New Medical Devices Approved in FY 2020

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Aug. 21, 2020 Total review time: 259 days Regulatory review time: 194 days	- Japanese clinical study results	1	CureApp SC Digital Therapeutic and CO Checker for Nicotine Dependence (CureApp, Inc.)	Approval	Instrument & apparatus 21 Smoking cessation treatment support system	This application was submitted for marketing approval of a smoking cessation treatment support system, consisting of a digital therapeutic and an exhaled CO meter to support the smoking cessation treatment for patients with nicotine dependence, to be used as an adjunct to the standard smoking cessation treatment program.
Robotic, ICT, and other devices (not classified as other categories)	Nov. 30, 2020 Total review time: 133 days Regulatory review time: 115 days	Aug. 28, 2020 No clinical study results	2	SpaceOAR System (Boston Scientific Corporation)	Change	Medical products 4 Absorbable tissue spacer for radiotherapy	A synthetic absorbable material intended to be injected and provide space between the prostate and anterior rectal wall, in order to reduce radiation exposure to the rectum during radiation therapy for prostate cancer. The application was submitted to add other types of powder vial and injection needle. (A “partial change” application submitted during the post-market performance review period)
Robotic, ICT, and other devices (not classified as other categories)	Mar. 22, 2021 Total review time: 356 days Regulatory review time: 208 days	Aug. 26, 2020 (P190032) Oct. 26, 2020 (P200006) No clinical study results	3	FoundationOne Liquid CDx Cancer Genomic Profile (Chugai Pharmaceutical Co., Ltd.)	Approval	Program 1 Software for gene variants analysis (for comprehensive genomic profiling for cancer)	This application was submitted for marketing approval of an analysis program to acquire comprehensive genomic profiling pertaining to 324 cancer-related genes in circulating tumor DNA in the whole blood obtained from patients with solid tumors which contributes to formulating a therapeutic policy and determining the eligibility of drugs. This product also falls under the category of a term name, “Software for analysis of somatic variants (for eligibility identification of antineoplastic agents).”
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 27, 2020 Total review time: 297 days Regulatory review time: 138 days	Mar. 22, 2019 No clinical study results	4	Gore Viabahn Stent Graft (W. L. Gore & Associates, G. K.)	Change	Instrument & apparatus 7 Heparin-coated stent-graft for central circulatory system	A stent graft system consisting of a stent graft with nitinol stent wires wound around the outside of the graft (external stent structure type) and a delivery catheter. The application was submitted to add the small diameter type that comprises the delivery catheters used for small diameter and stent grafts with diameter size of 9 to 13 mm combined (A "partial change" application). Although the number of folding back of a stent wire, etc. was changed for a loaded stent graft as a result of the additional combination of stent grafts and delivery catheters, the basic design of the stent graft has not changed. As tests to secure the performance and safety of the additional combination of stent grafts and delivery catheters, the test certificates of radial force testing, animal experiment, etc. were submitted. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 21, 2020 Total review time: 84 days Regulatory review time: 31 days	- No clinical study results	5	Woven EndoBridge Device (Terumo Corporation)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A prosthetic material for embolization in vessels of the central circulation system intended to be used to occlude wide-necked (defined the size as neck width ≥4 mm or dome-to-neck ratio <2) intracranial aneurysms located in the branch of anterior or posterior circulation. The application was submitted to change the manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 23, 2020 Total review time: 334 days Regulatory review time: 233 days	- Global clinical study results	6	IN.PACT AV Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in de novo or restenotic lesions in the native arteriovenous dialysis fistulae. The balloon surface of this product is coated with paclitaxel as a drug. The results of a global clinical study including Japan were submitted to evaluate the efficacy and safety of the product.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 8, 2021 Total review time: 497 days Regulatory review time: 48 days	Oct. 30, 2020 Global clinical trial	7	Ranger Drug-Coated Balloon Catheter (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	This application was submitted for marketing approval of a paclitaxel-coated balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in de novo or non-stented restenotic lesions in the superficial femoral or proximal popliteal arteries.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 8, 2021 Total review time: 221 days Regulatory review time: 68 days	Sep. 7, 2016 Foreign clinical study results	8	IN.PACT Admiral Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	A paclitaxel-coated balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the superficial femoral and popliteal arteries. The application was submitted for an additional indication of in-stent restenotic lesions. (A “partial change” application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 29, 2021 Total review time: 167 days Regulatory review time: 109 days	Sep. 11, 2016 No clinical study results	9	NeuroStar TMS Therapy System (Neuronetics, Inc.)	Change	Instrument & apparatus 12 Repetitive transcranial magnetic stimulator	A repetitive transcranial magnetic stimulator that provides treatment for adult patients with Major Depressive Disorder (MDD) (only for the patients who have not benefitted from conventional antidepressant medication). The application was submitted to add a model with a mechanism for cooling treatment coils. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 25, 2020 Total review time: 224 days Regulatory review time: 120 days	Apr. 8, 1987 Japanese clinical study results	10	Cellex ECP System (Mallinckrodt Pharmaceuticals Ireland Limited)	Approval	Instrument & apparatus 7 Extracorporeal photopheresis system	The product is a system used for extracorporeal photopheresis therapy for steroid-resistant or intolerant chronic graft versus host disease. The system consists of a main unit, kit, methoxsalen solution, and a UVA lamp. The results of a Japanese clinical study were submitted to evaluate the efficacy and safety of the product.
Gastroenterology, Genitourinary and Reproductive Medicine	Jan. 27, 2021 Total review time: 126 days Regulatory review time: 82 days	- No clinical study results	11	UroLift System (NeoTract, Inc.)	Change	Medical products 4 Implantable prostate tissue lifting system	An implantable prostate tissue lifting system indicated for the treatment of dysuria associated with prostatic hyperplasia. The system is composed of a delivery device and an implant. The application was submitted for design changes of the delivery device to reflect requests from clinical practice. (A "partial change" application submitted during the post-market performance review period)
Ophthalmology and Otorhinolaryngology	May 29, 2020 Total review time: 346 days Regulatory review time: 214 days	- Japanese clinical study results	12	Eustachian Tube Plug (Fuji Systems Corporation)	Approval	Medical products 4 Prosthetic material for eustachian tube	The application was submitted for marketing approval of a prosthetic material for the eustachian tube used to narrow the lumen by placing it into an excessively open eustachian tube to improve the symptoms of patients with refractory patulous eustachian tube who do not respond to conservative treatment. The results of Japanese clinical studies were submitted as clinical evaluation data.
Cardiopulmonary Circulation	Apr. 16, 2020 Total review time: 142 days Regulatory review time: 82 days	May 10, 2016 Foreign clinical study results	13	MitraClip NT System (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	Percutaneous repair system for mitral valve coaptation failure is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The application was submitted for the additional indication for patients who are difficult to undergo open heart surgery among the patients with symptomatic, severe MR (grade 3+ or 4+) whose left ventricular ejection fraction is 20% or higher but lower than 30% (A "partial change" application). As clinical evaluation data, the results of foreign clinical studies in patients with symptomatic, severe secondary MR (grade 3+ or 4+) were submitted. (A “partial change” application submitted during the post-market performance review period)

