

New Medical Devices Approved in FY2021

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
Robotics, IoT, and other devices (not classified as other categories)	Aug. 6, 2021	-	1	Oncotype DX Breast Recurrence Score Program (Exact Sciences K.K.)	Approval	Program 1	The application was submitted for marketing approval of a software program to support tumor malignancy determination which outputs a Recurrence Score that assists in determining chemotherapy use based on the RNA expression levels of 21 genes in tumor tissue of hormone receptor-positive, HER2-negative, early-stage invasive breast cancer patients.
	Total review time: 340 days Regulatory review time: 248 days	Clinical evaluation report				Software program to support tumor malignancy determination	
Orthopedic and Plastic Surgery	Jun. 7, 2021	-	2	EpiFix (MiiMedx Group, Inc.)	Approval	Medical products 4	A tissue-healing promoting material composed of human amniotic membranes intended to promote wound healing in patients with refractory ulcers who have not responded to conventional therapies. The product is made of dried human amniotic/chorionic membranes obtained from the human placenta, prepared by cleaning, drying, and sterilizing, and contains multiple types of extracellular matrix proteins, growth factors, cytokines, etc. A clinical evaluation report primarily consisting of the results of a foreign post-marketing clinical study, a literature review, and an adverse event report was submitted to evaluate the efficacy and safety of the product as a tissue-healing promoting material.
	Total review time: 363 days Regulatory review time: 262 days	Clinical evaluation report				Tissue-healing promoting material using human amniotic membrane	
Orthopedic and Plastic Surgery	Feb. 17, 2022	Sep. 20, 2018	3	RECELL Autologous Cell Harvesting and Non-cultured Cell Suspension Preparation Kit (Cosmotec Co., Ltd.)	Approval	Instrument & apparatus 58	An autologous skin cell grafting kit intended to produce a non-cultured cell suspension from a skin specimen collected from a patient and promote healing of the wound of acute burn and donor sites. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
	Total review time: 360 days Regulatory review time: 144 days	Foreign clinical study results				Autologous skin cell grafting kit	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 13, 2021	Mar. 13, 2020	4	ALTO Abdominal Stent Graft System (Endologix LLC)	Approval	Instrument & apparatus 7	The application was submitted for marketing approval of a stent graft system for the treatment of abdominal aorta that obtains adhesion to blood vessels by filling polymer.
	Total review time: 364 days Regulatory review time: 113 days	Foreign clinical study results				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 26, 2021	Apr. 30, 2014 P130008/INSPIRE II UPPER AIRWAY STIMULATOR May 5, 2017 P130008/S016/INSPIRE UPPER AIRWAY STIMULATOR, MODEL 3028	5	Inspire UAS System (Inspire Medical Systems, Inc.)	Change	Instrument & apparatus 12	An implantable device used to stimulate the hypoglossal nerve in synchronization with breathing to improve airway patency in patients with moderate-to-severe obstructive sleep apnea syndrome who are ineligible for, or intolerant to, continuous positive airway pressure therapy. The application was submitted to add a manufacturing site for sterilization and a programmer cable used for wireless communication between the programmer for physicians and the pulse generator. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 90 days Regulatory review time: 80 days	No clinical study results				Hypoglossal nerve stimulator	

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 8, 2021	-	6	GORE CTAG Thoracic Endoprosthesis (W. L. Gore & Associates, G. K.)	Change	Instrument & apparatus 7	An aortic stent graft system used for intravascular treatment of thoracic aortic diseases. The application was submitted to add blue pigment to the surgical sutures used of the stent graft and delivery catheter, in order to enhance its identifiability during the manufacturing process, 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: 97 days Regulatory review time: 39 days	No clinical study results				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 17, 2021	-	7	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A stent graft system used for the treatment of thoracic aorta. The application was submitted to partially change the raw materials of the delivery system, 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: 56 days Regulatory review time: 47 days	No clinical study results				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 21, 2021	-	8	MR Guided Focused Ultrasound Surgery ExAblate 4000 (InSightec Ltd.)	Change	Instrument & apparatus 12	A focused ultrasound system intended for focally heating the target and causing focal coagulative necrosis to deliver focused ultrasound energy to the target in the thalamus through the skull. The device is used to alleviate essential tremor and symptoms of Parkinson's disease in patients who are not respond sufficiently to drug therapies. The application was submitted to add components including a patient table and dedicated head coil, due to the addition of the MR device used with the system, to add and make improvements in final confirmation function of the radiation parameter, and to change the evaluation method for the image quality of the MR device used with the system. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 293 days Regulatory review time: 152 days	No clinical study results				Focused ultrasound system	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 13, 2021	-	9	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Change	Instrument & apparatus 51	A balloon-dilating catheter for angioplasty used for purposes including reducing restenosis of target blood vessels in the treatment of de novo or restenotic lesions within the autogenous femoropopliteal artery (excluding those within a stent). The balloon surface of this product is coated with a drug primarily composed of paclitaxel. The application was submitted for deletion of the specification for heavy metal in the drug substance (paclitaxel), 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: 71 days	No clinical study results				Balloon-dilating catheter for angioplasty	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 14, 2021	May 5, 2019 Valiant Thoracic Stent Graft With The Captivia Delivery System (P100040 S038)	10	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A stent graft system used for the treatment of thoracic aorta. The application was submitted to add ethylene oxide gas processing to the manufacturing process of stent graft for bioburden reduction. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 135 days Regulatory review time: 116 days	No clinical study results				Aortic stent graft	

