfunction caused by nerve roots, by inserting electrodes in the diaphragm muscle and sending electric pulses	Re-evaluation required
10	Prosthesis, Valve, Cardiac, Biological (B04030.02(4))	TPV1828 and 27 others	TaeWoong Medical, Inc	Manufacturing Approval No.18-658 (2018.10.1)	Used for the treatment of congenital heart disease patients who require a pulmonary valve transplant because of right ventricle expansion caused by an atresia, stenosis, or regurgitation at the pulmonary valves	Re-evaluation required
11	Coronary Artery Stent (B03300.13(4))	PK Papyrus (369380 and 16 others)	Biotronik Korea, Inc	Import Approval No.19-207 (2019.7.5)	Used for the treatment of acute coronary artery puncture	Re-evaluation required

Ⅱ-2. Item Category Certifications and Notifications

Categories of medical device items subject to certification and notification are those that pose little threat to life or health even in case of malfunction since they have low potential risk.

The Regulations on Approval, Notification, and Evaluation of Medical Devices specify the eligible items to allow for the management of the devices with a single certificate/notification form (effective on 2011.11.25).

Over the last 5 years, 1,181 manufactured devices and 2,639 imported devices were notified in the Class I item category, and 45 manufactured devices and 58 imported devices were notified in the Class II item category. Throughout the period, including 2020 (217 manufactured devices and 445 imported devices), the number of item category certifications and notifications was higher for imported devices than manufactured devices.

[Table 40] Item Category Certifications and Notifications by Year (2016-2020)

(Unit: Number of products)

Item	Category	2016	2017	2018	2019	2020	Total	Total
Certification (Class II)	Manufactured	11	6	13	7	8	45	103
	Imported	11	9	11	13	14	58	
Notification (Class I)	Manufactured	244	218	267	243	209	1,181	3820
	Imported	550	724	457	477	431	2,639	

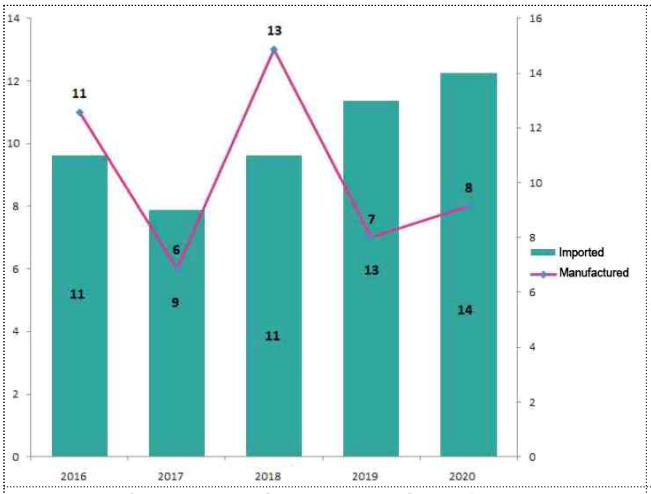


Figure 31. Item Category Certifications by Year (2016-2019)

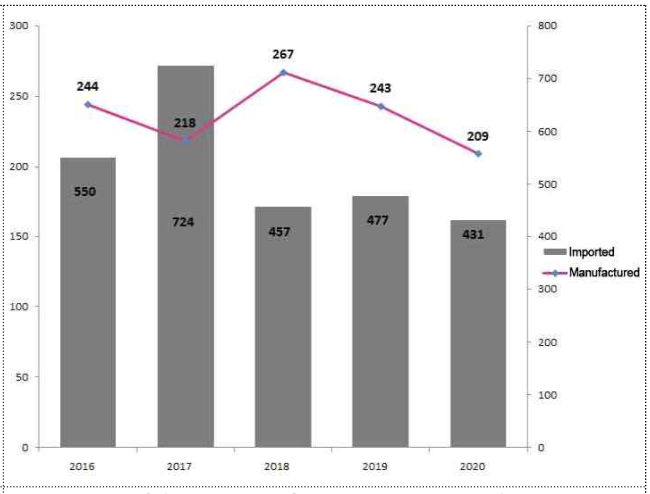


Figure 32. Item Category Notifications by Year (2016-2019)

Over the last 5 years, among the Class II item category certifications (103 devices), the highest number of certifications were for "Puncture Instrument, Surgical, Manually-Operated, Single Use (39)." Every year, a steady number of devices in this category are certified.

In addition, for 4 out of the total 19 item categories (Antroscope, Rigid; Scissors, Dental, Single-Use; Knife, Manually-Operated, Dental, Single-Use; and Chair, Examination/Treatment, Ophthalmic, Electrically-Powered), there have been no certifications after the public announcement of the devices eligible for each category.

[Table 41] Item Category Certifications by Year (2016-2020)

(Unit: Number of products)

Item Name	Category	2016	2017	2018	2019	2020	Total (Manufactured /Imported)
Puncture Instrument, Surgical, Manually-Operated, Single-Use	Manufactured	4	-	8	4	4	39 (20/19)
	Imported	6	5	1	5	2	
Knife, Manually-Operated, Dental, Single-Use	Manufactured	-	-	1	-	3	17 (4/13)
	Imported	2	-	3	3	5	
Freezer, Blood Product	Manufactured	-	2	2	1	-	10 (5/5)
	Imported	-	1	1	-	3	
Refrigerator for Medical Use, Blood	Manufactured	3	4	2	1	1	12 (11/1)
	Imported	-	-	-	-	1	

Knife, Ophthalmic, Single-Use	Manufactured	-	-	-	-	-	7 (-/7)
	Imported	-	2	2	2	1	
Forceps, Dressing, Manually-Operated, Single-Use	Manufactured	2	-	-	-	-	3 (2/1)
	Imported	-	-	-	1	-	
Sinoscope, Rigid	Manufactured	-	-	-	-	-	4 (-/4)
	Imported	1	-	1	1	1	
Chair, Examination/ Treatment, ENT (Ear/Nose/Throat), Electrically-Powered	Manufactured	1	-	-	1	-	2 (2/-)
	Imported	-	-	-	-	-	
Curette, Ophthalmic, Single-Use	Manufactured	-	-	-	-	-	3 (-/3)
	Imported	2	-	-	-	1	
Scissors, Ophthalmic, Single-Use	Manufactured	-	-	-	-	-	2 (-/2)
	Imported	-	1	-	1	-	
Gene analyser, Sequencing	Manufactured	-	-	-	-	-	2 (-/2)
	Imported	-	-	2	-	-	
Refrigerator for Medical Use, Medicine	Manufactured	1	-	-	-	-	1 (1/-)
	Imported	-	-	-	-	-	
Curette, Manually-Operated, Single-Use	Manufactured	-	-	-	-	-	1 (-/1)
	Imported	-	-	1	-	-	
Total		**22**	**15**	**24**	**20**	**22**	**103 (45/58)**

Over the last 5 years, “Splints (760)” had the highest percentage among devices notified under Class I item categories (3,820), followed by “Forceps, Reusable (451)” and “Scissors, Manually-Operated, Reusable (260).” The results were similar in 2020.

[Table 42] Item Category Notifications by Year (2016-2020)

(Unit: Number of products)

Item	Category	2016	2017	2018	2019	2020	Total (Manufactured /Imported)
Splints	Manufactured	118	87	74	80	62	760
	Imported	58	79	93	51	58	(421/339)
Forceps, Reusable	Manufactured	5	4	9	9	8	451
	Imported	70	131	61	78	76	(35/416)
Scissors, Manually-Operated, Reusable	Manufactured	1	2	6	4	6	260
	Imported	38	74	40	46	43	(19/241)
Forceps, Dressing, Manually-Operated, Reusable	Manufactured	4	1	2	2	13	173
	Imported	38	49	22	28	14	(22/151)
Puncture Instrument, Surgical, Manually-Operated, Reusable	Manufactured	4	7	13	13	8	185
	Imported	32	43	19	21	25	(45/140)
Curette, Manually-Operated, Reusable	Manufactured	4	5	8	9	4	168
	Imported	32	41	21	24	20	(30/138)
elevator, Surgical, Manually-Operated	Manufactured	2	5	11	9	2	149
	Imported	29	32	15	20	24	(29/120)
Chisel, Surgical, Manually-Operated	Manufactured	2	6	14	9	5	124
	Imported	23	20	8	23	14	(36/88)
Hammer, Surgical, Manually-Operated	Manufactured	2	6	6	8	5	110
	Imported	18	27	11	15	12	(27/83)
Surgical Drill Handpiece, Manual	Manufactured	1	4	23	15	5	115
	Imported	16	24	6	7	14	(48/67)
Forceps, Dental, Orthodontic	Manufactured	8	5	8	10	7	95
	Imported	12	13	13	14	5	(38/57)
Knife, Manually-Operated, Reusable	Manufactured	1	1	3	3	3	85
	Imported	22	17	13	11	11	(11/74)
Hand/Finger Splint	Manufactured	12	10	13	7	9	98
	Imported	8	11	7	8	13	(51/47)
Rasp, Surgical, Bone, Manually-Operated	Manufactured	-	2	5	4	2	70
	Imported	14	18	10	8	7	(13/57)
*Implant, Endosseous, Laboratory Supplies	Manufactured	24	-	-	-	-	29
	Imported	5	-	-	-	-	(24/5)
Dissector, Periosteum, Manually-Operated	Manufactured	-	7	-	-	1	65
	Imported	7	24	5	9	12	(8/57)
Forceps, Dental	Manufactured	3	1	2	1	2	52
	Imported	10	14	9	6	4	(9/43)
Dental Impression Material Tray	Manufactured	6	3	9	5	4	51
	Imported	6	4	2	7	5	(27/24)
Scissors, Ophthalmic, Reusable	Manufactured	1	-	1	1	-	58
	Imported	10	12	12	12	9	(3/55)
Splints, Mouldable	Manufactured	3	10	12	16	26	79

Item	Category	2016	2017	2018	2019	2020	Total (Manufactured /Imported)
	Imported	1	2	3	4	2	(67/12)
Splint, Extremity, Inflatable	Manufactured	2	7	15	6	3	54
	Imported	7	2	5	2	5	(33/21)
Splint, Denis Brown	Manufactured	5	6	4	-	1	31
	Imported	4	6	5	-	-	(16/15)
Tongue Depressor, Surgical	Manufactured	-	4	8	3	1	40
	Imported	10	3	-	7	4	(16/24)
Knife, Ophthalmic, Reusable	Manufactured	1	-	-	-	-	45
	Imported	8	8	9	9	10	(1/44)
Saw, Surgical, Manually-Operated, Flexible	Manufactured	3	3	1	-	-	31
	Imported	8	8	3	1	4	(7/24)
Wax, Casting	Manufactured	6	12	3	4	2	31
	Imported	1	-	1	2	-	(27/4)
Dental Articulation Paper	Manufactured	2	4	10	-	4	34
	Imported	4	3	4	1	2	(20/14)
Scissors, Dental, Reusable	Manufactured	2	1	2	2	1	31
	Imported	8	2	6	6	1	(8/23)
Spatula, Surgical, General-Purpose	Manufactured	-	1	-	-	1	36
	Imported	3	9	6	9	7	(2/34)
Root Elevator	Manufactured	1	-	-	4	3	29
	Imported	6	5	3	4	3	(8/21)
Curette, Ophthalmic, Reusable	Manufactured	-	-	-	-	-	29
	Imported	6	6	7	6	4	(-/29)
Refrigerator for Medical Use, Medicine	Manufactured	1	4	6	5	7	42
	Imported	-	1	1	9	8	(23/19)
Splint, Padded Stays	Manufactured	1	2	-	7	6	26
	Imported	2	1	3	3	1	(16/10)
Resin, Impression Tray	Manufactured	3	1	4	-	4	23
	Imported	1	4	2	3	1	(12/11)
* Impression Material, Model Duplicator, Elastomer	Manufactured	5	1	-	-	-	7
	Imported	1	-	-	-	-	(6/1)
Elevator, Dental, Crown Remover	Manufactured	3	-	-	1	1	13
	Imported	3	4	1	-	-	(5/8)
Depressors for Medical Use	Manufactured	-	1	-	-	-	7
	Imported	2	-	2	2	-	(1/6)
* Wax, Others	Manufactured	1	-	-	-	-	1
	Imported	-	-	-	-	-	(1/-)
Dental Rubber Dam	Manufactured	-	-	-	-	-	14
	Imported	1	3	3	5	2	(-/14)
Knife, Manually-Operated, Dental, Reusable	Manufactured	-	-	-	1	-	13
	Imported	2	3	3	3	1	(1/12)
Wax, Base Plate	Manufactured	-	-	-	2	-	10
	Imported	1	4	1	2	-	(2/8)
Forceps, Dental, Crown Remover	Manufactured	3	1	1	-	1	12
	Imported	1	2	-	1	2	(6/6)
Lever, Surgical, Bone, Manually-Operated	Manufactured	-	1	1	-	-	14
	Imported	3	3	2	2	2	(2/12)
Dental Rubber Dam Clamp	Manufactured	-	-	-	3	-	13
	Imported	2	2	1	2	3	(3/10)
Forceps, Articulation Paper	Manufactured	2	1	1	-	-	10
	Imported	2	-	3	-	1	(4/6)
Splint, Mouldable, Vacuum	Manufactured	-	-	-	-	-	9
	Imported	2	1	3	3	-	(-/9)
Spatula, Mixing	Manufactured	1	-	-	-	-	7
	Imported	4	-	-	1	1	(1/6)

Item	Category	2016	2017	2018	2019	2020	Total (Manufactured /Imported)
Cast Cutter, Manually-Operated	Manufactured	-	1	-	-	-	9
	Imported	4	4	-	-	-	(1/8)
Fluoride Gel Tray	Manufactured	1	1	-	-	-	5
	Imported	-	1	1	1	-	(2/3)
Dental Rubber Dam Frame	Manufactured	-	-	-	-	-	6
	Imported	3	-	2	-	1	(-/6)
Snare, Surgical, Bone, Manually-Operated	Manufactured	-	-	-	-	-	5
	Imported	2	2	-	1	-	(-/5)
Material, Fit Checker	Manufactured	-	-	-	-	-	1
	Imported	-	1	-	-	-	(-/1)
Wax, Base Plate, Shellac	Manufactured	-	-	-	-	-	2
	Imported	-	1	1	-	-	(-/2)
Dental Articulation Liquid	Manufactured	-	-	-	-	-	1
	Imported	-	-	1	-	-	(-/1)
Splint, Cogenital Hip Dislocation Abduction	Manufactured	-	-	-	-	2	2
	Imported	-	-	-	-	-	(2/-)
Total		**794**	**942**	**724**	**720**	**640**	**3,820 (1,189/2,631)**

※ Among the medical devices eligible for item category notification, “Implant, Endosseous, Laboratory Supplies,” “Impression Material, Model Duplicator, Elastomer,” “Wax, Others,” “Wax, Casting,” “Wax, Casting, Preformed,” “Impression Material, Model Duplicator, Agar,” and “Wax, Bite Registration” were removed from the list, as stated in the MFDS Public Announcement No. 2018-92 (2018.11.19).

Ⅱ-3. Certification of Recognized Substantial Equivalent Products

"Recognized substantial equivalent products" are Class II medical products that have been approved/certified for at least three times. These products have been announced by the Minister of Food and Drug Safety as recognized substantial equivalent products, including their names, intended uses, operating principles, raw materials, performance, test specifications, and instructions for use. There are 370 products currently announced as recognized substantial equivalent products.

* Equivalent product: Medical devices whose intended use, operating principles, raw materials (only for medical supplies), performance, testing specifications, or instructions for use are equivalent to those of medical devices that have already been approved

A total of 246 products were certified over the last 5 years, and the number of recognized substantial equivalent products that are manufactured had a steep decline after 2016. This can be attributed to the increased testing load on companies after the application of the Common Standard Specifications on Electric and Mechanic Safety of Medical Devices (Food and Drug Safety Administration Public Announcement No. 2014-122), which was revised to provide people with safer medical devices through global harmonization of domestic standard specifications, to Class II medical devices (2016.1.1.).

The following table shows the number of recognized substantial equivalent products certified over the last five years.

[Table 43] Certification of Recognized Substantial Equivalent Products by Year (2016-2020)

(Unit: Number of products)

Category	2016	2017	2018	2019	2020	Total
Manufactured	44 (80.0%)	31 (62.0%)	35 (55.6%)	24 (80.0%)	31 (64.6%)	**165 (67.1%)**
Imported	11 (20.0%)	19 (38.0%)	28 (44.4%)	6 (20.0%)	17 (35.4%)	**81 (32.9%)**
Total	**55**	**50**	**63**	**30**	**48**	**246**

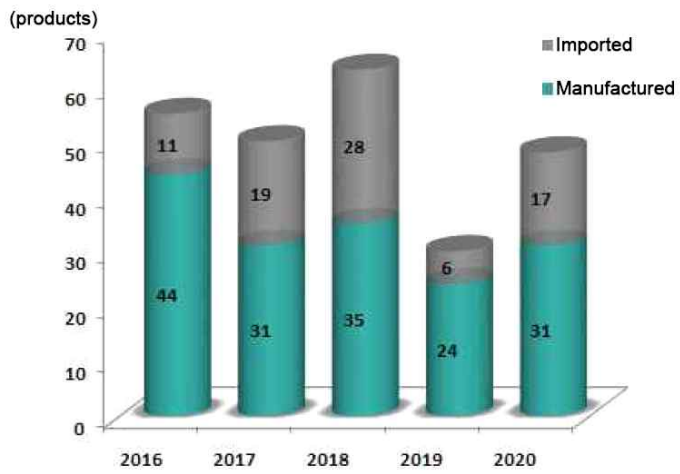


Figure 33. Certification of Recognized Substantial Equivalent Products by Year (2016-2020)

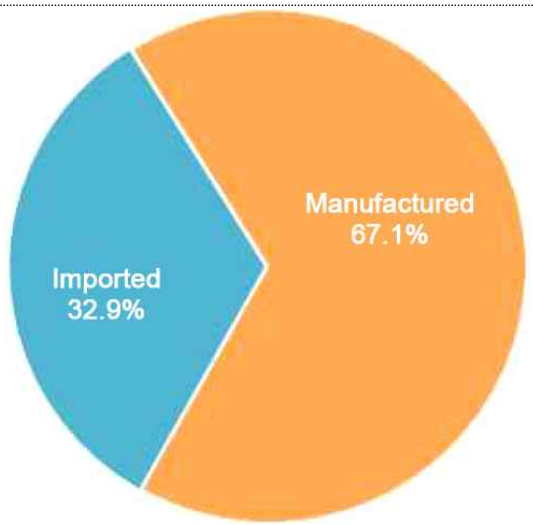
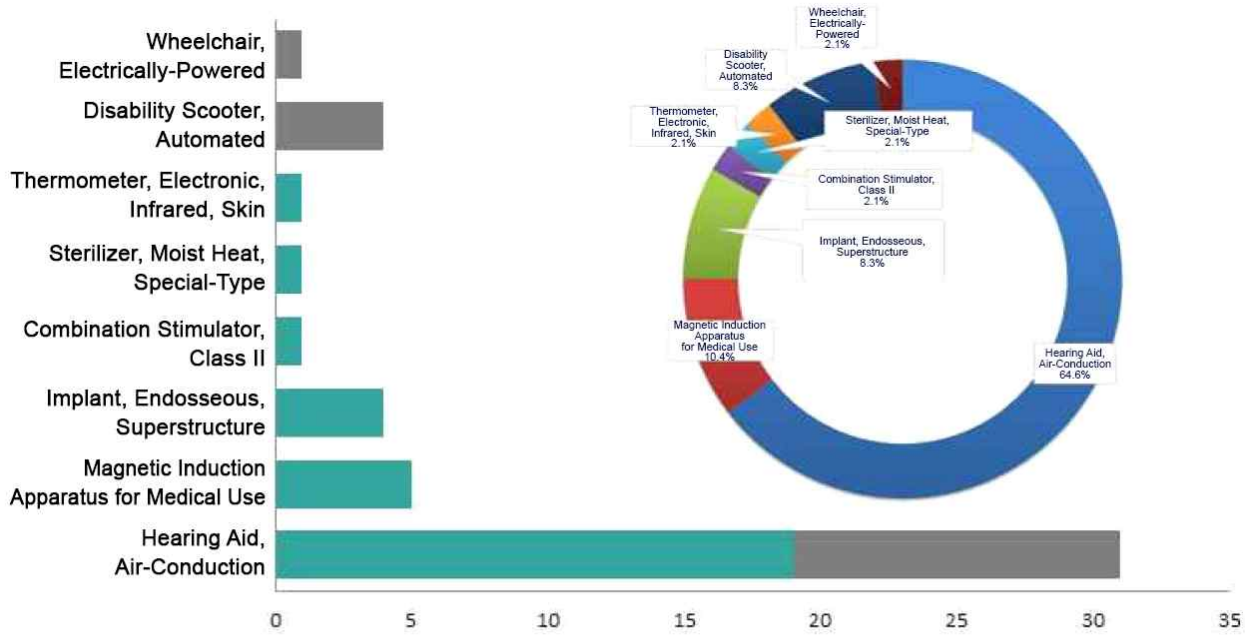


Figure 34. Percentages of Manufactured/Imported Substantial Equivalent Products Certified over the Last Five Years (2016-2020)

In 2020, 48 devices were certified as recognized substantial equivalent products, and the item with the highest number of devices was “Hearing Aid, Air-Conduction (31),” followed by “Magnetic Pulse Stimulator (5).” Notably, the number of devices under other items did not vary significantly.

