

New Medical Devices Approved in FY2022

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)	Apr. 26, 2022	-	1	nodoca (Aillis, Inc.)	Approval	Instrument & apparatus 25	A system used as an aid in the diagnosis of influenza virus infection by photographing pharynx and analyzing findings of pharynx such as lymph tissue on the images (including the tonsils and lymph follicles) and clinical data to detect findings, symptoms, etc. characteristic to influenza virus infection. It is not intended to make a definitive diagnosis based only on the analysis results of this product.
	Total review time: 322 days Regulatory review time: 206 days	Japanese clinical study results				Endoscopic telescope	
Orthopedic and Plastic Surgery	Nov. 28, 2022	-	2	AutoloGel System (Rohto Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 7	A kit used to prepare autologous platelet-rich plasma (PRP) gel for promoting healing or covering of wounds that have not responded to conventional treatments. PRP is obtained by centrifugation of patient's own blood, and it changes from liquid to gel by mixing the drugs as components of the product. The results of a Japanese clinical study were submitted to evaluate the efficacy and safety of the product.
	Total review time: 363 days Regulatory review time: 197 days	Japanese clinical study results				Platelet-rich plasma gel preparation kit	
Orthopedic and Plastic Surgery	Dec. 22, 2022	Feb. 2021 K202112/DUOLITH SD1 T-Top&Tower System with C-ACTOR Sepia Handpiece *Obtained 510(k) clearance as a treatment device for diabetic foot ulcer	3	DUOLITH SD1 Ultra (Karl Storz Endoscopy Japan K.K.)	Change	Instrument & apparatus 12	An extracorporeal shockwave pain treatment device designed to enable adjustment of output by the conventional electromagnetic induction-type extracorporeal shock wave lithotripter to the low power output. The application was submitted to add the indication of "refractory ulcer in patients with systemic scleroderma" as the "intended use or indication" of the product (A "partial change" application). The results of a Japanese clinical study were submitted to evaluate the efficacy and safety of the product.
	Total review time: 420 days Regulatory review time: 197 days	Japanese clinical study results				Extracorporeal shockwave pain treatment device	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 14, 2022	Turbo Power series Nov. 12, 2015 K152181/Turbo Power Laser Atherectomy Catheter Turbo Elite series Jul. 23, 2014 K140775/Turbo Elite Atherectomy Catheter	4	Excimer Laser Turbo Power Catheter (Philips Japan Ltd.)	Approval	Instrument & apparatus 51	A laser angioplasty catheter used in percutaneous endovascular treatment for lesions of restenosis or reocclusion that occur within a stent placed in the femoropopliteal artery. The product is used with an exclusive laser console, "Excimer Laser Angioplasty Device" (Approval No. 21300BZY00528000), and is used as an atherectomy device used to treat stenosis of lesions by vaporizing the tissue with limited heat damage to the surroundings using an excimer laser at a wavelength of around 308 nm.
	Total review time: 363 days Regulatory review time: 71 days	No clinical study results				Laser angioplasty catheter	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 2, 2022	Apr. 1, 2011 P100040 /Valiant Thoracic Stent Graft System with the Captivia Delivery System	5	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	A stent graft system used for treatment of thoracic aorta. The application was submitted to add the indication for "chronic complicated Stanford type B aortic dissections (including dissecting aortic aneurysm)" to the intended use. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 160 days Regulatory review time: 58 days	Clinical evaluation report				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 8, 2022	Apr. 30, 2014 P130008/INSPIRE II UPPER AIRWAY STIMULATOR May 5, 2017 P130008/S016/INSPIRE UPPER AIRWAY STIMULATOR MODEL 3028 [Additional type in this application] Lead: Approved Programmer for patients:	6	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 (CPAP). The application was submitted to add a new model aiming at improving the convenience of a programmer for patients, stimulation lead, and sensor lead. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 171 days Regulatory review time: 121 days	No clinical study results				Hypoglossal nerve stimulator	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 12, 2022	Mar. 10, 2016 K153485/ENROUTE Transcarotid Neuroprotection System	7	ENROUTE Transcarotid Neuroprotection System (Silk Road Medical, Inc.)	Approval	Instrument & apparatus 51	A device used to prevent embolization by transcarotid vascular access during carotid angioplasty and stent placement in patients with carotis stenosis. The results of foreign clinical study were submitted.
	Total review time: 512 days Regulatory review time: 259 days	Foreign clinical study results				Central circulatory catheter for trapping embolus	

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 28, 2022	Jun. 29, 2018 P180002/ZEPHYR ENDOBRONCHIAL VALVE SYSTEM Jul. 30, 2019 P180002/S005/ZEPHYR ENDOBRONCHIAL VALVE SYSTEM Nov. 13, 2019 P180002/S010/ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	8	Zephyr Endobronchial Valve System (Pulmonx Corporation)	Approval	Instrument & apparatus 7	An endobronchial valve used in patients who have severe chronic obstructive pulmonary disease with severe emphysema and hyperinflation and are receiving optimal non-invasive treatment and also whose physiological examination shows little to no collateral ventilation between adjacent pulmonary lobes. The results of foreign clinical studies were submitted.
	Total review time: 347 days Regulatory review time: 204 days	Foreign clinical study results				Endobronchial valve	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 22, 2022	Oct. 9, 2020 P200023/Zilver Vena Venous Self-Expanding Stent	9	Zilver Vena Venous Stent (Cook Medical Japan G.K.)	Approval	Instrument & apparatus 7	A venous stent used to maintain the lumen of the iliofemoral vein for symptomatic iliofemoral venous outflow obstruction that is difficult to treat with conventional therapies. The results of foreign clinical study were submitted.
	Total review time: 261 days Regulatory review time: 88 days	Foreign clinical study results				Venous stent	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Mar. 27, 2023	Mar. 13, 2019 P180037/Venovo Venous Stent System	10	VENOVO Venous Stent System (Medicon, Inc.)	Approval	Instrument & apparatus 7	A venous stent used to maintain the lumen of the iliofemoral vein for symptomatic iliofemoral venous outflow obstruction that is difficult to be treated with conventional therapies. The results of foreign clinical studies were submitted.