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 26, 2021	Apr. 10, 2013 Jetstream SC/XC Atherectomy Catheter/ Oct. 19, 2012 Jetstream Console/	11	Jetstream Atherectomy System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51	The application was submitted for marketing approval of a catheter system used to remove hard atherosclerotic disease and stenosis in the superficial femoral artery and/or proximal popliteal artery to facilitate pre-dilation of severely calcified lesions (excluding in-stent restenosis lesions) that do not pass through or are difficult to dilate with a PTA balloon catheter used for pre-dilatation prior to drug-coated balloons.
	Total review time: 356 days Regulatory review time: 217 days	Japanese clinical study results				Atherectomy ablative angioplasty catheter	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 22, 2021	Feb. 25, 2015 VenaSeal Closure System	12	VenaSeal Closure System (Covidien Japan Inc.)	Change	Instrument & apparatus 51	A vascular embolization prosthesis to occlude the blood vessel by injecting into the truncal saphenous veins with venous reflux. The application was submitted to change the raw material of the catheter hub and introducer hub and to change the specifications for leakage of the drug solution from the introducer hub. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 146 days Regulatory review time: 94 days	No clinical study results				Vascular embolization prosthesis	
Gastroenterology, Genitourinary and Reproductive Medicine	Jul. 14, 2021	-	13	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7	A purifier for blood cell removal to selectively adsorb and remove granulocytes and monocytes in peripheral blood by performing direct hemoperfusion using an extracorporeal circulation column which is filled with an adsorbent carrier made of cellulose acetate. The application was submitted to add the indication for maintaining remission during the remission phase in patients with refractory ulcerative colitis who have not responded, have not sufficiently responded, or are not amenable to conventional medications. A clinical evaluation report summarizing a Japanese clinical study and the contents of Japanese and foreign clinical literatures, etc. were submitted to evaluate the efficacy and safety of the product for this indication. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 161 days Regulatory review time: 101 days	Clinical evaluation report				Purifier for blood cell removal	
Gastroenterology, Genitourinary, and Reproductive Medicine	Oct. 13, 2021	Aug. 27, 2015 K150786/Rezum System	14	Rezum System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 29	A water vapour delivery system for prostatic tissue indicated for dysuria associated with prostatic hyperplasia. In the system, a needle in the delivery device is inserted into the site of enlarged prostate and the high-temperature water vapour is delivered from the holes of the needle tip. The system uses the thermal energy released from the liquefaction of the water vapour injected from the needle tip, to necrotise the enlarged prostate tissue with time, and improves dysuria. The results of a foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
	Total review time: 359 days Regulatory review time: 178 days	Foreign clinical study results				Water vapour delivery system for prostatic tissue	
Gastroenterology, Genitourinary and Reproductive Medicine	Feb. 8, 2022	Sep. 28, 2006 K060482/CYTORI CELUTION CELL CONCENTRATION DEVICE	15	Celution Cell Therapy Kit SUI (Cytori Therapeutics, K.K.)	Approval	Instrument & apparatus 7	An adipose tissue separation kit to clean, separate, and process adipose tissue by centrifugation to be administered specific cells and adipose tissue for the treatment of patients who have not responded or have not sufficiently responded to behavioral therapy or drug therapy for mild to moderate male stress urinary incontinence associated with urethral sphincter incompetence secondary to a surgery for prostatic hyperplasia or prostate cancer. The results of Japanese clinical studies were submitted to evaluate the efficacy and safety of the treatment using this product.
	Total review time: 776 days Regulatory review time: 520 days	Japanese clinical study results				Adipose tissue separation kit	

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Gastroenterology, Genitourinary and Reproductive Medicine	Feb. 8, 2022	Dec. 21, 2017 DEN170024/Not described	16	AQUABEAM Robotic System (PROCEPT BioRobotics Corporation)	Approval	Instrument & apparatus 12	A device to resect an enlarged prostate by inserting a handpiece transurethrally and using a high-pressure water injection of physiological saline. A physician sets a resection plan preoperatively, and the robot system performs treatment following the plan. The application was submitted for marketing approval of a medical device used for resection and removal of prostate tissue of male patients with lower urinary tract symptoms associated with prostatic hyperplasia.
	Total review time: 229 days Regulatory review time: 166 days	Foreign clinical study results				Surgical robot unit	
Gastroenterology, Genitourinary and Reproductive Medicine	Mar. 28, 2022	Aug. 27, 2015 K150786/Rezum System	17	Rezum System (Boston Scientific Japan K. K.)	Change	Instrument & apparatus 29	A water vapour delivery system for prostatic tissue indicated for dysuria associated with prostatic hyperplasia. In the system, a needle in the delivery device is inserted into the site of enlarged prostate and the high-temperature water vapour is delivered from the holes of the needle tip. The system uses the thermal energy released from the liquefaction of the water vapour injected from the needle tip, to necrotise the enlarged prostate tissue with time, and improves dysuria. The application was submitted to add a model whose a pressure safety valve located at the tip of a tube for injection water is removed. (A "partial change" application).
	Total review time: 115 days Regulatory review time: 33 days	No clinical study results				Water vapour delivery system for prostatic tissue	
Cardiopulmonary Circulation	Apr. 6, 2021	Aug. 16, 2019	18	CoreValve Evolut R (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a porcine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This device has been approved for the indication of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option" in the treatment for patients with severe symptomatic native aortic valve stenosis (Approval No.: 22800BZX00414000). The application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic valve stenosis who are at low surgical risk 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: 344 days Regulatory review time: 224 days (Review report, etc.)	Global clinical study results				Transcatheter porcine pericardial valve	
Cardiopulmonary Circulation	Apr. 6, 2021	Aug. 16, 2019	19	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-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 and transcatheter pulmonary valve replacement (Approval No.: 22800BZX00094000). For the treatment of patients with severe symptomatic native aortic valve stenosis, this product has been approved for the indication of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option." In addition to the indication mentioned above, the application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic valve stenosis who are at low surgical risk 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: 281 days Regulatory review time: 161 days	Global clinical study results				Transcatheter bovine cardiac valve	