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Cardiopulmonary Circulation	Apr. 27, 2020	May 1, 2017	14	Micra Transcatheter Pacing System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	An implantable electrode-integrated cardiac pacemaker intended to be percutaneously placed in the right ventricle using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add another model of a delivery catheter system, and to modify the descriptions on the details of approved items. (A “partial change” application submitted during the post-market performance review period)
	Total review time: 136 days Regulatory review time: 67 days	No clinical study results				Implantable leadless cardiac pacemaker	
Cardiopulmonary Circulation	Jun. 5, 2020	-	15	WATCHMAN Left Atrial Appendage Closure Device (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 51	An endocardial prosthetic material intended to reduce a risk of thromboembolism attributed to the left atrial appendage in patients with non-valvular atrial fibrillation who are at high risk of thromboembolism. The application was submitted to add a high density polyethylene with new raw material specifications as a raw material of a washer used in the hemostasis valve of an access system in order to enhance the production efficiency, falling under a “specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No.1110001 dated on November 10, 2008). (A "partial change" application submitted during the post-market performance review period)
	Total review time: 98 days Regulatory review time: 53 days	No clinical study results				Endocardial prosthetic material	
Cardiopulmonary Circulation	Jun. 19, 2020	Jul. 9, 2019	16	MitraClip NT System (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7	Percutaneous repair system for mitral valve coaptation failure is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The application was submitted to add variations of clip delivery system and steerable guide catheter. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 245 days Regulatory review time: 128 days	No clinical study results				Percutaneous repair system for mitral valve coaptation failure	
Cardiopulmonary Circulation	Aug. 28, 2020	Sep. 19, 2019	17	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation in the native aortic valve or the surgically placed aortic bioprosthetic valve for patients with severe symptomatic native aortic stenosis caused by the calcification of native aortic valve leaflets or patients with symptomatic valvular disease due to dysfunction (stenosis, insufficiency, or combined) of a surgically placed aortic bioprosthetic valve, and who are unable to undergo surgery. The product consists of a porcine pericardial-derived bioprosthetic valve, and a delivery set, which is composed of delivery catheter and loading system. The 23-mm, 26-mm, and 29-mm bioprosthetic valves are identical to those are approved as the components of "CoreValve Evolut PRO" (Approval No.: 23000BZX00196000). As for 34-mm bioprosthetic valve, it has an outer skirt attached to the inflow part of the 34-mm bioprosthetic valve which is approved as the components of "CoreValve Evolut R" (Approval No.: 22800BZX00414000). The profile of delivery catheter is smaller compared with that of CoreValve Evolut PRO. The results of some clinical studies on the previously approved products conducted in the US were submitted to evaluate the efficacy and safety of Evolut PRO+ System.
	Total review time: 246 days Regulatory review time: 179 days	Foreign clinical study results				Transcatheter porcine pericardial valve	

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Sep. 11, 2020 Total review time: 260 days Regulatory review time: 170 days	Aug. 31, 2020 Foreign clinical study results	18	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine pericardial valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system consists of a bovine pericardial-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This product has been approved as a medical device used for transcatheter aortic valve implantation (Approval No.: 22800BZX00094000). This application was submitted to add indications for the treatment of malfunctions of surgically implanted right ventricular outflow tract (RVOT) extracardiac conduit or the bioprosthetic valve in the pulmonic position in patients with a congenital heart diseases who are at high surgical risk, in accordance with the conditional early approval system for innovative medical devices based on “Conditional Early Approval System for Innovative Medical Device Products (Fast-Break Scheme)” (PSEHB Notification No. 0731-1, Director-General of the PSEHB, MHLW, dated on July 31, 2017). (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the product in the pulmonic position. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Nov. 19, 2020 Total review time: 238 days Regulatory review time: 34 days	- No clinical study results	19	Jarvik 2000 Implantable Ventricular Assist Device (Century Medical, Inc.)	Change	Instrument & apparatus 7 Implantable ventricular assist device	The device is an implantable ventricular assist device system used to improve the blood circulation until heart transplant. The device is used for severe cardiac failure patients who are qualified to receive heart transplant, shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system and considered difficult to survive without heart transplant. The application was submitted for changes including addition of a mobile battery that has been improved in response to the discontinued production of the cell incorporated in the current mobile battery and the suspension of product shipment due to malfunctions of the mobile battery. (A ”partial change” application submitted during the reexamination period)
Cardiopulmonary Circulation	Dec. 2, 2020 Total review time: 246 days Regulatory review time: 118 days	Jul. 21, 2020 Foreign clinical study results	20	WATCHMAN FLX Left Atrial Appendage Closure Device (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Endocardial prosthetic material	The device is an endocardial prosthetic material intended to reduce a risk of thromboembolism attributed to the left atrial appendage in patients with non-valvular atrial fibrillation who are at high risk of thromboembolism. This device consists of a delivery system loaded with a closure device and an access system. The device was developed based on the company’s approved product “WATCHMAN Left Atrial Appendage Closure System” (Approval No. 23100BZX00049000). The improvement was made by changing the design for application to a wider range of left atrial appendage size, for easier position adjustment, and for further reduction of the risks of damaging left atrial appendage and of thrombosis. The intended use was also changed so that not only warfarin but also other general anticoagulants can be used in the postoperative period. As clinical evaluation data, the results of US clinical studies were submitted to evaluate the efficacy and safety of this product in patients with non-valvular atrial fibrillation who are at high risk of thromboembolism.