	Total review time: 266 days Regulatory review time: 50 days	Foreign clinical study results				Venous stent	
Gastroenterology, Genitourinary, and Reproductive Medicine	Nov. 10, 2022	-	11	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7	A cytapheeresis column 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 mainly extend the shelf life and revise the approved items (specifications related to performance and safety). (A "partial change" application submitted during the post-market performance review period)
	Total review time: 133 days Regulatory review time: 101 days	No clinical study results				Cytapheresis column	
Cardiopulmonary Circulation	May 18, 2022	Mar. 30, 2018 P050006/S60/GORE CARDIOFORM SEPTAL OCCLUDER	12	GORE Cardioform Septal Occluder (W. L. Gore & Associates G.K.)	Approval	Medical products 4	This product is a percutaneous, transcatheter patent foramen ovale (PFO) closure device. This treatment is intended to close the PFO to reduce the risk of recurrence of ischemic stroke in patients who have had a cryptogenic stroke with possible involvement of a PFO due to a presumed paradoxical embolism. Data from the results of foreign clinical studies were submitted.
	Total review time: 359 days Regulatory review time: 134 days	Foreign clinical study results				Artificial pericardial prosthesis	
Cardiopulmonary Circulation	Aug. 2, 2022	Jul. 28, 2022 P140031 S141/SAPIEN 3 Ultra RESILIA	13	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 RESILIA-treated bioprosthetic valve models and a loader for 29-mm valve and a new introducer sheath set for the transfemoral/trans-subclavian/axillary approach. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 165 days Regulatory review time: 100 days	No clinical study results				Transcatheter bovine cardiac valve	
Cardiopulmonary Circulation	Aug. 17, 2022	Aug. 23, 2017 P160054/Heart Mate3 Left Ventricular Assist System Nov. 24, 2021 P160054/S040 Alternative Apical felt material supplier addition	14	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 for an apical cuff and coring tool as a surgical accessory. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 111 days Regulatory review time: 104 days	No clinical study results				Implantable assistant artificial heart system	

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Cardiopulmonary Circulation	Sep. 27, 2022	Sep. 9, 2020 P140031 S112/TAV in TAV	15	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 an indication of symptomatic valvular disease attributed to dysfunction of implanted transcatheter aortic bioprosthesis in patients who are not eligible for surgery. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 363 days Regulatory review time: 220 days	Foreign registry				Transcatheter bovine cardiac valve	
Cardiopulmonary Circulation	Oct. 31, 2022	Sep. 19, 2019	16	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 in patients with symptomatic valvular disease due to dysfunction of a surgically placed bioprosthetic aortic valve, and who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option. The application was submitted for an additional type of surgical valve designed for the indication. (A "partial change" application).
	Total review time: 137 days Regulatory review time: 84 days	No clinical study results				Transcatheter porcine pericardial valve	
Cardiopulmonary Circulation	Jan. 17, 2023	Aug. 12, 2021	17	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. The application was submitted to add a bioprosthetic valve with a frame to which 3 gold markers were added to improve visibility and a delivery catheter system specific to the model (A "partial change" application).
	Total review time: 158 days Regulatory review time: 133 days	No clinical study results				Transcatheter porcine pericardial valve	
Cardiopulmonary Circulation	Feb. 7, 2023	-	18	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 system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a manufacturing site. (A "partial change" application submitted during the post-market performance review period)
	Total review time: 119 days Regulatory review time: 118 days	No clinical study results				Transcatheter bovine cardiac valve	
Program	Apr. 26, 2022	-	19	CureApp HT Digital Therapeutic App for Hypertension Adjunctive Treatment (CureApp Inc.)	Approval	Program 2	The application was submitted for marketing approval of a supporting software for hypertension treatment used to support the treatment of hypertension by helping to modify lifestyle in the treatment of hypertension in patients with essential hypertension.
	Total review time: 334 days Regulatory review time: 143 days	Japanese clinical study results				Supporting software for hypertension treatment	
Program	Sep. 29, 2022	-	20	Syringe Pump Control Software for Assisting Total Intravenous Anesthesia (Nihon Kohden Corporation)	Approval	Program 2	The application was submitted for marketing approval of a software that controls the dose of sedatives, analgesics, and muscle relaxants by controlling the concomitantly used syringe pumps under the supervision of anesthesiologists in surgeries in which general anesthesia is provided with intravenous anesthetics.
	Total review time: 363 days Regulatory review time: 260 days	Japanese clinical study results				Software for automated drug delivery for general anesthesia	
Program	Feb. 15, 2023	-	21	SUSMED Med CBT-i App for Insomnia (Susmed, Inc.)	Approval	Program 2	The application was submitted for marketing approval of a software for insomnia that supports cognitive behavioral therapy provided by physicians for the treatment of insomnia.
	Total review time: 378 days Regulatory review time: 213 days	Japanese clinical study results				Software for insomnia	

Improved Medical Devices (With Clinical Data) Approved in FY2022

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Robotics, IoT, and other devices (not classified as other categories)	May 10, 2022	Date of license: Mar. 27, 2018 License No.: DEN170088	1	Dexcom G6 CGM System (Dexcom, Inc.)	Change	Instrument & apparatus 20	The device is a glucose monitor system which is intended to measure, record and display fluctuation patterns continuously. The application was submitted to change the intended use in association with the clinical standpoint of the product as management of daily blood glucose based on information regarding glucose levels in the interstitial fluid obtained from the product (A "partial change" application).