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Cardiopulmonary Circulation	Apr. 7, 2021	Oct. 27, 2016 510K (K160121)/CorPath GRX System Mar. 1, 2018 510K (K173806)/CorPath GRX System: RoR added	20	CorPath GRX System (Corindus, Inc.)	Change	Instrument & apparatus 51	Remote catheter manipulation equipment to be installed in a cardiac catheterization room to manipulate and hold guiding catheters, guidewires, rapid exchange balloon dilatation catheters for coronary angioplasty, and rapid exchange coronary stent catheters that are used for percutaneous coronary intervention. The application was submitted for an additional function to make several movements with this device (such as rotation and back and forward movement), which are commonly required when a guidewire and a therapeutic catheter are inserted to the lesion by a physician. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 208 days Regulatory review time: 111 days	No clinical study results				Catheter manipulation equipment for use in the cardiac and central circulatory system	
Cardiopulmonary Circulation	May 13, 2021	Dec. 27, 2018	21	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a bioprosthetic valve model in which the height of the outer skirt and the type of the cloth were changed in order to maintain the prevention of paravalvular regurgitation. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 286 days Regulatory review time: 191 days	No clinical study results				Transcatheter bovine cardiac valve	
Cardiopulmonary Circulation	Jun. 17, 2021	May 8, 2020	22	HeartLight Endoscopic Ablation System (Japan Lifeline Co., Ltd.)	Change	Instrument & apparatus 51	A balloon-type laser ablation catheter with an endoscope to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted to add a model with a laser autorotation mode (RAPID mode) in order to shorten procedure time. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the additional model. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 351 days Regulatory review time: 169 days (Review report, etc.)	Foreign clinical study results				Catheter for cardiac ablation	
Cardiopulmonary Circulation	Jun. 30, 2021	Jan. 8, 2016	23	Perceval Bioprosthetic Valve (LivaNova Canada Corp.)	Change	Instrument & apparatus 7	A bovine pericardium valve designed to replace a diseased native aortic valve or a malfunctioning prosthetic aortic valve via open-heart surgery. The application was submitted to change the transportation time for bovine pericardium. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 159 days Regulatory review time: 145 days	No clinical study results				Bovine pericardium valve	
Cardiopulmonary Circulation	Jul. 29, 2021	Jan. 15, 2020	24	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 mainly add a model with an atrioventricular synchronization function. The results of foreign clinical studies were submitted as clinical evaluation data. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 314 days Regulatory review time: 197 days	Foreign clinical study results				Implantable leadless cardiac pacemaker	

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Cardiopulmonary Circulation	Jul. 29, 2021	Sep. 19, 2019 P130021S059/Medtronic Evolut PRO+ System	25	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a porcine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. This device has been approved for the indication of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option" in the treatment for patients with severe symptomatic native aortic stenosis (Approval No.: 30200BZX00272000). The application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic stenosis who are at a low surgical risk were submitted as the clinical study data on the indication expansion.
	Total review time: 269 days Regulatory review time: 248 days	Global clinical study results				Transcatheter porcine pericardial valve	
Cardiopulmonary Circulation	Aug. 23, 2021	Mar. 26, 2021	26	Harmony Transcatheter Pulmonary Valve Replacement System (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 7	A transcatheter porcine pericardial valve used in patients with severe pulmonary regurgitation who have a medical history of surgical repair of the right ventricular outflow tract or transcatheter intervention (balloon valvuloplasty) and for whom pulmonary valve replacement is clinically required. The results of a global clinical study were submitted to evaluate the efficacy and safety of the product.
	Total review time: 266 days Regulatory review time: 116 days	Global clinical study results				Transcatheter porcine pericardial valve	
Cardiopulmonary Circulation	Oct. 26, 2021	Nov. 2017 P170008/EluNIR Ridaforolimus Eluting Coronary Stent System	27	EluNIR Drug-Eluting Stent (Medinol Ltd.)	Approval	Instrument & apparatus 7	A coronary stent used for the treatment of patients with symptomatic heart disease who have de novo native coronary artery lesions (a lesion length of 42 mm or less) with a reference vessel diameter of 2.50-4.25 mm. The results of foreign and Japanese clinical studies were submitted to evaluate the efficacy and safety of the product.
	Total review time: 971 days Regulatory review time: 192 days	Foreign and Japanese clinical study results				Coronary stent	
Cardiopulmonary Circulation	Oct. 27, 2021	Jan. 27, 2021	28	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a manufacturing site and to modify the descriptions in the manufacturing method column. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 111 days Regulatory review time: 36 days	No clinical study results				Transcatheter bovine cardiac valve	
Cardiopulmonary Circulation	Jan. 17, 2022	-	29	AMPLATZER PFO Occluder (Abbott Medical Japan LLC.)	Change	Medical products 4	A percutaneous transcatheter closure device of a patent foramen ovale (PFO) intended to close PFO in patients with a history of cryptogenic cerebral infarction in whom the existence of PFO is determined to be related to the onset of cerebral infarction. The device is used to reduce the risk of recurrence of cerebral infarction. The application was submitted to change the left atrial disc, size of 30 mm and add a model in which the occluder is connected to the delivery cable in advance (A "partial change" application).
	Total review time: 145 days Regulatory review time: 93 days	No clinical study results				Prosthetic material for artificial cardiac membrane	
Cardiopulmonary Circulation	Jan. 17, 2022	-	30	Navitor Transcatheter Aortic Valve Implantation System (Abbott Medical Japan LLC.)	Approval	Instrument & apparatus 7	A self-expandable percutaneous aortic bioprosthetic valve system for a percutaneous aortic valve replacement used in symptomatic patients with severe aortic valve stenosis attributed to calcification and degeneration of the native aortic valve cusps, who are not eligible for surgery and of which this treatment is considered as their best therapeutic option. This product consists of a self-expanding bioprosthetic valve, delivery system, and loading system. As clinical evaluation data, the results of foreign clinical studies were submitted.
	Total review time: 292 days Regulatory review time: 223 days	Foreign clinical study results				Transcatheter bovine cardiac valve	