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Cardiopulmonary Circulation	Dec. 28, 2020	Oct. 18, 2018	21	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7	The device is an implantable ventricular assist device system (LVAD) used to assist the blood circulation for severe cardiac failure in patients who are shown continuous decompensation in spite of drug therapy or circulation assist techniques, such as an external ventricular assist system. The device has been approved for treatment with LVAD of severe cardiac failure in patients who are qualified to receive heart transplant as a bridge therapy until heart transplantation (Approval No. 23100BZI00006000). This application was submitted to add an indication of destination therapy, in which LVAD is used to improve the life prognosis and to provide home care for better quality of life for patients with serious heart failure for whom heart transplantation is not indicated (A “partial change” application). As clinical evaluation data, the results of the foreign clinical studies and the Japanese clinical studies for the previous generation product “HeartMate II Left Ventricular Assist System” (Approval No. 22400BZI00017000) were submitted to evaluate the efficacy and safety of the product in destination therapy.
	Total review time: 357 days Regulatory review time: 145 days (Review report, etc.)	Japanese and foreign clinical study results				Implantable ventricular assist device	
Cardiopulmonary Circulation	Jan. 8, 2021	Jun. 17, 2015 (transfemoral approach) Dec. 2, 2016 (transapical/transaortic approach)	22	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7	A transcatheter bioprosthetic valve replacement system primarily consists of a transcatheter bioprosthetic aortic valve derived from bovine pericardium and a delivery catheter system to deliver the bioprosthetic aortic valve to the position of the aortic or pulmonary valve. The product has already been approved for the indications of (1) symptomatic severe stenosis of the native aortic valve or symptomatic valvular disease attributed to dysfunction of a surgical bioprosthetic aortic valve, or (2) treatment for patients with dysfunction of an implanted extracardiac conduit in the right ventricular outflow tract or a bioprosthetic valve at the position of the pulmonary valve, for whom surgery cannot be performed, and who are not receiving chronic dialysis (Approval No. 22800BZX00094000). The application was submitted to expand the indication for patients on chronic dialysis with findings of (1) (A “partial change” application). The results of a Japanese prospective, single-arm study in 28 patients on chronic dialysis, and a prospective, single-arm trial conducted for humanitarian reasons (extension trial) in 13 patients on chronic dialysis, were submitted as the clinical study data on the indication expansion. (A “partial change” application submitted during the post-market performance review period)
	Total review time: 315 days Regulatory review time: 176 days	Japanese clinical study results				Transcatheter bovine pericardial valve	

Improved Medical Devices (With Clinical Data) Approved in FY2020

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Robotic, ICT, and other devices (not classified as other categories)	Jun. 26, 2020 Total review time: 268 days Regulatory review time: 232 days	- Japanese clinical study results	1	Automated Hematology Analyzer XN-31 (SYSMEX CORPORATION)	Approval	Instrument & apparatus 17 Malaria diagnostic device	Automated Hematology Analyzer XN-31 is a medical device that assists the diagnosis of malaria by counting DNA-containing erythrocytes including malaria parasites in the whole blood leveraging flow cytometry. To demonstrate the evaluation of malaria diagnosis made by Automated Hematology Analyzer XN-31, the study result, which agrees with that obtained by performing microscopy using peripheral blood smears was submitted as the clinical study.
Robotic, ICT, and other devices (not classified as other categories)	Jun. 29, 2020 Total review time: 27 days Regulatory review time: 22 days	- Clinical evaluation report	2	COVID-19 Pneumonia Image Analysis Program Ali-M3 (MIC Medical Corp.)	Approval	Program 1 Software for diagnostic X-ray imaging system workstation	The application was submitted for marketing approval of a computer detection support software which processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT image when performing the image diagnosis of pneumonia.
Robotic, ICT, and other devices (not classified as other categories)	Aug. 11, 2020 Total review time: 22 days Regulatory review time: 18 days	- Japanese clinical study results	3	COVID-19 Pneumonia Image Analysis AI Program InferRead CT Pneumonia (CES Descartes Co., Ltd.)	Change	Program 1 Software for diagnostic X-ray imaging system workstation	A computer-aided detection support software that processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT images when performing the image diagnosis of pneumonia. This application was submitted to change the product name, the intended use or the efficacy, and the performance and safety specifications in order to reflect the results of a newly conducted clinical study on the approved product information (A "partial change" application).
Robotic, ICT, and other devices (not classified as other categories)	Nov. 13, 2020 Total review time: 259 days Regulatory review time: 167 days	Mar. 8, 2018 Foreign clinical study results	4	Medtronic Guardian Connect (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 20 Glucose monitoring system	The device is a glucose monitoring system that continuously measures glucose levels in the interstitial fluid under the skin in persons with diabetes. The application was submitted to add a new glucose sensor (A "partial change" application).
Robotic, ICT, and other devices (not classified as other categories)	Nov. 30, 2020 Total review time: 264 days Regulatory review time: 210 days	May 20, 2019 Clinical evaluation report	5	Leica Virtual Slide System AT2 DX (Leica Microsystems K.K.)	Approval	Instrument & apparatus 21 Diagnostic assistant device for pathological whole slide image	The application was submitted for marketing approval of a diagnostic assistant device for pathological whole slide image, which automatically captures, displays, and stores pathological whole slide images, and is intended to assist pathologists to evaluate and diagnose histopathological images.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 23, 2020 Total review time: 268 days Regulatory review time: 216 days	Aug. 29, 2019 Clinical evaluation report	6	HemoSphere Advanced Monitoring Platform (Edwards Lifesciences Ltd.)	Approval	Instrument & apparatus 21 Multiparameter monitor with critical parameters	The application was submitted for marketing approval of a multiparameter monitor with critical parameters intended to measure thermodilution cardiac output, arterial pressure-based cardiac output, blood pressure, venous oxygen saturation, and tissue oxygen saturation, and use to collect and monitor various physiological information.
Robotic, ICT, and other devices (not classified as other categories)	Dec. 23, 2020 Total review time: 254 days Regulatory review time: 120 days	Sep. 27, 2017 Foreign clinical study results	7	FreeStyle Libre (Abbott Japan LLC)	Change	Instrument & apparatus 20 Glucose monitoring system	A glucose monitoring system to continuously measure and record glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen. The application was submitted to mainly change the algorithm for calculation of glucose level with an aim to improve the accuracy of measuring glucose level in the interstitial fluid.