	Total review time: 327 days Regulatory review time: 266 days	Foreign clinical study results				Glucose monitor system	
Robotics, IoT, and other devices (not classified as other categories)	Oct. 24, 2022	Progressive incurable neuromuscular diseases (8 diseases) Date of license: Oct. 2, 2020, 510k (License No. K201559)	2	HAL for Medical USE (Lower Limb Type) (CYBERDYNE Inc.)	Change	Instrument & apparatus 58	The device is used to improve the gait function through repeated gait exercise with assistance for the movement of the lower limbs based on biological signals by wearing the device intermittently. This application was submitted to add patients with declined gait instability due to HTLV-1 associated myelopathy or spastic paraplegia resulting from hereditary spastic paraplegia to the indication for this device (A "partial change" application).
	Total review time: 423 days Regulatory review time: 255 days	Japanese clinical study results				Physiological signal use motion function improvement supporting system	
Robotics, IoT, and other devices (not classified as other categories)	Oct. 27, 2022	-	3	NanoZoomer S360MD Slide scanner system (Hamamatsu Photonics K.K.)	Approval	Instrument & apparatus 21	The application was submitted for marketing approval of a diagnostic assistant device for pathological whole slide image, which is intended to assist pathologists to evaluate and diagnose high magnification digital images of whole pathological slide samples. This product automatically creates, displays, and stores pathological whole slide images.
	Total review time: 268 days Regulatory review time: 162 days	Clinical evaluation report				Diagnostic assistant device for pathological whole slide image	
Robotics, IoT, and other devices (not classified as other categories)	Feb. 24, 2023	-	4	Medtronic Guardian Connect (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 20	The device is a glucose monitor system that continuously measures glucose levels in the interstitial fluid under the skin in persons with diabetes mellitus. The application was submitted to add a new transmitter and sensor to the component in order to reduce the number of calibrations by self-monitoring of blood glucose levels and improve the reliability of sensor glucose value obtained by using the product, and to change the clinical positioning of the product in daily blood glucose management when using the component (A "partial change" application). The results of foreign clinical studies showing that the product or its equivalent can similarly make the blood glucose management to using a blood glucose self-monitoring device were submitted. In addition, the results of foreign clinical studies demonstrating that the accuracy of the glucose levels measured by the product was acceptable to be used as an aid for management of self-monitoring blood glucose level for patients with diabetes mellitus were submitted.
	Total review time: 270 days Regulatory review time: 219 days	Foreign clinical study results				Glucose monitor system	
Robotics, IoT, and other devices (not classified as other categories)	Feb. 24, 2023	Date of license: Under review License No.: - Brand name: MiniMed 780G System Number of units shipped: -	5	Medtronic MiniMed 700 Series (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 74	An insulin pump used for continuous subcutaneous infusion of basal insulin at a selected rate and bolus infusion of insulin at a selected dose. The application was submitted mainly to add a new model of portable insulin infusion pump, in which a function to automatically inject correction bolus insulin based on glucose concentration in interstitial fluid obtained from the product was added to the AutoMode automatically injecting basal insulin, and a transmitter and sensor that can be used with the pump to the component (A "partial change" application). The results of foreign clinical studies evaluating the efficacy and safety of the product using the automatic mode were submitted.
	Total review time: 270 days Regulatory review time: 236 days	Foreign clinical study results				Portable insulin infusion pump	

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Orthopedic and Plastic Surgery	Apr. 7, 2022	-	6	Medicarbo Hip Nail (B.I.TEC Co., Ltd.)	Approval	Medical products 4	An implantable femur intramedullary fixation nail that is inserted into the medullary cavity of the femur for fixation or stabilization of fracture of the base of the femoral neck or trochanteric femoral fracture. Carbon fiber reinforced PEEK resin is used as the raw material for the nail and lag screw body contained in the component. The results of a Japanese clinical study conducted as a multicenter, single-arm, open-label design were submitted to evaluate the performance of this product for bone union as well as malfunctions and adverse events.
	Total review time: 765 days Regulatory review time: 701 days	Japanese clinical study results				Implantable femur intramedullary fixation nail	
Orthopedic and Plastic Surgery	Sep. 6, 2022	Jun. 8, 2007 K062937X/COOLIEF* Cooled Radiofrequency Sterile Tube Kit Dec. 16, 2016 K163236/COOLIEF* Radiofrequency Fluid Delivery Introducer Apr. 13, 2017 K163461/COOLIEF* Cooled Radiofrequency Probe Feb. 21, 2020 K192491/COOLIEF* Pain Management RF Generator System Dec. 22, 2020 K203066 COOLIEF* Cooled Radiofrequency Kit Advanced	7	Coolief Radiofrequency Pain Management System (Avanos Medical Japan Inc.)	Approval	Instrument & apparatus 29	An electrosurgical unit for ablation to treat pain by supplying a high-frequency current to the peripheral nerve to warm and coagulate (cauterize) the nerve in patients with chronic pain associated with knee osteoarthritis who are not candidates for orthopedic surgery and do not respond to conventional conservative therapy. The product can also be used to treat chronic pain of the face, neck, and back. The results of foreign clinical studies in which the effectiveness of product was compared with that of adrenocorticosteroid injection for pain relief in patients with chronic knee pain due to knee osteoarthritis were submitted.
		Total review time: 258 days Regulatory review time: 175 days				Foreign clinical study results	
Orthopedic and Plastic Surgery	Oct. 14, 2022	2012 Classification I *510(k) exemption/overseas brand name: StrataXRT	8	Radiation Dermatitis Film-forming Material StrataXRT (Toyo Medic Co., Ltd.)	Approval	Medical products 4	A local control hydrogel dressing made of silicone gel used to reduce skin disorders caused by irradiation and promote healing. The product was developed to cover the inflammatory area and maintain a moist environment for the purpose of promoting healing of radiation dermatitis. A clinical evaluation report summarizing foreign clinical literatures, etc. was submitted to evaluate that this product is effective in suppressing or improving the severity of radiation dermatitis and that there are no risks of adverse events specific to this product.