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Cardiopulmonary Circulation	Mar. 14, 2022	Feb. 17, 2021	31	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to extend the shelf life of the bioprosthetic valve from 2 years to 3 years. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 171 days Regulatory review time: 53 days	No clinical study results				Transcatheter bovine cardiac valve	
Cardiopulmonary Circulation	Mar. 23, 2022	Jan. 27, 2020	32	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7	The device is an implantable ventricular assist device system 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 application was submitted to add HeartMate Touch monitor, etc. developed as an alternative to a component system monitor. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 170 days Regulatory review time: 141 days	No clinical study results				Implantable ventricular assist device	
Cardiopulmonary Circulation	Mar. 23, 2022	-	33	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7	The device is an implantable ventricular assist device system 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 application was submitted to add a raw material of an outflow graft with bend relief, etc. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 111 days Regulatory review time: 91 days	No clinical study results				Implantable ventricular assist device	
Cardiopulmonary Circulation	Mar. 28, 2022	Feb. 12, 2021	34	IVL Generator (Shockwave Medical, Inc.)	Approval	Instrument & apparatus 29	A generator used to disrupt severely calcified <i>de novo</i> coronary artery lesions. As clinical evaluation data, the results of foreign clinical studies and Japanese studies were submitted.
	Total review time: 363 days Regulatory review time: 162 days	Foreign and Japanese clinical study results				Driving unit for angioplasty atherectomy catheter	
Cardiopulmonary Circulation	Mar. 28, 2022	Feb. 12, 2021	35	C ² Coronary IVL Catheter (Shockwave Medical, Inc.)	Approval	Instrument & apparatus 51	A catheter used to disrupt severely calcified <i>de novo</i> coronary artery lesions. As clinical evaluation data, the results of foreign clinical studies and Japanese studies were submitted.
	Total review time: 363 days Regulatory review time: 156 days	Foreign and Japanese clinical study results				Atherectomy ablative angioplasty catheter	

Improved Medical Devices (With Clinical Data) Approved in FY 2021

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Robotics, IoT, and other devices (not classified as other categories)	Apr. 21, 2021	Jun. 12, 2020	1	FreeStyle Libre 2 (Abbott Japan LLC)	Approval	Instrument & apparatus 20	The application was submitted for marketing approval of a glucose monitor system that continuously measures glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen.
		Foreign clinical study results				Glucose monitor system	
Robotics, IoT, and other devices (not classified as other categories)	Sep. 17, 2021	Sep. 1, 2020	2	Medtronic MiniMed 700 Series (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 74	The application was submitted for marketing approval of a glucose monitoring system used for continuous subcutaneous infusion of basal insulin at a selectable rate and bolus infusion of insulin at a selectable dose.
		Foreign clinical study results				Portable insulin infusion pump	
Robotics, IoT, and other devices (not classified as other categories)	Oct. 27, 2021	-	3	Octopal R Pulse Oximeter DMO-8000 (Nihon Kohden Corporation)	Approval	Instrument & apparatus 21	This application was submitted for marketing approval of a pulse oximeter that has a function of measuring patients' vital signs (percutaneous arterial oxygen saturation, carboxyhemoglobin concentration, methemoglobin concentration, and pulse rate), displaying them on the screen, and issuing an alarm.
		Foreign clinical study results				Pulse oximeter	
Robotics, IoT, and other devices (not classified as other categories)	Oct. 28, 2021	Oct. 26, 2012 Cyberknife M6 System	4	CyberKnife M6 Series (Accuray Japan K.K.)	Change	Instrument & apparatus 9	A cyber knife intended to be used for non-incisional surgery with high-energy X-ray stereotactic irradiation through the acquisition of a treatment plan and images of lesions requiring radiotherapy, such as head and neck (including intracranial region), cerebral arteriovenous malformation, and arteriovenous malformation of trunk and spinal cord. The application was submitted to add trigeminal neuralgia whose pain is difficult to control with drug therapy to the indication of this product (A "partial change" application). There is no change in the specifications, and change and addition of components of this product in this application.
		Clinical evaluation report				Stereotactic radiotherapy accelerator system	
Robotics, IoT, and other devices (not classified as other categories)	Oct. 28, 2021	Jul. 14, 1999 CyberKnife Radiosurgery System	5	CyberKnife Radiosurgery System (Accuray Japan K.K.)	Change	Instrument & apparatus 9	A cyber knife intended to be used for non-incisional surgery with high-energy X-ray stereotactic irradiation through the acquisition of a treatment plan and images of lesions requiring radiotherapy, such as head and neck (including intracranial region), cerebral arteriovenous malformation, and arteriovenous malformation of trunk and spinal cord. The application was submitted to add trigeminal neuralgia whose pain is difficult to control with drug therapy to the indication of this product (A "partial change" application). There is no change in the specifications, and change and addition of components of this product in this application.
		Clinical evaluation report				Stereotactic radiotherapy accelerator system	

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Robotics, IoT, and other devices (not classified as other categories)	Jan. 7, 2022	Nov. 16, 2018 K180881/HemoSphere advanced monitor, hemoSphere pressure cable May 21, 2019 K183646/Acumen hypotension prediction index-EV1000 clinical platform, Acumen hypotension prediction index-hemosphere advanced monitoring platform, Acumen hypotension prediction index-hemosphere advanced monitoring platform-pressure Aug. 29, 2019 K190205/HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module Number of units shipped (total): Approximately 2500 units	6	Acumen HPI System (Edwards Lifesciences Limited)	Approval	Instrument & apparatus 21	The application was submitted for marketing approval of a multiparameter monitor to measure hemodynamics such as thermodilution cardiac output and arterial pressure-based cardiac output and to collect and monitor various biological information.
	Total review time: 266 days Regulatory review time: 201 days	Foreign clinical study results				Multiparameter monitor	
Robotics, IoT, and other devices (not classified as other categories)	Jan. 20, 2022	None	7	ait (Peace of Mind Co., Ltd.)	Approval	Instrument & apparatus 12	The application was submitted for marketing approval of an alternating magnetic field therapy device used to relieve pain by transcutaneously irradiating 2 types of alternating magnetic fields and stimulating the nerves.
	Total review time: 269 days Regulatory review time: 225 days	Japanese clinical study results				Alternating magnetic field therapy device	
Orthopedic and Plastic Surgery	Jun. 16, 2021	-	8	TNS Alloy Stem (Mizuho Corporation)	Approval	Medical products 4	A femoral component for hip prosthesis used for total hip replacement or prosthesis replacement in patients with hip joint functional disorders including osteoarthritis, rheumatoid arthritis and necrosis of the femoral head. The product has only a direct fixation type of femoral stem, and is used with an approved stem head. The product is made from Ti-Nb-Sn alloy, and obtains elastic gradient from proximal to distal by thermal processing of the base material. The results of a Japanese clinical study designed as a single-arm, open-label, multicenter study were submitted to evaluate the improvement in JOA hip score after surgery as efficacy and malfunctions and adverse events as safety.
	Total review time: 266 days Regulatory review time: 147 days	Japanese clinical study results				Femoral component for hip prosthesis	
Orthopedic and Plastic Surgery	Dec. 13, 2021	-	9	Motiva Breast Implants (Establishment Labs S.A.)	Approval	Medical products 4	A gel-filled mammary prosthesis 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 SmoothSilk Series implant and SmoothSilk Ergonomix Series implant as components, both of which are round in shape and have a smooth surface finish. A clinical evaluation report consisting of data related to foreign clinical study and clinical publications was submitted to prove there are not unacceptable risks of product-specific adverse events.
	Total review time: 269 days Regulatory review time: 124 days	Clinical evaluation report				Gel-filled mammary prosthesis	
Orthopedic and Plastic Surgery	Feb. 10, 2022	Jul. 15, 2015	10	Phototherapy Device for Pigmentary Skin Disease Nordlys (Syneron Candela K.K.)	Approval	Instrument & apparatus 12	A phototherapy device for skin diseases used to treat benign superficial skin pigmentary disease by thermal action of continuous spectral light from visible to infrared rays using intense pulsed light. A clinical evaluation report summarizing clinical literatures, etc. on the previous generation product of this device and similar products of other companies was submitted to evaluate the improvement effect on pigmentary disease and the acceptability of anticipated adverse events for the efficacy.
	Total review time: 182 days Regulatory review time: 144 days	Clinical evaluation report				Phototherapy device for skin diseases	