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Orthopedic and Plastic Surgery	Jun. 9, 2020 Total review time: 253 days Regulatory review time: 127 days	- Clinical evaluation report	8	Vertecem V+ Bone Cement Kit (Johnson & Johnson K.K.)	Approval	Medical products 4 Orthopedic bone cement	A bone cement for orthopedic surgery used by filling into the vertebral body through a spinal screw with fenestrations in order to fix and stabilize the screw when performing posterior spinal fusion for the spine with lowered bone strength due to osteoporosis, osteopenia, or malignant spinal tumor. The product is used with the company's "Expedium Verse Fenestrated Screw System (Approval No.: 30200BZX00193000)". A clinical evaluation report summarizing the foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the concomitant use of this product and spinal screw.
Orthopedic and Plastic Surgery	Jun. 9, 2020 Total review time: 253 days Regulatory review time: 156 days	Dec.20, 2016 Clinical evaluation report	9	Expedium Verse Fenestrated Screw System (Johnson & Johnson K.K.)	Approval	Medical products 4 Spinal internal fixation system	A spinal internal fixation system used for temporary fixation, support or alignment correction of the spine in patients with spinal diseases such as degenerative disease, trauma, and tumor in the thoracic vertebra, lumbar vertebra, and sacral vertebra. The fenestrations are provided on the screw shaft portion so that bone cement can be injected into the vertebral body. For the spine with lowered bone strength due to osteoporosis, osteopenia, or malignant spinal tumor and thereby may lose the fixability of the screw in the bone, the product is used with the company's bone cement "Vertecem V+ Bone Cement Kit (Approval No.: 30200BZX00192000)". A clinical evaluation report summarizing the foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the concomitant use of this product and bone cement.
Orthopedic and Plastic Surgery	Jul. 3, 2020 Total review time: 259 days Regulatory review time: 160 days	Sep. 28, 2017 Clinical evaluation report	10	Traumacem V+ Bone Cement Kit (Johnson & Johnson K.K.)	Approval	Medical products 4 Orthopedic bone cement	Orthopedic bone cement used for augmentation of the head element of intramedullary femoral nail in patients with poor bone quality. This product consists of polymethylmethacrylate-based polymer powder and methylmethacrylate-based monomer liquid, and is used with the company's intramedullary femoral nail, "TFN-Advanced Proximal Femoral Nail System" (Approval No.: 22700BZX00142000). A clinical evaluation report summarizing the foreign clinical literatures was submitted to evaluate the safety and efficacy of this product used with the intramedullary femoral nail.
Orthopedic and Plastic Surgery	Jul. 3, 2020 Total review time: 259 days Regulatory review time: 160 days	Feb.28, 2014 Clinical evaluation report	11	TFN-Advanced Proximal Femoral Nail System (Johnson & Johnson K.K.)	Change	Medical products 4 Intramedullary femoral nail	An intramedullary femoral nail system made of titanium alloy for internal fixation of femoral fracture used for reduction and fixation proximal femoral fracture. This product consists of a nail, a head element (with or without fenestrations), and an end cap. The head element with fenestrations can be used with the company's orthopedic bone cement, "Traumacem V+ Bone Cement Kit" (Approval No.: 30200BZX00222000). A clinical evaluation report summarizing the clinical literatures was submitted to evaluate the safety and efficacy of this product used with the bone cement.
Orthopedic and Plastic Surgery	Aug. 4, 2020 Total review time: 223 days Regulatory review time: 202 days	- Foreign clinical study results	12	Juvederm Vista Volux XC (Allergan Japan K. K.)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material to a soft tissue using hyaluronic acid injected subcutaneously or into supraperiosteal space to correct volume loss and increase the volume in adult faces. This product consists of hyaluronic acid gel and a syringe. The hyaluronic acid gel contains lidocaine hydrochloride 0.3 wt% for pain relief during the procedure. The results of a foreign clinical study on injection of the product in the chin and jaw were submitted as an evaluation of the efficacy and safety.
Orthopedic and Plastic Surgery	Aug. 19, 2020 Total review time: 189 days Regulatory review time: 130 days	Oct. 19, 2018 Clinical evaluation report	13	Ultrasound Bone Densitometer EchoS System (Toyo Medic Co., Ltd.)	Approval	Instrument & apparatus 12 Ultrasound bone densitometer	An ultrasound bone densitometer to analyze the estimated bone density by measuring the ultrasound pulse reflected from the bone to diagnose the bone nature. This product consists of a main body of EchoS, a transducer, and a personal computer installed with the dedicated software and is not used for definitive diagnosis. A clinical evaluation report consisting of foreign clinical literatures was submitted to confirm the correlation of the estimated bone density analyzed by this product and the bone density measured by a dual-energy x-ray absorptiometry.