		Total review time: 261 days Regulatory review time: 139 days				Clinical evaluation report	
Orthopedic and Plastic Surgery	Jan. 13, 2023	Jun. 9, 2005 K042415/Mendec Spine	9	Conamon PVP Kit (J-Sol Medical Co., Ltd.)	Approval	Medical products 4	An orthopedic bone cement used for percutaneous vertebroplasty. It mainly consists of a polymethyl methacrylate bone cement and instruments used for preparation (mixer, injector, and needle). The bone cement of the product is identical with the company's approved product "Mendec Spine Bone Cement Kit" (22800BZX00185000), which has approval for the indication of painful vertebral fracture due to malignant spinal tumor. The difference from the approved product is that the indication of vertebral fracture due to osteoporosis is included in addition to the indication of the approved product.
		Total review time: 276 days Regulatory review time: 191 days				Clinical evaluation report	
Orthopedic and Plastic Surgery	Mar. 3, 2023	Jul. 15, 2015 K150907/Ellipse Nordlys (with IPL and Nd: YAG hand pieces/applicators)	10	Phototherapy Device for Skin Disease Nordlys (Syneron Candela K.K.)	Change	Instrument & apparatus 12	A phototherapy device for skin diseases used to treat superficial skin benign pigmentary diseases and superficial telangiectasia symptoms in benign cutaneous vascular lesions by thermal action of continuous spectral light from visible to infrared rays contained in intense pulse light. The application was submitted to add the treatment of superficial telangiectatic symptoms to the indication of the product (A "partial change" application).
		Total review time: 150 days Regulatory review time: 67 days				Clinical evaluation report	

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 28, 2022	-	11	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Change	Instrument & apparatus 51	A catheter for balloon dilatation 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. The balloon surface of this product is coated with a drug primarily composed of paclitaxel. The application was submitted for additional indications of in-stent restenotic lesions and long lesions up to 30 cm in length and the addition of the balloon length associated with the additional indication (A "partial change" application). A clinical evaluation report summarizing the results of foreign clinical studies, etc. evaluating the efficacy and safety of the product for in-stent restenotic lesions and long lesions were submitted as clinical evaluation data.
	Total review time: 260 days Regulatory review time: 77 days	Clinical evaluation report				Catheter for balloon dilatation angioplasty	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 26, 2022	-	12	PENTAS Stent (PENTAS Inc.)	Approval	Instrument & apparatus 51	A self-expandable assist stent used to prevent a coil mass from protruding into and dropout from the parent artery during the coil embolization treatment in patients with a parent artery with a diameter of 2.5-4.6 mm among patients with unruptured cerebral aneurysm (the maximum diameter of 5 mm or greater) that are difficult to be treated with surgery or coil embolization with embolic coil alone and wide-necked (neck part of 4 mm or greater or dome-to-neck ratio of less than 2). The product was developed as a stent expected to have the maximum blood flow suppression effect with the minimum metal area. An available treatment planning program is included to supplementally support the stent placement. The results of Japanese clinical studies were submitted as clinical evaluation data.
	Total review time: 268 days Regulatory review time: 124 days	Japanese clinical trial results				Central circulatory intravascular embolization prosthesis	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 29, 2022	(Approved size) Mar, 2014 P120020/Supera Peripheral Stent System (LV size) May 2021 P120020, S026/Supera Peripheral Stent System	13	Supera Stent (Abbott Medical Japan LLC.)	Change	Instrument & apparatus 7	A self-expanding vascular stent used for the treatment of symptomatic vascular disease with a reference vessel diameter of 4.0-7.5mm and a lesion length up to 140 mm in the superficial femoral artery and proximal popliteal artery, and for the treatment of acute or impending occlusion in the aforementioned sites following the failure of interventional treatment. The application was submitted for an additional stent size of 7.0 mm and 7.5 mm in diameter (reference vessel diameter 6.5-7.5 mm) (A "partial change" application). As clinical evaluation data, a clinical evaluation report summarizing the results of additional analysis of foreign clinical studies using the approved size, foreign literature on the additional size and approved size, and the clinical usage in Japan and foreign countries.
	Total review time: 154 days Regulatory review time: 131 days	Clinical evaluation report				Vascular stent	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 27, 2022	Aug. 2021 Not described/RelayPro Thoracic Stent Graft System	14	RelayPro Thoracic Stent Graft System (Terumo Corporation)	Change	Instrument & apparatus 7	An aortic stent graft system used for endovascular treatment of descending thoracic aorta. The application was submitted to add "acute complicated Stanford type B aortic dissection" as the "intended use or indication" of the product (A "partial change" application). The results of foreign clinical studies were submitted as clinical evaluation data.
	Total review time: 179 days Regulatory review time: 100 days	Foreign clinical study results				Aortic stent graft	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 12, 2022	May 18, 2015 P140026/ENROUTE Transcarotid Stent System	15	ENROUTE Transcarotid Stent System (Silk Road Medical, Inc.)	Approval	Instrument & apparatus 7	A stent system is used for extending and maintaining the vascular lumen through a transcarotid approach to be inserted and placed in the site of stenosis in the cervical carotid artery (common carotid artery, internal carotid artery). The results of foreign clinical study were submitted.
	Total review time: 512 days Regulatory review time: 215 days	Foreign clinical study results				Carotid artery stent	

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Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Feb. 8, 2023	-	16	Medtronic Inceptiv (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 12	An implantable stimulator for pain relief used to relieve chronic intractable pain by applying an electrical stimulation to the spinal epidural space. A function to sense evoked compound action potentials (ECAPs) from the spinal cord (ECAP sensing) and automatically optimize the stimulus strength (neurosensing function) were installed based on the company's approved product "Intellis" (Approval No. 22900BZX00255000). ECAP sensing and neurosensing function reduce hyperstimulation and discomfort caused by the momentary approach of the distance between the spinal cord and lead, such as coughing and sneezing. The results of foreign clinical studies to evaluate the efficacy and safety of ECAP sensing and neurosensing function were submitted.
