New Medical Devices Approved in FY2023

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	Nov. 2, 2023 Total review time: 335 days Regulatory review time: 310 days	— No clinical study results	1	EpiFix (MiMedx Group, Inc.)	Change	Medical products 4 Healing promoting material using human amnion	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 amniotic/chorionic membrane-derived extracellular matrix proteins, growth factors, cytokines, etc. The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 29, 2023 Total review time: 53 days Regulatory review time: 39 days	- No clinical study results	2	Jetstream Atherectomy System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 51 Atherectomy ablative angioplasty catheter	An atherectomy ablative angioplasty catheter that is percutaneously inserted into the peripheral blood vessel to cut, crush, and suck the lesion by rotating the tip of the catheter. The application was submitted to add a raw material of the catheter (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 7, 2023 Total review time: 261 days Regulatory review time: 116 days	Jun. 24, 2020 P960009/S361/Percept PC Clinical evaluation report	3	Medtronic Percept PC (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 12 Tremor brain electrical stimulator	An implantable stimulator for deep brain stimulation (DBS) used to improve motor disorders by applying an electrical stimulation to the deep brain. The application was submitted to add an indication for the reduction of focal epileptic seizures in drug-resistant epilepsy by stimulating the anterior nucleus of thalamus (ANT) (A “partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 11, 2023 Total review time: 116 days Regulatory review time: 52 days	Dec. 2019 No description/Flow Re-Direction Endoluminal Device (FRED) system No clinical study results	4	FRED System (Terumo Corporation)	Change	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	FRED System is a flow diverter system intended to be used to occlude intracranial aneurysms (including fusiform aneurysm) 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 the petrous segment of the internal carotid artery to the proximal regions of the middle cerebral artery and anterior cerebral artery, and in basilar and vertebral arteries, except for acute phase ruptured aneurysms. The application was submitted to add the fixation points of the inner layer and outer layer to the edge of the stent (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 16, 2023 Total review time: 33 days Regulatory review time: 28 days	— No clinical study results	5	Woven EndoBridge Device (Terumo Corporation)	Change	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	A central circulatory intravascular embolization device intended to be used for endovascular treatment of wide-necked (defined the size as neck width 4 mm or greater or dome-to-neck ratio less than 2) bifurcation intracranial aneurysms located in anterior or posterior circulation. The application was submitted to add electron beam sterilization method (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 4, 2023 Total review time: 350 days Regulatory review time: 126 days	Feb. 16, 2017 original 510k: K163549/ClotTriever Thrombectomy System Sep. 9, 2020 K193462/ClotTriever Thrombectomy System Foreign clinical study results	6	ClotTriever Thrombectomy System (Inari Medical, Inc.)	Approval	Instrument & apparatus 51 Catheter for non-central circulatory embolectomy	A catheter for non-central circulatory embolectomy used to restart blood flow in patients with deep vein thrombosis with severe acute symptoms excluding post-thrombotic syndrome. The results of foreign clinical studies 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	Dec. 5, 2023	[Type 1] Dec. 2019 No description/Flow Re-Direction Endoluminal Device (FRED) system [Type 2] Sep. 2021 No description/Flow Re-Direction Endoluminal Device (FRED) system	7	FRED System (Terumo Corporation)	Change	Instrument & apparatus 51	FRED System is a flow diverter system intended to be used to occlude intracranial aneurysms (including fusiform aneurysm) 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 the petrous segment of the internal carotid artery to the proximal regions of the middle cerebral artery and anterior cerebral artery, and in basilar and vertebral arteries, except for acute phase ruptured aneurysms. The application was submitted to add a product type treated with surface processing using hemocompatible poly(2-methoxyethylacrylate) to the surface of the stent to improve operability (A “partial change” application).
	Total review time: 146 days Regulatory review time: 76 days	No clinical study results				Central circulatory intravascular embolization prosthesis	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 21, 2023	—	8	Toraymyxin (Toray Industries, Inc.)	Change	Instrument & apparatus 7	An endotoxin removal adsorption hemoperfusion column intended to selectively adsorb and remove disease agents, primarily blood endotoxins, by whole blood perfusion. This product has been approved as a device to improve disease state in patients with severe conditions caused by endotoxemia or suspected gram-negative bacterial infection (Approval No. 20500BZZ00926000). The application was submitted to add the indication for acute exacerbation of idiopathic pulmonary fibrosis utilizing the Conditional Early Approval System for Medical Devices (A “partial change” application).