(Unit: Number of products)



	Hearing Aid, Air-Conduction	Magnetic Induction Apparatus for Medical Use	Implant, Endosseous, Superstructure	Combination Stimulator, Class II	Sterilizer, Moist Heat, Special-Type	Thermometer, Electronic, Infrared, Skin	Disability Scooter, Automated	Wheelchair, Electrically-Powered
Manu-factured	19	5	4	1	1	1		
Imported	12						4	1

Figure 35. Certification of Recognized Substantial Equivalent Products in 2020

Between 2016 and 2020, 155 “Hearing Aid, Air-Conduction” products were certified, which accounted for 63.1% of all products (246) certified through equivalence announcements over the last 5 years.

This is considered to be attributed to the increased demand for “Hearing Aid, Air-Conduction” products caused by social ageing and the fact that these products, compared to other products, tend to be manufactured in standardized forms similar to the existing products rather than being released new functions.

[Table 44] Certification of the Recognized Substantial Equivalent Product, “Hearing Aid, Air-Conduction,” by Year (2016-2020)

(Unit: Number of products)

Category	2016	2017	2018	2019	2020	Total
Manufactured	28 (77.8%)	13 (43.3%)	17 (42.5%)	13 (72.2%)	19 (61.3%)	**90 (58.1%)**
Imported	8 (22.2%)	17 (56.7%)	23 (57.5%)	5 (27.8%)	12 (38.7%)	**65 (41.9%)**
Total	**36**	**30**	**40**	**18**	**31**	**155**

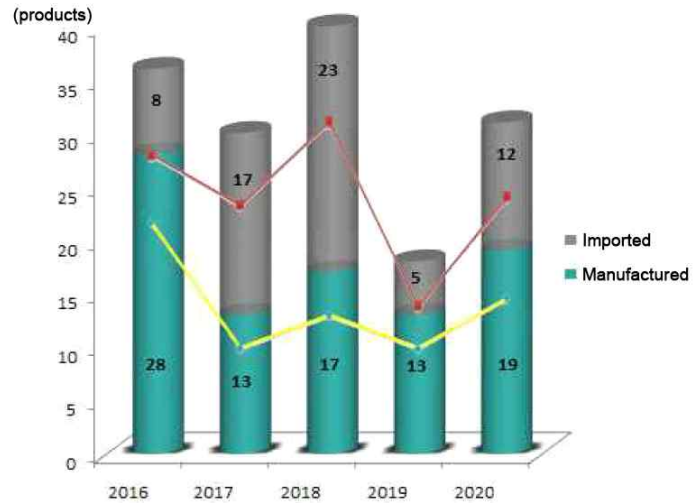


Figure 36. Certification of the Recognized Substantial Equivalent Product, “Hearing Aid, Air-Conduction,” by Year (2016-2020)

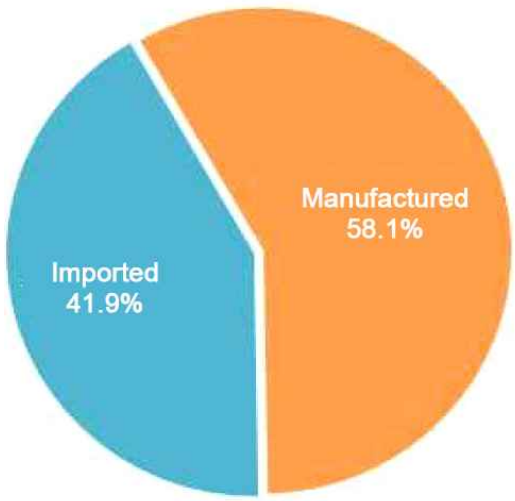


Figure 37. Percentages of Manufactured/Imported “Hearing Aids, Air-Conduction (Substantial Equivalent Devices)” Certified Over the Last Five Years (2016-2020)

Ⅱ-4. Approval of Medical Devices Subject to Clinical Trial Data Submission Requirements

In 2020, the number of approved medical devices whose clinical trial data are subject to submission was 123, which is less than the previous year by 13 (9.6%). Meanwhile, the numbers of manufactured and imported products were 80 (65.0%) and 43 (35.0%), respectively, which were not significantly different from the previous year (65 manufactured products (47.8%) and 71 imported products (52.2%) in 2019).

[Table 45] Medical Devices Subject to Clinical Trial Data Submission Requirements in 2020

(Unit: Number of products)

Class	Manufactured	Imported	Total
2	17	19	**36**
3	52	17	**69**
4	11	7	**18**
Total	**80**	**43**	**123**

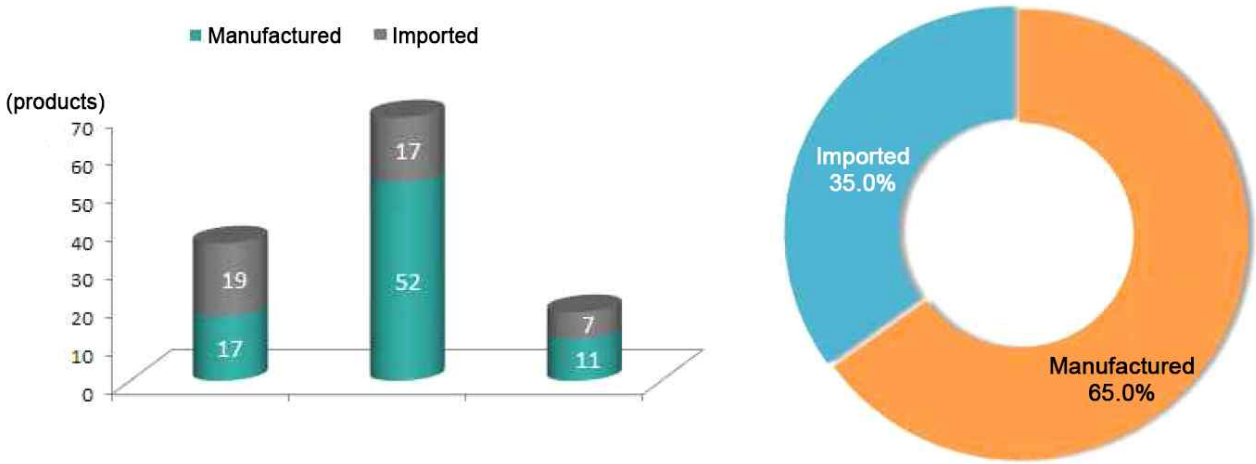


Figure 38. Medical Devices Subject to Clinical Trial Data Submission Requirements in 2020

The most frequently approved products were “IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))” (28, 22.8%), followed by “IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))” (10, 8.1%) and “Graft/Prothesis, Biomaterial (B04230.01(4))” (6, 4.9%).

The high percentages are considered due to two main factors. First, the amendment to the Regulations on Approval, Notification, and Evaluation of Medical Devices on 2016.8.31. expanded the scope of the exemption from clinical trial plan approval, raising the number of IVD medical devices with which clinical trials can be performed without the MFDS’ clinical trial plan approval. Second, for IVD medical devices, companies submit “data regarding clinical performance tests” instead of “clinical test data” which are required for other medical device approvals. Since “clinical performance tests” use samples derived from humans (often previously acquired samples, such as blood), they require less time and financial resources than “clinical trials”, which involve actual human subjects.

In addition, the highest number of manufacturing approvals in Class III items is considered as a result of the increased development of IVD reagents caused by the spread of the COVID-19 virus.

[Table 46] (Top 5) High-Frequency Items Subject to Clinical Trial Data Submission Requirements in 2020

(Unit: Number of products)

No.	Item (Classification No.(Class))	No. of Products	Manufactured	Imported
1	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	28	24	4
2	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	10	9	1
3	Graft/Prothesis, Biomaterial (B04230.01(4))	6	5	1
4	Molecular Diagnostic Reagents for Congenital or Genetic Disease (N02010.01(3))	5	5	-
5	Computer Aided Detection Software (A26430.16(2))	4	4	-

Besides “IVD Reagents,” frequently approved items in 2020 included 56 products in total. “Graft/Prosthesis, Biomaterial (B04230.01(4))” (6, 10.7%) and “Computer Aided Detection Software (A26430.16(2))” (4, 7.1%) accounted for the highest percentage, while the number of products under other items did not vary significantly. In particular, it is worth noting that “Computer Aided Detection Software” products, which assist in the detection of specific lesions using big data and artificial intelligence technologies were all manufactured in Korea.

[Table 47] High-Frequency Items Subject to Clinical Trial Data Submission Requirements in 2020 (Except IVD Products)

(Unit: Number of products)

No.	Item (Classification No.(Class))	No. of Products	Manufactured	Imported
1	Graft/Prothesis, Biomaterial (B04230.01(4))	6	5	1
2	Computer Aided Detection Software (A26430.16(2))	4	4	-
3	Computer Aided Diagnosis Software (A26430.14(3))	4	2	2
4	Electrocardiographic Analyser (A26010.01(2))	3	1	2
5	Computer Aided Detection and Diagnosis Software, Class II (E11030.01(2))	2	2	-

Figure 39. Locations of Medical Device Clinical Trial Centers in Korea

[Table 48] Approval of Medical Devices Subject to Clinical Trial Data Submission Requirement in 2020

No.	Item (Classification No. (Class))	Model	Company	Approval No. (Date)
1	Graft/Prothesis, Biomaterial (B04230.01(4))	Elravie Premier Ultra-G 2mL	Humedix, Inc	Manufacturing Approval No. 20-9 (2020.01.03)
2	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Rea-Q RV II Detection Kit	BioSewoom, Inc	In Vitro Manufacturing Approval No. 20-51 (2020.01.22)
3	Graft/Prothesis, Biomaterial (B04230.01(4))	Renefil	BMI KOREA Co,. Ltd.	Manufacturing Approval No. 20-63 (2020.01.30)
4	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	BA-2005 and 1 other	Boditech Med, Inc	In Vitro Manufacturing Approval No. 20-64 (2020.01.30)
5	Hard Contact Lens, Extended-Wear (A77020.02(3))	Vision	Visioncaretec Co., Ltd.	Manufacturing Approval No. 20-67 (2020.01.31)
6	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	INFINA™ HPV 35 types Genotyping	BIOWITHUS. Co., Ltd.	In Vitro Manufacturing Approval No. 20-115 (2020.02.13)
7	IVD Reagents for Serotyping for Patient Monitoring of HIV, HBV, HCV, HTLV, Immunological Method (K05020.01(3))	STANDARD™ Q Anti-HBs Test (QAHB01B) and 1 other	SD Biosensor, Inc	In Vitro Manufacturing Approval No. 20-116 (2020.02.13)
8	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Anyplex™ II STI-12 Detection and 1 other	Seegene, Inc	In Vitro Manufacturing Approval No. 20-117 (2020.02.13)
9	Molecular Diagnostic Reagents for Congenital or Genetic Disease (N02010.01(3))	Patio™ NIPT Detection Kit	SEASUN BIOMATERIALS, Inc	In Vitro Manufacturing Approval No. 20-127 (2020.02.18)
10	Analyser, Medical Image, Software (A26430.11(2))	MDAI-BA-01	Crescom, Inc	Manufacturing Approval No. 20-153 (2020.03.03)

No.	Item (Classification No. (Class))	Model	Company	Approval No. (Date)
11	Analyser, Medical Image, Software (A26430.11(2))	BoneAge.io	Healthhub Co., Ltd.	Manufacturing Approval No. 20-166 (2020.03.10)
12	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Green Care Tuberculosis/Nontuberculosis Mycobacteria Detection Kit	Green Cross Medical Science, Inc	In Vitro Manufacturing Approval No. 20-172 (2020.03.10)
13	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Ezplex® Bacterial Pneumonia Real-time PCR Kit	SML Genetree, Inc	In Vitro Manufacturing Approval No. 20-173 (2020.03.10)
14	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Ezplex® Viral Respiratory Real-time PCR Kit	SML Genetree, Inc	In Vitro Manufacturing Approval No. 20-174 (2020.03.10)
15	Molecular Diagnostic Reagents for Congenital or Genetic Disease (N02010.01(3))	U-TOP™ HL Genotyping Kit ver2	SEASUN BIOMATERIALS, Inc	In Vitro Manufacturing Approval No. 20-183 (2020.03.16)
16	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	NG01A	Genemaxtirx, Inc	In Vitro Manufacturing Approval No. 20-184 (2020.03.16)
17	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	MolecuTech Real HPV 16/18/HR	YD-Diagnostics, Inc	In Vitro Manufacturing Approval No. 20-185 (2020.03.16)
18	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	R-FIND Mycoplasma Pneumoniae IgG ELISA	SG Medical, Inc	In Vitro Manufacturing Approval No. 20-198 (2020.03.20)
19	Hard Contact Lens, Extended-Wear (A77020.02(3))	White OK	Interojo, Inc	Manufacturing Approval No. 20-203 (2020.03.20)
20	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	AdvanSure™ i3 TB-IGRA	LG Chem, Inc	In Vitro Manufacturing Approval No. 20-205 (2020.03.23)
21	Dressing, Occlusive, Hydrogel (B07070.03(2))	DDL-05	D.R.Nano Co., Ltd.	Manufacturing Approval No. 20-238 (2020.04.01)
22	Ophthalmic Image, Computer Aided Detection/ Diagnosis Software (E08020.01(3))	VN-M-03S and 1 other	VUNO, Inc	Manufacturing Approval No. 20-244 (2020.04.01)
23	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	TR-02-48T	EUDIPIA, Inc	In Vitro Manufacturing Approval No. 20-272 (2020.04.09)
24	Sphygmomanometers and Sphygmographs (A23000(2))	Blood Pressure Monitoring Application	Samsung Electronics Co., Ltd.	Manufacturing Approval No. 20-295 (2020.04.20)
25	Computer Aided Detection and Diagnosis Software, Class II (E11030.01(2))	VN-M-04S and 1 other	VUNO, Inc	Manufacturing Approval No. 20-298 (2020.04.21)
26	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	PaxView TB/NTM MPCR-ULFA Kit	PaxGenBio Co., Ltd.	In Vitro Manufacturing Approval No. 20-303 (2020.04.21)
27	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Ezplex® SFTS Virus Real-time PCR kit	SML Genetree, Inc	In Vitro Manufacturing Approval No. 20-304 (2020.04.21)
28	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	NR03A	Genemaxtirx, Inc	In Vitro Manufacturing Approval No. 20-336 (2020.04.28)
29	IVD Reagents for Tumor Marker, Immunological Test (K02080.01(3))	Ci01	PCL, Inc	In Vitro Manufacturing Approval No. 20-339 (2020.04.28)
30	Graft/Prothesis, Biomaterial (B04230.01(4))	Replengen Pro with Lidocaine	Reanzen Co., Ltd.	Manufacturing Approval No. 20-347 (2020.05.06)
31	Coronary Artery Stent (B03300.13(4))	DE-225-008 and 53 others	CG Bio, Inc	Manufacturing Approval No. 20-364 (2020.05.14)
32	IVE Reagents for Autoimmune Disease (K03010.01(2))	K-EDN ELISA KIT	SKIMS-Bio, Inc	In Vitro Manufacturing Approval No. 20-365 (2020.05.14)
33	IVD Software for Diagnosis (P01000(3))	DeepDx-Prostate-v1	Deep Bio, Inc	In Vitro Manufacturing Approval No. 20-373 (2020.05.19)
34	Electrocardiographic Analyser (A26010.01(2))	ECG Application	Samsung Electronics Co., Ltd.	Manufacturing Approval No. 20-378 (2020.05.21)
35	IVD Reagents for Bone Mineral	IME-001	Sejong Biomed, Inc	In Vitro Manufacturing Approval

No.	Item (Classification No. (Class))	Model	Company	Approval No. (Date)
	Metabolite Measurement Test (J11030.01(2))			No. 20-442 (2020.06.04)
36	Barrier, Intra Oral, Resorbable (C23030.01(4))	CB-1520 and 2 others	Kuwotech Co., Ltd.	Manufacturing Approval No. 20-460 (2020.06.09)
37	Computer Aided Detection Software (A26430.16(2))	DN-CA-01	DEEPNOID, Inc	Manufacturing Approval No. 20-467 (2020.06.10)
38	Computer Aided Detection Software (A26430.16(2))	AVIEW LUNG Nodule CAD	Coreline Soft, Co., Ltd.	Manufacturing Approval No. 20-484 (2020.06.16)
39	Angioplasty Catheter, Balloon Dilatation, Coronary, Perfusing (A57130.21(4))	GDEB-10-200 and 161 others	Genoss, Inc	Manufacturing Approval No. 20-501 (2020.06.23)
40	Graft/Prothesis, Biomaterial (B04230.01(4))	Lorient No. 2 and 2 others	Joonghun Pharmaceutical Co., Ltd.	Manufacturing Approval No. 20-552 (2020.07.09)
41	Capsule Endoscope for Medical Use (A31090.44(2))	MC2400-U	IntroMedic Co., Ltd.	Manufacturing Approval No. 20-555 (2020.07.09)
42	Capsule Endoscope for Medical Use (A31090.44(2))	MC2400-UE	IntroMedic Co., Ltd.	Manufacturing Approval No. 20-556 (2020.07.09)
43	Computer Aided Detection Software (A26430.16(2))	DL-LN-01	DEEPNOID, Inc	Manufacturing Approval No. 20-578 (2020.07.16)
44	IVD Reagents for General Immune Test (K02050.01(2))	QMALD01	QuantaMatrix, Inc	In Vitro Manufacturing Approval No. 20-589 (2020.07.20)
45	Graft/Prothesis (B04230.02(4))	ULTRACOL200	ULTRA V Co., Ltd.	Manufacturing Approval No. 20-598 (2020.07.22)
46	Computer Aided Diagnosis Software (A26430.14(3))	ML-02	Monitor Corporation, Inc	Manufacturing Approval No. 20-602 (2020.07.27)
47	Computer Aided Detection Software (A26430.16(2))	DrNoon for Fundus screening	Medi-Whale, Inc	Manufacturing Approval No. 20-618 (2020.08.03)
48	Perception and Organs Diagnostic Devices (A30000(2))	ISB-M-001	iMediSync, Inc	Manufacturing Approval No. 20-750 (2020.08.26)
49	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	FRFL 015	NanoEntek, Inc	In Vitro Manufacturing Approval No. 20-759 (2020.08.28)
50	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	STANDARD™ M nCoV Real-Time Detection kit (M-NCOV-01)	SD Biosensor, Inc	In Vitro Manufacturing Approval No. 20-767 (2020.08.31)
51	Laser, Therapeutic (A37020.01(3))	HGN1 and 2 others	LG Electronics, Inc	Manufacturing Approval No. 20-780 (2020.09.03)
52	Molecular Diagnostic Reagents for Congenital or Genetic Disease (N02010.01(3))	U2C001	U2Bio Co., Ltd.	In Vitro Manufacturing Approval No. 20-840 (2020.09.24)
53	IVD Reagents for Diagnosis of HIV, HBV, HCV, HTLV, Immunological Method (K05010.01(4))	STANDARD™ Q HBsAg Test (QHBS01G) and 1 other	SD Biosensor, Inc	In Vitro Manufacturing Approval No. 20-841 (2020.09.24)
54	Computer Aided Diagnosis Software (A26430.14(3))	EyeView	AIMS, Inc	Manufacturing Approval No. 20-847 (2020.09.28)
55	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	NR04A	Genemaxtirx, Inc	In Vitro Manufacturing Approval No. 20-857 (2020.10.05)
56	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Real-Q 2019-nCoV detection Kit	BioSewoom, Inc	In Vitro Manufacturing Approval No. 20-860 (2020.10.06)
57	Molecular Diagnostic Reagents for Congenital or Genetic Disease (N02010.01(3))	U2C003	U2Bio Co., Ltd.	In Vitro Manufacturing Approval No. 20-861 (2020.10.06)
58	Molecular Diagnostic Reagents for Congenital or Genetic Disease (N02010.01(3))	U2C002	U2Bio Co., Ltd.	In Vitro Manufacturing Approval No. 20-862 (2020.10.06)
59	Graft/Prothesis, Biomaterial (B04230.01(4))	HARA	Humedix, Inc	Manufacturing Approval No. 20-867 (2020.10.08)
60	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics)	U-TOPTM COVID-19 Detection Kit Plus	SEASUN BIOMATERIALS, Inc	In Vitro Manufacturing Approval No. 20-871 (2020.10.08)