	Total review time: 188 days Regulatory review time: 76 days	Foreign clinical study results				Implantable stimulator for pain relief	
Gastroenterology, Genitourinary, and Reproductive Medicine	Jul. 4, 2022	-	17	Niti-S EUS-BD System (Century Medical, Inc.)	Approval	Instrument & apparatus 51	The product is a stent for maintaining the drainage route between the punctured gastrointestinal tract and bile duct in endoscopic ultrasound-guided biliary drainage (EUS-BD). The application was submitted to expand the indication of the company's approved product "Niti-S Biliary Silicone Covered Stent (Approval No.: 22200BZX00699000)" to EUS-BD. The clinical evaluation report on the treatment outcome of EUS-BD using the product was submitted.
	Total review time: 193 days Regulatory review time: 144 days	Clinical evaluation report				Transgastric biliary drainage stent	
Gastroenterology, Genitourinary, and Reproductive Medicine	Sep. 9, 2022	Sep. 29, 2010 (Proposed product: Jan. 23, 2018)/ Not described/C2 Cryo Ballon Ablation System	18	C2 CryoBalloon Ablation System (HOYA Corporation)	Approval	Instrument & apparatus 31	A general-purpose cryosurgical unit for endoscopic cryoablation of lesion tissue in patients with Barrett's esophageal lesion associated with dysplasia or non-invasive adenocarcinoma. The product consists of a balloon catheter and a controller that sprays and exhausts nitrous oxide gas. By spraying nitrous oxide gas into the balloon, cryoablation can be provided to the lesion based on the principle of adiabatic expansion. A clinical evaluation report was submitted to evaluate the clinical efficacy and safety of cryoablation of lesions.
	Total review time: 528 days Regulatory review time: 135 days	Clinical evaluation report				General-purpose cryosurgical unit	
Gastroenterology, Genitourinary and Reproductive Medicine	Mar. 30, 2023	-	19	EBL Device (SB-Kawasumi Laboratories, Inc.)	Change	Instrument & apparatus 30	An endoscopic loop ligator to be mounted on the tip of an endoscope and to be used to ligate internal hemorrhoid, colonic diverticula bleeding points, or neuroendocrine tumor (rectal NET) with a diameter of less than 10 mm developed in the rectum with an O-ring by drawing them into the device. The application was submitted to expand the indication of the device to draw and ligate rectal NET using the product in the ESMR-L method (A "partial change" application). The clinical evaluation reports were attached for the clinical efficacy and safety evaluation of the ESMR-L method using this product.
	Total review time: 113 days Regulatory review time: 81 days	Clinical evaluation report				Endoscopic loop ligator	
Dentistry and Oral Medicine	Sep. 9, 2022	-	20	Apajet (Sangi Co., Ltd.)	Approval	Instrument & apparatus 60	A tooth surface coating spray device with which the tooth surface is coated with hydroxyapatite layer to suppress hypersensitivity of dentin or formed dentin and reline the cavity containing dentin. The results of Japanese clinical studies conducted to verify the efficacy and safety based on novelty of the principle of coating the tooth surface by spraying the dedicated powder were submitted.
	Total review time: 247 days Regulatory review time: 193 days	Japanese clinical study results				Tooth surface coating spray device	
Ophthalmology and Otorhinolaryngology	Jun. 2, 2022	Nov. 21, 2016	21	WaveLight EX 500 (Alcon Japan Ltd.)	Change	Instrument & apparatus 31	An ophthalmic corneal surgery laser system for correction of refractive error or resection of corneal lesions by removing corneal tissues using laser irradiation. The application was submitted to mainly add photorefractive keratectomy (PRK) to the intended use (A "partial change" application).
	Total review time: 269 days Regulatory review time: 191 days	Foreign clinical study results				Ophthalmic corneal surgery laser 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
Ophthalmology and Otorhinolaryngology	Sep. 6, 2022	-	22	FINEVISION HP (Beaver-Visitec International Japan K.K.)	Approval	Instrument & apparatus 72	The application was submitted for marketing approval of a multifocal posterior chamber lens to be inserted as a substitute for the crystalline lens in the posterior chamber to correct near, intermediate, and far vision of an aphakia eye.
	Total review time: 253 days Regulatory review time: 157 days	Foreign and Japanese clinical study results				Multifocal posterior chamber lens	
Ophthalmology and Otorhinolaryngology	Sep. 20, 2022	-	23	Avansee Preload1P Toric (Kowa Company, Ltd.)	Approval	Instrument & apparatus 72	The application was submitted for marketing approval of posterior chamber lens with inserter having cylindrical refractivity, which is intended to be used for visual correction of corneal astigmatism.
	Total review time: 267 days Regulatory review time: 192 days	Japanese clinical study results				Posterior chamber lens with inserter	
Ophthalmology and Otorhinolaryngology	Oct. 11, 2022	-	24	Airy One Day (HOYA Corporation)	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 48% and an oxygen permeability (Dk) of 112×10^{-11} (cm ² /sec)·(mLO ₂ /[mL × mmHg]).
	Total review time: 224 days Regulatory review time: 169 days	Foreign clinical study results				Single-use colored vision corrective contact lens	
Ophthalmology and Otorhinolaryngology	Oct. 11, 2022	-	25	hoyaONE treasured (HOYA Corporation)	Approval	Instrument & apparatus 72	A product with multiple brand name of "Airy One Day."
	Total review time: 224 days Regulatory review time: 169 days	No clinical study results				Single-use colored vision corrective contact lens	
Ophthalmology and Otorhinolaryngology	Dec. 21, 2022	Jul. 26, 2021 510(k) LTF K193500 and DEN200028/OptiLight System	26	OptiLight M22 IPL model (Lumenis Be Japan K.K.)	Approval	Instrument & apparatus 12	The application was submitted for marketing approval of a xenon beam light therapy unit used to improve blood flow and relieve pain and inflammation by hyperthermia effect and for providing localized heat to the eyelids in patients with meibomian gland dysfunction.