	Total review time: 262 days Regulatory review time: 117 days	Clinical evaluation report				Endotoxin removal adsorption hemoperfusion column	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 22, 2023	Feb. 16, 2021	9	Relivion (Sawai Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 12	A transcutaneous electrical nerve stimulator for the head intended for the acute treatment of migraine with or without aura. The results of foreign clinical studies were submitted.
	Total review time: 360 days Regulatory review time: 208 days	Foreign clinical study results				Transcutaneous electrical nerve stimulator for the head	
Gastroenterology, Genitourinary and Reproductive Medicine	Jul. 7, 2023	Feb. 25, 2022	10	Cool-tip RFA System E Series (Covidien Japan Inc.)	Change	Instrument & apparatus 29	A radio-frequency ablation system used for coagulating and ablating tissues. The product has already been approved for the indications of "hepatic tumors and small-diameter renal malignant tumor," "blood flow blockage to an acardiac fetus of acardiac twins," and "pulmonary malignant tumor, malignant bone tumors, osteoid osteomas, 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." The application was submitted to add an indication of mammary tumors (single, localized, early breast cancer with a tumor diameter of 1.5 cm or less, free of axillary lymph node metastasis and distant metastasis by palpation and diagnostic imaging) (A “partial change” application).
	Total review time: 219 days Regulatory review time: 166 days	Japanese clinical study results				Radio-frequency ablation system	

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	Oct. 30, 2023 Total review time: 125 days Regulatory review time: 92 days	- Clinical evaluation report	11	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Cytapheresis column	A cytapheresis column to adsorb and remove leukocytes (mainly granulocytes) from the blood by extracorporeal circulation. The product has already been approved for indications for "remission induction in severe ulcerative colitis," etc. The application was submitted to add patients with refractory moderate ulcerative colitis to the indication for remission induction in ulcerative colitis. (A "partial change" application submitted during the post-market performance review period)
Gastroenterology, Genitourinary, and Reproductive Medicine	Mar. 29, 2024 Total review time: 99 days Regulatory review time: 81 days	Dec. 21, 2017 No clinical study results	12	AQUABEAM Robotic System (PROCEPT BioRobotics Corporation)	Change	Instrument & apparatus 12 Surgical robot unit	A device to resect and remove prostate tissues of male patients with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	May 8, 2023 Total review time: 199 days Regulatory review time: 148 days	Sep. 19, 2019 Foreign and Japanese clinical study results	13	Evolut PRO+ System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Transcatheter porcine pericardial valve	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 position of the aortic valve. The device has been approved for the indication of severe symptomatic native aortic stenosis or treatment in patients with symptomatic valvular disease due to dysfunction of a surgically placed bioprosthetic aortic valve who are not receiving chronic dialysis. The application was submitted to expand the indication for patients on chronic dialysis with these findings for whom surgery cannot be performed (A “partial change” application).
Cardiopulmonary Circulation	May 11, 2023 Total review time: 867 days Regulatory review time: 510 days	- Japanese clinical study results	14	Paravalvular Leak Closure Set (Japan Lifeline Co., Ltd.)	Approval	Medical products 4 Artificial pericardial prosthesis	A set consisting of an occluder, pusher, and loader intended to be used for percutaneous closure of a defect hole for prosthetic paravalvular regurgitation.
Cardiopulmonary Circulation	Jun. 12, 2023 Total review time: 56 days Regulatory review time: 56 days	- No clinical study results	15	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 to add a raw material, 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)
Cardiopulmonary Circulation	Jul. 11, 2023 Total review time: 169 days Regulatory review time: 142 days	- Japanese clinical study results	16	SYNFOLIUM (TEIJIN MEDICAL TECHNOLOGIES CO.,LTD.)	Approval	Instrument & apparatus 7 Synthetic cardiovascular patch	A synthetic cardiovascular patch used for correction of blood flow, securing blood flow paths, and generation/reconstruction of surrounding tissues in congenital cardiac surgery. The product has an integrated structure in which a knitted fabric composed of biodegradable synthetic polymer (poly-L-lactic acid yarn) and a non-biodegradable synthetic polymer (polyethylene terephthalate yarn) is coated with a crosslinked gelatin membrane.