No.	Item (Classification No. (Class))	Model	Company	Approval No. (Date)
	(N05030.01(3))			
61	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Q-Sens® COVID-19 Detection kit	CancerRop, Inc	In Vitro Manufacturing Approval No. 20-872 (2020.10.08)
62	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	ichroma™ TRIAS Flu/RSV and 1 other	Boditech Med, Inc	In Vitro Manufacturing Approval No. 20-876 (2020.10.13)
63	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Allplex™ GI- Bacteria(II) Assay and 1 other	Seegene, Inc	In Vitro Manufacturing Approval No. 20-895 (2020.10.19)
64	Computer Aided Detection and Diagnosis Software, Class II (E11030.01(2))	Lunit INSIGHT CXR	Lunit, Inc	Manufacturing Approval No. 20-896 (2020.10.19)
65	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	IR6903T and 5 others	KoGene Biotech, Inc	In Vitro Manufacturing Approval No. 20-923 (2020.11.03)
66	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	STANDARD™ Q COVID-19 IgM/IgG Plus Test(Q-NCOV-02C) and 1 other	SD Biosensor, Inc	In Vitro Manufacturing Approval No. 20-941 (2020.11.06)
67	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	STANDARD™ Q COVID-19 Ag Test(Q-NCOV- 01G)	SD Biosensor, Inc	In Vitro Manufacturing Approval No. 20-955 (2020.11.11)
68	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	AQ-TOPTM COVID-19 Rapid Detection Kit Plus	SEASUN BIOMATERIALS, Inc	In Vitro Manufacturing Approval No. 20-990 (2020.11.23)
69	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Allplex™ RV Essential Assay and 1 other	Seegene, Inc	In Vitro Manufacturing Approval No. 20-1005 (2020.11.30)
70	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	IR6902	KoGene Biotech, Inc	In Vitro Manufacturing Approval No. 20-1000 (2020.11.26)
71	IVD Reagents for Infectious Disease Marker (Detection of Low Infectivity Pathogen) (K05040.01(2))	IFA-BT-G	Map Science	In Vitro Manufacturing Approval No. 20-1018 (2020.11.30)
72	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Allplex SARS-CoV-2 Assay and 1 other	Seegene, Inc	In Vitro Manufacturing Approval No. 20-1049 (2020.12.07)
73	IVD Strip for Glucose Self Test (J14010.01(3))	ChekB Blood Glucose Test Strips (50) and 2 others	B-Bio Co., Ltd.	In Vitro Manufacturing Approval No. 20-1067 (2020.12.10)
74	Blood Glucose Meter for Self Test (J04010.01(3))	ChekB Blood Glucose Meters and 1 other	B-Bio Co., Ltd.	In Vitro Manufacturing Approval No. 20-1068 (2020.12.10)
75	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Q-Sensⓡ COVID-19 Detection Kit V2	CancerRop, Inc	In Vitro Manufacturing Approval No. 20-1088 (2020.12.14)
76	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	SGTi-flex COVID-19 IgM/IgG and 1 other	Sugentech, Inc	In Vitro Manufacturing Approval No. 20-1112 (2020.12.18)
77	IVD Strip for Glucose Self Test (J14010.01(3))	G19	1drop, Inc	In Vitro Manufacturing Approval No. 20-1148 (2020.12.24)
78	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	COVAG025 and 1 other	GenBody, Inc	In Vitro Manufacturing Approval No. 20-1150 (2020.12.24)
79	Neural Image, Computer Aided Detection/Diagnosis Software (E06090.01(3))	VN-M-07	VUNO, Inc	Manufacturing Approval No. 20-1159 (2020.12.29)
80	Coronary Artery Stent (B03300.13(4))	TS07-22509 and 55 others	OSSTEM CARDIOTEC Co., Ltd.	Manufacturing Approval No. 20-1162 (2020.12.31)
81	IVD Reagents for Tumor Marker, Immunological Test (K02080.01(3))	08333602190 and 1 other	Roche Diagnostics Korea, Inc	In Vitro Import Approval No. 20-8 (2020.01.13)
82	Electrosurgical System, Ophthalmic (A35010.03(3))	CP1700	Aracare, Co., Ltd.	Import Approval No. 20-11 (2020.01.16)
83	IVD Reagents for Infectious Inflammatory Test (K05050.01(2))	ADVIA Centaur BRAHMS Procalcitonin and 1 other	Siemens Healthineers, Inc	In Vitro Import Approval No. 20-14 (2020.01.16)

No.	Item (Classification No. (Class))	Model	Company	Approval No. (Date)
84	IVD Reagents for Companion Diagnostics with Protein Level (O04020.01(3))	VENTANA PD-L1 (SP142) Assay	Roche Diagnostics Korea, Inc	In Vitro Import Approval No. 20-20 (2020.01.30)
85	Continuous Glucose Monitoring System, Self Testing, In Vivo (A26110.02(3))	Dexcom G6ⓡ Continuous Glucose Monitoring System	Synex Consulting Ltd.	Import Approval No. 20-35 (2020.02.25)
86	IVD Reagents for Diagnosis of HIV, HBV, HCV, HTLV, Immunological Method (K05010.01(4))	Lumipulse G HCV Ab	JW Bioscience, Inc	In Vitro Import Approval No. 20-36 (2020.02.25)
87	IVD Reagents for Infectious Disease Marker (Detection of Low Infectivity Pathogen) (K05040.01(2))	602005PLA and 5 others	Bom Medical, Inc	In Vitro Import Approval No. 20-37 (2020.02.25)
88	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	FilmArray Respiratory Panel 2 plus (RP2plus)	BioMérieux, Inc	In Vitro Import Approval No. 20-44 (2020.03.03)
89	IVD Reagents for Diagnosis of HIV, HBV, HCV, HTLV, Immunological Method (K05010.01(4))	Lumipulse G HIV Ag/Ab	JW Bioscience, Inc	In Vitro Import Approval No. 20-50 (2020.03.10)
90	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Xpert MTB/RIF Ultra	Gene X, Inc	In Vitro Import Approval No. 20-54 (2020.03.20)
91	Pulse Oximeter, Line-Powered (A17190.01(2))	O3 Regional Oximeter	Masimo Korea, LLC.	Import Approval No. 20-59 (2020.03.23)
92	Stent, Vascular (B03300.12(4))	VENEM10040 and 83 others	Bard Korea, Ltd.	Import Approval No. 20-73 (2020.04.13)
93	Endotherapy Device, General-Purpose, Single-Use (A31010.33(2))	FG04176 and 1 other	Medifocus, Inc	Import Approval No. 20-74 (2020.04.14)
94	Graft/Prothesis, Biomaterial (B04230.01(4))	Juvederm VOLUX	Allergan Korea, Inc	Import Approval No. 20-90 (2020.04.28)
95	IVD Reagents for Endocrine Test (J11000(3))	07957190 and 1 other	Roche Diagnostics Korea, Inc	In Vitro Import Approval No. 20-91 (2020.04.28)
96	Electrocardiographic Holter Analyser (A26040.01(2))	AC-009	Synex Consulting Ltd.	Import Approval No. 20-115 (2020.05.28)
97	IVD Reagents for Genotyping or Patient Monitoring of HIV, HBV, HCV, HTLV, Molecular Diagnostics (N05020.01(3))	4538366 artus HCV QS-RGQ Kit V2	Qiagen Korea, Ltd.	In Vitro Import Approval No. 20-116 (2020.05.28)
98	Cardiovascular Devices (A17000(2))	HyperView	Kove, Inc	Import Approval No. 20-120 (2020.06.02)
99	Circulatory Assist System, Artificial Heart (A09150.02(4))	HeartMate 3™ LVAS	Abbott Medical Korea, Inc	Import Approval No. 20-124 (2020.06.03)
100	Electromagnetic Therapy Stimulator (A85020.01(2))	104	Withhealthcare, Inc	Import Approval No. 20-125 (2020.06.04)
101	Other Software, Class III, for IVD (P20010.02(3))	VeriSeq NIPT Assay Software V2	Illumina Korea, Ltd.	In Vitro Import Approval No. 20-136 (2020.06.17)
102	Cell and Tissue Processing Apparatus for Medical Use (A91000(3))	Integra 3	Pavmed Co., Ltd.	Import Approval No. 20-145 (2020.06.30)
103	IVD Reagents for Infectious Disease Marker (Immunological Method) (K05030.01(3))	ADVIA Centaur Herpes-2 IgG (HSV2)	Siemens Healthineers, Inc	In Vitro Import Approval No. 20-144 (2020.06.29)
104	IVD Reagents for Infectious Disease Marker (Detection of Low Infectivity Pathogen) (K05040.01(2))	MAGLUMI H. Pylori IgG (CLIA)	AGBIO Diagnostics, Inc	In Vitro Import Approval No. 20-147 (2020.07.02)
105	Computer Aided Diagnosis Software (A26430.14(3))	QAngio XA 3D	NK & D Co., Ltd.	Import Approval No. 20-149 (2020.07.13)
106	Intraocular Lens (B04140.01(4))	ZCB00V	AMO Asia, Ltd. (Business Office)	Import Approval No. 20-153 (2020.07.15)
107	Eye Testing Instruments	rtx1	Aracare, Co., Ltd.	Import Approval No. 20-163

No.	Item (Classification No. (Class))	Model	Company	Approval No. (Date)
	(A28000(2))			(2020.07.27)
108	Pressure Monitor, General-Purpose (A30230.01(2))	TPM-02	JMS Korea, Inc	Import Approval No. 20-164 (2020.07.27)
109	Electrocardiographic Analyser (A26010.01(2))	Irregular Rhythm Notification Feature (IRNF)	Emergo Korea, Ltd.	Import Approval No. 20-176 (2020.08.14)
110	Electrocardiographic Analyser (A26010.01(2))	ECG App	Emergo Korea, Ltd.	Import Approval No. 20-177 (2020.08.14)
111	Sphygmomanometers and Sphygmographs (A23000(2))	Acumen Hypotension Prediction Index Software	Edwards Lifesciences Korea, Inc	Import Approval No. 20-174 (2020.08.13)
112	Multifocal Intraocular Lens (B04140.02(4))	DFT015	Alcon Korea, Inc	Import Approval No. 20-178 (2020.08.14)
113	Computer Aided Diagnosis Software (A26430.14(3))	Transpara	Siemens Healthineers, Inc	Import Approval No. 20-187 (2020.08.21)
114	Camera, Ophthalmic (A28090.02(2))	KOWA FM-600	Kuk-Je Medience	Import Approval No. 20-194 (2020.09.04)
115	IVD Reagents for Infectious Disease Marker, (Drug Resistant Microorganism) (M02030.01(3))	cobas MTB-RIF/INH	Roche Diagnostics Korea, Inc	In Vitro Import Approval No. 20-210 (2020.09.28)
116	Soft Contact Lens, Daily-Wear (A77030.01(2))	MiSight 1day	CooperVision Korea, Inc	Import Approval No. 20-228 (2020.11.04)
117	Heating Pad System, Under/Overlay, Electric, Home Use (A83060.01(2))	BiteAway	Bio-Medical Science Co., Ltd.	Import Approval No. 20-229 (2020.11.06)
118	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Alinity m STI AMP Kit	Abbott Korea, Ltd.	In Vitro Import Approval No. 20-239 (2020.11.16)
119	Perception and Organs Diagnostic Devices (A30000(2))	PEA POD Infant Body Composition System	Synex Consulting Ltd.	Import Approval No. 20-251 (2020.11.27)
120	Nucleic Acid In Situ Hybridization, (FISH, SISH) II (O03010.02(2))	IGH/MAF Plus v2 Translocation, Dual Fusion Probe	Kormed, Inc	In Vitro Import Approval No. 20-257 (2020.12.14)
121	Cell/Histopathology Diagnosis Analyzer (O01020.01(2))	ThinPrep Imager Duo Imaging System	Seongkohn Traders Co., Ltd.	In Vitro Import Approval No. 20-263 (2020.12.23)
122	Haemoperfusion Unit (A09250.01(3))	CytoSorb 300mL Device	Fresenius Medical Care Korea, Inc	Import Approval No. 20-266 (2020.12.24)
123	IVD Reagents for Infectious Disease Marker (Molecular Diagnostics) (N05030.01(3))	Panther Fusion Flu A/B/RSV Assay	Anse Co., Ltd.	In Vitro Import Approval No. 20-269 (2020.12.31)

Ⅱ-5. Conditional Approvals and Certifications

Under the conditional approval/certification scheme, a company may apply for approval or certification without submitting a certificate of GMP, on the condition that it establishes a quality control system for manufacturing and facilities within a set period of time. Since conditional approvals are valid for two years, companies should submit a certificate of GMP within two years and have the conditional approval replaced with a valid approval.

As the GMP system was revised by the amendment to the Medical Devices Act in January 2015, it requires a company to submit a certificate of GMP when applying for approval or certification. For this reason, the Korean government has been actively promoting the conditional approval/certification scheme since 2016 to help companies without GMP certificates obtain approval/certification as a priority.

The following table shows the number of conditional approvals and certifications by year. The number of conditional approvals and certifications has remained steady at 146 in 2016, 209 in 2017, 163 in 2018, 152 in 2019, and 168 in 2020.

[Table 49] Conditional Approval/Certification of Medical Devices by Year (2016-2020)

(Unit: Number of products)

Item	Category	2016	2017	2018	2019	2020	Total	Total
Approval	Manufactured	17	64	31	46	31	189	**456**
	Imported	40	86	47	57	37	267	
Certification	Manufactured	29	28	44	21	51	173	**382**
	Imported	60	31	41	28	49	209	
Total		**146**	**209**	**163**	**152**	**168**	**838**	**838**

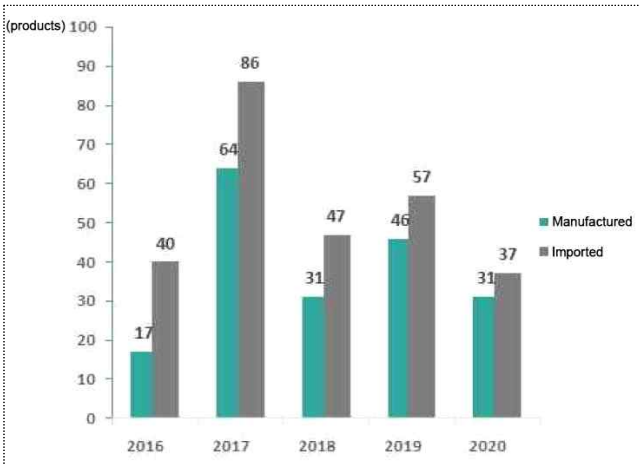


Figure 40. Conditional Approval of Manufactured/Imported Devices by Year (2016-2020)

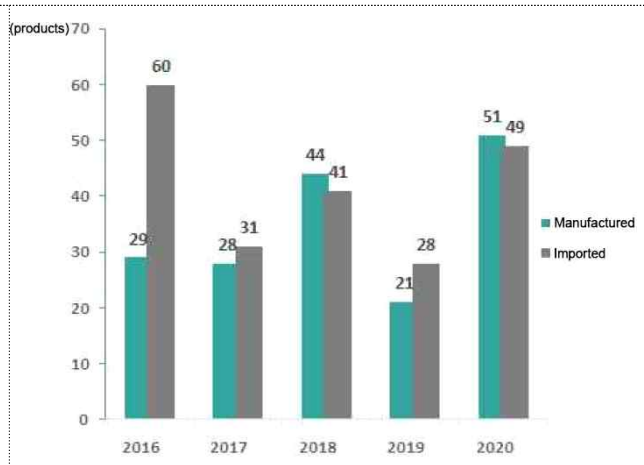


Figure 41. Conditional Certification of Manufactured/Imported Devices by Year (2016-2020)

Ⅱ-6. Approval of Medical Devices Subject to Tracking Management

Medical devices subject to tracking management are those that have to be located at all times as they may cause critical damage in human bodies in case of malfunction or defects. Currently, 44 items are designated in this category, of which 41 are medical devices implanted in human bodies for a year or longer, and the other 3 are life-supporting medical devices that can be used outside medical institutions. For reference, people in charge of handling medical devices are required to prepare monthly records and data about medical devices subject to tracking management and submit them to the Minister of Food and Drug Safety.

For the last 5 years, a total of 94 devices have been designated as medical devices subject to tracking management. The number of imported products (81, 86.0%) far exceeds the number of manufactured products (13, 14.0%). This is considered because importation is the only reliable source of some high-risk medical devices and life support medical devices which are inserted in human bodies due to the high entry barriers of technologies and regulations.

[Table 50] Approval of Medical Devices Subject to Tracking Management by Year (2016-2020)

(Unit: Number of products)

Category	2016	2017	2018	2019	2020	Total
Manufactured	- (0.0%)	1 (3.0%)	3 (30.0%)	4 (25.0%)	5 (31.3%)	**13 (14.0%)**
Imported	19 (100%)	32 (97.0%)	7 (70.0%)	12* (75.0%)	11 (68.7%)	**81 (86.0%)**
Total	**19**	**33**	**10**	**16**	**16**	**94**

* 1 EA of an imported item was added to the list of medical devices subject to tracking management in 2019.

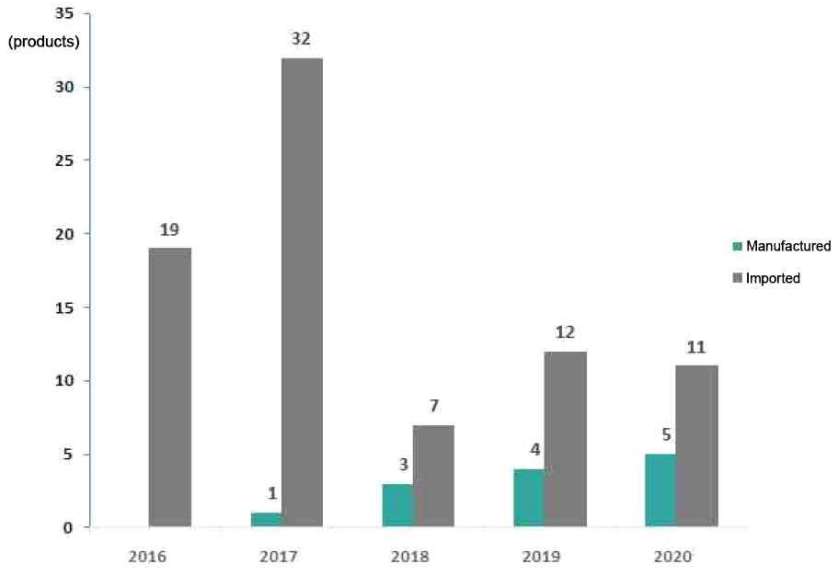


Figure 42. Medical Devices Subject to Tracking Management by Year (2016-2020)

Over the last 5 years, 23 “Defibrillator, Low Powered (A17010.01)” products, 11 “Ventilator, Continuous, Home-Use (A07010.02)” products, 10 “Defibrillator, Implantable (A17280.01)” products, 8 “Pacemaker, Cardiac, Implantable (A09270.01)” products, and 6 “Knee Prosthesis, Internal, Total Biodegradable (B03050.02)” products have been approved.

[Table 51] Approved Medical Devices Subject to Tracking Management over the Last Five Years (2016-2020) by Item

(Unit: Number of products)

No.	Classification No.	Item	Manufactured	Imported	Total
1	A17010.01	Defibrillator, lowpowered	8	15	**23**
2	A07010.02	Ventilator, Continuous, Home-Use	-	11	**11**
3	A17280.01	Defibrillator, Implantable	-	10	**10**
4	A09270.01	Pacemaker, Cardiac, Implantable	-	8	**8**
5	B03050.02	Knee Prosthesis, Internal, Total Biodegradable	-	6	**6**
6	A16280.01	Electrode for Electrical Stimulation System, Implantable	-	5	**5**
7	B03300.12	Stent, Vascular	2	2	**4**
8	A09280.01	Pacemaker Electrode Cardiac, Implantable	-	3	**3**
9	A16180.14	Brain Electrical Stimulation	-	3	**3**

		System, Antitremor			
10	B03040.02	Hip Prothesis, Internal, Total, Biodegradable	-	3	**3**
11	B04030.02	Prosthesis, Valve, Cardiac, Biological	1	2	**3**
12	B04050.02	Breast Prosthesis, Internal, Gel-Filled	-	3	**3**
13	A16180.09	Stimulator, Electrical, Analgesic, Implantable	-	2	**2**
14	B04010.01	Prosthesis, Vascular, Peripheral	-	2	**2**
15	A09150.02	Circulatory Assist System, Artificial Heart	-	1	**1**
16	A16180.20	Diaphragm/Phrenic Nerve Electrical Stimulation System	-	1	**1**
17	A17020.01	Resuscitator, Cardiopulmonary, Electrically-Powered	1	-	**1**
18	A17290.01	Electrode/Lead, Defibrillator, Implantable	-	1	**1**
19	B03010.02	Prosthesis, Ankle, Internal Total Biodegradable	-	1	**1**
20	B03230.05	Prothesis, Temporomandibular	1	-	**1**
21	B03300.04	Stent, Iliac	-	1	**1**
22	B04040.01	Annuloplasty Ring	-	1	**1**

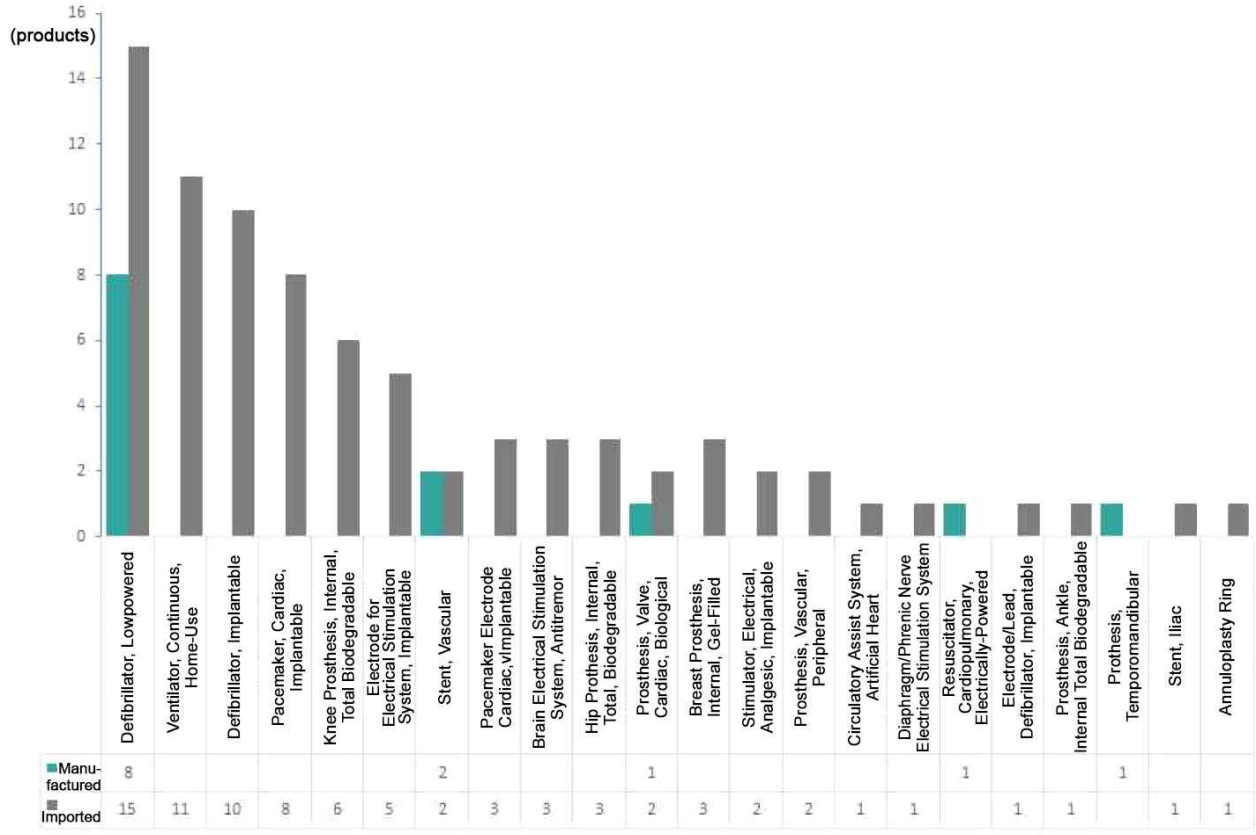


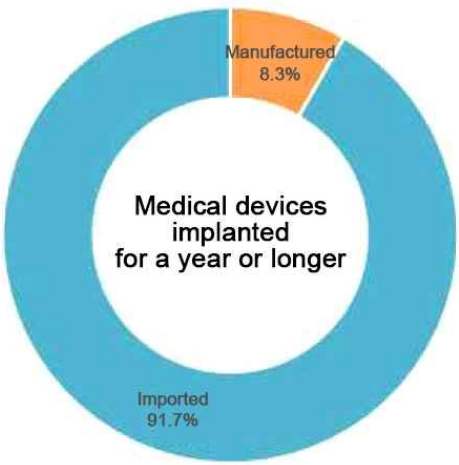
Figure 43. Approved Medical Devices Subject to Tracking Management over the Last Five Years (2016-2020) by Item

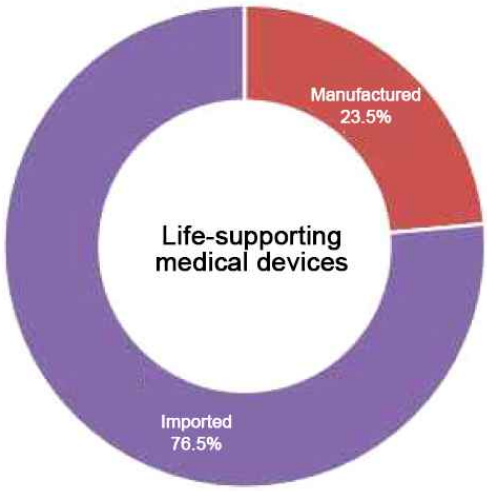
In terms of product characteristics, 60 of the approved devices are devices implanted in human bodies for a year or longer, and the remaining 34 are life-supporting medical devices.