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. 14, 2022	Mar. 26, 2014 REGENETEN Implant Jul. 12, 2013 Tendon Staple Aug. 29, 2013 Bone Staple, Staple Delivery Set Dec. 22, 2011 Tendon Marker Dec. 22, 2011 Tendon Guide	11	REGENETEN Implant (Smith & Nephew KK)	Approval	Medical products 4	A collagen containing absorbable tendon regeneration material that manages and protects tendons with oriented collagen fibers that act as a scaffold for tendon tissue, in order to promote repair of a cuff injury site without substantial loss of tissue. A clinical evaluation report organizing the results of non-GCP-compliant foreign clinical studies and clinical literatures, etc. was submitted to evaluate the facts that this product contributes to the repair of the cuff such as a tendency towards increased tendon thickness and that the risks associated with the use of this product are acceptable for the efficacy.
	Total review time: 391 days Regulatory review time: 183 days	Clinical evaluation report				Collagen-containing absorbable tendon regeneration material	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 23, 2021	May 4, 2020	12	TREGO Abdominal Stent Graft System (Terumo Corporation)	Approval	Instrument & apparatus 7	An aortic stent graft indicated for the intravascular treatment of infrarenal abdominal aortic aneurysm that satisfies the specific anatomical conditions. The results of a single-arm clinical study conducted in the US were submitted to evaluate the efficacy and safety of the product.
	Total review time: 263 days Regulatory review time: 118 days	Foreign clinical study results				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 2, 2021	-	13	LUNAWAVE (Terumo Corporation)	Change	Instrument & apparatus 12	An optical coherence tomography (OCT) imaging system to perform intravascular optical coherence tomography (OCT), connected to the dedicated intravascular optical tomographic catheter, "FastView" (Approval No.: 22500BZX00057000). The application was submitted to add an indication for the arteries of the lower limb in addition to the current indication for the coronary arteries.
	Total review time: 187 days Regulatory review time: 115 days	Japanese clinical study results				Optical coherence tomography (OCT) imaging system	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 2, 2021	-	14	FastView (Terumo Corporation)	Change	Instrument & apparatus 51	An intravascular optical tomographic catheter to perform intravascular optical coherence tomography (OCT), connected to the dedicated OCT imaging system, "LUNAWAVE" (Approval No.: 22500BZX00058000). The application was submitted to add an indication for the arteries of the lower limb in addition to the current indication for the coronary arteries.
	Total review time: 187 days Regulatory review time: 109 days	Japanese clinical study results				Intravascular optical tomographic catheter	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 28, 2021	May 4, 2015 ERBECRYO2/K151041	15	ERBE CRYO2 (Amco Inc.)	Change	Instrument & apparatus 31	A cryosurgery unit used for tissue biopsy or removal of foreign matters by cooling/freezing the bronchus, bronchial peripheral tissues, or foreign matters in the bronchus by touching with the probe tip cooled by high-pressure carbon dioxide. The application was submitted to add removal of airway obstruction in patients in whom a tumor obstructs the central airway and who require immediate airway securing to the intended use (A "partial change" application).
	Total review time: 255 days Regulatory review time: 61 days	Clinical evaluation report				Versatile cryosurgical unit	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 29, 2021	-	16	RelayPro Thoracic Stent Graft System (Terumo Corporation)	Approval	Instrument & apparatus 7	The application was submitted for marketing approval of an arterial stent graft used for the endovascular treatment of descending thoracic aortic aneurysm. The product was designed based on the company's approved product "Relay Plus Thoracic Stent Graft System" (Approval No. 22500BZX00160000) and for which different stent graft types were added and the delivery system was improved. The results of physicochemical characterization tests, biological safety test, durability test, animal test, and clinical studies were submitted to secure the application content.
	Total review time: 301 days Regulatory review time: 201 days	Global clinical study results				Aortic stent graft	