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. 18, 2023 Total review time: 322 days Regulatory review time: 173 days	Sep. 14, 2022 Foreign clinical study results	17	PASCAL Precision System (Edwards Lifesciences Limited)	Approval	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 device is indicated for degenerative mitral regurgitation (DMR). The device consists of an implant system equipped with a clip and a guide sheath set that is used to deliver the implant system to the left atrium. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	Nov. 2, 2023 Total review time: 363 days Regulatory review time: 59 days	Oct. 16, 2020 No clinical study results	18	Perceval Bioprosthetic Valve (Corcym Canada Corp,)	Change	Instrument & apparatus 7 Bovine pericardium valve	A bioprosthetic valve primarily consisting of a bovine pericardium and a self-expandable metallic stent is used for replacing a diseased native aortic valve or malfunctioning prosthetic aortic valve. The application was submitted mainly to change dimensions of the XL size of the valve as well as treatment processes for phospholipid reduction and calcification inhibition of the valve and add accessory kits. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Dec. 22, 2023 Total review time: 322 days Regulatory review time: 229 days	— Foreign clinical study results	19	VARIPULSE Pulsed Field Ablation Catheter (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	A multielectrode catheter is used for conducting pulsed field ablation and cardiac electrophysiological mapping for the treatment of patients with drug-refractory symptomatic paroxysmal atrial fibrillation.
Cardiopulmonary Circulation	Dec. 22, 2023 Total review time: 322 days Regulatory review time: 231 days	— Foreign clinical study results	20	TRUPULSE Generator (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 29 Percutaneous cardiac coagulation/ ablation electrosurgical unit	A generator that delivers pulsed field ablation energy for percutaneous myocardial catheter ablation is used for the treatment of patients with tachyarrhythmia.
Cardiopulmonary Circulation	Feb. 6, 2024 Total review time: 221 days Regulatory review time: 182 days	— No clinical study results	21	Paravalvular Leak Closure Set (Japan Lifeline Co., Ltd.)	Change	Medical products 4 Artificial pericardial prosthesis	A device consisting of an occluder, pusher, and loader intended to be used for percutaneous closure of a defect hole for prosthetic paravalvular regurgitation. This application was submitted mainly to add a pistol pusher. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Feb. 13, 2024 Total review time: 231 days Regulatory review time: 179 days	Jun. 17, 2015 Clinical evaluation report	22	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a method to deliver a prosthetic valve via the common carotid artery, which is a route to be considered for patients for whom the valve cannot be delivered safely via the femoral artery. (A "partial change" application submitted during the post-market performance review period)
Cardiopulmonary Circulation	Mar. 5, 2024 Total review time: 151 days Regulatory review time: 118 days	— No clinical study results	23	Edwards SAPIEN 3 (Edwards Lifesciences Limited)	Change	Instrument & apparatus 7 Transcatheter bovine cardiac valve	A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add ISO80369-7 to the applicable standards of plural connectors included in the components of this product and to add raw materials for the introducer and loader. (A "partial change" application submitted during the post-market performance review period)

Improved Medical Devices (With Clinical Data) Approved in FY 2023

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. 25, 2023 Total review time: 120 days Regulatory review time: 70 days	- Clinical evaluation report	1	Automated Synthesizer for Radiopharmaceuticals Synthera+ (CMI Inc.)	Change	Instrument & apparatus 10 Radioactive compound synthesizing facilities	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound, fluorodeoxyglucose (18F) injection and florbetaben (18F) injection used for positron emission tomography, by remote control system. This application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease to the indications of florbetaben (18 F) injection (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Sep. 28, 2023 Total review time: 300 days Regulatory review time: 227 days	- Foreign clinical study results	2	Dexcom G7 CGM System (Dexcom, Inc.)	Approval	Instrument & apparatus 20 Glucose monitor system	The application was submitted for marketing approval of a continuous glucose monitoring system that continuously measures glucose levels in the interstitial fluid in people with diabetes mellitus and displays the trends and the patterns of glucose fluctuation. The product is used for assisting the detection of hyperglycemia and hypoglycemia and daily self-management by people with diabetes mellitus.