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Orthopedic and Plastic Surgery	Aug. 20, 2020 Total review time: 181 days Regulatory review time: 54 days	Mar. 9, 2012 Clinical evaluation report	14	Sientra Breast Implant (Medical U&A, Inc.)	Approval	Medical products 4 Gel-filled mammary prosthesis	A gel-filled artificial breast made of a silicone gel used for breast reconstruction or augmentation in adult women to restore or form the shape of a breast. This product contains a breast implant (round smooth, round textured, and anatomical textured) and a sizer as components. A clinical evaluation report consisting of data related to foreign clinical studies and clinical literatures was submitted to evaluate the incidence of adverse events as the efficacy and safety of the artificial breast.
Orthopedic and Plastic Surgery	Dec. 10, 2020 Total review time: 163 days Regulatory review time: 147 days	- Foreign clinical study results	15	Juvederm Vista Volite XC (Allergan Japan K.K.)	Approval	Medical products 4 Injectable material to a soft tissue using hyaluronic acid	An injectable material to a soft tissue using hyaluronic acid intended to be used to correct superficial cutaneous depressions such as fine lines and for improvement of skin quality in face and neck in adults by injecting it intradermally. This product consists of hyaluronic acid gel and a syringe. The hyaluronic acid gel contains 0.3 wt% of lidocaine hydrochloride for pain relief during the procedure. The results of a foreign clinical study on injection of the product into the face and neck were submitted as the evaluation of the efficacy and the safety.
Orthopedic and Plastic Surgery	Dec. 24, 2020 Total review time: 267 days Regulatory review time: 205 days	- Japanese clinical study results	16	VBS Vertecem V+ Bone Cement Kit (Johnson & Johnson K.K.)	Approval	Medical products 4 Orthopedic bone cement	An orthopedic bone cement intended to be used to stabilize the fractured vertebral body and thereby relieves the pain of patients in acute phase of painful compression fracture of spine due to primary osteoporosis in the one vertebral body from the fifth thoracic vertebrae to the fifth lumbar vertebrate. The product is used for the patients whose lower back pain has not relieved after receiving sufficient conservative treatment. The results of a Japanese multicenter, single-arm study were submitted to evaluate the rate of restoration of vertebral height and pain score for the efficacy and the adverse events for the safety.
Orthopedic and Plastic Surgery	Dec. 24, 2020 Total review time: 262 days Regulatory review time: 200 days	- Japanese clinical study results	17	VBS Stent Balloon (Johnson & Johnson K.K.)	Approval	Medical products 4 Vertebral body support material	A vertebral body support material which creates a cavity in the fractured vertebral body to restore and maintain the vertebral height of fractured vertebral body for patients in acute phase of painful compression fracture of spine due to primary osteoporosis in the one vertebral body from the fifth thoracic vertebrae to the fifth lumbar vertebrate. The product is used for patients whose lower back pain has not relieved after receiving sufficient conservative treatment. The results of a Japanese multicenter, single-arm study were submitted to evaluate the rate of restoration of vertebral height and pain score for the efficacy and the adverse events for the safety.
Orthopedic and Plastic Surgery	Jan. 14, 2021 Total review time: 266 days Regulatory review time: 115 days	Jul. 2014 Japanese clinical study results	18	SHILLA Growth Guidance System (Medtronic Sofamor Danek, Co., Ltd.)	Approval	Medical products 4 Spinal internal fixation system	A spinal internal fixation system used generally in patients aged less than 10 years, with potentially life-threatening, severe, progressive, early-onset scoliosis. The product is used in patients for whom surgical correction and maintaining of correction are necessary, who are with a Cobb angle of 50 degrees or greater, and whose spinal curvature covers at least 6 segments of the spine from the upper end vertebra to the lower end vertebra. The results of a Japanese multicenter study in patients with early-onset scoliosis were submitted to evaluate the level of correction of the Cobb angle at 24 months after surgery for efficacy, and the incidence rate of adverse events and device failures for safety.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Mar. 29, 2021 Total review time: 208 days Regulatory review time: 141 days	- Japanese clinical study results	19	ReBOSSIS-J (ORTHOREBIRTH Co., Ltd.)	Approval	Medical products 4 Absorbable bone regeneration material	An absorbable bone regeneration material used to fill bony defects caused by trauma, autogenous bone harvesting or treatment of diseases, and to support autogenous bone graft (allograft). The product is a cotton-shaped material consisting of fine fiber combined with β-tricalcium phosphate and a lactic acid-glycolic acid copolymer. The results of a multicenter, open-label study conducted in Japan were submitted to demonstrate the meeting of standard for achieving bone replacement capability based on results of clinical study conducted by another company for its approved product, and to confirm the state of developing no unacceptable adverse event peculiar to this product.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 6, 2020 Total review time: 166 days Regulatory review time: 98 days	Jul. 16, 2010 Clinical evaluation report	20	Arctic Sun 5000 Temperature Management System (Medicon, Inc.)	Change	Instrument & apparatus 12 Water pad specific heating control unit	A water pad specific heating control unit used to cool or warm the patient's body. The application was submitted to add the indication of the product for “body temperature management (temperature management therapy) in adult with return of spontaneous circulation following cardiac arrest (A "partial change" application). A clinical evaluation report summarizing the clinical literature, etc. on the temperature management (temperature management therapy) using this product was submitted to evaluate the efficacy and safety for the additional indication.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 16, 2020 Total review time: 160 days Regulatory review time: 61 days	Apr. 2013 / Feb. 2018 Clinical evaluation report	21	Perclose PROGLIDE (Abbott Medical Japan LLC)	Change	Medical products 2 Non-absorbable suture set	A non-absorbable suture set used for hemostasis of femoral arterial or venous access sites following percutaneous catheterization procedures. The application was submitted to add the indications of the product for the procedure of using a large diameter introducer sheath such as endovascular aortic repair at femoral arterial access site and for the procedure at femoral venous access site such as percutaneous repair for mitral valve coaptation failure (A "partial change" application). The clinical evaluation report summarizing clinical literature, etc. was submitted as an evaluation material for the additional indications.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 16, 2020 Total review time: 267 days Regulatory review time: 150 days	- Japanese clinical study results	22	PuraStat (3-D Matrix, Ltd.)	Approval	Medical products 4 Absorbable topical hemostatic material	The product is an absorbable topical hemostatic material in a pre-filled syringe, which is filled with clear synthetic peptide solution, and used for reducing the number of ablation with hemostatic forceps to stop oozing in gastrointestinal endoscopy. In a Japanese clinical study using the frequency in use of hemostatic forceps in gastrointestinal endoscopy as the primary endpoint, it was evaluated that the frequency of use of hemostatic forceps was significantly lower when using this product compared with the conventional hemostatic method.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 3, 2020 Total review time: 263 days Regulatory review time: 102 days	- Japanese clinical study results	23	Rheocarna (Kaneka Corporation)	Approval	Instrument & apparatus 7 Adsorption hemoperfusion column	An adsorption hemoperfusion column filled with dextran sulfate and L-tryptophan immobilized cellulose beads used for improving ulcers in arteriosclerosis obliterans for which revascularization is not indicated. The results of Japanese clinical study that evaluated the efficacy and safety of the product were submitted.