[Table 52] Approved Medical Devices Subject to Tracking Management over the Last Five Years (2016-2020) by Characteristic

(Unit: Number of products)

Category	Manufactured	Imported	Total
Medical devices implanted for a year or longer	5	55	**60**
Life-supporting medical devices	8	26	**34**





[Figure 44. Approved Medical Devices Subject to Tracking Management over the Last Five Years (2016-2020) by Characteristic]

Ⅲ

Approvals, Certifications, and Notifications by Composition

Ⅲ. Approvals, Certifications, and Notifications by Composition

Ⅲ-1. Approval of Medical Devices Combined/Compounded with Drugs

As of 2020, there are 23 medical devices combined/compounded with drugs, of which 16 (69.6%) are manufactured products and 7 (30.4%) are imported products. The items with the highest number of products are “Graft/Prosthesis, Biomaterial” at 6 products (26.1%), followed by “Coronary Artery Stent” at 3 products (13.0%).

Lidocaine hydrochloride hydrate was used as local anesthetics to reduce pain during implantation, while isopropanol and hypochlorous acid water were used to sterilize and disinfect the implanted medical devices.

For catheters implanted in blood vessels, a large amount of paclitaxel was used to prevent blood vessel stenosis, along with gentamycin sulfate which served as an antibiotic.

Drugs used in medical devices are evaluated by the Pharmaceutical Evaluation Department and the Biopharmaceutical and Herbal Medicine Evaluation Department. The former consults with the Oncology and Antimicrobial Products Division and the Cardiovascular and Neurology Products Division, and the Biopharmaceutical and Herbal Medicine Evaluation Department consults with the Biologics Division to evaluate and approve products.

[Table 53] Approval of Products Combined/Compounded with Drugs, Etc. in 2020

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Product Name (Model Name)	Intended Use of Drug
1	Graft/Prothesis, Biomaterial (B04230.01[4])	BM-PHA (Renefil Ultra Plus)	BMI KOREA Co,. Ltd.	Manufacturing Approval No. 20-63 (2020-01-30)	Local anesthetics
2	Dressing, Collagen, Wound	Caregel	Pharmbio Korea,	Manufacturing	Antibiotics

No.	Item (Classification No. (Class))	Product Name (Model)	Company	Product Name (Model Name)	Intended Use of Drug
	(B07070.10[3])	(CG-1.0 and 3 others	Inc	Approval No. 20-139 (2020-02-25)	
3	Catheterization Kit, Haemodialysis (A57250.01[2])	BD PureHub Disinfecting Cap (306598 and 1 other	Becton Dickinson Korea, Inc	Import Approval No. 20-52 (2020-03-13)	Disinfection
4	Graft/Prothesis, Biomaterial (B04230.01[4])	(Elravie Premier Ultra Volume-L)	Humedix, Inc	Manufacturing Approval No. 20-206 (2020-03-23)	Local anesthetics
5	Syringes (A54010.01[2])	Hemlibra Injection Kit	Bandgold Co., Ltd.	Manufacturing Approval No. 20-264 (2020-04-08)	Disinfection
6	Graft/Prothesis, Biomaterial (B04230.01[4])	(Juvederm VOLUX)	Allergan Korea, Inc	Import Approval No. 20-90 (2020-04-28)	Local anesthetics
7	Direct Infusion Device (A79160.02[2])	SD3(SF)-10 and 24 others	BNB Medical Co., Ltd.	Manufacturing Approval No. 20-337 (2020-04-28)	-
8	Graft/Prothesis, Biomaterial (B04230.01[4])	Replengen (Replengen Pro with Lidocaine) and 1 other	Reanzen Co., Ltd.	Manufacturing Approval No. 20-347 (2020-05-06)	Local anesthetics
9	Coronary Artery Stent (B03300.13[4])	(DE-225-008 and 53 others)	CG Bio, Inc	Manufacturing Approval No. 20-364 (2020-05-14)	Blood vessel stenosis prevention
10	Forceps, Dressing, Manually-Operated, Reusable (A45010.01[1])	Soosung Povis Dressing Forceps Kit (SS-PDK-A1 and 19 others)	Soosung Hygiene Material Solution	Import Approval No. 20-127 (2020-06-05)	Absorber
11	Forceps, Dressing, Manually-Operated, Single-Use (A45010.02[2])	(GDFK200-P-3오 30 others)	Sejong Healthcare Co., Ltd.	Manufacturing Approval No. 20-494 (2020-06-11)	Absorber
12	Angioplasty Catheter, Balloon Dilatation, Coronary, Perfusing (A57130.21[4])	GENOSS DCB(GDEB-10-200 and 161 others)	Genoss, Inc	Manufacturing Approval No. 20-501 (2020-06-23)	Blood vessel stenosis prevention
13	Oxygen Concentrator (A07040.01[2])	MOSS-450BS[OCD0050], MOSS-300BS[OCD0050], MOSS-150BS[OCD0050] (MOSS-450BS[OCD0050] and 3 others	NF Co., Ltd.	Manufacturing Approval No. 20-528 (2020-07-01)	-
14	Graft/Prothesis, Biomaterial (B04230.01[4])	Lorient No. 2 and 2 others	Joonghun Pharmaceutical Co., Ltd.	Manufacturing Approval No. 20-552 (2020-07-09)	Local anesthetics
15	Clip, Surgical, External (A38090.05[1])	Inguinal Hemo Band (P-TNQ-NAS)	ICM Co., Ltd.	Manufacturing Approval No. 20-640 (2020-8-10)	-
16	Surgical Supplies (B07000[1])	Patient Controlled Heating Kit (PCBT-SB01 and 6 others	ICM Co., Ltd.	Manufacturing Approval No. 20-762 (2020-8-31)	-
17	Graft/Prothesis, Biomaterial (B04230.01[4])	Revolline HARA-L	Humedix, Inc	Manufacturing Approval No. 20-867 (2020-10-08)	Local anesthetics
18	Mask, Non-Rebreathing (A07025.04[1])	RB Mask (M-Fix Silicone Bandages) (WKM92-001(s) and 2 others	Medi-Force, Inc	Import Approval No. 20-218 (2020-10-26)	-
19	Mask, Ventilator (A07025.01[1])	Oxygen Mask (M-Fix Silicone Bandages) (WKM91-001(S) and 5 others	Medi-Force, Inc	Import Approval No. 20-219 (2020-10-26)	-
20	Catheterization Kit, Haemodialysis (A57250.01[2])	(MultiFix I.V-L and 7 others	Unimedics Co., Ltd.	Manufacturing Approval No. 20-911 (2020-10-28)	-
21	Coronary Artery Stent (B03300.13[4])	Firehawk Liberty™ RTECSS (FR2213 and 59 others)	ECoRA, Ltd.	Import Approval No. 20-242 (2020-11-19)	Blood vessel stenosis prevention
22	Oxygen Tube and Catheter, Single-Use (A57070.01[1])	Nasal Cannula (M-Fix Silicone Bandages) (WKT11-001(S) and 3 others	Medi-Force, Inc	Import Approval No. 20-254 (2020-11-25)	-
23	Coronary Artery Stent (B03300.13[4])	CENTUM™ Everolimus Eluting Coronary Stent System (TS07-22509 and 55 others)	OSSTEM CARDIOTEC Co., Ltd.	Manufacturing Approval No. 20-1162 (2020-12-31)	Blood vessel stenosis prevention

* Medical devices for export only, identical medical devices and medical device classification excluded

Ⅲ-2. Approvals, Certifications, and Notifications of Combination Medical Devices

A "combined medical device" is a single medical device comprised of two or more devices which work together to provide multiple functions. Among 337 combined medical devices which were approved, certified, and notified in 2020, 220 were manufactured devices (65.3%) and 117 were imported devices (34.7%).

The number of manufactured devices exceeds the number of imported devices by twofold, which suggests that, compared with foreign companies, Korean companies are more actively engaged in the development of combined medical devices as they come with various functions in a single product.

In particular, 149 manufactured devices were approved (67.7%), 61 were certified (27.7%), and 10 were notified (4.6%). Approved products accounted for the highest percentage or manufactured products. Meanwhile, 11 imported devices were approved (9.4%), 82 were certified (70.1%), and 24 were notified (20.5%). Certified products accounted for the highest percentage of imported products.

[Table 54] Approval, Certification, and Notification of Combined Medical Devices in 2020

(Unit: Number of products)

Category	Combined Medical Devices			Total
	Notification	Certification	Approval	
Manufactured	10 (4.6%)	61 (27.7%)	149 (67.7%)	**220 (65.3%)**
Imported	24 (20.5%)	82 (70.1%)	11 (9.4%)	**117 (34.7%)**
Total	**34 (10.1%)**	**143 (42.4%)**	**160 (47.5%)**	**337**

In terms of classes, 113 of the approved/certified/notified devices were Class IV devices (33.5%), 47 were Class III devices (14.0%), 143 were Class II devices (42.4%), and 34 were Class I devices (10.1%).

The high percentage of Class IV combined medical devices can be explained by the fact that items with high percentages among approved products, such as "Thread for Facial Tissue Fixation, Absorbable or Non-Absorbable" and "Graft/Prosthesis, Biomaterial," have to be combined with other separate medical devices (e.g., needle, syringe, etc.) to be used. "Hearing Aid, Air-Conduction (Antistammering Device)" had the highest percentage among Class II combined medical devices. This is considered due to the fact that these products amplify sound and deliver it through the air to compensate for hearing impairments or generate noises to help users adapt to tinnitus.

Meanwhile, the percentage of manufactured products is higher among higher-class products. This is attributed to the fact that Korean manufacturers use previously certified or notified products to develop and commercialize combined medical devices as a prompt response to the diverse demands from consumers of Class III and IV medical devices.

[Table 55] Approval, Certification, and Notification of Combined Medical Devices in 2020 by Class

(Unit: Number of products)

Category	Combined Medical Devices				Total
	Class I	Class II	Class III	Class IV	
Manufactured	10 (29.4%)	61 (42.7%)	38 (80.9%)	111 (98.2%)	**220 (65.3%)**
Imported	24 (70.6%)	82 (57.3%)	9 (19.1%)	2 (1.8%)	**117 (34.7%)**
Total	**34**	**143**	**47**	**113**	**337**

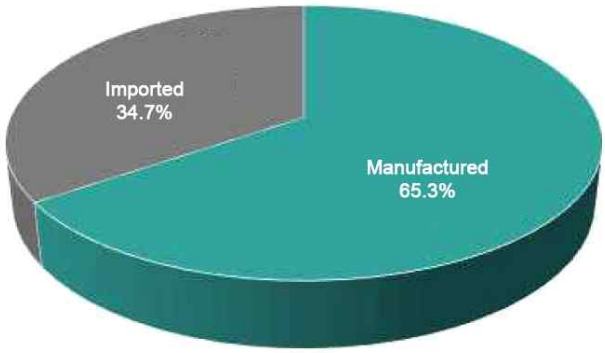


Figure 45. Percentages of Manufactured/Imported Combined Medical Devices Approved, Certified, and Notified in 2020

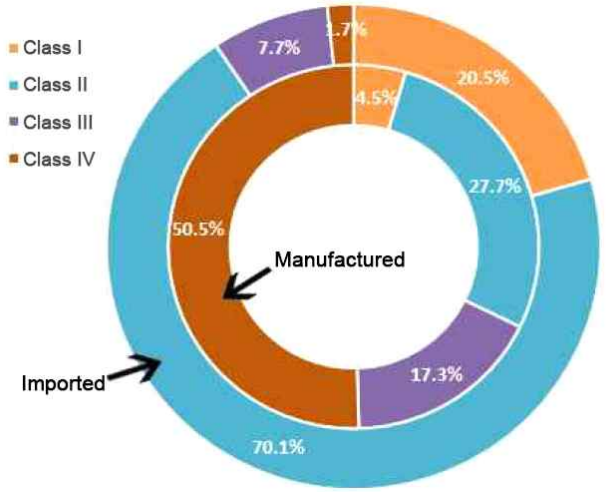


Figure 46. Percentages of Combined Medical Devices Approved, Certified, and Notified in 2020 by Class

Ⅲ-3. Approvals, Certifications, and Notifications of Medical Device Packages

A “medical device package” is two or more medical devices packaged in a single unit. In 2020, a total of 451 medical device packages were approved, certified, and notified, of which 325 were manufactured devices (72.1%) and 126 were imported devices (27.9%).

As was the case with combined medical devices, in the medical device package category, the number of manufactured products exceeds the number of imported products by twofold. This is viewed as a result of manufacturers preferring to combine multiple medical devices in a single package to facilitate product supply and improve user convenience. In addition, it is easier to respond to consumer demand with manufactured products compared to imported products.

In particular, 76 manufactured devices were approved (23.4%), 67 were certified (20.6%), and 182 were notified (56.0%). Approved products accounted for the highest percentage of manufactured products. Meanwhile, 18 imported devices were approved (14.3%), 18 were certified (14.3%), and 90 were notified (71.4%). Certified products accounted for the highest percentage of imported products.

[Table 56] Approvals, Certifications, and Notifications of Medical Device Packages in2020

(Unit: Number of products)

Category	Medical Device Packages			Total
	Notification	Certification	Approval	
Manufactured	182 (56.0%)	67 (20.6%)	76 (23.4%)	**325 (72.1%)**
Imported	90 (71.4%)	18 (14.3%)	18 (14.3%)	**126 (27.9%)**
Total	**272 (60.3%)**	**85 (18.9%)**	**94 (20.8%)**	**451**

In terms of classes, 8 of the approved/certified/notified devices were Class IV devices (1.8%), 81 were Class III devices (17.9%), 90 were Class II devices (20.0%), and 272 were Class I devices (60.3%). Notably, the percentages of manufactured products exceed those of imported products in all classes.

[Table 57] Approvals, Certifications, and Notifications of Medical Device Packages in 2020 by Class

(Unit: Number of products)

Category	Combined Medical Devices				Total
	Class I	Class II	Class III	Class IV	
Manufactured	182 (66.9%)	71 (78.9%)	71 (87.7%)	1 (12.5%)	**325 (72.1%)**
Imported	90 (33.1%)	19 (21.1%)	10 (12.3%)	7 (87.5%)	**126 (27.9%)**
Total	**272**	**90**	**81**	**8**	**451**

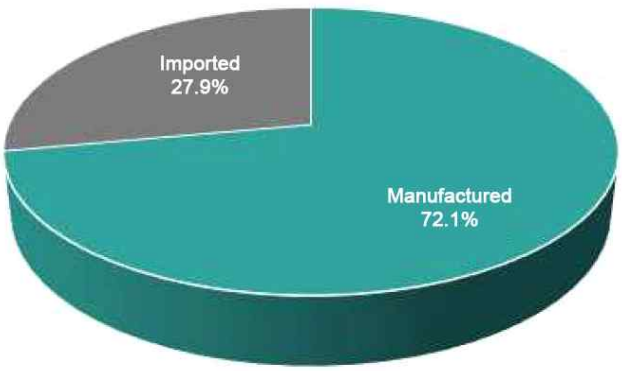


Figure 47. Percentages of Manufactured/Imported Medical Device Packages Approved, Certified, and Notified in 2020

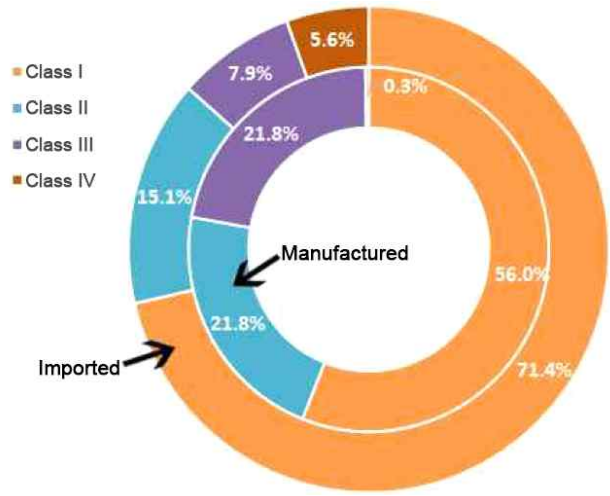


Figure 48. Percentages of Manufactured/Imported Medical Device Packages Approved, Certified, and Notified in 2020 by Class

Ⅲ－4. Approval, Certification, and Notification of Combined/Compounded Items of Medical Devices/IVD Medical Devices

As the Act on In Vitro Diagnostic Medical Devices became effective on 2020.5.1, matters necessary for the management and support were stipulated to establish a safety management system in which the characteristics of general medical devices and IVD medical devices are reflected.

“Combined/Compounded Items of Medical Devices/IVD Medical Devices” are IVD medical devices which are combined with each other or organized in a complex formation. In 2020, a total of 136 combined/compounded medical device/IVD medical device items were approved, certified, and notified, of which 132 were manufactured devices (97.1%) and 4 were imported devices (2.9%).

In particular, 86 manufactured devices were approved (65.1%), 5 were certified (3.8%), and 41 were notified (31.1%). Approved products accounted for the highest percentage of manufactured products. Meanwhile, 1 imported device was approved (25.0%), and 3 were notified (75.0%). Certified products accounted for the highest percentage of imported products.

[Table 58] Approval, Certification, and Notification of Combined/Compounded Items of Medical Devices/IVD Medical Devices in 2020

(Unit: Number of products)

Category	Combined/Compounded Items of Medical Devices/IVD Medical Devices			Total
	Notification	Certification	Approval	
Manufactured	41 (31.1%)	5 (3.8%)	86 (65.1%)	**132 (97.1%)**
Imported	3 (75.0%)	-	1 (25.0%)	**4 (2.9%)**
Total	**44 (32.4%)**	**5 (3.7%)**	**87 (63.9%)**	**136**

In terms of classes, 86 of the approved/certified/notified devices were Class III devices (63.2%), 6 were Class II devices (4.4%), and 44 were Class I devices (32.4%). The percentage of manufactured devices was higher in all classes than that of imported devices.