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	Nov. 30, 2021	-	17	Wire for Lymphatic Vessels (TRS Co., Ltd.)	Approval	Instrument & apparatus 51	The application was submitted for marketing approval of a non-vascular guidewire used to be inserted into the lymphatic vessels to confirm their courses, locations, etc. in lymphatic-venous anastomosis for treatment of lymphoedema. A clinical evaluation report summarizing literatures, etc. on lymphatic-venous anastomosis at the sites where this product is expected to be used was submitted.
	Total review time: 179 days Regulatory review time: 125 days	Clinical evaluation report				Non-vascular guidewire	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 2, 2022	-	18	Histoacryl (B. Braun Aesculap Japan Co., Ltd.)	Change	Instrument & apparatus 51	The application was submitted to add the indication regarding vascular embolization for hemostasis, prevention of bleeding, alleviation of symptoms, etc. (A "partial change" application). A clinical evaluation report summarizing the contents of Japanese and foreign literatures, etc. was submitted to evaluate the efficacy and safety of the product.
	Total review time: 485 days Regulatory review time: 145 days	Clinical evaluation report				Central circulatory intravascular embolization prosthesis	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 2, 2022	-	19	NEOVEIL (GUNZE LIMITED)	Change	Medical products 4	The application was submitted to add reinforcement of defective and fragile parts in organs/tissue, and prevent of air leakage. (A "partial change" application). A clinical evaluation report summarizing literatures, etc. related to the results of use of this product in defective and fragile parts in organs and tissue was submitted.
	Total review time: 243 days Regulatory review time: 106 days	Clinical evaluation report				Absorbable tissue reinforcement material	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 28, 2022	Dec. 22, 2020 PMA approved/GORE EXCLUDER Conformable AAA Endoprosthesis	20	GORE Excluder Conformable AAA Stent Graft System (W. L. Gore & Associates G.K.)	Approval	Instrument & apparatus 7	An aortic stent graft used for the intravascular treatment of infrarenal abdominal aortic aneurysm (including aneurysms extending from the abdominal aorta to the iliac artery) that satisfies the specific anatomical requirements. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
	Total review time: 364 days Regulatory review time: 144 days	Foreign clinical study results				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 28, 2022	-	21	EIT Monitor PulmoVista 500 (Dräger Japan Ltd.)	Approval	Instrument & apparatus 21	The application was submitted for marketing approval of a respiratory function measuring system which displays information on changes in lung volume and local distribution in the internal electrode surface by measuring the biological impedance distribution in the chest using electric impedance tomography technology. This product displays the tomographic image data related to impedance changes in real time and analyzes the data.
	Total review time: 238 days Regulatory review time: 83 days	Foreign clinical study results				Respiratory function measuring system	
Gastroenterology, Genitourinary and Reproductive Medicine	May 26, 2021	Nov. 22, 2011	22	RENASYS Abdominal Kit (Smith & Nephew KK)	Approval	Medical products 4	The application was submitted for marketing approval of a dressing kit intended to facilitate early closure of the peritoneum. The product provides the protection of abdominal contents from external environment, efficient drainage, suppression of inflammation, and alleviation of edema by covering the organs inside the abdomen and applying controlled negative pressure in the case where open abdominal wounds are accompanied by exposure of abdominal organs and also abdominal closure by primary suture is difficult. The product consists of an organ protective layer, form filler, drape, and soft port. An approved product, "RENASYS Wound Therapy System" is used in combination with the product for negative pressure control.
	Total review time: 321 days Regulatory review time: 167 days	Clinical evaluation report				Open abdominal wound dressing kit	
Gastroenterology, Genitourinary, and Reproductive Medicine	Oct. 27, 2021	-	23	Tenaleaf (GUNZE LIMITED)	Approval	Medical products 4	A sheet-type absorbable adhesion-prevention dressing to reduce the frequency, extent, and severity of postoperative adhesions in patients undergoing surgery of abdominal or pelvic cavity. The product becomes gel by absorbing water in the damaged site or abdominal cavity, prevents formation of fibrin networks in the damaged site and surrounding tissues as a physical barrier, and exerts an adhesion-reducing effect.
	Total review time: 245 days Regulatory review time: 147 days	Japanese clinical study results				Absorbable adhesion-prevention dressing	

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
Gastroenterology, Genitourinary, and Reproductive Medicine	Dec. 24, 2021	-	24	Cool-tip RFA System E Series (Covidien Japan Inc.)	Change	Instrument & apparatus 29	A radiofrequency ablation system used for coagulating and ablating tissues. The application was submitted to add the followings to the intended use of this product: "small-diameter renal malignant tumor," "malignant bone tumor," "osteoid osteoma," "pelvic malignant tumor," and "soft tissue tumors that developed in the extremities, thoracic cavity, and abdominal cavity" that are ineligible for or refractory to standard therapy (A "partial change" application). A clinical evaluation report based on Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the product.
	Total review time: 228 days Regulatory review time: 118 days	Clinical evaluation report				Radiofrequency ablation system	
Dentistry and Oral Medicine	Jul. 14, 2021	-	25	Opalescence GO (ULTRADENT PRODUCTS, INC.)	Approval	Instrument & apparatus 62	A drug-containing dental tooth surface cleaner auxiliary material whose ready-made tray is pre- filled with 6% hydrogen peroxide. This product is used by patients on their teeth at home, etc., under the management of a dentist. The results of a Japanese clinical study designed as a multicenter, open-label controlled study were submitted to evaluate the efficacy and safety of the product.
	Total review time: 226 days Regulatory review time: 161 days	Japanese clinical study results				Drug-containing dental tooth surface cleaner auxiliary material	
Ophthalmology and Otorhinolaryngology	May 11, 2021	Jun. 2, 2020	26	Bausch & Lomb Aqualox One Day UV Shin (Bausch & Lomb Japan Co., Ltd.)	Approval	Instrument & apparatus 72	The application was submitted for marketing approval of daily wear, single-use colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (kalifilcon A) with a moisture content of 55% and an oxygen permeability (Dk) of 107×10^{-11} (cm ² /sec)·(mLO ₂ /[mL x mmHg]).
	Total review time: 242 days Regulatory review time: 189 days	Foreign clinical study results				Single-use colored vision corrective contact lens	
Ophthalmology and Otorhinolaryngology	Jun. 11, 2021	-	27	2 Week Fresh View S (Rohto Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 72	The application was submitted for marketing approval of daily wear, reusable colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (toufilcon B) with a moisture content of 50% and an oxygen permeability (Dk) of 91×10^{-11} (cm ² /sec)·(mLO ₂ /[mL x mmHg]).
	Total review time: 248 days Regulatory review time: 163 days	Japanese clinical study results				Reusable colored vision corrective contact lens	
Ophthalmology and Otorhinolaryngology	Oct. 14, 2021	-	28	1day SD01H-S (SEED Co., Ltd.)	Approval	Instrument & apparatus 72	The application was submitted for marketing approval of daily wear, single-use colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel with a water content of 68% and an oxygen permeability (Dk) of 60×10^{-11} (cm ² /sec)·(mLO ₂ /[mL x mmHg]).
	Total review time: 269 days Regulatory review time: 129 days	Japanese clinical study results				Single-use colored vision corrective contact lens	
Ophthalmology and Otorhinolaryngology	Dec. 17, 2021	Dec. 31, 2013	29	Nasaleze (Nasaleze Limited)	Approval	Medical products 4	The application was submitted for marketing approval of a home-use nasal mucosal protector used for alleviation of symptoms associated with allergic rhinitis (sneezing, runny nose, and stuffy nose).
	Total review time: 267 days Regulatory review time: 135 days	Clinical evaluation report				Home-use nasal mucosal protector	
Ophthalmology and Otorhinolaryngology	Dec. 20, 2021	-	30	Total 14 (Alcon Japan Ltd.)	Approval	Instrument & apparatus 72	The application was submitted for marketing approval of daily wear, reusable colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (Lehfilcon A) with a moisture content of 55% and an oxygen permeability (Dk) of 123×10^{-11} (cm ² /sec)·(mLO ₂ /[mL x mmHg]).
	Total review time: 264 days Regulatory review time: 190 days	Foreign clinical study results				Reusable colored vision corrective contact lens	