Robotics, IoT, and other devices (not classified as other categories)	Oct. 30, 2023 Total review time: 168 days Regulatory review time: 131 days	- Clinical evaluation report	3	Radioactive Pharmaceutical Synthesizer FASTlab (GE Healthcare Japan Corporation)	Change	Instrument & apparatus 10 Radioactive compound synthesizing facilities	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound injection by remote control system. The application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease (MCI due to AD) to the indications of flutemetamol (18F) injection (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Oct. 30, 2023 Total review time: 168 days Regulatory review time: 131 days	- Clinical evaluation report	4	Radioactive Pharmaceutical Synthesizer FASTlab 2 (GE Healthcare Japan Corporation)	Change	Instrument & apparatus 10 Radioactive compound synthesizing facilities	A radioactive pharmaceutical synthesizer used for the semi-automated preparation of a radioisotope labeled compound injection by remote control system. The application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease (MCI due to AD) to the indications of flutemetamol (18F) injection (A “partial change” application).
Robotics, IoT, and other devices (not classified as other categories)	Jan. 22, 2024 Total review time: 270 days Regulatory review time: 204 days	License date: May 2022 License No.: - Brand Name: FreeStyle Libre 3 Continuous Glucose Monitoring System Foreign clinical study results	5	FreeStyle Libre 3 (Abbott Japan LLC)	Approval	Instrument & apparatus 20 Glucose monitor system	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.
Robotics, IoT, and other devices (not classified as other categories)	Feb. 6, 2024 Total review time: 364 days Regulatory review time: 177 days	License date: Oct. 2017 License No.: K170840 Brand name: MAGNETOM Terra Clinical evaluation report	6	MAGNETOM Terra (Siemens Healthcare K.K.)	Approval	Instrument & apparatus 21 Superconducting magnet head/extremity imaging MRI system	The application was submitted for marketing approval of a superconducting magnet head/extremity imaging MRI system with a static magnetic field strength of 7T that performs computer processing magnetic resonance signals related to the patient's head or extremity and presents the reconstructed imaging for medical care purposes.
Orthopedic and Plastic Surgery	Jun. 12, 2023 Total review time: 252 days Regulatory review time: 175 days	Apr. --, 2004 K033801/KyphX HV-R Jul. --, 2004 K041584/KyphX HV-R Aug. --, 2010 K093828/KyphX HV-R Apr. --, 2015 K150460/KYPHON HV-R Aug. --, 2016 K160983/KYPHON HV-R May --, 2018 K180700/KYPHON HV-R Clinical evaluation report	7	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4 Orthopedic bone cement	An orthopedic bone cement used to restore the vertebral height of the fractured vertebral body and to relieve pain in patients with vertebral fracture due to osteoporosis, multiple myeloma, or metastatic bone tumor. The application was submitted to add the indication of simultaneous treatment of multiple vertebral bodies, to delete the indications restricted to primary osteoporosis and acute spinal compression fracture, and to add the indication for patients who are considered unlikely to respond to conservative therapy, in the case to use the medical device for vertebral fracture due to osteoporosis (A “partial change” application).

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Orthopedic and Plastic Surgery	Oct. 12, 2023 Total review time: 261 days Regulatory review time: 184 days	Jun. 9, 2005 Clinical evaluation report	8	Mendec Spine Bone Cement Kit (J-Sol Medical Co., Ltd.)	Change	Medical products 4 Orthopedic bone cement	An orthopedic bone cement used for percutaneous vertebroplasty and balloon kyphoplasty. The application was submitted to add the indication of simultaneous treatment of multiple vertebral bodies, to delate the indications restricted to primary osteoporosis and acute vertebral compression fractures, and to add the indication for patients who are considered unlikely to respond to conservative therapy, in the indications for osteoporosis for use in balloon kyphoplasty (A “partial change” approval application).