	Total review time: 337 days Regulatory review time: 177 days	Foreign clinical study results				Xenon beam light therapy unit	
Ophthalmology and Otorhinolaryngology	Feb. 8, 2023	-	27	Clareon Aspheric PanOptix TORIC Trifocal Hydrophobic Acrylic IOL (Alcon Japan Ltd.)	Change	Instrument & apparatus 72	A multifocal posterior chamber lens to be inserted as a substitute for a crystalline lens in the posterior chamber to correct near, intermediate, and far vision of an aphakic eyes with corneal astigmatism. The application was submitted to add a model with a cylindrical power of 1.00 D to deal with correction of lower power of astigmatism (A "partial change" application).
	Total review time: 267 days Regulatory review time: 104 days	Japanese clinical study results				Multifocal posterior chamber lens	
Ophthalmology and Otorhinolaryngology	Feb. 24, 2023	Jan. 26, 2022 Unlisted/Clareon Vivivity Extended Vision Hydrophobic IOL with the AutoNoMe Automated Pre-loaded Delivery System (CNAET0)	28	Clareon Vivivity Extended Vision IOL AutoNoMe Automated Preload Delivery System (Alcon Japan Ltd)	Approval	Instrument & apparatus 72	The application was submitted for marketing approval of posterior chamber lenses with inserter preloaded with a multifocal intraocular lens which is used to correct near, intermediate, and far vision of an aphakic eye and reduce spectacle dependence.
	Total review time: 275 days Regulatory review time: 202 days	Foreign clinical study results				Posterior chamber lens with inserter	
Ophthalmology and Otorhinolaryngology	Mar. 22, 2023	Sep. 13, 2016	29	VisuMax Femtosecond Laser (Carl Zeiss Meditec Co., Ltd.)	Change	Instrument & apparatus 31	An ophthalmic corneal surgery laser system used for incision and resection of corneal tissue by focusing and irradiating ultra-short pulse laser light to corneal tissue. The application was submitted mainly to add refractive correction by small incision lenticule extraction (SMILE) to the intended use (A "partial change" application).
	Total review time: 295 days Regulatory review time: 254 days	Foreign clinical study results				Ophthalmic corneal surgery laser 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
Ophthalmology and Otorhinolaryngology	Mar. 28, 2023	-	30	Kao Steam Eye Care Mask (Kao Corporation)	Approval	Medical products 4	The application was submitted for marketing approval of a single-use pack to alleviate symptoms such as dry eyes and tired eyes by applying heat with steam generated by oxidation reaction of iron to the skin around the eyes.
	Total review time: 270 days Regulatory review time: 158 days	Foreign clinical study results				Home-use eyelid warming pack	
Cardiopulmonary Circulation	May 30, 2022	Jun. 18, 2021	31	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51	A balloon ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is used for cryoablation for cardiac tissue. The application was submitted to mainly remove "drug-refractory" from the indication of the catheter for paroxysmal atrial fibrillation (drug-refractory recurrent symptomatic paroxysmal atrial fibrillation), change the raw material of the guide wire luer, and change the requirements for performance and safety related to tensile strength and leakage (A "partial change" application). Results of foreign clinical studies were submitted as clinical evaluation data.
	Total review time: 161 days Regulatory review time: 105 days	Foreign clinical study results				Catheter for cardiac ablation	
Cardiopulmonary Circulation	May 30, 2022	Dec. 17, 2010	32	Freezor MAX Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51	An ablation catheter utilizing liquid nitrous oxide as a refrigerant, which is intended to be used for gap cryoablation to complete electrical isolation of the pulmonary veins, cryoablation of focal trigger sites for the treatment of atrial fibrillation, or creation of an ablation line between the inferior vena cava and the tricuspid valve when performing the procedure of cryoablation for cardiac tissue. The application was submitted to mainly remove "drug-refractory" from the indication of the catheter for paroxysmal atrial fibrillation (drug-refractory recurrent symptomatic paroxysmal atrial fibrillation) (A "partial change" application). Results of foreign clinical studies were submitted as clinical evaluation data.
	Total review time: 161 days Regulatory review time: 105 days	Foreign clinical study results				Catheter for cardiac ablation	
Cardiopulmonary Circulation	Jun. 9, 2022	Aug. 2015 ReDS Wearable System/K150095 Feb. 2019 ReDS System/K180479	33	ReDS Pro System (Century Medical, Inc.)	Approval	Instrument & apparatus 21	A device to provide the lung fluid composition ratio by measuring the lung fluid content using electromagnetic waves, consisting of a console, a sensor unit, etc. The device was developed for the intention of the use as an auxiliary positioning in the treatment of heart failure by monitoring the lung fluid composition ratio quantitatively measured with this device. As the clinical evaluation data, the clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted.
	Total review time: 224 days Regulatory review time: 135 days	Clinical evaluation report				Electromagnetic component analyzer	
Cardiopulmonary Circulation	Aug. 2, 2022	-	34	M-DES Coronary Stent (Nipro Corporation)	Approval	Instrument & apparatus 7	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.5-4.25 mm and a delivery catheter used to implant the stent to the site of stenosis. The results of a Japanese clinical study were submitted for evaluation of the efficacy and safety of the product.
	Total review time: 260 days Regulatory review time: 86 days	Japanese clinical study results				Coronary stent	
Cardiopulmonary Circulation	Aug. 19, 2022	Apr. 12, 2019 510(k):K183599/Makoto Intravascular Imaging System, TVC-MC10/TVC-MC10i Dualpro IVUS + NIRS Imaging Catheter, TVC-C195-42	35	TVC NIRS Catheter (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51	A catheter with a near-infrared spectroscopy (NIRS) function using NIRS to detect lipid core plaque in the vascular wall. This device provides imaging information for diagnosis. NIRS function presents one of the risk factors associated with major cardiovascular events. At the same time, the shape and characteristics of the central circulatory vascular lumen and vascular wall are visualized with ultrasound to provide diagnostic image information. The results of foreign clinical studies were submitted.