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 4, 2020 Total review time: 253 days Regulatory review time: 144 days	Dec. 14, 2018 Foreign clinical study results	24	Pipeline Flex Flow Diverter System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system intended to be used for endovascular therapy for intracranial aneurysms that are difficult to treat surgically or by coil embolization with a maximum diameter of 5 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from petrous segment to the supraclinoid segment of the internal carotid artery and the vertebral artery, except for the acute ruptured aneurysms. This application was submitted to primarily add supraclinoid segment of internal carotid artery and vertebral artery as indicated sites and change the maximum diameter (from 10 mm to 5 mm) of target aneurysms (A "partial change" application). The results of foreign clinical study including the additional indications as study subject were submitted as the clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 17, 2020 Total review time: 268 days Regulatory review time: 116 days	Aug. 11, 2010 Foreign clinical study results	25	Wingman Catheter System (Century Medical, Inc.)	Approval	Instrument & apparatus 51 Catheter for penetrating vascular stenosis	Catheter for penetrating vascular stenosis used to assist the passage of guide wire and secure the passing parts in chronic total occlusion lesions in the artery of lower extremity which the guide wire is difficult to pass, except the region of iliac arteries. The results of foreign clinical study conducted to evaluate the efficacy and safety of the product were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 9, 2020 Total review time: 266 days Regulatory review time: 62 days	Apr. 2017 Foreign clinical study results	26	LIFESTREAM Vascular Stent System (Medicon, Inc.)	Approval	Instrument & apparatus 7 Stent-graft for central circulatory system	The application was submitted for marketing approval of a stent-graft for central circulatory system which consists of a stent graft and a delivery catheter used to treat de novo or restenotic lesions in the iliac arteries.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 8, 2021 Total review time: 262 days Regulatory review time: 80 days	- Clinical evaluation report	27	Prosthesis for Microvascular Decompression of Cranial Nerve (Kono Seisakusho Co.,Ltd.)	Approval	Medical products 4 Surgical mesh	A surgical mesh consisting of polytetrafluoroethylene (PTFE) resin used to keep blood vessels away from nerves during microvascular decompression for trigeminal neuralgia, hemifacial spasm or glossopharyngeal neuralgia. The clinical evaluation report was submitted to evaluate the efficacy and safety of microvascular decompression of cranial nerve.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jan. 21, 2021 Total review time: 269 days Regulatory review time: 68 days	Jul. 13, 2018 Foreign and Japanese clinical study results	28	Surpass Streamline Flow Diverter System (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Prosthetic material for embolization in vessels of the central circulation system	A flow diverter system intended to be used for endovascular therapy for intracranial aneurysms that are difficult to treat surgically or by coil embolization with a maximum diameter of 10 mm or greater and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2) located from the petrous segment to the supraclinoid segment of the internal carotid artery (except for the acute ruptured aneurysms). The results of foreign and Japanese clinical studies to evaluate the efficacy and safety of the product were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 5, 2021 Total review time: 245 days Regulatory review time: 91 days	Jun. 14, 2017 Clinical evaluation report	29	ULTRASCORE Scoring PTA Balloon Catheter 035 OTW (Medicon, Inc.)	Approval	Instrument & apparatus 51 Balloon-dilating catheter for angioplasty	The application was submitted for marketing approval of a balloon-dilating catheter for angioplasty used for expanding lesions that are resistant to expansion by a normal balloon catheter in the renal artery, artery of lower extremity, or shunt in the percutaneous transluminal angioplasty (PTA) or for post-expansion at the time of stent placement in these blood vessels.
Ophthalmology and Otorhinolaryngology	Apr. 16, 2020 Total review time: 170 days Regulatory review time: 130 days	Dec. 11, 2018 Foreign clinical study results	30	Clariti 1 Day (CooperVision Japan Inc.)	Approval	Instrument & apparatus 72 Single-use colored contact lenses for correcting visual acuity	The application was submitted for marketing approval of daily wear, single-use, colored contact lenses for correction of visual acuity, which are intended to be used for visual correction. The lens is composed of silicone hydrogel (Somofilcon A) with a moisture content of 56% and an oxygen permeability (Dk) of 60.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Apr. 28, 2020 Total review time: 123 days Regulatory review time: 109 days	- Foreign clinical study results	31	Tecnis Synergy TVB Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	The device is a posterior chamber lens with an injector in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct near, intermediate and far vision of an aphakic eye with corneal astigmatism. The results of foreign clinical studies were submitted as clinical evaluation data.
Ophthalmology and Otorhinolaryngology	Jul. 17, 2020 Total review time: 260 days Regulatory review time: 161 days	- Foreign clinical study results	32	Clareon TORIC Intraocular Lens AutonoMe Auto-pre-loaded Delivery System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	The application was submitted for marketing approval of posterior chamber lenses with an injector having cylindrical refractivity, which are intended to be used for visual correction of corneal astigmatism.
Ophthalmology and Otorhinolaryngology	Sep. 2, 2020 Total review time: 253 days Regulatory review time: 217 days	- Foreign clinical study results	33	Clareon TORIC Aspherical Hydrophobic Acryl Intraocular Lens (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens	The application was submitted for marketing approval of posterior chamber lenses having cylindrical refractivity, which are intended to be used for visual correction of corneal astigmatism.
Ophthalmology and Otorhinolaryngology	Sep. 2, 2020 Total review time: 167 days Regulatory review time: 115 days	- Clinical evaluation report	34	BioBlade Laser System (Rakuten Medical Japan K.K.)	Approval	Instrument & apparatus 31 PDT semiconductor laser	The application was submitted for marketing approval of a laser system to be used in combination with Akalux IV Infusion 250 mg (non-proprietary name: cetuximab sarotalocan sodium [genetical recombination]) for the treatment of unresectable, locally advanced or recurrent head and neck cancer.
Ophthalmology and Otorhinolaryngology	Jan. 26, 2021 Total review time: 244 days Regulatory review time: 170 days	- Foreign clinical study results	35	Tecnis Symfony Plus VB Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lenses with an injector	The application was submitted for marketing approval of a posterior chamber lens with an injector in which a multifocal posterior chamber lens is preloaded into a single-use intraocular lens injector, and the lens is intended to be inserted as a substitute for a crystalline lens to correct far, intermediate and near vision of an aphakic eye.
Ophthalmology and Otorhinolaryngology	Feb. 9, 2021 Total review time: 266 days Regulatory review time: 49 days	Dec. 26, 2017 Foreign clinical study results	36	iLux System (Alcon Japan Ltd.)	Approval	Instrument & apparatus 12 Eyelid thermal pulsation system	The application was submitted for marketing approval of an eyelid thermal pulsation system used for providing localized heat and pressures to the eyelids in patients with meibomian gland dysfunction.
Ophthalmology and Otorhinolaryngology	Mar. 15, 2021 Total review time: 474 days Regulatory review time: 223 days	- Foreign clinical study results	37	1-Day Acuvue Theravision K (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 72 Single-use colored drug-containing contact lenses for correcting visual acuity	The application was submitted for marketing approval of single-use colored drug-containing contact lenses used for vision correction, and alleviation of ocular allergic symptoms when wearing contact lenses in patients with allergic conjunctivitis.
Cardiopulmonary Circulation	Jun. 29, 2020 Total review time: 411 days Regulatory review time: 80 days	- Japanese clinical study results	38	Coroflex ISAR Neo Coronary Stent (Nipro Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-4.25 mm, and a delivery catheter used to implant a stent to the site of stenosis. Probucol is used for the product instead of non-biodegradable polymers, as a base to retain the drug. The results of Japanese clinical studies were submitted as clinical evaluation data.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Jun. 29, 2020 Total review time: 151 days Regulatory review time: 122 days	Jun. 23, 2020 Global clinical trial	39	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	A balloon ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is used for cardiac cryoablation to treat drug refractory recurrent symptomatic paroxysmal and persistent atrial fibrillation. The application was submitted to add drug refractory recurrent symptomatic persistent atrial fibrillation as the intended use (A "partial change" application). The results of global clinical studies evaluating the efficacy and safety of the product in patients with drug refractory recurrent symptomatic persistent atrial fibrillation were submitted.