Orthopedic and Plastic Surgery	Feb. 15, 2024 Total review time: 290 days Regulatory review time: 252 days	Jul. 15, 2015 K150907/Ellipse Nordlys (with IPL and Nd: YAG hand pieces/applicators) Clinical evaluation report	9	Phototherapy Device for Skin Disease/Long-term Hair Reduction Nordlys (Syneron Candela K.K.)	Change	Instrument & apparatus 12 Phototherapy device for skin disease	A phototherapy device for skin diseases used to treat superficial skin benign pigmentary diseases, improve superficial telangiectasia symptoms in benign cutaneous vascular lesions, and achieve long-term hair reduction by thermal action of continuous spectral light from visible to infrared rays contained in intense pulse light. The application was submitted to add the long-term hair reduction to the indication of the product (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 3, 2023 Total review time: 264 days Regulatory review time: 116 days	Nov. 27, 2018 ー/VASCADE MVP® Venous Vascular Closure System Foreign clinical study results	10	VASCADE MVP (Haemonetics Japan G.K.)	Approval	Medical products 4 Absorbable topical hemostatic material with collagen	The application was submitted for marketing approval of an absorbable topical hemostatic material with collagen used for hemostasis at the femoral venous access site following percutaneous catheterization. As clinical evaluation data, the results of foreign clinical studies were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 20, 2023 Total review time: 115 days Regulatory review time: 50 days	Sep. 2012 K121917/CAT/SEP 3 & 5 May 2015 K142870/CAT/SEP 6 & 8 Jul. 2016 K161523/CAT/SEP 6 & 8 May 2018 K180939/Aspiration Tubing Clinical evaluation report	11	INDIGO System (Penumbra, Inc.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	The application was submitted for marketing approval of catheter for central circulatory embolectomy used to aspirate thrombus from a peripheral artery or vein. A clinical evaluation report summarizing foreign clinical studies and the contents of foreign literatures was submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 25, 2023 Total review time: 207 days Regulatory review time: 119 days	- Japanese clinical study results	12	Envi-SR Retriever for Mechanical Thrombectomy (NeuroVasc Technologies, Inc.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy intended for use to restore blood flow in patients with acute ischemic stroke in whom intravenous tissue plasminogen activator (tPA) therapy is not indicated or fails to achieve reperfusion. As clinical evaluation data, the results of clinical studies conducted in Japan were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 8, 2023 Total review time: 269 days Regulatory review time: 156 days	Jun. 15, 2004 K040835/XenoSure Bioligic Patch Clinical evaluation report	13	Bovine Pericardium Patch XenoSure (LeMaitre Vascular G.K.)	Change	Instrument & apparatus 7 Bovine pericardial patch	A bovine pericardial patch used for repair or procedure of femoral artery, femoral vein, and carotid artery. The application was submitted to add an indication for carotid artery (A “partial change” application). The clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 29, 2023 Total review time: 320 days Regulatory review time: 194 days	Apr. 2022 −/Thoraflex Hybrid Foreign clinical study results	14	Thoraflex Hybrid (Terumo Corporation)	Approval	Instrument & apparatus 7 Aortic stent graft	An aortic stent graft and gelatin coated vascular graft used for surgical repair in patients with aneurysms or dissections of the aortic arch and descending aorta. The aortic stent graft and gelatin coated vascular graft are sutured and integrated in advance for the purpose of simplifying the procedure. The results of foreign clinical studies were submitted as clinical evaluation data.