	Total review time: 435 days Regulatory review time: 166 days	Foreign clinical study results				Central circulation system intravascular near-infrared catheter	

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	No.	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Aug. 19, 2022	Apr. 12, 2019 510(k):K183599/Makoto Intravascular Imaging System, TVC-MC10/TVC-MC10i Dualpro IVUS + NIRS Imaging Catheter, TVC-C195-42	36	TVC Imaging System TVC-MC10 (Goodman Co., Ltd.)	Change	Instrument & apparatus 12	A diagnostic imaging device with a near-infrared spectroscopy (NIRS) function using NIRS to detect lipid core plaque in the vascular wall. This device provides imaging information for diagnosis. NIRS function presents one of the risk factors associated with major cardiovascular events. At the same time, the shape and characteristics of the central circulatory vascular lumen and vascular wall are visualized with ultrasound to provide diagnostic image information. The application was submitted to change the NIRS function from accessory function to main function (A "partial change" application). The results of foreign clinical studies were submitted.
	Total review time: 435 days Regulatory review time: 166 days	Foreign clinical study results				Intravascular near-infrared diagnostic imaging system	
Cardiopulmonary Circulation	Aug. 24, 2022	Mar. 13, 2019 Acticor 7 HF-T DF4 IS -1 ProMRI/Acticor 7 HF-T QP DF4 IS4 ProMRI/P050023/S125	37	Acticor 7 CRT-D ProMRI (Biotronik Japan, Inc.)	Change	Instrument & apparatus 7	The device is an implantable biventricular pacing pulse generator with defibrillation feature. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add a function to provide indicators related to the changes in the patient's biological information (HeartInsight function) based on the concept of "testing/diagnostic devices that measure physiological parameters to obtain potential reference information for diagnosis" provided in "Handling on the Scope of Situations where 'Documents related to Clinical Study Results' is Necessary on Medical Devices (Operations based on Measures through Pre-and Post-Marketing Phases), (PSEHB/MDED Notification No. 1117-1, PSEHB/SD Notification No. 1117-1, dated on November 17, 2017)" (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted to demonstrate that the HeartInsight function can provide indicators related to changes in biological information.
	Total review time: 261 days Regulatory review time: 220 days	Clinical evaluation report				Implantable biventricular pacing pulse generator with defibrillation feature	
Cardiopulmonary Circulation	Sep. 9, 2022	Apr. 23, 2020 Cobalt XT HF Quad CRT-D MRI SureScan/Cobalt XT HF CRT-D MRI SureScan/Cobalt HF Quad CRT-D MRI SureScan/Cobalt HF CRT-D MRI SureScan Other 2 types/P010031/S674	38	Cobalt MRI CRT- D Series (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	The device is an implantable biventricular pacing pulse generator with defibrillation feature. 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 include improvement of symptoms or delay in progression of heart failure in the indication for patients with heart failure whose left ventricular ejection fraction is 50% or less and who are expected to frequently depend on ventricular pacing among patients indicated for a pacemaker or an implantable defibrillator (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted as data related to results of clinical study.
	Total review time: 295 days Regulatory review time: 231 days	Clinical evaluation report				Implantable biventricular pacing pulse generator with defibrillation feature	
Cardiopulmonary Circulation	Sep. 9, 2022	May 6, 2017 Percepta Quad CRT-P MRI SureScan/Percepta CRT-P MRI SureScan/P010015/S317	39	Percepta MRI CRT- P Series (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7	The device is an implantable biventricular pacing pulse generator without defibrillation feature. 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 include improvement of symptoms or delay in progression of heart failure in the indication for patients with heart failure whose left ventricular ejection fraction is 50% or less and who are expected to frequently depend on ventricular pacing among patients indicated for a pacemaker (A "partial change" application). A clinical evaluation report summarizing the contents of foreign clinical literature, etc. was submitted as data related to results of clinical study.
	Total review time: 295 days Regulatory review time: 231 days	Clinical evaluation report				Implantable biventricular pacing pulse generator without defibrillation feature	

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. 14, 2022	Mar. 13, 2019 P050023/S125/Acticor 7 DR-T ProMRI / Acticor 7 VR-T ProMRI	40	Acticor 7 ICD ProMRI (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12	The device is an automatic implantable defibrillator. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to add a function to provide indicators related to the changes in the patient's biological information (HeartInsight function) based on the concept of "testing/diagnostic devices that measure physiological parameters to obtain potential reference information for diagnosis" provided in "Handling on the Scope of Situations where 'Documents related to Clinical Study Results' is Necessary on Medical Devices (Operations based on Measures through Pre- and Post-Marketing Phases), (PSEHB/MDED Notification No. 1117-1, PSEHB/SD Notification No. 1117-1, dated on November 17, 2017)" (A "partial change" application).
	Total review time: 128 days Regulatory review time: 114 days	Clinical evaluation report				Automatic implantable defibrillator	
Cardiopulmonary Circulation	Oct. 18, 2022	Dec. 13, 2021 SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System and DIRECT Sirolimus Eluting Coronary Stent Rapid Exchange Delivery System/P210014	41	Svelte Sirolimus-eluting Coronary Stent System (Svelte Medical Systems, Inc.)	Approval	Instrument & apparatus 7	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 34 mm or less) with a reference vessel diameter of 2.25-4.00 mm, and a delivery catheter to implant the stent to the site of stenosis.
	Total review time: 263 days Regulatory review time: 155 days	Global clinical trial				Coronary stent	
Program	Nov. 11, 2022	Date of license: Oct. 8, 2020 License No.: K201525 Brand name: ECG App Number of units shipped: 92,900 (2020), 16.4 million (2021)	42	Apple's ECG App (Apple Inc.)	Change	Program 1	A home-use software that creates, records, stores, transfers, and displays single channel ECGs similar to lead-I ECGs. It analyzes the obtained ECG, classifies the wave form as being suggestive of sinus rhythm or atrial fibrillation and notifies the results to the user. The application was submitted to add the classification results to notify the users, expand the range of heart rate to be analyzed, and change the signal processing requirements of the platform (A "partial change" application). A clinical evaluation report summarizing overseas clinical data including literature was submitted to evaluate the efficacy and safety of the product.