Cardiopulmonary Circulation	Jun. 29, 2020 Total review time: 151 days Regulatory review time: 122 days	Jun. 23, 2020 Global clinical trial	40	Freezor MAX Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Cardiovascular ablation catheter	An ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is intended to be used for gap cryoablation to complete electrical isolation of the pulmonary veins, cryoablation of focal trigger sites for the treatment of atrial fibrillation, or creation of an ablation line between the inferior vena cava and the tricuspid valve when performing the procedure of cryoablation for the treatment of drug refractory recurrent symptomatic paroxysmal and persistent atrial fibrillation. The application was submitted to add drug refractory recurrent symptomatic persistent atrial fibrillation as the intended use (A "partial change" application). The results of global clinical studies evaluating the efficacy and safety of the product in patients with drug refractory recurrent symptomatic persistent atrial fibrillation were submitted.
Cardiopulmonary Circulation	Jul. 9, 2020 Total review time: 195 days Regulatory review time: 93 days	May 2, 2017 Clinical evaluation report	41	RESONATE CRT-D Series (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 7 Implantable biventricular pacing pulse generator with defibrillator function	The device is an implantable biventricular pacing pulse generator with a defibrillator function. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add a model with a function to provide indicators related to the changes in the patient's biological information (HeartLogic function) based on the concept of "testing/diagnostic devices that measure physiological parameters to obtain potential reference information for diagnosis" provided in "Handling on the Scope of Situations where 'Documents related to Clinical Study Results' is Necessary on Medical Devices (Operations based on Measures through Pre-and Post-Marketing Phases), (PSEHB/MDED Notification No. 1117-1, PSEHB/SD Notification No. 1117-1, dated on November 17, 2017). " (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted to demonstrate that the HeartLogic function can provide indicators related to changes in biological information.
Cardiopulmonary Circulation	Aug. 4, 2020 Total review time: 151 days Regulatory review time: 84 days	May 28, 2020 Foreign clinical study results	42	Synergy Stent System (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of an everolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo coronary artery lesions (legion length of 44 mm or less) with a reference vessel diameter of 2.25-5.00 mm and a delivery catheter used to implant the stent to the site of stenosis. The application was submitted for additional stent size of 48 mm in length (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the additional size.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Aug. 20, 2020 Total review time: 265 days Regulatory review time: 94 days	- Japanese clinical study results	43	ECMO System HLS SET Advanced-LT (Getinge Group Japan K.K.)	Approval	Instrument & apparatus 7 Heparin-coated percutaneous cardiopulmonary support system	This device is a heparin coated extracorporeal circulation system used for cardiopulmonary support. This device consists of a centrifugal pump with an oxygenator, a blood parameter measuring cell, a patient circuit, a gas line filter, a priming set, and a cannulae, and is used with a dedicated driving device, "CARDIOHELP Console" (Approval No.: 22500BZX00277000). This device is a combination of the approved product, "ECMO System HLS Set Advanced" (Approval No.: 22800BZX00092000) and "HLS Cannulae" (Approval No.: 22600BZX00042000), and developed as an ECMO for mid to long-term use by extending the maximum designed duration of use from conventional 6 hours to 14 days. The results of Japanese clinical study were submitted as clinical evaluation data to evaluate clinical efficacy and safety of the product for the use in maximum designed duration.
Cardiopulmonary Circulation	Aug. 21, 2020 Total review time: 162 days Regulatory review time: 58 days	Apr. 28, 2017 Foreign clinical study results	44	Resolute Onyx Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Coronary stent	A stent system consisting of a zotarolimus-eluting stent used for treating patients with symptomatic ischemic cardiac disease who have a new coronary artery lesions (legion length of 35 mm or less) with a reference vessel diameter of 2.25-4.2 mm and a delivery catheter to place the stent at the site of stenosis. The application was submitted for additional stent size of 2.25 mm in diameter and the stent length of 34 mm and 38 mm (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the additional sizes.
Cardiopulmonary Circulation	Sep. 4, 2020 Total review time: 119 days Regulatory review time: 50 days	Sep. 11, 2018 Clinical evaluation report	45	Apple’s ECG App (Apple Inc.)	Approval	Program 1 Home-use ECG program	A home-use program that creates, records, stores, transfers, and displays single channel ECGs similar to lead-I ECGs. It analyzes the obtained ECG, classifies the wave form as being suggestive of sinus rhythm or atrial fibrillation and notifies the results to the user. A clinical evaluation report summarizing overseas clinical literature was submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Sep. 4, 2020 Total review time: 116 days Regulatory review time: 47 days	Sep. 11, 2018 Clinical evaluation report	46	Apple’s Irregular Rhythm Notification Feature (Apple Inc.)	Approval	Program 1 Home-use cardiac rate monitoring program	A home-use program that analyzes pulse rate data, detects irregular heartbeats suggestive of atrial fibrillation and notifies the user. A clinical evaluation report summarizing overseas clinical literature was submitted to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Oct. 19, 2020 Total review time: 146 days Regulatory review time: 89 days	- Foreign clinical study results	47	XIENCE Skypoint 48 Drug-Eluting Stent (Abbott Medical Japan LLC)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesions (a lesion length of 44 mm or less) with a reference vessel diameter of 2.25-4.25 mm, and a delivery catheter used to implant a stent to the site of stenosis. The results of foreign clinical studies were submitted as clinical evaluation data to evaluate the efficacy and safety of the product.
Cardiopulmonary Circulation	Mar. 29, 2021 Total review time: 292 days Regulatory review time: 140 days	- Japanese clinical study results	48	Biofloat Console (Nipro Corporation)	Change	Instrument & apparatus 7 Assistant artificial heart driving unit	A blood circulation device that drives an exclusive centrifugal pump incorporated in the extracorporeal circuit is used for extracorporeal circulation in patients for whom cardiotomy or cardiac functional recovery is necessary, or for assisted circulation intended to maintain normal systemic circulation and improve the cardiac insufficiency in patients with severe heart failure. The application was submitted to add “Biofloat Ventricular Assist Device Set HC” (Approval No. 30300BZX00093000) as a concomitant device, and also to add the indication of the product as an assistant artificial heart driving unit (A "partial change" application). As clinical evaluation data, the results of a Japanese clinical study were submitted to evaluate the clinical efficacy and safety of the combined use with the additional concomitant device.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Mar. 29, 2021	-	49	Biofloat Ventricular Assist Device Set HC (Nipro Corporation)	Approval	Instrument & apparatus 7	A single-use extracorporeal assistant artificial cardiac pump used to maintain normal systemic circulation including the heart itself and improve cardiac insufficiency in patients with severe heart failure exceeding the limit that can be treated with conventional medication or existing assisted circulation (such as intraaortic balloon pumping or venoarterial bypass) due to severe heart failure or cardiogenic shock. This product is concomitantly used with a dedicated driving device “Biofloat Console” (Approval No. 22800BZX00322000). The product adopts an approved device “Biofloat Centrifugal Pump” (Approval No. 22800BZX00321000) as a blood pump. The product was developed to increase auxiliary flow and reduce the risk of hemolysis and thrombus compared to the similar approved device with a pulsating type pump, “Nipro Heparin-Coated Ventricular Assist Device Set” (Approval No. 21700BZZ00011000). As clinical evaluation data, the results of a Japanese clinical study were submitted to evaluate the clinical efficacy and safety of the product for the use in maximum designed duration.
	Total review time: 292 days Regulatory review time: 140 days	Japanese clinical study results				Single-use extracorporeal assistant artificial cardiac pump	