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	Feb. 24, 2022	-	31	Preserflo MicroShunt Glaucoma Drainage System Core Kit (Santen Pharmaceutical Co., Ltd.)	Approval	Medical products 4	The application was submitted for marketing approval of an intraocular drain used to reduce intraocular pressure in patients with glaucoma whose intraocular pressure can not be sufficiently reduced by treatments including drug and laser therapies.
	Total review time: 269 days Regulatory review time: 114 days	Foreign clinical study results				Intraocular drain	
Cardiopulmonary Circulation	Apr. 27, 2021	May 30, 2008 K063727/IMPELLA 2.5 Apr. 15, 2009 K083111/IMPELLA 5.0 Sep. 6, 2012 K112892/IMPELLA CP Mar. 22, 2018 P140003_S026/IMPELLA CP SmartAssist (CP-Op)	32	Impella Circulatory Assist Pump Catheter (Abiomed, Inc.)	Change	Instrument & apparatus 51	A catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through femoral artery or axillary/subclavian artery and placed in the left ventricle. This device removes blood directly from the left ventricle and sends the blood from the catheter into the ascending aorta. The application was submitted to add a procedure for inserting the device through the axillary/subclavian artery as a part of the usage of the product, a model in which the shape and raw material of the pigtail at the tip of the Impella CP and CP-Op were changed, and a raw material of the lure connector on the branch connector line in the set for purge. A clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted to evaluate the safety of the procedure for inserting the device through the axillary/subclavian artery.
	Total review time: 270 days Regulatory review time: 155 days	Clinical evaluation report				Controler for temporary non-roller type cardiac support blood pump	
Cardiopulmonary Circulation	Jun. 17, 2021	May 28, 2019	33	GORE Cardioform ASD Occluder (W. L. Gore & Associates G.K.)	Approval	Medical products 4	An artificial pericardial prosthesis used to percutaneously close ostium secundum atrial septal defect. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
	Total review time: 261 days Regulatory review time: 103 days	Foreign clinical study results				Artificial pericardial prosthesis	
Cardiopulmonary Circulation	Jul. 21, 2021	-	34	POLARx Cryoablation Balloon Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51	A balloon catheter used for cryoablation of cardiac tissue in the treatment of drug-refractory, recurrent, symptomatic, paroxysmal atrial fibrillation. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product.
	Total review time: 250 days Regulatory review time: 102 days	Foreign clinical study results				Catheter for cardiac ablation	
Cardiopulmonary Circulation	Aug. 26, 2021	Jan. 28, 2021	35	DiamondTemp Ablation Catheter (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 51	An electrode catheter to be used for conducting cardiac electrophysiological mapping, and percutaneous cardiac ablation with high-frequency current for the treatment of patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation and common type atrial flutter. The results of foreign clinical studies were submitted as clinical evaluation data .
	Total review time: 269 days Regulatory review time: 175 days	Foreign clinical study results				Catheter for cardiac ablation	
Cardiopulmonary Circulation	Oct. 5, 2021	-	36	Ultimaster Nagomi (Terumo Corporation)	Approval	Instrument & apparatus 7	A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo native coronary artery lesions (a lesion length of 45 mm or less) with a reference vessel diameter of 2.25-4.0 mm, and a delivery catheter used to implant a stent to the target lesion. The results from a subgroup analysis of global clinical study data using the previous generation product of this product "Ultimaster" (Approval No.: 22700BZX00224000) were submitted to evaluate the efficacy and safety of this product.
	Total review time: 256 days Regulatory review time: 181 days	Global clinical study results				Coronary stent	