	Total review time: 193 days Regulatory review time: 104 days	Clinical evaluation report				Software for home use electrocardiograph	
Cardiopulmonary Circulation	Nov. 25, 2022	-	43	Agent Paclitaxel-coated Balloon Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51	A catheter for coronary balloon dilatation angioplasty used to inhibit restenosis in revascularization for coronary in-stent restenosis and de novo coronary lesions.
	Total review time: 224 days Regulatory review time: 58 days	Japanese clinical study results				Catheter for coronary balloon dilatation angioplasty	
Cardiopulmonary Circulation	Dec. 20, 2022	Mar. 31, 2022	44	Aveir LP (Abbott Medical Japan LLC)	Approval	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.
	Total review time: 265 days Regulatory review time: 105 days	Foreign and Japanese clinical study results				Implantable leadless cardiac pacemaker	
Cardiopulmonary Circulation	Mar. 29, 2023	-	45	OSYPKA DefiPace (Heiwa Bussan Co., Ltd.)	Approval	Instrument & apparatus 7	An external cardiac pacemaker for temporary atrial pacing, ventricular pacing, or atrial-ventricular sequential pacing. The product was developed based on the company's approved product "Osypka PACE300" (Approval No.: 22400BZX00123000). The major improvement is that the electrode can be placed in both atria by the combined use of the cardiac electrode, "OSYPKA TMA" (Approval No.: 30500BZX00092000) with the device so that cardioversion can be performed for atrial fibrillation.
	Total review time: 267 days Regulatory review time: 82 days	Clinical evaluation report				Invasive external cardiac pacemaker	

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	Jun. 2, 2022	-	46	COVID-19 Pneumonia Analysis Program SCO-PA01 (Canon Medical Systems 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: 98 days Regulatory review time: 47 days	Clinical evaluation report				Software for diagnostic X-ray imaging system workstation	
Program	Dec. 8, 2022	iSchemaView RAPID: Obtained 510(k) in Oct. 2013 (K121447), added the indication of usefulness of endovascular thrombectomy (K182130) in Dec. 2018, added CTA function (K172477) in Apr. 2018 RAPID ASPECTS: Obtained 510(k) in Jun. 2020 (K200760) RAPID LVO 1.0: Obtained 510(k) in Jul. 2020 (K200941) RAPID ICH: Obtained 510(k) in Mar. 2020 (K193087)	47	Brain Image Analysis Program iSchemaView Rapid (iSchemaView, Inc.)	Approval	Program 1	A software for general-purpose imaging system workstation used to assist the determination on mechanical thrombectomy in patients with acute-phase cerebral infarction based on the results of analysis on the volume of ischemic core, hypoperfusion area and their differences/ratios.
	Total review time: 268 days Regulatory review time: 164 days	Clinical evaluation report				Software for general-purpose imaging system workstation	

Reprocessed Single-Use Medical Devices Approved in FY2022

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)	May 13, 2022	-	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 extend the shelf life after the first reprocessing and the storage period before cleaning (A "partial change" application).
	Total review time: 225 days Regulatory review time: 185 days	No clinical study results				Reprocessed cuff for pneumatically-powered massager	
Orthopedic and Plastic Surgery	Aug. 17, 2022	-	2	Reprocessed Saw Blade S (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 40	Reprocessed single-use medical device originating from the existing certified device, "Stryker Bone Saw Blade" (226AFBZX00019000), which is a surgical saw for cutting or separating anatomical structure.
	Total review time: 294 days Regulatory review time: 227 days	No clinical study results				Reprocessed single-use surgical saw	
Gastroenterology, Genitourinary and Reproductive Medicine	Jun. 7, 2022	-	3	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 add the manufacturing site in charge of sterilization and storage, a manufacturing flow as a dedicated product for manufacture, a lineup of the same product as that of the approved "Reprocessed Trocar E2 (HOGY)" (Approval No.: 30300BZX00079000), and an approved single-use trocar sleeve that can be used in combination with the sleeve of this product (A "partial change" application).
	Total review time: 211 days Regulatory review time: 106 days	No clinical study results				Reprocessed single-use trocar sleeve	
Gastroenterology, Genitourinary, and Reproductive Medicine	Aug. 19, 2022	-	4	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 mainly add the large size and change the specifications related to performance and safety (A "partial change" application).
	Total review time: 141 days Regulatory review time: 125 days	No clinical study results				Reprocessed single-use natural orifices endoscopic dilator	
Cardiopulmonary Circulation	Jun. 7, 2022	May 8, 2019	5	Reprocessed Intracardiac Ultrasound Catheter V (Stryker Japan) (Stryker Japan K.K.)	Approval	Instrument & apparatus 51	A catheter for imaging of structure and blood flow of the heart, etc. with a built-in transducer whose tip transmits/receives ultrasound. The product is a reprocessed single-use medical device originating from "ViewFlex Xtra ICE Catheter" (Approval No.: 22600BZX00091000).
	Total review time: 442 days Regulatory review time: 295 days	No clinical study results				Remanufactured central circulatory intravascular ultrasound catheter	
Cardiopulmonary Circulation	Sep. 1, 2022	Jul. 9, 2008	6	Reprocessed Steerable Electrode Catheter (Stryker Japan) (Stryker Japan K.K.)	Approval	Instrument & apparatus 51	A reprocessed single-use medical device originating from "Inquiry Catheter" (Approval No. 21600BZY00253000), which is a cardiac catheter-tip electrode and is used placed percutaneously and transluminally in the heart to perform a cardiac electrophysiological study and temporary pacing.
	Total review time: 505 days Regulatory review time: 285 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.