[Table 59] Approval, Certification, and Notification of Combined/Compounded Items of Medical Devices/IVD Medical Devices in 2020 by Class

(Unit: Number of products)

Category	Combined/Compounded Items of Medical Devices/IVD Medical Devices				Total
	Class I	Class II	Class III	Class IV	
Manufactured	41 (93.2%)	5 (83.3%)	86 (100%)	-	**132 (97.1%)**
Imported	3 (6.8%)	1 (16.7%)	-	-	**4 (2.9%)**
Total	**44**	**6**	**86**	**0**	**136**

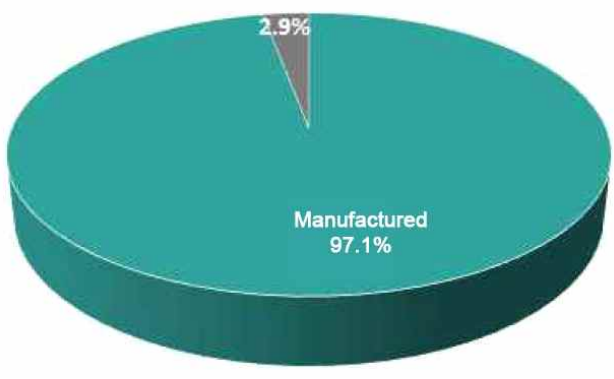


Figure 49. Percentages of Manufactured/Imported Combined/Compounded Items of Medical Devices/IVD Medical Devices in 2020

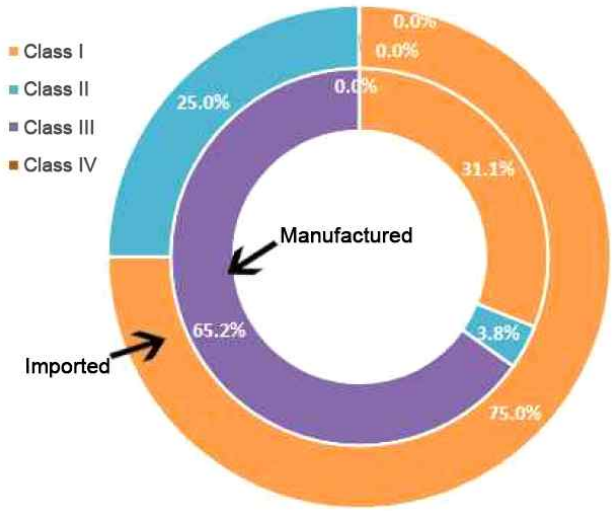


Figure 50. Percentages of Combined/Compounded Items of Medical Devices/IVD Medical Devices in 2020 by Class

Ⅳ

Approvals, Certifications, and Notifications of Advanced Medical Devices

Ⅳ. Approvals, Certifications, and Notifications of Advanced Medical Devices

Ⅳ-1. (A) Instruments

○ Approvals, Certifications, and Notifications of 3D-Printed Medical Devices

3D-printed medical devices are made from a technology that uses medical images (CT/MRI/3D scans, etc.) to design medical devices and laminates materials to construct medical devices and their peripherals. The 3D printing technology allows for the construction of medical devices that cannot be manufactured or designed with conventional technologies. In addition, it also allows for small-scale productions of multiple types of products.

In particular, the 3D printing technology is used in orthopedics, neurosurgery, plastic surgery, and dentistry departments to construct patient-tailored medical devices such as orthopedic fixation plates, spinal cages, artificial joints, cranioplasty plates, and guides for medical use.

3D printing technology is currently being popularized across all industrial sectors, and the MFDS is providing Korean medical device manufacturers with continuous support including the publication of “Evaluation Guideline for Approval of Tailored Medical Devices Manufactured by 3D Printing” to facilitate their approval.

In the “(A) Instruments” section, 3D-printed medical devices exhibited a rising trend after 2015, but there was no approval, certification, or notification in 2020.

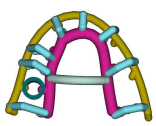
[Table 60] Approval, Certification, and Notification of 3D-Printed Medical Devices by Year (2016-2020) (Instruments)[2)]

(Unit: Number of products)

Category		2015	2016	2017	2018	2019	2020
Total		1	3	7	10	10	-
Instruments	Manufactured	1	2	7	10	9	-
	Imported	-	1	-	-	1	-

The following table shows 3D-printed "(A) Instruments" that were approved, certified, or notified over the last five years.

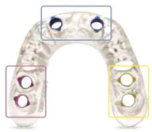
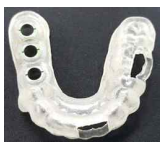
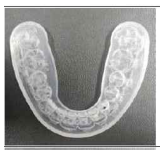
[Table 61] Approval, Certification, and Notification of 3D-Printed Medical Devices by Year (2015-2020) (Instruments)[3)]

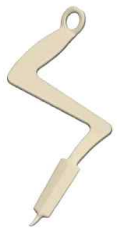
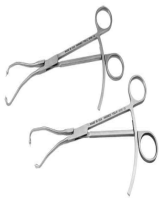
No.	Company	Item (Class)	Approval/ Notification No. (Approval/ Notification Date)	Intended Use	Appearance
1	Asan Medical Center	Guide for Medical Use (1)	Seoul Manufacturing Notification No. 15-503 (2015.12.4)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
2	Gwanggyo Factory, Dentium ICT, Inc	Guide for Medical Use (1)	Import Notification No. 16-2327 (2016.9.5)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
3	Asan Medical Center	Guide for Medical Use (1)	Manufacturing Notification No. 16-1293 (2016.10.31)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	

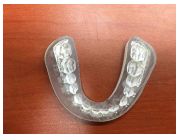
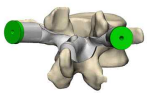
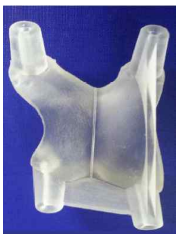
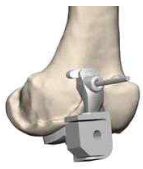
2) Export products excluded

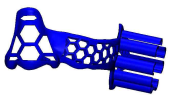
No.	Company	Item (Class)	Approval/ Notification No. (Approval/ Notification Date)	Intended Use	Appearance
4	Coreline Soft, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 16-1472 (2016.12.12)	A device used to guide the route , position of an implant or a device, and the indications of surgical sites, etc.	
5	Medisay, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 17-116 (2017.2.3)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (bone resection and drilling)	
6	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 17-118 (2017.2.3)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (orbital region)	
7	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 17-120 (2017.2.3)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (breast cancer)	
8	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 17-123 (2017.2.3)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (renal cancer)	
9	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 17-1151 (2017.10.10)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (lower jawbone)	
10	Kuwotech, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 17-1152 (2017.10.10)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (dental implant)	

3) Export products excluded

No.	Company	Item (Class)	Approval/ Notification No. (Approval/ Notification Date)	Intended Use	Appearance
11	Next Core, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 17-1414 (2017.12.15)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (nose)	
12	Kairos 3D, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 18-238 (2018.2.27)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (dental implant)	
13	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 18-282 (2018.3.9)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (upper jawbone)	
14	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 18-307 (2018.3.14)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (lower jawbone)	
15	Vistech Korea, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 18-690 (2018.6.7)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
16	Industry-University Cooperation Center, Korea National University of Transportation	Guide for Medical Use (1)	Manufacturing Notification No. 18-758 (2018.6.25)	A device used to guide the route , position of an implant or a device, and the indications of surgical sites, etc.	
17	NTO, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 18-1042 (2018.8.13)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (lower jawbone)	

No.	Company	Item (Class)	Approval/ Notification No. (Approval/ Notification Date)	Intended Use	Appearance
18	Industry-University Cooperation Center, Korea National University of Transportation	Retractor, Surgical, Manually-Operated (1)	Manufacturing Notification No. 18-1536 (2018.11.16.)	A manually operated medical device similar to hooks, retractors, separators, retainers, etc. that is used to expand or stretch affected sites.	
19	Industry-University Cooperation Center, Korea National University of Transportation	Clamp, Manually-Operated, Reusable (1)	Manufacturing Notification No. 18-1549 (2018.11.19.)	A reusable device, which includes a tube clamp, used to hold pincers or tissues during treatment.	
20	Institute of Advanced Convergence Technology	Guide for Medical Use, Invasive, Single Use (2)	Manufacturing Certification No. 18-5032 (2018.12.10)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
21	Institute of Advanced Convergence Technology	Guide for Medical Use, Invasive, Single Use (2)	Manufacturing Certification No. 18-5036 (2018.12.10)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
22	Next Core, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 19-442 (2019.4.8)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (nose)	
23	Next Core, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 19-464 (2019.4.12)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
24	Next Core, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 19-509 (2019.4.22)	A device used to guide the route, position of an implant or a device, and the	

No.	Company	Item (Class)	Approval/ Notification No. (Approval/ Notification Date)	Intended Use	Appearance
				indications of surgical sites, etc. (excluding invasive single-use products and dental products)	
25	ECoRA, Ltd.	Guide for Medical Use, Invasive, Single Use (2)	Import Certification No. 19-4367 (2019.6.5)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
26	CEP Tech, Inc	Guide for Medical Use, Invasive, Single Use (2)	Manufacturing Certification No. 19-4818 (2019.10.01)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
27	TJC Life, Inc	Guide for Medical Use, Invasive, Single Use (2)	Manufacturing Certification No. 19-4850 (2019.10.17)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
28	TJC Life, Inc	Guide for Medical Use, Invasive, Single Use (2)	Manufacturing Certification No. 19-4849 (2019.10.17)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
29	TJC Life, Inc	Guide for Medical Use, Invasive, Single Use (2)	Manufacturing Certification No. 19-4857 (2019.10.21)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
30	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 19-1531 (2019.11.22)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (excluding	

No.	Company	Item (Class)	Approval/ Notification No. (Approval/ Notification Date)	Intended Use	Appearance
				invasive single-use products and dental products)	
31	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 19-1583 (2019.12.4)	A device used to guide the route , position of an implant or a device, and the indications of surgical sites, etc. (excluding invasive single-use products and dental products)	

○ **Approvals, Certifications, and Notifications of AI-Based Medical Devices**

Software products powered by artificial intelligence (AI) technologies have been on the rise in recent years, and technological advancements are expected to spur the development of advanced products equipped with more diverse and complex functionalities.

"Artificial Intelligence" refers to technologies in which a part of or the entire intellectual abilities of humans, such as cognition and learning, are implemented by computers using machine learning, etc.

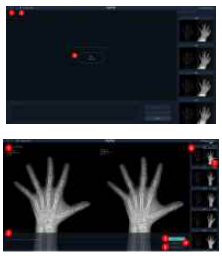
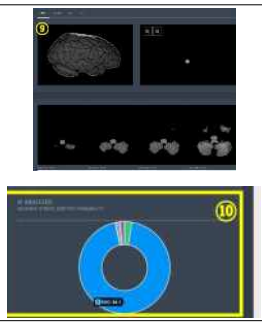
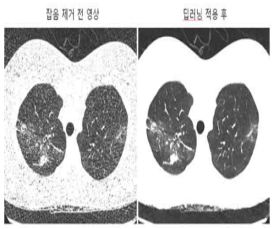
AI-powered medical devices learn medical big data to discern specific patterns for the diagnosis or prediction of diseases or the identification of treatments suitable for different patients.

In 2020, a total of 50 AI-based medical devices were approved and certified, recording a 150% increase from the previous year (10 devices). In particular, unlike the previous year when all of the approved and certified medical devices were manufactured in Korea, there were 5 imported products. However, the fact that the majority were manufactured products (45 devices)

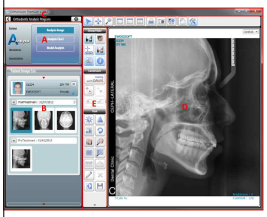
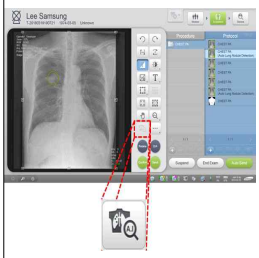
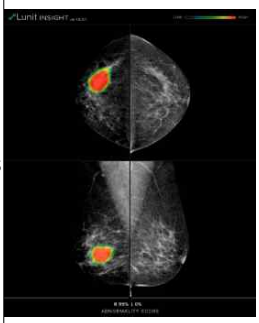
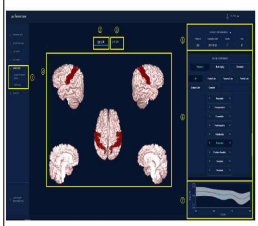
demonstrates Korea's active efforts in the development of AI-based medical devices.

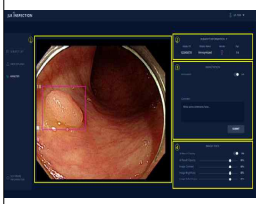
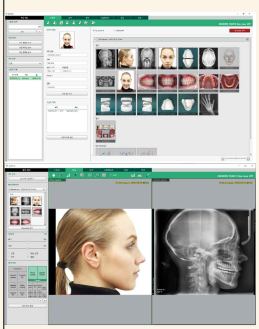
The following table shows the approvals, certifications, and notifications of AI-based medical devices for the last five years.

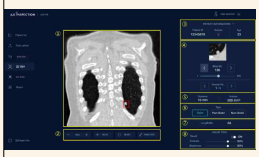
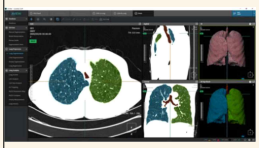
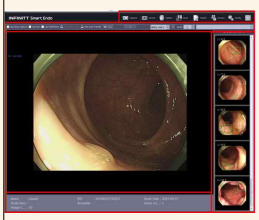
[Table 62] Approved and Certified AI-Based Medical Devices over the Last Six Years (2015-2020)[4)]

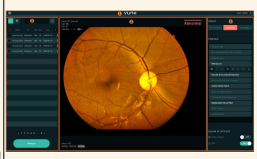
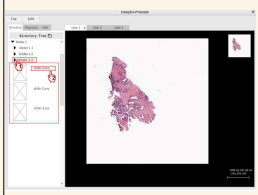
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
1	Vuno, Inc	Analyser, Medical Image, Software(2)	Manufacturing Approval No. 18-360 (2018.5.16)	A software designed to help healthcare professionals determine the bone age of patients by analyzing the X-ray image of the patient's left hand based on the bone age model of the Greulich-Pyle (GP) method	
2	JLK Inspection, Inc	Computer Aided Diagnosis Software (3)	Manufacturing Approval No. 18-573 (2018.8.14)	A software used to assist medical professionals in diagnosing cerebral infarction (ischemic stroke) by classifying its type automatically based on magnetic resonance (MR) images and clinical data	
3	Lunit, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 18-574 (2018.8.14)	A software that detects solitary pulmonary nodules from chest X-ray images and calculates the probability of lesions to help medical professionals interpret the images	
4	Clasrify, Inc	Picture Archiving and Communication System, Image Processing, Software (2)	Manufacturing Certification No. 16-4704 (revised on 2018.7.17)	A software that uses deep learning to separate noise from low-dose (high-noise) CT images and display/transmit noiseless images	

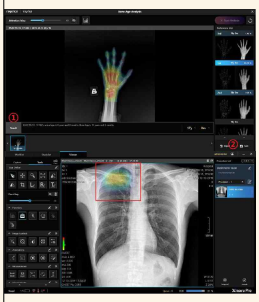
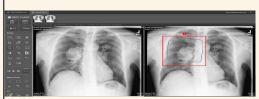
4) Export products excluded

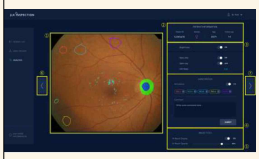
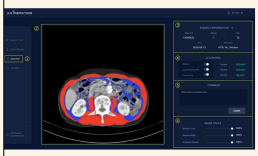
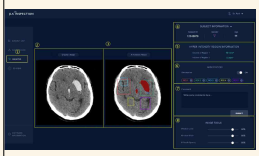
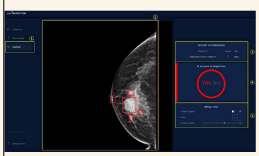
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
5	Ewoosoft, Inc	Picture Archiving and Communication System, Dental Image Processing, Software (2)	Manufacturing Certification No. 13-751 (2013.4.26.) SW V2.2 Revised (2019.2.26.)	A software used in devices that store, enlarge, reduce, view, analyze, transmit, and display dental images (uses the tracing with DAVIS (Auto Ceph Tracing) feature powered by AI learning to auto-generate landmarks and outlines)	
6	Samsung Electronics Co., Ltd.	Computer Aided Detection Software (2)	Manufacturing Approval No. 19-357 (2019.6.7)	A software that detects areas with suspected single pulmonary nodules to help health-care professionals in diagnosis	
7	Lunit, Inc	Computer Aided Diagnosis Software (3)	Manufacturing Approval No. 19-493 (2019.7.29)	A software that detects areas with suspected breast cancer in mammographic images, marks areas with suspected malignant lesions, and displays the probability of malignant lesions to assist the interpreting physician's in diagnosis	
8	JLK Inspection, Inc	Analyser, Medical Image, Software(2)	Manufacturing Certification No. 19-4654 (2019.8.5)	A software that uses medical images (brain MRI images) to provide simulation treatments and procedures as well as diagnoses (uses CNN to learn big data and analyze the volume of the cerebral substructure and the cerebral cortex atrophy)	
9	Vuno, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 19-551 (2019.8.20)	A software that detects abnormal areas in chest X-ray images and highlights them with outlines and colors to assist with image interpretation	

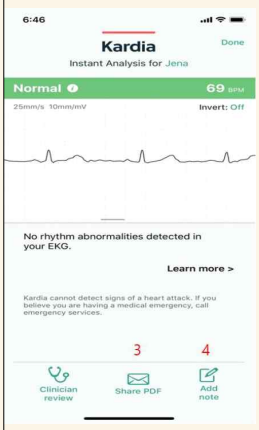
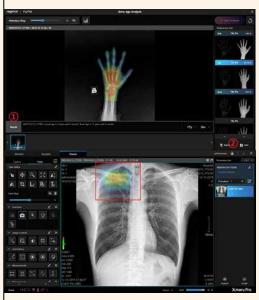
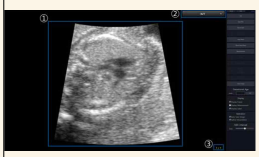
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
10	Deepnoid, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 19-550 (2019.8.20)	A software that detects areas with suspected compression fractions in lumbar X-ray images to help health-care professionals in making diagnostic decisions	
11	JLK Inspection, Inc	Analyser, Medical Image, Software(2)	Manufacturing Certification No. 19-4822 (2019.10.2)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (lung image analysis)	
12	JLK Inspection, Inc	Analyser, Medical Image, Software(2)	Manufacturing Certification No. 19-4828 (2019.10.4)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (gastroscope image analysis)	
13	JLK Inspection, Inc	Analyser, Medical Image, Software(2)	Manufacturing Certification No. 19-4829 (2019.10.4)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (colonoscopy image analysis)	
14	Lunit, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 19-660 (2019.10.21)	A software that detects abnormal areas in chest X-ray images to assist the interpreting physician in making diagnostic decisions	
15	Ewoosoft, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4020 (2020.1.9.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (uses the tracing with DAVIS (Auto Ceph Tracing) feature powered by AI learning to auto-generate landmarks and outlines)	

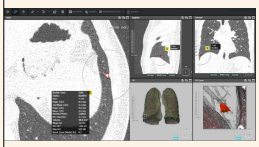
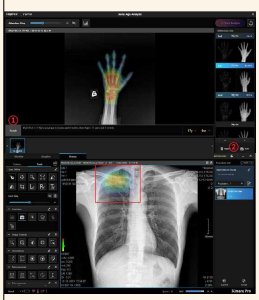
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
16	JLK Inspection, Inc	Picture Archiving and Communication System, Image Processing, Software (2)	Manufacturing Certification No. 20-4029 (2020.1.13)	A software used in devices which save, enlarge, reduce, view, analyze, send, and print medical images (lung image analysis)	
17	JLK Inspection, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4030 (2020.1.13)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (lung image analysis)	
18	Coreline Soft, Inc	Picture Archiving and Communication System, Image Processing, Software (2)	Manufacturing Certification No. 16-4603 (2016.7.21) Addition of AI Technology Applied (2020.2.17)	A software used in devices which save medical images, view, analyze them using the enlarging, reducing, splitting, and adjusting functions, send, and print the results of the analysis (AI technology is used to auto-split lung regions)	
19	INFINITT Healthcare Co., Ltd.	Computer Aided Detection Software (2)	Manufacturing Certification No. 20-4154 (2020.2.25)	A software used to detect abnormal regions (raised or depressed patterns) in colonoscopy images and highlight them with outlines to assist healthcare professionals in making diagnostic decisions	
20	Crescom, Inc	Analyser, Medical Image, Software (2)	Manufacturing Approval No. 20-153 (2020.3.3)	A software designed to help healthcare professionals determine the bone age of patients by analyzing the X-ray image of the patient's left hand using an AI technique that combines the Tanner-Whitehouse3 (TW3) and Greulich-Pyle (GP) methods	
21	Healthhub Co., Ltd.	Analyser, Medical Image, Software (2)	Manufacturing Approval No. 20-166 (2020.3.10)	A software designed to help healthcare professionals determine the bone age of patients by automatically analyzing the bone age of the patient's left hand in the X-ray image using the TW-3 method	

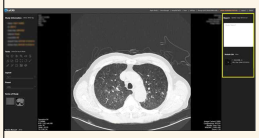
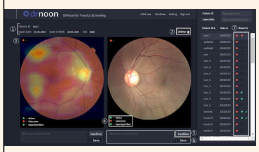
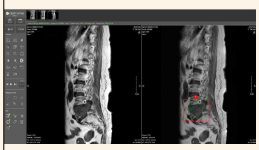
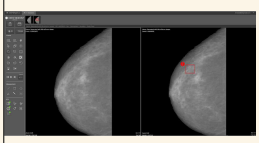
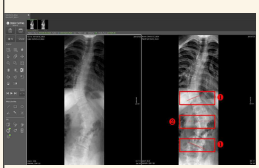
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
22	Vuno, Inc	Computer Aided Diagnosis Software (3)	Manufacturing Approval No. 20-244 (2020.4.1)	A software that assists healthcare professionals in diagnoses by analyzing abnormal findings in fundus images, providing analysis results about the normal and abnormal findings, commenting about the abnormal findings, and highlighting their locations.	
23	Deep Bio, Inc	IVD Software (3)	Manufacturing Approval No. 20-248 (2020.4.3) - Conditional Approval Granted In Vitro Manufacturing Approval No. 20-373 (2020.5.19.)	An IVD medical device which assists physicians with the diagnosis of prostate cancer by analyzing the presence of cancer tissues in digital images of hematoxylin and eosin(H&E)-stained prostate tissues from patients with suspected prostate diseases using a software	
24	Rayence, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4273 (2020.4.10.)	A software used in devices with save, enlarge, reduce, view, analyze, and send medical images; it includes the software designed to help medical staff determine the bone age of patients by analyzing the X-ray image of the patient's left hand based on the bone age model of the GP (Greulich-Pyle) method (Vuno "Manufacturing Certification No. 18-360") (Combined with Picture Archiving and Communication System, Image Processing, Software (2))	