Reprocessed Single-Use Medical Devices Approved in FY2020

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotic, ICT, and other devices (not classified as other categories)	Aug. 20, 2020	-	1	Reprocessed Flowtron ACS900 (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 12	Reprocessed single-use medical device originating from the component of "Flowtron ACS900 (Certification No.: 228ADBZX00013000), which is a pneumatically-powered massager to prevent venous thrombosis by compressing the patient's leg with pneumatic pressure to promote venous blood circulation.
	Total review time: 511 days Regulatory review time: 360 days	No clinical study results				Reprocessed cuff for pneumatically-powered massager	
Gastroenterology, Genitourinary and Reproductive Medicine	Nov. 24, 2020	-	2	Reprocessed V-pipe (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 25	Reprocessed single-use medical device originating from "Vagi-pipe" (Notification No. 20B1X00005000001), which is an endoscopic dilator used to dilate the vaginal opening during total laparoscopic hysterectomy.
	Total review time: 333 days Regulatory review time: 222 days	No clinical study results				Reprocessed single-use natural orifices endoscopic dilator	
Gastroenterology, Genitourinary and Reproductive Medicine	Dec. 10, 2020	-	3	Reprocessed Trocar E (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 49	Reprocessed single-use medical device originating from "Endopath Trocar System" (Certification No. 21900BZX00882000), which is a set of a trocar and a sleeve used to provide a working channel by puncturing it into the abdominal or thoracic cavity.
	Total review time: 259 days Regulatory review time: 182 days	\				Reprocessed single-use trocar sleeve	
Gastroenterology, Genitourinary and Reproductive Medicine	Mar. 18, 2021	-	4	Reprocessed Trocar E2 (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 49	Reprocessed single-use medical device originating from "Endopath Trocar System" (Certification No. 21900BZX00882000), which is a set of a trocar and a sleeve used to provide a working channel by puncturing it into the abdominal or thoracic cavity. The difference from the company's approved device "Reprocessed Trocar E (HOGY)" (Approval No. 30200BZX00393000) is that this product originates from the original medical device made with different components.
	Total review time: 170 days Regulatory review time: 129 days	No clinical study results				Reprocessed single-use trocar sleeve	

Notes

1.

"Review Category" in the list shows the review team which reviewed the product. It is usually decided on the therapeutic area the product is indicated for. Please refer to the following table.

Review Category	Products
Robotic, ICT, and other devices (not classified as other categories)	Mainly innovative medical devices utilizing robotics and advanced ICT technologies, multicategory medical devices, and other uncategorized medical devices
Orthopedic and Plastic Surgery	・Medical devices mainly pertaining to hips, knees, upper extremities, hands, and digits, etc. among orthopedic devices ・Medical devices such as plates, screws, intramedullary nails, spinal implants and related instruments, as well as medical devices used in plastic surgery, dermatology, etc.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	・Materials used in the fields of brain and circulatory medicine (excluding cardiology) as well as respiratory medicine, neurology, and psychiatry ・Mechanical appliances used in the fields of brain and circulatory medicine (excluding cardiology) as well as respiratory medicine, neurology, and psychiatry
Gastroenterology, Genitourinary, and Reproductive Medicine	Mainly devices pertaining to the fields of gastroenterology, urology, and obstetrics/gynecology (OB/GYN)
Dentistry and Oral Medicine	Mainly devices used in the field of dentistry
Ophthalmology and Otorhinolaryngology	Mainly devices pertaining to the fields of ophthalmology and otorhinolaryngology
Cardiopulmonary Circulation	・Mainly cardiology-related materials used in medical devices pertaining to the circulatory system ・Mainly cardiology-related mechanical appliances pertaining to the circulatory system
Bio-derived Devices (Quality)	Devices subject to "partial change" applications related to the Standards for Biological Ingredients, viral safety, etc.

2.

An "Orphan Medical Device" is defined as a medical device designated by Minister of Health, Labour and Welfare as an orphan device, based on the PMD Act. Orphan Medical Devices receive priority review.

Orphan Medical Devices are those with number of targeted patients less than 50,000 in Japan. In addition, the medical device has to meet one of the following requirements to show its clinical value to obtain Orphan Medical Device designation:
- no other medical devices or treatments are considered appropriate for the indication
- significant efficacy or safety is expected compared to the treatment/therapy provided with available medical devices

The medical devices described as [Orphan device] in the list are those designated as an Orphan Medical Device.

3.

"Priority Review" is a review process under which priority is given. Besides orphan-designated medical devices, those satisfying one of the following requirements are given with priority review:
- its indication is considered serious
- significant efficacy or safety is expected compared to the treatment/therapy provided with available medical devices

For medical devices that are not Orphan Medical Devices, whether the priority review is applied or not is judged by Ministry of Health, Labour and Welfare based on "How to manage the priority review" (PFSB/ELD Notification No. 0227016 dated February 27, 2004).

4.

The medical devices described as [Priority review] in the list are those to which the priority review was applied.