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 25, 2023 Total review time: 277 days Regulatory review time: 81 days	Mar. 23, 2021 K203592/Tigertriever Mar. 23, 2021 K203592/Tigertriever 17 Foreign clinical study results	15	Tigertriever Thrombectomy Device (Rapid Medical Ltd.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy that is intended for use to restore blood flow by removing clots from the intracranial blood vessel in patients with acute ischemic stroke (in principle, within 8 hours from the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with the t-PA therapy. The results of foreign clinical studies were submitted as clinical evaluation data.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 10, 2023 Total review time: 221 days Regulatory review time: 78 days	Jul. 13, 2018 P170024/Surpass Evolve Flow Diverter Foreign clinical study results	16	Surpass Evolve Flow Diverter System (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	The application was submitted for marketing approval of 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).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 15, 2023 Total review time: 259 days Regulatory review time: 137 days	Sep. 11, 2016 K161519/NeuroStar TMS Therapy System Clinical evaluation report	17	NeuroStar TMS Therapy System (Neuronetics, Inc.)	Change	Instrument & apparatus 12 Magnetic stimulator for transcranial treatment	A repetitive transcranical 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 (1) enable to set the short intertrain interval (off-time) in the treatment protocol, (2) add the new model (Model 3) with a mechanism for cooling treatment coils, wide monitor and fingerprint recognition module, and (3) add the MT-cap and D-Tect as new accessories (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 18, 2023 Total review time: 907 days Regulatory review time: 215 days	— Clinical evaluation report	18	Thymatron (Koden Medical Co., Ltd.)	Change	Instrument & apparatus 12 Convulsive therapy brain electrical stimulator	An electrical stimulator for electroconvulsive therapy in patients with severe drug-resistant depression, manic depression, or schizophrenia who have strong suicidal tendency or rejection symptoms and require imminent treatment for life support. The application was submitted to add a model (Model 200) whose maximum output power was raised from 504 mC to 1,008 mC (A “partial change” application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 13, 2024 Total review time: 270 days Regulatory review time: 179 days	Sep. 2014 PMA approved/GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface Foreign clinical study results and clinical evaluation report	19	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 for an additional indication of in-stent restenosis lesions among symptomatic peripheral arterial diseases in the superficial femoral artery (A "partial change" application).
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 27, 2024 Total review time: 271 days Regulatory review time: 105 days	May 25, 2018 No description/IN.PACT Admiral Paclitaxel-coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter Foreign clinical study results	20	IN.PACT Admiral Drug-Coated Balloon (DCB) Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for balloon dilatation 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 to add a balloon length of 250 mm and change the target maximum lesion length from 200 mm to 350 mm (A "partial change" application).
Gastroenterology, Genitourinary and Reproductive Medicine	Aug. 31, 2023 Total review time: 251 days Regulatory review time: 179 days	May 7, 2018 De Novo: DEN170015/Hemospray Endoscopic Hemostat Foreign clinical study results and clinical evaluation report	21	COOK Hemospray Endoscopic Non-absorbable Hemostatic Material (Cook Medical Japan G.K.)	Approval	Medical products 4 Non-absorbable topical hemostatic material	A non-absorbable hemostatic material is used to stop non-variceal gastrointestinal bleeding by endoscopically inserted into the gastrointestinal tract. The product is composed of hemostatic material and the delivery system.

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	Jan. 26, 2024 Total review time: 217 days Regulatory review time: 116 days	Generator: Not licensed Electrode: Mar. 14, 2018 Clinical evaluation report	22	RFA Lesion System (Century Medical, Inc.)	Change	Instrument & apparatus 29 Radio-frequency ablation system	A radio-frequency ablation system used for coagulating and ablating tissues. The application was submitted to add the followings to the intended use of this product; "small malignant renal mass" as well as "pulmonary malignant tumor," "malignant bone tumor," "osteoid osteoma," "intrapelvic 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).
Dentistry and Oral Medicine	Jul. 11, 2023 Total review time: 476 days Regulatory review time: 276 days	- Japanese clinical study results	23	Blue Radical P-01 (Luke Co., Ltd.)	Approval	Instrument & apparatus 62 Ultrasonic periodontal scaler in combination with drugs	An ultrasonic periodontal scaler in combination with drugs is used for removing dental calculus and other deposits and sterilizing the base of periodontal pockets in the treatment of patients with periodontitis at stage III or IV. The product consists of a scaler tip attached handpiece, dedicated hydrogen peroxide solution, and laser unit.
Ophthalmology and Otorhinolaryngology	Aug. 18, 2023 Total review time: 233 days Regulatory review time: 190 days	- Clinical evaluation report	24	MED-EL Cochlear Implant System Mi1250 SYNCHRONY2 FLEX (MED-EL Elektro-Medizinische Ger äte GmbH)	Change	Medical products 4 Auditory electrical stimulator	An implant that constitutes cochlear implant system for severe hearing disabilities (CI) or patients with ski-slope hearing loss, in which there is good hearing for lower frequencies (EAS), who have not responded sufficiently to wearing hearing aids. The application was submitted to add the FLEX electrode included in the company's approved implant "MED-EL Cochlear Implant SYNCHRONY2" (Approval No.: 30400BZI00025000) used only for CI indicated patients to this product so that it can be used for EAS indicated patients (A “partial change” application).