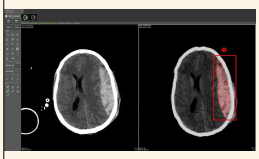
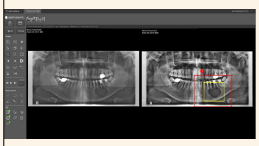
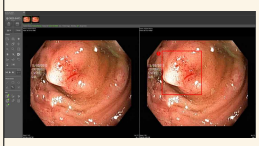
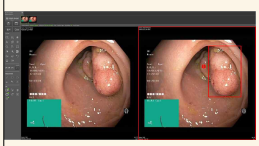
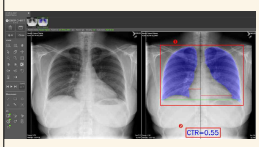
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
25	Rayence, Inc	Computer Aided Detection Software (2)	Manufacturing Certification No. 20-4274 (2020.4.10.)	A software used in devices with save, enlarge, reduce, view, analyze, and send medical images; it includes the function that detects abnormal regions in chest X-ray images and highlights them with outlines and colors to assist with the interpretation of the images (Vuno "Manufacturing Certification No. 19-551") and the software designed to help healthcare professionals determine the bone age of patients by analyzing the X-ray image of the patient's left hand based on the bone age model of the GP (Greulich-Pyle) method (Vuno "Manufacturing Certification No. 18-360") [a combination of Picture Archiving and Communication System, Image Processing, Software (2) and Analyser, Medical Image, Software (2)]	
26	Vuno, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 20-298 (2020.4.21)	A software designed to detect nodules in CT images of the lung and provide quantitative information about the nodules to assist healthcare professionals who interpret the images in making diagnostic decisions	
27	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4378 (2020.5.15.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (a function that finds the form, size, and location of bright regions with a round shape in X-ray images)	

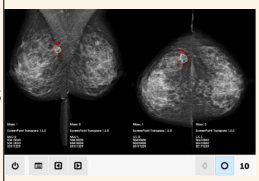
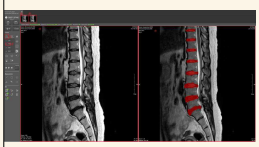
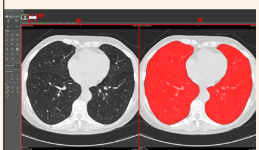
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
28	JLK Inspection, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4398 (2020.5.20.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (analyzes optic cups, optic discs, and bright regions in fundus images)	
29	JLK Inspection, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4399 (2020.5.20.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (analyzes fatty and muscular regions of abdominal CT images)	
30	JLK Inspection, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4404 (2020.5.21.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (analyzes bright regions in brain CT images)	
31	JLK Inspection, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4405 (2020.5.21.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (analyzes dark regions in brain CT images)	
32	JLK Inspection, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4406 (2020.5.21.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (analyzes bright regions in breast CT images)	

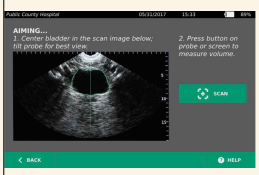
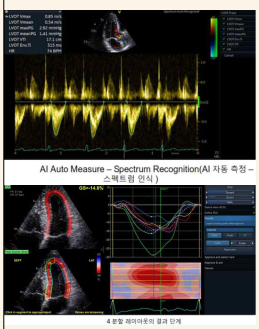
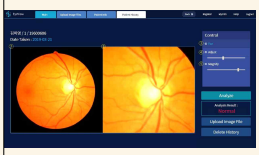
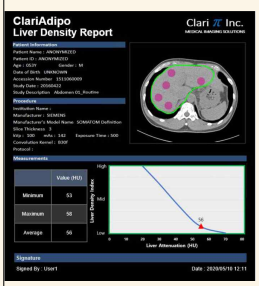
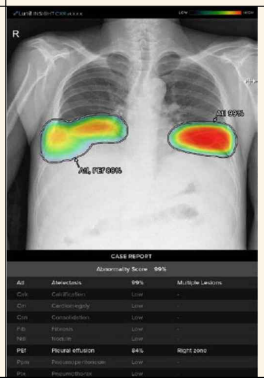
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
33	Synex Consulting Ltd.	Electrocardiographic Holter Analyser (2)	Import Approval No. 20-115 (2020.5.28.) [Manufacturer : China Turnkey Solutions Logistics (Shenzhen) Co., Ltd. (China)]	A product which records, saves, and transmits single channel electrocardiogram signals; the measured signals are used in analyzing the normal state, atrial fibrillation, bradycardia, tachycardia, etc. through an algorithm to assist healthcare professionals in diagnosis (assists in the diagnosis of arrhythmia using the information about atrial fibrillation, tachycardia, etc. analyzed through an algorithm)	
34	Listem, Inc	Medical Image, Analog to Digital Transform, DR, CR (2)	Manufacturing Certification No. 08-226 Revised (2020.6.1.)	A device or software which saves, enlarges, reduces, views, analyzes, sends, and prints medical images (a function that analyzes bone ages and detects abnormal chest regions has been added by adding a previously approved software (Manufacturing Certification No. 20-4273 and Manufacturing Certification No. 20-4274))	
35	Samsung Medison Co., Ltd.	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4468 (2020.6.2.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (provides information about classification, splitting, and measurement of ultrasonographic images of the standard fetal heart)	
36	Deepnoid, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 20-467 (2020.6.10.)	A software which detects abnormal regions with suspected cerebral aneurysm in human cerebrovascular MRA (Magnetic Resonance Angiography) images using big data and artificial intelligence (AI) technologies to assist healthcare professionals in making diagnostic decisions	

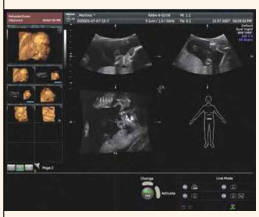
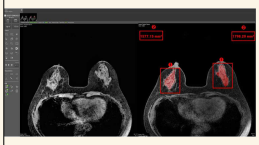
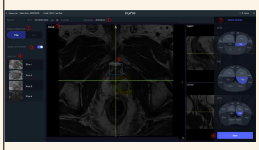
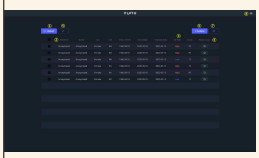
No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
37	Laon People, Inc	Picture Archiving and Communication System, Dental Image Processing, Software (2)	Manufacturing Certification No. 19-4368 (2019.5.8.) Revised (2020.6.11.)	A software used in analysis devices to obtain dental images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (automatically extracts 54 landmarks learned using lateral X-ray images based on AI technology)	
38	Coreline Soft, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 20-484 (2020.6.16.)	A computer aided detection software used to automatically detect lung nodules 4mm or larger to 30mm or smaller in CT images of the chest using AI technology.	
39	Coreline Soft, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4631 (2020.7.16)	A software that splits organs according to their classifications based on a split model trained with CT (chest) images by AI	
40	Deepnoid, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 20-578 (2020.7.16)	A software which detects lung nodules, regions with suspected lung nodules, the size of lung nodules, and the probability (%) of nodules in the relevant regions in low-dose CT images of the human chest using big data and artificial intelligence (AI) technologies to assist healthcare professionals in making diagnostic decisions	
41	Rayence, Inc	Medical Image, Analog to Digital Transform, DR, CR (2)	Manufacturing Certification No. 20-4639 (2020.7.20.)	A device which digitizes medical images using computer-aided radiographic imaging devices (CR) and digital radiographic imaging devices (DR), saves, and sends the images; it often includes a software (Manufacturing Approval No. 20-4273 and Manufacturing Approval No. 20-4274 software of the company come as options)	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
42	Monitor Corporation, Inc	Computer Aided Diagnosis Software (3)	Manufacturing Approval No. 20-602 (2020.7.27)	A software used by the interpreting physician in the interpretation of chest CT images; it provides information about the probability of malignancy in lung nodules, location, and characteristics of lung nodules to assist in making decisions regarding the final diagnosis and management of patients based on the information extracted from medical images	
43	Medi-Whale, Inc	Computer Aided Detection Software (2)	Manufacturing Approval No. 20-618 (2020.8.3)	A software that detects and highlights regions with fundus abnormalities and suspected diseases (cataract, glaucoma, and retinal diseases) to assist healthcare professionals in making diagnostic decisions	
44	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4709 (2020.8.6.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (automatically detects regions in the spine that are darker than the surroundings)	
45	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4742 (2020.8.12.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (highlights bright regions with round shapes in breast CT images)	
46	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4743 (2020.8.12.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (automatically detects the spines at both ends of curvatures)	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
47	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4749 (2020.8.13.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (automatically detects bright regions in the brain)	
48	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4751 (2020.8.13.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (automatically detects dark regions near dental roots)	
49	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4761 (2020.8.18.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (highlights raised regions in gastroscopy)	
50	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4762 (2020.8.18.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (highlights raised regions in colonoscopy)	
51	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4764 (2020.8.19.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (automatically detects the lung regions in chest X-ray images)	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
52	iMediSync, Inc	Electroencephalograph, Analysis Software (2)	Manufacturing Approval No. 20-750 (2020.8.26)	An online-based brainwave analysis software that classifies mild cognitive impairments known as the stage prior to Alzheimer's dementia in patients with amnestic mild cognitive impairment (aMCI) through a quantitative brainwave analysis; it presents the results of brainwave analysis by displaying the probability of aMCI as a percentage based on a trained aMCI model to assist healthcare professionals in diagnosis	
53	Siemens Healthineers, Inc	Computer Aided Diagnosis Software (3)	Import Approval No. 20-187 (2020.8.21) [Manufacturer : ScreenPoint Medical B.V. (Netherlands)]	A software that detects areas with suspected breast cancer in mammographic images, marks the locations of malignant lesions, and displays the probability of malignant lesions as a score to assist the interpreting physician in diagnosis	
54	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4804 (2020.9.2.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (Automatically detects and visualizes intervertebral discs in lateral MRI images of the spine)	
55	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-4805 (2020.9.2.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (visualizes the lung regions in chest CT images)	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
56	Medial Supply, Inc	Bladder Volume Measurement System, Ultrasonic (2)	Import Certification No. 20-4609 (2020.9.16.) [Manufacturer : Verathon Inc (United States)]	A device that measures the volume of bladders using ultrasonic waves (highlights the bladder regions in ultrasonic images)	
57	GE Healthcare Korea Co., Ltd.	Ultrasound Imaging System, General-Purpose	Import Certification No. 16-4615 (2016.10.27.) Additional Revision (2020.9.29) [Manufacturer : GE Vingmed Ultrasound AS (Norway)]	A general-purpose ultrasound imaging system that transmits ultrasound energy to affected areas (including cardiovascular areas), receives reflected signals, and visualizes them (measures the distance of diastolic interventricular septum, etc. in the heart area, labels different areas, recognizes images, determines what types of measurements are needed, and measures the relevant Auto Doppler)	
58	AIMS, Inc	Computer Aided Diagnosis Software (3)	Manufacturing Approval No. 20-847 (2020.9.28.)	A software used to assist the physician in making diagnostic decisions about glaucoma based on retinographs of the patient taken with the fundus camera	
59	ClariPi, Inc	Picture Archiving and Communication System, Image Processing, Software (2)	Manufacturing Certification No. 20-4233 (2020.3.24.) Additional Revision (2020.10.29.)	A software used in devices which save, enlarge, reduce, view, analyze, view, and print medical images (automatically splits the liver area and displays ROI; reduces noise in low-dose CT images and increases the SNR of images (equivalent to Manufacturing Certification No. 16-4704))	
60	Lunit, Inc	Computer Aided Detection and Diagnosis Software, Class II (2)	Manufacturing Approval No. 20-896 (2020.10.19.)	A software that detects abnormal areas in chest X-ray images to help health-care professionals in diagnosis	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
61	GE Healthcare Korea Co., Ltd.	Ultrasound Imaging System, General-Purpose (2)	Import Certification No. 07-522 (2007.6.18.) Additional Revision (2020.11.02.)	A device that transmits ultrasound energy to affected areas, receives reflected signals, and visualizes the physiological or artificial structure (automatically senses and displays the central nervous system (CNS) of the fetus).	
62	Deepnoid, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-5104 (2020.12.14.)	A software used in the analysis of medical images (MRI images of the breast) (visualizes the surface area of breast fibroadenoma tissues)	
63	Vuno, Inc	Analyser, Medical Image, Software (2)	Manufacturing Certification No. 20-5145 (2020.12.23.)	A software used in analysis devices to obtain medical images and make them usable in simulation treatments, simulation procedures, and simulation diagnoses (automatically analyzes MR images of the prostate and highlights areas with low signal)	
64	Vuno, Inc	Neural Image, Computer Aided Detection/Diagnosis Software (3)	Manufacturing Approval No. 20-1159 (2020.12.29)	A software that automatically analyzes T1 weighted MR images of the brain and digitizes the probability of Alzheimer's disease to assist healthcare professionals in making diagnostic decisions	

○ Approval of Robot-Based Surgical and Rehabilitation Medical Devices

A surgical robot is a medical device featuring a robotic system directly or remotely controlled by a surgeon to perform laparoscopic or endoscopic surgeries. The item's full name is "Robotic Surgical System, Navigation (A67050.04, Class III)." Over the last five years, 8 surgical robots were approved, of which 3 were manufactured products and 5 were imported products.

A "rehabilitation robot" is a medical device featuring a robotic system used for rehabilitating a disabled patient or treating/reducing the patient's disability. The item's full name is "Robotic-Guidance Rehabilitation System (A67080.01, Class III)." Over the last 5 years, 2 rehabilitation robots were approved, of which 2 were imported products. However, surgical and rehabilitation robots do not seem to be widely used by hospitals in Korea because of various factors, such as medical insurance fees.

[Table 63] Approval of Robot-Based Surgical and Rehabilitation Medical Devices by Year (2016-2020)[5)]

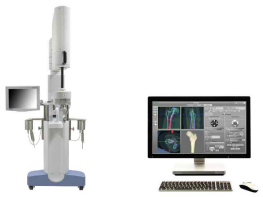
(Unit: Number of products)

Category		2016	2017	2018	2019	2020
Surgical Robot	Manufactured	-	1	1	-	1
	Imported	-	3	1	1	-
Rehabilitation Robot	Manufactured	-	-	-	-	-
	Imported	-	1	-	-	1
Total		-	5	2	1	2

5) Export products excluded

The following table shows the surgical and rehabilitation robotic devices approved over the last five years.

[Table 64] Robotic Surgical and Rehabilitation Medical Devices Approved Over the Last Five Years (2016-2020)[6)]

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
1	Curexo, Inc	Robotic Surgical System, Navigation[3]	Import Approval No.17-79 (2017.2.27)	TSolution One Surgical System is a surgical robot used for artificial knee joint surgery. The included program (TPLAN) analyzes the medical images (CT) from the patient to assist the physician in making preoperation plans. In particular, this system is used under the control of a physician for the identification of surgery areas, incisions, cutting, and the insertion and fixation of implants	
2	Curexo, Inc	Robotic Surgical System, Navigation[3]	Import Approval No.17-126 (2017.3.17)	TSolution One Surgical System is a surgical robot used for artificial hip joint surgery. The included program (TPLAN) analyzes the medical images (CT) from the patient to assist the physician in making preoperation plans. In particular, this system is used under the control of a physician for the identification of surgery areas, incisions, cutting, and the insertion and fixation of implants	
3	Woorim	Robotic-Guid	Import	A robotic guidance	

6) Export products excluded

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
	Technology Company, Ltd.	ance Rehabilitation System [3]	Approval No.17-327 (2017.7.19)	rehabilitation system used for muscle reconstruction or the recovery of joint movement in patients requiring hand and lower arm rehabilitation	
4	Meerecompany, Inc	Robotic Surgical System, Navigation[3]	Import Approval No.17-596 (2017.8.3)	A robotic surgery system used under the control of a physician in common endoscopic surgeries, including cholecystectomies and prostatectomies, for the identification of surgery areas, incisions, cutting, ligatures, cauterization, sutures, and the insertion and fixation of implants	 
5	Intuitive Surgical Korea Co., Ltd.	Robotic Surgical System, Navigation[3]	Import Approval No.17-464 (2017.9.29)	1. Robotic Surgical System, Navigation Intuitive Surgical Endoscopic Instrument Control System (da Vinci X Surgical System, Model IS4200) is intended to assist with the accurate control of intuitive surgical endoscopic instruments during endoscopic surgeries including urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures, open heart surgeries for thoracoscopy, and orally	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
				performed otolaryngologic surgeries. In particular, the system may be used in adult and pediatric patients to connect coronary arteries via image-guided mediastinectomy in coronary artery reconstruction surgeries (except for transoral surgeries). 2. Electrosurgical System, General-Purpose This instrument is used with high-frequency electricity for incisions or coagulation 3. Visceral Function Testing Instruments da Vinci® Fluorescence Imaging Vision System provides endoscopic images and near-infrared fluorescent images of blood vessels, blood flow, tissues, and extrahepatic bile ducts (cystic duct, common bile duct, and hepatic duct) 4. Imager for Medical Use An instrument that displays X-ray and ultrasound images on a monitor	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
6	Meerecompany, Inc	Robotic Surgical System, Navigation[3]	Import Approval No.18-170 (2018.3.13)	An automated robotic surgery system used under the control of a physician in common endoscopic (laparoscopic) surgeries, including cholecystectomies and prostatectomies, for the identification of surgery areas, incisions, cutting, ligatures, cauterization, sutures, and the insertion and fixation of implants	
7	Intuitive Surgical Korea Co., Ltd.	Robotic Surgical System, Navigation[3]	Import Approval No.18-153 (2018.5.28)	1. Robotic Surgical System, Navigation Intuitive Surgical Endoscopic Instrument Control System (da Vinci SP Surgical System, Model SP1098) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments during endoscopic surgeries including urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and orally performed otolaryngologic surgeries. The system is indicated for adult and pediatric use (except for transoral surgeries). 2. Electrosurgical System, General-Purpose This instrument is used with high-frequency electricity for incisions or coagulation, etc.	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
				3. Visceral Function Testing Instruments da Vinci® Fluorescence Imaging Vision System provides endoscopic images and near-infrared fluorescent images of blood vessels, blood flow, tissues, and extrahepatic bile ducts (cystic duct, common bile duct, and hepatic duct) 4. Imager for Medical Use An instrument that displays X-ray and ultrasound images on a monitor	
8	Smith & Nephew, Inc	Robotic Surgical System, Navigation[3]	Import Approval No.19-151 (2019.5.29)	The NAVIO Surgical System is an automated robotic system that assists with determining the standards for the anatomical bone structure, identifying the surgery area for inserting artificial knee joints, and performing osteotomy in orthopedic surgical procedures.	
9	Curexo, Inc	Robotic-Guidance Rehabilitation System [3]	Import Approval No.20-6 (2020-01-08)	A Robotic-Guidance Rehabilitation System is used for muscle reconstruction or the recovery of joint movement in patients requiring rehabilitation of the upper limbs (arms and shoulders) under the supervision of professionals at professional medical care centers	
10	Curexo, Inc	Robotic Surgical System, Navigation	Manufacturing Approval No.20-429 (2020-06-02)	A Robotic Surgical System that assists the physician in making preoperation plans and in locating surgical areas,	

No.	Company	Item (Class)	Approval No. (Date)	Intended Use	Appearance
		[3]		incisions, osteotomy, insertion and fixation of implants using medical diagnostic images obtained from patients; used in artificial knee joint surgeries.	

Ⅳ-2. (B) Medical Supplies

○ Approvals, Certifications, and Notifications of 3D-Printed Medical Devices

"(B) Medical Supplies" has been the most active area for medical device development using 3D printers. Although the number of approvals for 3D-printed medical devices decreased slightly (15 → 5) in 2019 from the previous year, a total of 21 3D-printed medical devices were approved in 2020.

[Table 65] Approval, Certification, and Notification of 3D-Printed Medical Devices by Year (Medical Supplies)[7)]

(Unit: Number of products)

Category		2016	2017	2018	2019	2020
Total		3	13	15	5	21
Medical Supplies	Manufactured	3	10	13	5	21
	Imported	-	3	2	-	-

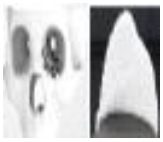
The following table shows 3D-printed "(B) Medical Supplies" that were approved, certified, or notified over the last 5 years.

7) Export products excluded

[Table 66] Approved 3D-Printed Products in Medical Supplies Section[8)]

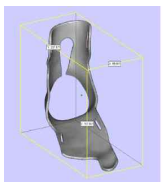
No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
1	Standing Tall Medical, Inc	Splints (1)	Manufacturing Notification No. 16-47 (2016.01.13.)	A supportive device designed to pressurize and immobilize a part of the body (waist, knee, neck, etc.). It includes a casting tape and dental splint. Splints without supporting functions are excluded.	
2	Medisay, Inc	Orthopedic Materials (3)	Manufacturing Approval No.16-236 (2016.3.30)	A patient-tailored, 3D-printed implant used to replace bone defects in patients caused by a trauma or a tumor, or to fuse the damaged joints in conservative treatment.	
3	T&R Biofab, Inc	Cranioplasty Plate, Biological/ Biodegradable (4)	Manufacturing Approval No.16-745 (2016.10.10)	A 3D-printed, patient-tailored device made of absorptive materials and used in the reconstruction of burr hole defects	
4	Artificial Organ Research Center Co., Ltd.	Spinal Cage (3)	Manufacturing Approval No.17-156 (2017.2.28)	A patient-tailored, 3D-printed spinal cage that is implanted between bones or bone grafts and used in orthopedic surgeries for the treatment of structural abnormalities resulting from degenerative intervertebral disks	
5	T&R Biofab, Inc	Cranioplasty Plate, Biological/ Biodegradable (4)	Manufacturing Approval No.17-312 (2017.5.12)	A 3D-printed, absorptive product used in the reconstruction of sphenoid bone defects. Each model comes in a single size.	