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	Oct. 21, 2021	-	37	SATAKE HotBalloon Catheter (Toray Industries, Inc.)	Change	Instrument & apparatus 51	A balloon ablation catheter utilizing a high frequency current. The application was submitted to add drug-resistant recurrent symptomatic persistent atrial fibrillation to the conventional intended use (drug-resistant recurrent symptomatic paroxysmal atrial fibrillation) (A "partial change" approval application). A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to secure the application content.
	Total review time: 262 days Regulatory review time: 224 days	Clinical evaluation report				Catheter for cardiac ablation	
Cardiopulmonary Circulation	Nov. 22, 2021	Sep. 24, 2019 None/IMPELLA 5.5	38	Impella 5.5 SmartAssist (Abiomed, Inc.)	Approval	Instrument & apparatus 51	A catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through axillary/subclavian artery and placed in the left ventricle. This device removes blood directly from the left ventricle and sends the blood from the catheter into the ascending aorta. The product is concomitantly used with a dedicated driving device "Impella Controller" (Approval No.: 22800BZX00031000). This product was developed with the aim of limiting the insertion site to the axillary/subclavian artery according to the clinical needs, increasing the circulatory support flow, and reducing the size of the catheter pump based on the approved "Impella Circulatory Assist Pump Catheter" (Approval No.: 228000BZI00032000). A clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted as the data for clinical evaluation of the product.
	Total review time: 270 days Regulatory review time: 139 days	Clinical evaluation report				Controler for temporary non- roller type cardiac support blood pump	
Cardiopulmonary Circulation	Jan. 25, 2022	Mar. 11, 2022	39	XIENCE Skypoint Drug-Eluting Coronary Stent System (Abbott Medical Japan LLC.)	Change	Instrument & apparatus 7	A stent system consisting of an everolimus- eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-5.25 mm, and a delivery catheter used to implant the stent to the site of stenosis. The application was submitted to add stent sizes of 4.50 mm and 5.00 mm in diameter (A "partial change" application). As clinical evaluation data, the results of foreign clinical studies were submitted.
	Total review time: 147 days Regulatory review time: 100 days	Foreign clinical study results				Coronary stent	
Cardiopulmonary Circulation	Feb. 15, 2022	Apr. 28, 2017 Number unknown/Resolute Onyx Zotarolimus-Eluting Coronary Stent System	40	Resolute Onyx Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A drug-eluting stent system used for the treatment of patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 35 mm or less) with a reference vessel diameter of 2.25-4.2 mm. The application was submitted to expand the maximum diameter of a stent by 0.25 mm, extend the shelf life, and add results of the clinical study in which the period of dual antiplatelet therapy (DAPT) after the implantation of this product was set for 1 month to the Clinical Studies section of the package insert (A "partial change" application). The results of a global clinical study were submitted as clinical evaluation data.
	Total review time: 251 days Regulatory review time: 125 days	Global clinical study results				Coronary stent	
Cardiopulmonary Circulation	Feb. 15, 2022	Apr. 28, 2017 Number unknown/Resolute Onyx Zotarolimus-Eluting Coronary Stent System	41	Resolute Onyx SV Coronary Stent System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A drug-eluting stent system used for the treatment of patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 27 mm or less) that have a reference vessel diameter of 2.0-2.25 mm and are considered as dissection of the blood vessel or acute or impending coronary occlusion associated with angioplasty. The application was submitted to expand the maximum diameter of a stent by 0.25 mm, extend the shelf life, and add results of the clinical study in which the period of dual antiplatelet therapy (DAPT) after the implantation of this product was set for 1 month to the Clinical Studies section of the package insert (A "partial change" application). The results of a global clinical study were submitted as clinical evaluation data.
	Total review time: 251 days Regulatory review time: 125 days	Global clinical study results				Coronary stent	

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	Feb. 24, 2022	Nov. 4, 2021	42	TactiCath SE Irrigation Catheter (Abbott Medical Japan LLC.)	Change	Instrument & apparatus 51	An electrode catheter to be used for conducting cardiac electrophysiological mapping, and percutaneous catheter ablation with high-frequency current. The application was submitted to add the treatment of drug-resistant symptomatic persistent atrial fibrillation to the conventional intended use (treatment of drug-resistant symptomatic paroxysmal atrial fibrillation and common atrial flutter) (A "partial change" application). As clinical evaluation data, the results of foreign clinical studies were submitted.
	Total review time: 239 days Regulatory review time: 113 days	Foreign clinical study results				Catheter for cardiac ablation	
Cardiopulmonary Circulation	Mar. 31, 2022	-	43	BioFreedom Ultra Drug-coated Stent (Biosensors Japan Co., Ltd.)	Approval	Instrument & apparatus 7	A stent system consisting of a biolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary artery lesion (a lesion length of 33 mm or less) with a reference vessel diameter of 2.5-4.0 mm and a delivery catheter used to implant the stent to the site of stenosis. As clinical evaluation data, the results of foreign clinical studies were submitted.
	Total review time: 489 days Regulatory review time: 147 days	Foreign clinical study results				Coronary stent	
Program	May 26, 2021	-	44	COVID-19 Pneumonia Image Analysis Program FS-AI693 (FUJIFILM Corporation)	Approval	Program 1	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.
	Total review time: 65 days Regulatory review time: 35 days	Clinical evaluation report				Software for general-purpose imaging system workstation	
Program	Dec. 24, 2021	-	45	HOPE LifeMark-CAD Pneumonia Image Analysis Program for COVID-19 (Fujitsu Japan Limited)	Approval	Program 1	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.
	Total review time: 60 days Regulatory review time: 44 days	Clinical evaluation report				Software for diagnostic X-ray imaging system workstation	

Reprocessed Single-Use Medical Devices Approved in FY2021

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
Robotics, IoT, and other devices (not classified as other categories)	Sep. 17, 2021	-	1	Reprocessed Flowtron ACS900 (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 12	Reprocessed single-use medical device originating from the component of "Flowtron ACS900" (Certification No.: 228ADBZX00013000), which is a cuff for a pneumatically-powered massager used to prevent venous thrombosis by promoting venous blood circulation. The application was submitted to add a collection container of the original medical device and change the manufacturing site (A "partial change" application).
	Total review time: 171 days Regulatory review time: 155 days	No clinical study results				Reprocessed cuff for pneumatically-powered massager	
Robotics, IoT, and other devices (not classified as other categories)	Dec. 24, 2021	-	2	Reprocessed cuff C (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 12	Reprocessed single-use medical device originating from the component of "SCD 700 Series" (Certification No.: 223AABZX00029000), which is a cuff for a pneumatically-powered massager used to prevent venous thrombosis by promoting venous blood circulation.
	Total review time: 267 days Regulatory review time: 231 days	No clinical study results				Reprocessed cuff for pneumatically-powered massager	
Gastroenterology, Genitourinary and Reproductive Medicine	Aug. 26, 2021	-	3	Reprocessed V-pipe (HOGY) (HOGY MEDICAL CO., LTD.)	Change	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. The application was submitted to extend the storage period before cleansing (A "partial change" application).
	Total review time: 217 days Regulatory review time: 171 days	No clinical study results				Reprocessed single-use natural orifices endoscopic dilator	
Gastroenterology, Genitourinary and Reproductive Medicine	Aug. 26, 2021	-	4	Reprocessed Trocar E (HOGY) (HOGY MEDICAL CO., LTD.)	Change	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 application was submitted to extend the storage period before cleansing (A "partial change" application).
	Total review time: 150 days Regulatory review time: 113 days	No clinical study results				Reprocessed single-use trocar sleeve	

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“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
Robotics, IoT, and other devices (not classified as other categories)	Mainly innovative medical devices utilizing robotics and advanced IoT 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.