Ophthalmology and Otorhinolaryngology	Nov. 21, 2023 Total review time: 265 days Regulatory review time: 156 days	- Japanese clinical study results	25	Vivinex Gemetric (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter 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	Nov. 21, 2023 Total review time: 265 days Regulatory review time: 192 days	- Japanese clinical study results	26	Vivinex Gemetric Toric (HOYA Corporation)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter 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 aphakic eyes with corneal astigmatism.
Cardiopulmonary Circulation	Apr. 25, 2023 Total review time: 827 days Regulatory review time: 485 days	- Clinical evaluation report	27	Filtrap (Nipro Corporation)	Change	Instrument & apparatus 51 Central circulatory catheter for trapping embolus	A basket catheter set that is temporarily placed in the blood vessel to capture or remove intravascular foreign matters such as floating thrombus and blood clots. The application was submitted to add the intended use of capture or removal of substances causing embolization during percutaneous coronary intervention in patients with acute coronary syndrome in whom a large amount of plaque at a high risk for distal embolization was found in the native coronary lesions on intravascular imaging (A “partial change” application).
Cardiopulmonary Circulation	Apr. 26, 2023 Total review time: 295 days Regulatory review time: 181 days	- Clinical evaluation report	28	OSYPKA TMA (Heiwa Bussan Co., Ltd.)	Approval	Instrument & apparatus 7 Extracorporeal pacemaker electrode wire	A wire-type cardiac electrode that is connected to the external pacemaker "OSYPKA DefiPace" (Approval No.: 30500BZX00068000) for temporary cardiac pacing after open heart surgery. When the product is placed in both atria, biatrial pacing and cardioversion for atrial fibrillation can be performed.

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	May 29, 2023 Total review time: 935 days Regulatory review time: 240 days	- Clinical evaluation report	29	External Ventricular Assist Device EVAD (Sun Medical Technology Research Corp.)	Approval	Instrument & apparatus 7 Single-use extracorporeal assistant artificial cardiac pump	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 of treating with conventional medication or existing assisted circulation (such as intra-aortic balloon pumping or venoarterial bypass) due to severe heart failure or cardiogenic shock. The device consists of the internal components of the inflow cuff and outflow graft, external components such as the cannula carrying blood into and from the body, blood pump, and controller, and accessories. They are identical to those of the company's approved product "implantable Ventricular Assist System EVAHEART" (Approval No.: 22200BZX00939000) except for the cannula and tunneler.
Cardiopulmonary Circulation	Jul. 27, 2023 Total review time: 269 days Regulatory review time: 92 days	− Japanese clinical study results	30	Soft Life-size 3D Cardiac Model (crossMedical, Inc.)	Approval	Instrument & apparatus 21 Heart model supporting surgical plan	A 3D life-size cardiac model created based on multi-slice CT image information for patients with complex congenital heart disease for which diagnosis and surgical procedure are difficult to be determined with conventional diagnostic imaging. The product is provided in order to diagnose the cardiac structure of complex congenital heart diseases for which it is difficult to diagnose or determine surgical procedures with conventional diagnostic imaging, and it is used with other medical information to support the planning of surgery.
Cardiopulmonary Circulation	Aug. 8, 2023 Total review time: 246 days Regulatory review time: 105 days	− Japanese clinical study results and clinical evaluation report	31	SeQuent Please Neo Drug Eluting Balloon Catheter (Nipro Corporation)	Change	Instrument & apparatus 51 Catheter for coronary balloon dilatation angioplasty	A catheter for coronary balloon dilatation angioplasty with a paclitaxel-coated balloon to inhibit restenosis in revascularization. The product is used for coronary in-stent restenosis lesions and de novo coronary lesions. The application was submitted to expand the indication of de novo coronary artery lesions with a reference vessel diameter of 3.0 mm or greater and add a balloon size (A "partial change" application).