8) Export products excluded

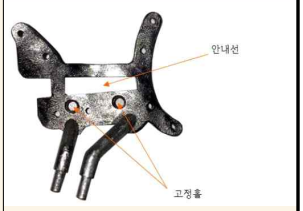
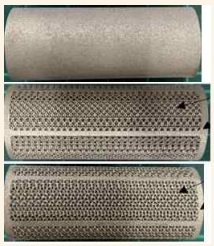
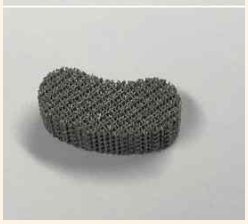
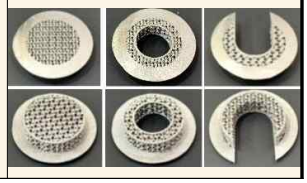
No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
6	T&R Biofab, Inc	Cranioplasty Plate, Biological/ Biodegradable (4)	Manufacturing Approval No.17-351 (2017.5.26)	A 3D-printed, absorptive product used in the reconstruction of sphenoid bone defects. Each model comes in a single size.	
7	Implantcast Asia, Inc	Hip Prothesis, Internal, Total (3)	Import Approval No.17-272 (2017.6.13)	A 3D-printed implant used for the arthroplasty of the hip joint	
8	T&R Biofab, Inc	Cranioplasty Plate, Biological/ Biodegradable (4)	Manufacturing Approval No.17-648 (2017.8.24)	A 3D-printed, absorptive product used in the reconstruction of burr hole defects. Each model comes in a single size.	
9	T&R Biofab, Inc	Cranioplasty Plate, Biological/ Biodegradable (4)	Manufacturing Approval No.17-649 (2017.8.24)	A 3D-printed, absorptive product used in the reconstruction of burr hole defects. Each model comes in a single size	
10	T&R Biofab, Inc	Cranioplasty Plate, Biological/ Biodegradable (4)	Manufacturing Approval No.17-650 (2017.8.24)	A 3D-printed, absorptive product used in the reconstruction of burr hole defects. Each model comes in a single size.	
11	T&R Biofab, Inc	Cranioplasty Plate, Biological/ Biodegradable (4)	Manufacturing Approval No.17-651 (2017.8.24)	A 3D-printed, absorptive product used in the reconstruction of burr hole defects. Each model comes in a single size	
12	Stryker Korea, Inc	Knee Prosthesis, Internal, Total (3)	Import Approval No.17-413 (2017.9.7)	A 3D-printed implant used for the arthroplasty of the knee joint	
13	Stryker Korea, Inc	Knee Prosthesis, Internal, Total (3)	Import Approval No.17-415 (2017.9.7)	A 3D-printed implant used for the arthroplasty of the knee joint	

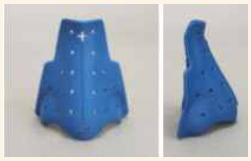
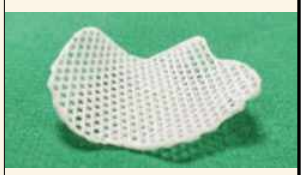
No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
14	Cusmedi, Inc	Cranioplasty Plate (3)	Manufacturing Approval No.17-779 (2017.10.12)	A 3D-printed, patient-tailored cranioplasty plate used to replace and support defective areas in the cranium	
15	Artificial Organ Research Center Co., Ltd.	Spinal Cage (3)	Manufacturing Approval No.17-878 (2017.11.17)	A 3D-printed, patient-tailored spinal cage used to treat structural abnormalities resulting from degenerative intervertebral disks in the cervical vertebra.	
16	Next Core, Inc	Splints, Mouldable (1)	Manufacturing Notification No. 17-1439 (2017.12.26)	A device which can be molded to fit in different body types and used to immobilize injured body parts.	
17	Cusmedi, Inc	Orbital Rim Prothesis (3)	Manufacturing Approval No.18-9 (2018.01.05)	A 3D-printed, patient-tailored orbital rim prosthesis used to replace and support defective areas in the orbital rim and orbital floor	
18	Cusmedi, Inc	Prothesis, Zygomatic (3)	Manufacturing Approval No.18-10 (2018.01.05.)	A 3D-printed, patient-tailored zygomatic prosthesis used to replace and support defective areas in the zygoma	
19	Artificial Organ Research Center Co., Ltd.	Orthopaedic Fixation Plate, Non-Biodegradable (3)	Manufacturing Approval No.18-77 (2018.02.07.)	A 3D-printed device used to immobilize broken bones in the tibia. Each model comes in a single size.	

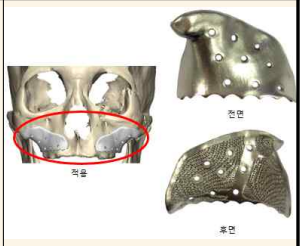
No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
20	CG Bio, Inc	Prothesis, Zygomatic (3)	Manufacturing Approval No.18-236 (2018.04.06.)	A 3D-printed, patient-tailored zygoma prosthesis used to replace or restore the zygoma.	
21	Artificial Organ Research Center Co., Ltd.	Spinal Cage (3)	Manufacturing Approval No.18-323 (2018.05.03.)	A 3D-printed spinal cage used along with the spinal fixation system to provide interbody stability or replace a vertebral body.	
22	Zimmer Biomet Korea Co., Ltd.	Hip Prothesis, Internal, Total (3)	Import Approval No.18-136 (2018.05.10.)	A 3D-printed implant used to replace a hip joint	
23	Institute of Advanced Convergence Technology	Splints (1)	Manufacturing Notification No. 18-695 (2018.06.08.)	A supportive device designed to pressurize and immobilize a part of the body (waist, knee, neck, etc.). It includes a casting tape and dental splint. Splints without supporting functions are excluded.	
24	Institute of Advanced Convergence Technology	Spinal Cage (3)	Manufacturing Approval No.18-590 (2018.08.27.)	A 3D-printed device implanted between bones and bone grafts (lumbar) to provide enough space for intervertebral fusion to treat structural abnormalities resulting from degenerative intervertebral disks	
25	Artificial Organ Research Center Co., Ltd.	Spinal Internal Fixation System, Intervertebral Body (3)	Manufacturing Approval No.18-619 (2018.09.07.)	This is a 3D-printed device used in orthopedic surgeries to fix and support the spine or for its correct alignment. It is used with plates and screws to treat spinal	

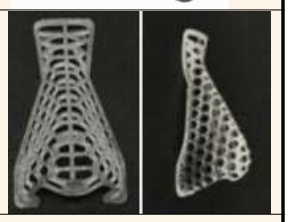
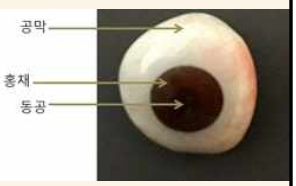
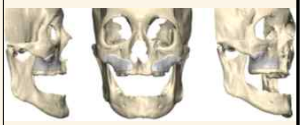
No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
				cord herniation or spinal curvature.	
26	Industry-University Cooperation Center, Korea National University of Transportation	Splints, Mouldable (1)	Manufacturing Notification No. 18-1557 (2018.11.22.)	A device which can be molded to fit in different body types and used to immobilize injured body parts.	
27	Industry-University Cooperation Center, Korea National University of Transportation	Splints, Mouldable (1)	Manufacturing Notification No. 18-1558 (2018.11.22.)	A device which can be molded to fit in different body types and used to immobilize injured body parts.	
28	Industry-University Cooperation Center, Korea National University of Transportation	Splints, Mouldable (1)	Manufacturing Notification No. 18-1584 (2018.11.30.)	A device which can be molded to fit in different body types and used to immobilize injured body parts.	
29	Industry-University Cooperation Center, Korea National University of Transportation	Splints, Mouldable (1)	Manufacturing Notification No. 18-1641 (2018.12.12.)	A device which can be molded to fit in different body types and used to immobilize injured body parts.	
30	Cusmedi, Inc	Orthopedic Materials (3)	Manufacturing Approval No.18-825 (2018.12.26.)	A 3D-printed, patient-tailored implant in which loads are not transferred directly; it is used to replace or support bone defects in the mandibula and in areas not associated with joint movement.	 
31	Stryker Korea, Inc	Hip Prothesis, Internal, Total (3)	Import Approval No.18-374 (2018.12.26.)	A 3D-printed artificial acetabulum used in the arthroplasty of the hip joint, with a surface	

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
				3D-coated with metallic materials.	
32	Cusmedi, Inc	Spinal Cage (3)	Manufacturing Approval No.19-194 (2019.03.29.)	A 3D-printed device implanted between the cervical vertebra to provide enough space for intervertebral fusion and used in the treatment of structural abnormalities resulting from degenerative intervertebral disks.	
33	Cusmedi, Inc	Spinal Cage (3)	Manufacturing Approval No.19-196 (2019.03.29.)	A 3D-printed device implanted between the lumbar vertebra to provide enough space for intervertebral fusion and used in the treatment of structural abnormalities resulting from degenerative intervertebral disks.	
34	Mantiz Logitech, Inc	Spinal Cage (3)	Manufacturing Approval No.19-290 (2019.05.03.)	A 3D-printed spinal cage used to treat structural abnormalities resulting from degenerative intervertebral disks in the lumbar spine.	
35	Artificial Organ Research Center Co., Ltd.	Orthopaedic Fixation Plate, Non-Biodegradable (3)	Manufacturing Approval No.19-495 (2019.07.29.)	A 3D-printed plate used to fix fractured bones (collar bones).	
36	Artificial Organ Research Center Co., Ltd.	Orthopaedic Bone Screw, Non-Biodegradable (3)	Manufacturing Approval No.19-731 (2019.11.15.)	A screw made of safety-verified materials, including surface-treated products, (metallic porous coating, oxide film, etc.) and used to fix fractured bones.	

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
37	Cusmedi, Inc	Guide for Medical Use, Invasive, Single Use (2)	Manufacturing Certification No. 20-4045 (2020-01-21)	This patient-tailored, single-use product is an invasive guide for medical use, constructed with the SLM 3D printer based on CT images of the patient, and used inside the body to guide the route, position of implants or devices, and the indication of surgical parts.	 
38	Cusmedi, Inc	Orthopedic Materials (3)	Manufacturing Approval No. 20-2 (2020.01.02.)	This product is a patient-tailored medical device constructed with the SLM 3D printer based on CT and MRI information of the patient and is used to replace bone defects in the lower limbs (ankles and feet).	
39	Artificial Organ Research Center Co., Ltd.	Orthopaedic Fixation Plate, Non-Biodegradable (3)	Manufacturing Approval No. 20-113 (2020.02.12.)	A 3D-printed, patient-tailored plate used to fix fractured bones (collar bones).	
40	Medisay, Inc	Spinal Cage (3)	Manufacturing Approval No. 20-140 (2020.02.25.)	A patient-tailored, 3D-printed spinal cage that is implanted between lumbar bodies to provide enough space for mechanical safety or intervertebral fusion and used in orthopedic surgeries for the treatment of structural abnormalities resulting from degenerative intervertebral disks.	 
41	Cusmedi, Inc	Cranioplasty Plate (3)	Manufacturing Approval No.20-159 (2020.03.04)	This product is a patient-tailored implant constructed with a metal 3D printer and used to	

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
				fix bone defects in the skull.	
42	Next Core, Inc	Nasal Splint, External (1)	Manufacturing Notification No. 20-346 (2020.03.17.)	A support device that fixes the nose externally	
43	Dentium, Inc Yongin Factory	Spinal Cage (3)	Manufacturing Approval No. 20-219 (2020.03.19.)	A patient-tailored, 3D-printed spinal cage that is implanted between bones or bone grafts to provide enough space for mechanical safety or intervertebral fusion and used in orthopedic surgeries for the treatment of structural abnormalities resulting from degenerative intervertebral disks.	
44	ANIMEDi Solution, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 20-525 (2020.04.16)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (excluding invasive single-use products and dental products)	
45	SeeAnn Solution, Inc	Splints, Mouldable (1)	Manufacturing Notification No. 20-645 (2020.05.13.)	A device which can be molded to fit in different body types and used to immobilize injured body parts.	
46	Lomic Korea, Inc (Branch)	Sizer for Medical or Dental Use (1)	Manufacturing Notification No. 20-1111 (2020.07.22.)	A surgical device that measures the size of anatomical structures to assist with the replacement of prostheses and determination of the size of transplant tissues in	

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
				surgeries. It may also be used in dental surgeries.	
47	GS Medical, Inc	Prothesis, Zygomatic (3)	Manufacturing Approval No. 20-760 (2020.08.28)	A 3D-printed, patient-tailored zygomatic prosthesis used to replace and support defective areas in the zygoma	
48	Next Core, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 20-1379 (2020.09.08.)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (excluding invasive single-use products and dental products)	
49	Next Core, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 20-1380 (2020.09.08.)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (excluding invasive single-use products and dental products)	
50	Next Core, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 20-1381 (2020.09.08.)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (excluding invasive single-use products and dental products)	
51	GS Medical, Inc	Orthopaedic Fixation Plate, Non-Biodegradable (3)	Manufacturing Approval No. 20-790 (2020.09.09)	A 3D-printed orthopaedic fixation plate used to fix broken and fractured clavicles and patellas in orthopaedic surgeries.	
52	T&R Biofab, Inc	Splints, Mouldable (1)	Manufacturing Notification No. 20-1401 (2020.09.11.)	A device which can be molded to fit in different body types and used to immobilize injured body parts.	

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
					
53	ANIMEDi Solution, Inc	Nasal Splint, External (1)	Manufacturing Notification No. 20-1416 (2020.09.15.)	A support device that fixes the nose externally	
54	Medical IP, Inc	Guide for Medical Use (1)	Manufacturing Notification No. 20-1461 (2020.09.24)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc. (excluding invasive single-use products and dental products)	
55	Yonsei University	Artificial Eye (2)	Manufacturing Certification No. 20-4947 (2020.10.21)	An artificial eye replacement with a 3D-printed sclera coated with PMMA	
56	GS Medical, Inc	Implant, Fixation Plate (3)	Manufacturing Approval No.20-910 (2020.10.27)	A patient-tailored plate material constructed with the SLM 3D printer based on the CT and MRI information of the patient to fix and support fractured bones in the oral and maxillofacial areas	
57	Industry-University Cooperation Center, Korea National University of Transportation	Orthopedics Appliance (2)	Manufacturing Certification No. 20-5059 (2020.12.03)	A 3D-printed corrective helmet tailored for infants (3 -18 months old) with plagiocephaly, brachcephaly, etc., which are deformation of the head caused by innate or acquired factors.	

Ⅳ-3. (C) Dental Materials

○ Approvals, Certifications, and Notifications of 3D-Printed Medical Devices

"(C) Dental Materials" has been another area with active development of medical devices using 3D printers. In 2020, 3 3D-printed medical devices were approved and certified.

[Table 67] Approval, Certification, and Notification of 3D-Printed Medical Devices by Year (Dental Materials)[9)]

(Unit: Number of products)

Category		2016	2017	2018	2019	2020
Total		2	1	5	11	3
Dental Materials	Manufactured	2	1	4	10	3
	Imported	-	-	1	1	-

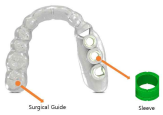
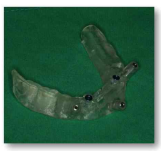
The following table shows 3D-printed "(C) Dental Materials" that were approved, certified, or notified over the last 5 years.

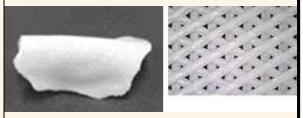
[Table 68] Approved 3D-Printed Products in Dental Materials Section[10)]

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
1	T&R Biofab, Inc	Barrier, Intra Oral, Resorbable (4)	Manufacturing Approval No.16-802 (2016.11.3.)	An absorptive material that serves as a barrier between the gingiva and alveolar bone to induce the regeneration of periodontal tissues; no secondary surgery required.	

9) Export products excluded
10) Export products excluded

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
2	Dio Implant Co., Ltd.	Bracket, Orthodontic (2)	Manufacturing Certification No. 16-4909 (2016.12.6)	A 3D-printed, patient-tailored bracket made of polymer materials and is adhered to the teeth for orthodontic treatment.	
3	T&R Biofab, Inc	Barrier, Intra Oral, Resorbable (4)	Manufacturing Approval No.17-117 (2017.2.16.)	A 3D-printed absorptive material that serves as a barrier between the gingiva and alveolar bone to induce the regeneration of periodontal tissues; no secondary surgery required.	
4	Dio Implant Co., Ltd.	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 18-237 (2018.4.9)	A dental polymer material for a 3D-printed device used to guide the route of an implant or device, positions, the indications of surgical parts, etc.	
5	The Apex Global, Inc	Implant, Surgical, Guide for Medical Use (2)	Import Certification No. 18-311 (2018.10.30)	A prosthetic material for a 3D-printed device used to guide the route of an implant or device, positions, the indications of surgical parts, etc.	 -액상-
6	Vistech Korea, Inc	Resin, Impression Tray (1)	Manufacturing Notification No. 18-632 (2018.5.21)	A material made of resin, such as methyl methacrylate, used to make an impression tray	
7	Vistech Korea, Inc	Resin, Impression Tray (1)	Manufacturing Notification No. 18-685 (2018.6.5)	A material made of resin, such as methyl methacrylate, used to make an impression tray	
8	Dentis, Inc	Resin, Impression Tray (1)	Manufacturing Notification No. 18-1154 (2018.9.4)	A material made of resin, such as methyl methacrylate, used to make an impression tray	
9	Dentsply Sirona Korea Co.,	Implant, Surgical, Guide for	Import Certification No. 19-4104	A device used to guide the route, position of an implant or a device, and	

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
	Ltd	Medical Use (2)	(2019.2.18)	the indications of surgical sites, etc. (jaw)	
10	Dentis, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 19-4309 (2019.4.19)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
11	Neobiotech Digital Business Division, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 19-4463 (2019.6.11)	A device used to guide the route, position of an implant or a device, and the indications of surgical sites, etc.	
12	Osstem Implant, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 19-4481 (2019.6.18)	A polymer material for a 3D-printed device used to guide the route of an implant or device, positions, the indications of surgical parts, etc.	
13	Cellumed, Inc	Barrier, Intra Oral, Resorbable (4)	Manufacturing Approval No.19-374 (2019.6.18)	An absorptive material that serves as a barrier between the gingiva and alveolar bone to induce the regeneration of periodontal tissues.	
14	Cybermed, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 19-4567 (2019.7.8)	A device used to guide positions.	
15	Ray, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 19-448 (2019.7.10)	A prosthetic material for a 3D-printed device used to guide the route of an implant or device, positions, the indications of surgical parts, etc.	
16	ODS, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Approval No.19-513 (2019.7.31)	A prosthetic material for a 3D-printed device used to guide the route of an implant or device, positions, the indications of surgical parts, etc.	

No.	Company	Item(Class)	Approval No. (Date)	Intended Use	Appearance
17	Vericom, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 19-4791 (2019.9.20)	A material that constitutes a device which is used to plan the site of a dental implant and guide its direction, depth, and location based on the results using a DLP 3D printer in dental implant procedures.	
18	Eion, Inc	Crown & Bridge Material for Dental Use (2)	Manufacturing Approval No.19-609 (2019.9.25)	A paste type material made of zirconia and binder and used to make restorations such as inlays, crowns, bridges, etc. (molded in the 3D printing method)	
19	Dentis, Inc	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 19-4996 (2019.12.12)	A prosthetic material for manufacturing a device used to guide the route of an implant or device, positions, the indications of surgical parts, etc. by 3D-printing a feature and hardening it using an ultraviolet dental polymerization activator.	
20	Dio Implant Co., Ltd.	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 20-4795 (2020-08-28)	A 3D-printed device used to guide the route of an implant or device, positions, the indications of surgical parts, etc.	
21	Dio Implant Co., Ltd.	Implant, Surgical, Guide for Medical Use (2)	Manufacturing Certification No. 20-4822 (2020-09-07)	A 3D-printed device used to guide the route of an implant or device, positions, the indications of surgical parts, etc.	
22	T&R Biofab, Inc	Barrier, Intra Oral, Resorbable (4)	Manufacturing Approval No.20-961 (2020.11.12)	A 3D-printed, patient-tailored absorptive material that serves as a barrier between the gingiva and alveolar bone to induce the regeneration of periodontal tissues	

V

Approval of COVID-19 Diagnostic Reagents

Ⅴ. Approval of COVID-19 Diagnostic Reagents

Ⅴ-1. Formal Approval of COVID-19 Diagnostic Reagents

When social and economic disasters occurred in Korea as a result of the national outbreak of COVID-19 in February 2020, a rapid supply of COVID-19 diagnostic reagents was demanded. To meet the demand, the Ministry of Food and Drug Safety established a prompt approval plan and a support system to formally approve manufacturers of COVID-19 diagnostic reagents. In addition, the MFDS implemented tailored consulting solutions, a matching system that allows for a convenient sample acquisition by matching manufacturers with medical care centers with confirmed samples, and an accelerated examination for COVID-19 products to support the prompt approval plan.

COVID-19 diagnostic reagents can be classified largely into 3 types: PCR (genetic) test, antigen test, and antibody test. PCR test is a test method that checks the presence of the coronavirus gene and amplifies the gene so that it can be diagnosed early even if there is a small amount of the virus. It is used for confirmation due to its high accuracy. Antigen test is a test method that checks the presence of the coronavirus-specific proteins, and although less accurate compared with the PCR test, it has a shorter testing time. Antibody test is a test method to confirm the formation of antibodies for the coronavirus; it is difficult to check the presence of the virus directly in samples.

In 2020, a total of 13 (9 PCR, 2 antigen, and 2antibody tests) diagnostic reagents were formally approved. The formal approvals of COVID-19 diagnostic reagents are listed in the following table.

[Table 69] Formal Approval of COVID-19 Diagnostic Reagents

No.	Company	Product Name	Date of Approval	Approval No.	Note
1	SD Biosensor, Inc	STANDARD™ M nCoV Real-Time Detection kit	2020.8.31.	In Vitro Manufacturing Approval No. 20-767	PCR
2	BioSewoom, Inc	Real-Q 2019-nCoV Detection Kit	2020.10.6.	In Vitro Manufacturing Approval No. 20-860	PCR
3	SEASUN BIOMATERIALS, Inc	U-TOP™ COVID-19 Detection Kit Plus	2020.10.8.	In Vitro Manufacturing Approval No. 20-871	PCR
4	CancerRop, Inc	Q-Sens® COVID-19 Detection kit	2020.10.8.	In Vitro Manufacturing Approval No. 20-872	PCR
5	KoGene Biotech, Inc	PowerChek™ SARS-CoV-2, Influenza A&B Multiplex Real-time PCR Kit	2020.11.3.	In Vitro Manufacturing Approval No. 20-923	PCR
6	SD Biosensor, Inc	STANDARD™ Q COVID-19 IgM/IgG Plus Test	2020.11.6.	In Vitro Manufacturing Approval No. 20-941	Antibody
7	SD Biosensor, Inc	STANDARD™ Q COVID-19 Ag Test	2020.11.11.	In Vitro Manufacturing Approval No. 20-955	Antigen
8	SEASUN BIOMATERIALS, Inc	AQ-TOP™ COVID-19 Rapid Detection Kit Plus	2020.11.23.	In Vitro Manufacturing Approval No. 20-990	PCR
9	KoGene Biotech, Inc	PowerChek™ SARS-CoV-2 Real-time PCR Kit	2020.11.26.	In Vitro Manufacturing Approval No. 20-1000	PCR
10	Seegene, Inc	Allplex SARS-CoV-2 Assay	2020.12.7.	In Vitro Manufacturing Approval No. 20-1049	PCR
11	CancerRop, Inc	Q-Sens® COVID-19 Detection Kit V2	2020.12.14.	In Vitro Manufacturing Approval No. 20-1088	PCR

12	Sugentech, Inc	SGTi-flex COVID-19 IgM/IgG	2020.12.18.	In Vitro Manufacturing Approval No. 20-1112	Antibody
13	GenBody, Inc	GenBody COVID-19 Ag	2020.12.24.	In Vitro Manufacturing Approval No. 20-1150	Antigen

Ⅴ-2. Approval of COVID-19 Diagnostic Reagents for Export

Unlike the formal approval, the approval of COVID-19 diagnostic reagents for export is exclusively for products that are not to be sold and used domestically.

While the first formally approved item was approved in August 2020, a total of 236 products (107 PCR, 58 antigen, and 71 antibody tests) were approved for export in 2020 starting from February 2020 when COVID-19 broke out.

In particular, PCR test products accounted for 75.5% of the total approvals as of April, taking up the majority since the occurrence of the virus. On the other hand, antigen test products had a steady increase from March to December, while antibody test products have been developed and approved consistently since March.

The following table lists the approval of COVID-19 diagnostic reagents for export in 2020.

[Table 70] Approval of COVID-19 Diagnostic Reagents for Export

(Unit: Number of products)

	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	Total
Total	**2**	**20**	**27**	**26**	**26**	**23**	**25**	**21**	**18**	**24**	**24**	**236**
PCR	2	13	22	11	13	11	8	10	6	6	5	107
Antigen	-	1	1	2	2	2	4	4	9	16	17	58
Antibody	-	6	4	13	11	10	13	7	3	2	2	71

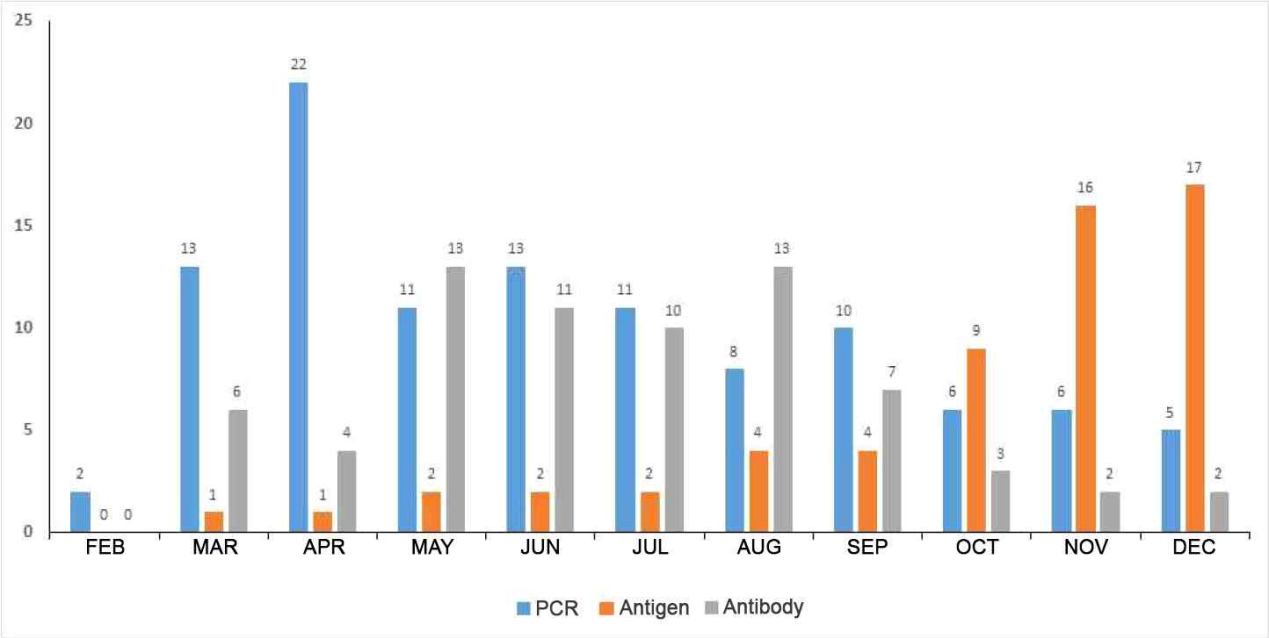
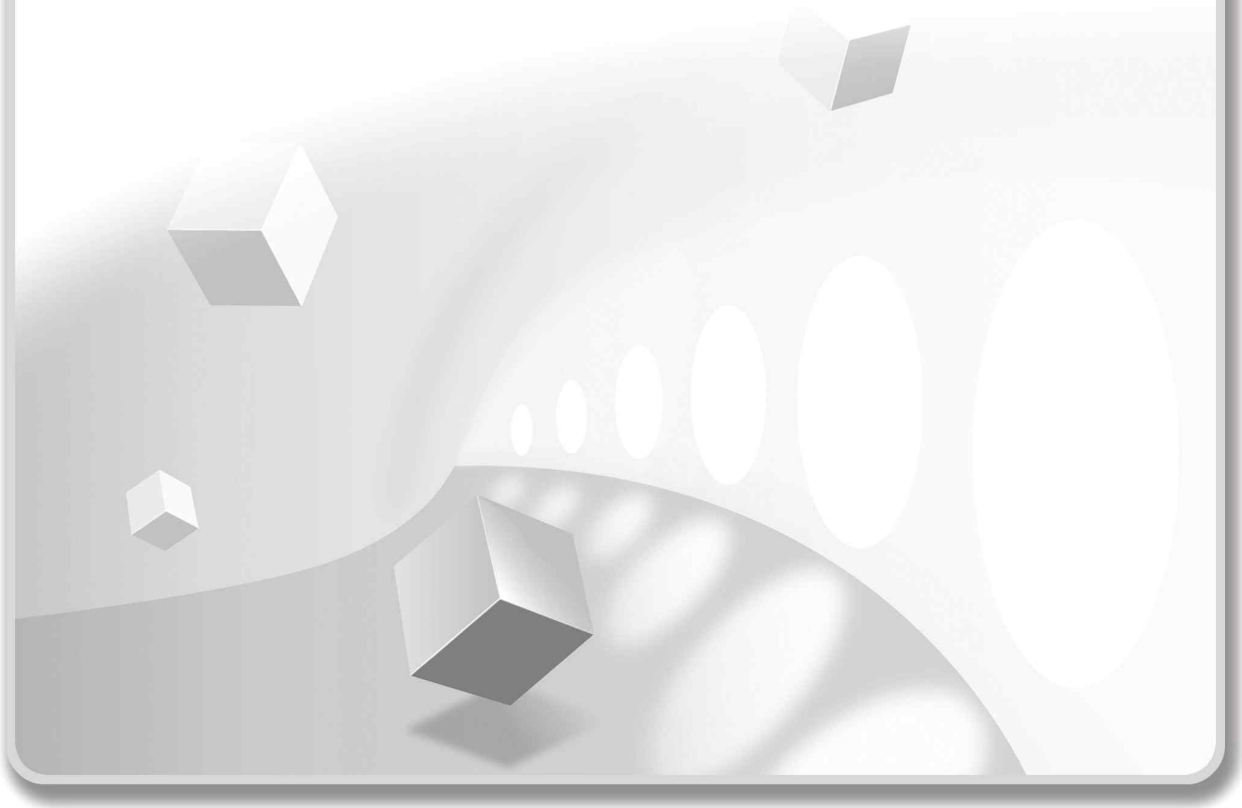


Figure 51. Approval of COVID-19 Diagnostic Reagents for Export

Medical Device Evaluation Process



[Attachment] Medical Device Evaluation Process

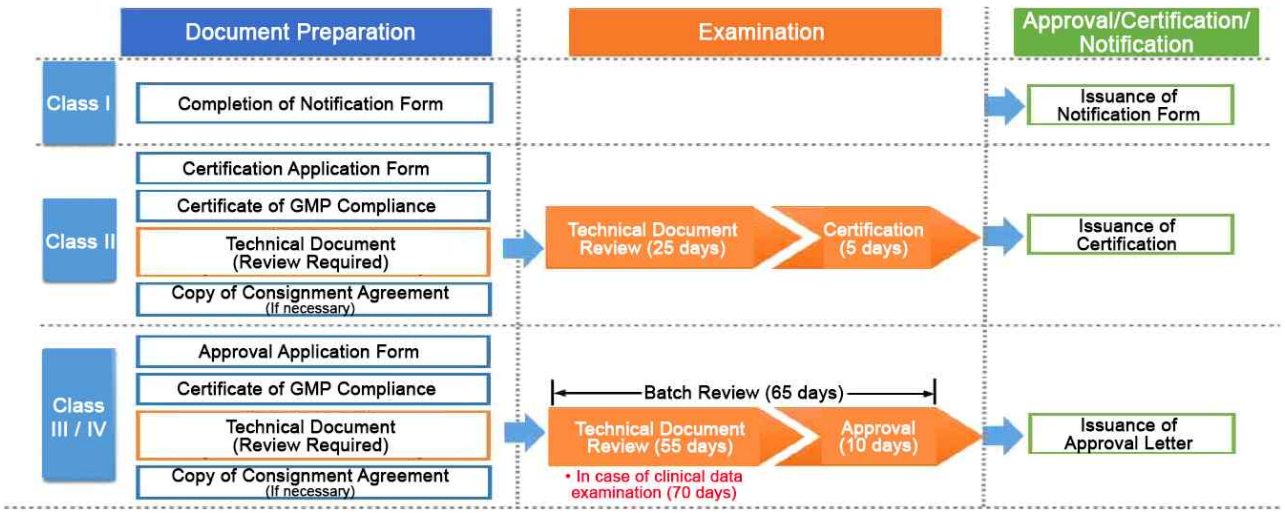
1.1. Medical Device Approval/Certification/Notification Process

The approval/certification/notification process for manufactured and imported medical devices varies depending on the hazard level of the device. Class I and Class II medical devices with a low hazard level are certified by the National Institute of Medical Device Safety Information (NIDS), while the MFDS evaluates Class III and Class IV products with high hazard levels for approval. The following section outlines the process and time required for the evaluation of each class of products.

○ **Class I (Notification)** : A certificate of notification is issued immediately after a notification form (NIDS) has been submitted.

○ **Class II (Certification)** : A certificate is issued (NIDS) after a technical document review by a private entity (technical document reviewer)

○ **Class III and IV (Approval)** : A certificate of approval is issued (MFDS) after a technical document review by the Medical Device Evaluation Department.



1) Technical Document Reviewers (7): Korea Testing Laboratory (KTL), Korea Testing & Research Institute (KTR), Korea Testing Certification (KTC), SGS Korea, Korea Conformity Laboratories (KCL), Daegu-Gyeongbuk Medical Innovation, and Yonsei University Health System Dental Medical Device Testing and Evaluation Center

1.2. Certification Process for Recognized Substantial Equivalent Products

The substantial equivalent product recognition is a simplified certification process for manufactured/imported products with the same intended uses, operating principles, raw materials (only applicable to medical supplies and dental materials), performance, test specifications, and instructions for use as Class II medical products that pose minimal potential risks to human bodies and have been approved/certified for at least 3 times.

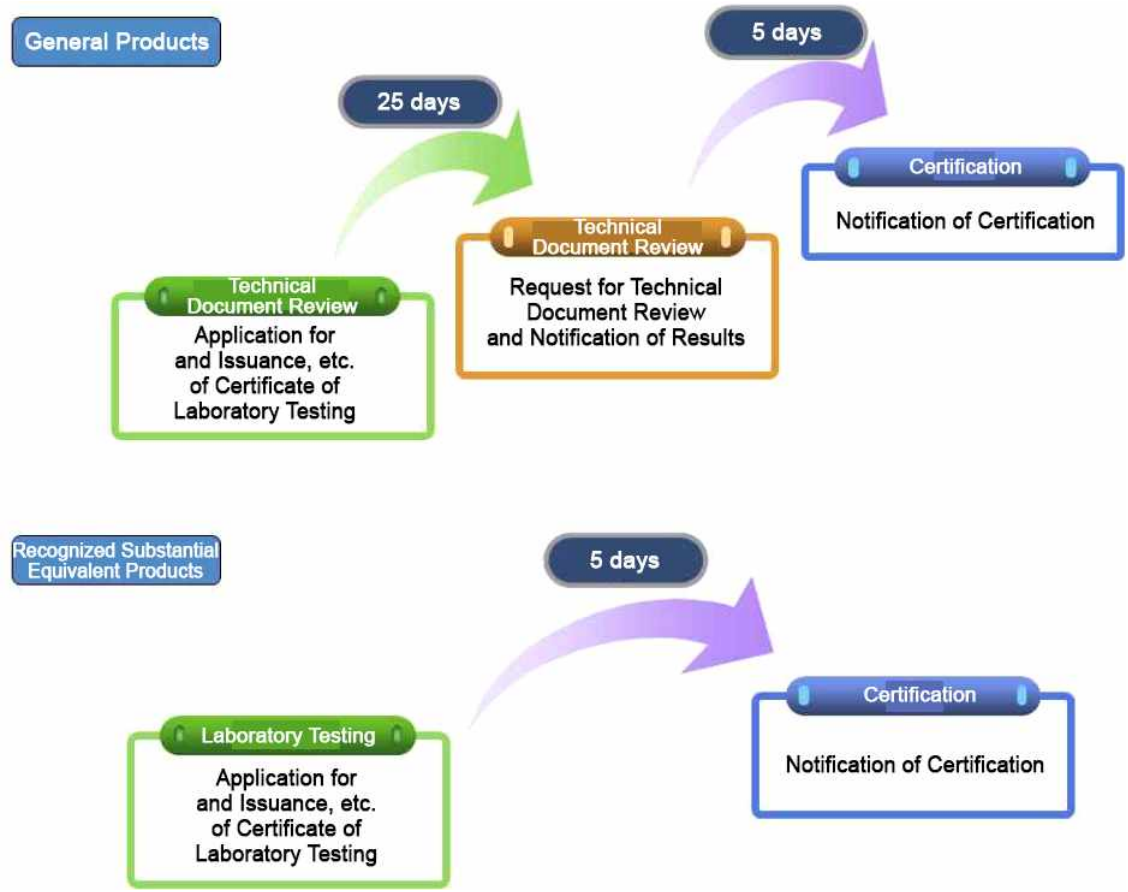
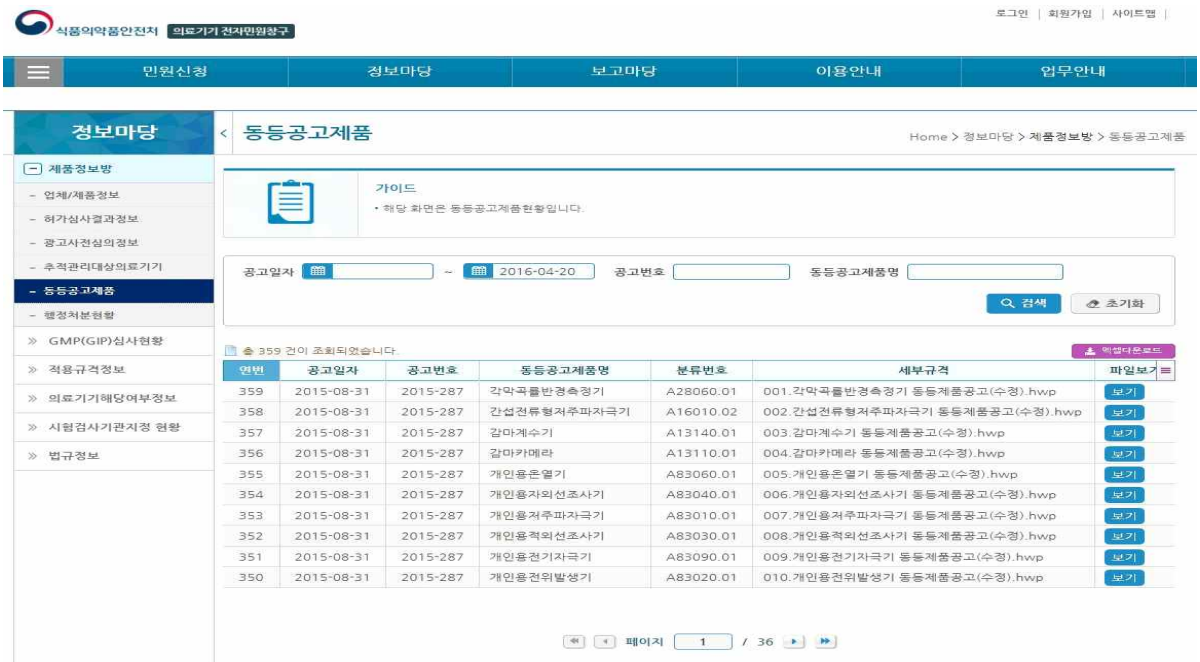


Figure 52. Comparison of Certification Procedures for Substantial Equivalent Products and Other Products

In obtaining certification for a recognized substantial equivalent product, the manufacturer/importer should verify whether the product for manufacture or import is equivalent to a product in the “Substantial Equivalent Medical Device Product Announcement” from the Minister of Food and Drug Safety. Currently, 370 products have been announced as recognized substantial equivalent products. The announcement can be accessed at “MFDS website > 전자민원창구 (Electronic Civil Service) > 정보마당 (Information Forum) > 제품정보방 (Product Information) > 동등공고제품 (Recognized Substantial Equivalent Products).”



If the product is equivalent to a recognized substantial equivalent product announced by the Minister of Food and Drug Safety, the manufacturer/importer may apply for a manufacture (import) certification in the following steps. The manufacturer/importer prepares technical documents (evaluation request) in lieu of the documents under Article 5 (1) 2 of the Enforcement Rule of the Medical Devices Act (Technical Documents or Technical Document Review Result Notice), as per the substantial equivalent product announcement. Afterward, the manufacturer/importer acquires a test report from a medical device testing lab in accordance with the same test

specifications as the recognized substantial equivalent product. Then, the manufacturer/importer sends an application to the certification office at the National Institute of Medical Device Safety Information (NIDS) along with the test report and the technical documents (evaluation request). An application is processed within five days because of the omission of the technical document review (review request).

The test report submitted along with the application should be a test report issued by a medical device testing lab designated by the Minister of Food and Drug Safety, in accordance with Article 6 (2) 4 of the Act on Testing and Inspection in the Food and Drug Industry.

However, “Soft Contact Lens, Daily-Wear” and “Hard Contact Lens, Daily-Wear” require an approval from the MFDS instead of the manufacture (import) certification from NIDS because these devices are used on a continuous basis and may have biological effects on the human body.

2020 Medical Device Approval Report

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Introduction of Public Interest Reporter Protection System

The Public Interest Reporter Protection Act always protects your conscience.
If a public official or representative of the Ministry of Food and Drug Safety has committed an irregularity or handled any issue unfairly, please report it as follows. We guarantee the identity of the reporter and promise to do our best to ensure that there is no inconvenience in handling civil complaints in the future.

What is Public Interest Reporter Protection System?
A system for protecting public interest reporters, etc. (including relatives or partner) through **confidentiality, disadvantage protection measures, personal protection measures,** etc. so that they are not harmed by public interest reports, etc.

※ How to request protection measures
Ministry of Food and Drug Safety website (www.mfds.go.kr) > National Communication > National Newspaper > Public Official Corruption Report