Cardiopulmonary Circulation	Sep. 28, 2023 Total review time: 189 days Regulatory review time: 121 days	Jan. 22, 2021 Foreign clinical study results	32	Synergy Megatron Stent System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consists of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo coronary artery lesions at the length of 28 mm or less with a reference vessel diameter of 3.50-5.00 mm, and a delivery catheter to implant a stent to the target lesion.
Cardiopulmonary Circulation	Nov. 29, 2023 Total review time: 61 days Regulatory review time: 55 days	- Clinical evaluation report	33	HeartLight Endoscopic Ablation System (Japan Lifeline Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon-type laser ablation catheter with an endoscope. The application was submitted to add the treatment of drug-resistant recurrent symptomatic persistent atrial fibrillation to the conventional intended use (treatment of drug-resistant recurrent symptomatic paroxysmal arterial fibrillation) (A "partial change" application).

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
Program	May 23, 2023	1) IRNF Version 2.0 License date: Oct. 22, 2021 License No.: K212516 Brand name: IRNF App Number of units shipped: -- 2) IRNF Version 1.0 License date: Sep. 11, 2020 License No.: DEN180042 Brand name: Irregular Rhythm Notification Feature Number of units shipped: 397,800 (2018), 4499,700 (2019), 3922,500 (2020)	34	Apple's Irregular Rhythm Notification Feature (Apple Inc.)	Change	Program 1	A home-use program that analyzes pulse rate data, detects irregular heartbeats suggestive of atrial fibrillation and notifies the user. The application was submitted to change the requirements for the platform to install the product and the classification algorithms to classify irregular heartbeats (A “partial change” application). Data on the platform study under the changed platform requirements and data on validation of the algorithm were submitted. Also, a clinical evaluation report summarizing the contents of foreign clinical literatures, etc. was submitted as data related to results of clinical study results.
	Total review time: 323 days Regulatory review time: 84 days	Clinical evaluation report				Software for home use heart rate monitor	
Program	Aug. 8, 2023	May 30, 2019	35	Medis QFR (Medis medical imaging systems)	Approval	Program 1	Software that calculates QFR (Quantitative Flow Ratio) and supports the diagnosis of patients suspected of having coronary artery disease by reconstructing a three-dimensional model of the coronary artery from angiographic projections and performing numerical analyses.
	Total review time: 252 days Regulatory review time: 161 days	Japanese clinical study results				Analyzing software for hemodynamics or cardiac function	
Program	Oct. 5, 2023	—	36	MIREVO (Ai-BrainScience Inc.)	Approval	Program 1	The application was submitted for marketing approval of a program to continuously collect information on patient’s gaze for use in neuropsychological assessment in order to support medical care for patients with dementia.
	Total review time: 646 days Regulatory review time: 502 days	Japanese clinical study results				Neuropsychological assessment application program	

Reprocessed Single-Use Medical Devices Approved in FY2023

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. 31, 2023	—	1	Reprocessed Stabilizer G (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 42	A reprocessed single-use medical device originated from the existing certified device "ACROBAT-i stabilizer" (Certification No.: 224AABZX00035000), which is an organ fixation pelotte used to partially immobilize areas around the blood vessel undergoing surgery for stabilizing the anastomotic site under pulsatile conditions during cardiac surgery using sternotomy.
	Total review time: 456 days Regulatory review time: 308 days	No clinical study results				Reprocessed single-use organ fixation pelotte	
Cardiopulmonary Circulation	Mar. 14, 2024	-	2	Reprocessed Loop Electrode Catheter (Stryker Japan) (Stryker Japan K.K.)	Change	Instrument & apparatus 51	A reprocessed single-use medical device originating from “LASSO 2515” (Approval No. 21600BZY00209000) and “LASSO 2515 Navi” (Approval No. 22200BZX00740000), which is a cardiac catheter-tip electrode and is used percutaneously and transluminally placed in the heart to perform a cardiac electrophysiological study and temporary pacing. The application was submitted to change the manufacturing process (A "partial change" application).
	Total review time: 87 days Regulatory review time: 45 days	No clinical study results				Reprocessed cardiac catheter-tip electrode	

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
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.