New Medical Devices Approved from April to December 2022

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	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 Total review time: 322 days Regulatory review time: 206 days	- Japanese clinical study results	nodoca (Aillis, Inc.)	Approval	Instrument & apparatus 25 Endoscopic telescope	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.
Orthopedic and Plastic Surgery	Nov. 28, 2022 Total review time: 363 days Regulatory review time: 197 days	- Japanese clinical study results	AutoloGel System (Rohto Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 7 Platelet-rich plasma gel preparation kit	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.
Orthopedic and Plastic Surgery	Dec. 22, 2022 Total review time: 420 days Regulatory review time: 197 days	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 Japanese clinical study results	DUOLITH SD1 Ultra (Karl Storz Endoscopy Japan K.K.)	Change	Instrument & apparatus 12 Extracorporeal shockwave pain treatment device	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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 14, 2022 Total review time: 363 days Regulatory review time: 71 days	Turbo Power series Nov. 12, 2015 K152181/Turbo Power Laser Atherectomy Catheter Turbo Elite series Jul. 23, 2014 K140775/Turbo Elite Atherectomy Catheter No clinical study results	Excimer Laser Turbo Power Catheter (Philips Japan Ltd.)	Approval	Instrument & apparatus 51 Laser angioplasty catheter	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 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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 2, 2022 Total review time: 160 days Regulatory review time: 58 days	Apr. 1, 2011 P100040 /Valiant Thoracic Stent Graft System with the Captivia Delivery System Clinical evaluation report	VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Aortic stent graft	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)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 8, 2022 Total review time: 171 days Regulatory review time: 121 days	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: Approved No clinical study results	Inspire UAS System (Inspire Medical Systems, Inc.)	Change	Instrument & apparatus 12 Hypoglossal nerve stimulator	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)
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 12, 2022 Total review time: 512 days Regulatory review time: 259 days	Mar. 10, 2016 K153485/ENROUTE Transcarotid Neuroprotection System Foreign clinical study results	ENROUTE Transcarotid Neuroprotection System (Silk Road Medical, Inc.)	Approval	Instrument & apparatus 51 Central circulatory catheter for trapping embolus	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.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Nov. 28, 2022 Total review time: 347 days Regulatory review time: 204 days	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 Foreign clinical study results	Zephyr Endobronchial Valve System (Pulmonx Corporation)	Approval	Instrument & apparatus 7 Endobronchial valve	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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Dec. 22, 2022 Total review time: 261 days Regulatory review time: 88 days	Oct. 9, 2020 P200023/Zilver Vena Venous Self-Expanding Stent Foreign clinical study results	Zilver Vena Venous Stent (Cook Medical Japan G.K.)	Approval	Instrument & apparatus 7 Venous stent	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.
Gastroenterology, Genitourinary, and Reproductive Medicine	Nov. 10, 2022 Total review time: 133 days Regulatory review time: 101 days	- No clinical study results	Adacolumn (JIMRO Co., Ltd.)	Change	Instrument & apparatus 7 Cytapheresis column	A cytapheresis 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)
Cardiopulmonary Circulation	May 18, 2022 Total review time: 359 days Regulatory review time: 134 days	Mar. 30, 2018 P050006/S60/GORE CARDIOFORM SEPTAL OCCLUDER Foreign clinical study results	GORE Cardioform Septal Occluder (W. L. Gore & Associates G.K.)	Approval	Medical products 4 Artifitial pericardial prosthesis	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.
Cardiopulmonary Circulation	Aug. 2, 2022 Total review time: 165 days Regulatory review time: 100 days	Jul. 28, 2022 P140031 S141/SAPIEN 3 Ultra RESILIA No clinical study results	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 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)
Cardiopulmonary Circulation	Aug. 17, 2022 Total review time: 111 days Regulatory review time: 104 days	Aug. 23, 2017 P160054/Heart Mate3 Left Ventricular Assist System Nov. 24, 2021 P160054/S040 Alternative Apical felt material supplier addition No clinical study results	HeartMate 3 Left Ventricular Assist System (Thoratec Corporation)	Change	Instrument & apparatus 7 Implantable assistant artificial heart system	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)

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Sep. 27, 2022 Total review time: 363 days Regulatory review time: 220 days	Sep. 9, 2020 P140031 S112/TAV in TAV Foreign registry	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 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)
Cardiopulmonary Circulation	Oct. 31, 2022 Total review time: 137 days Regulatory review time: 84 days	Sep. 19, 2019 No clinical study results	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 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).
Program	Apr. 26, 2022 Total review time: 334 days Regulatory review time: 143 days	- Japanese clinical study results	CureApp HT Digital Therapeutic App for Hypertension Adjunctive Treatment (CureApp Inc.)	Approval	Program 2 Supporting software for hypertension treatment	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.
Program	Sep. 29, 2022 Total review time: 363 days Regulatory review time: 260 days	- Japanese clinical study results	Syringe Pump Control Software for Assisting Total Intravenous Anesthesia (Nihon Kohden Corporation)	Approval	Program 2 Software for automated drug delivery for general anesthesia	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.

Improved Medical Devices (With Clinical Data) Approved from April to December 2022

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Robotics, IoT, and other devices (not classified as other categories)	May 10, 2022 Total review time: 327 days Regulatory review time: 266 days	Date of license: Mar. 27, 2018 License No.: DEN170088 Foreign clinical study results	Dexcom G6 CGM System (Dexcom. Inc.)	Change	Instrument & apparatus 20 Glucose monitor system	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).
Robotics, IoT, and other devices (not classified as other categories)	Oct. 24, 2022 Total review time: 423 days Regulatory review time: 255 days	Progressive incurable neuromuscular diseases (8 diseases) Date of license: Oct. 2, 2020, 510k (License No. K201559) Japanese clinical study results	HAL for Medical USE (Lower Limb Type) (CYBERDYNE Inc.)	Change	Instrument & apparatus 58 Physiological signal use motion function improvement supporting system	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).
Robotics, IoT, and other devices (not classified as other categories)	Oct. 27, 2022 Total review time: 268 days Regulatory review time: 162 days	- Clinical evaluation report	NanoZoomer S360MD Slide scanner system (Hamamatsu Photonics K.K.)	Approval	Instrument & apparatus 21 Diagnostic assistant device for pathological whole slide image	The application was submitted for marketing approval of a diagnostic assistant device for pathological whole slide image, which 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.
Orthopedic and Plastic Surgery	Apr. 7, 2022 Total review time: 765 days Regulatory review time: 701 days	- Japanese clinical study results	Medicarbo Hip Nail (B.I.TEC Co., Ltd.)	Approval	Medical products 4 Implantable femur intramedullary fixation nail	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.
Orthopedic and Plastic Surgery	Sep. 6, 2022 Total review time: 258 days Regulatory review time: 175 days	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 Foreign clinical study results	Coolief Radiofrequency Pain Management System (Avanos Medical Japan Inc.)	Approval	Instrument & apparatus 29 Electrosurgical unit for cardiac ablation	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.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Orthopedic and Plastic Surgery	Oct. 14, 2022 Total review time: 261 days Regulatory review time: 139 days	2012 Classification I *510(k) exemption/overseas brand name: StrataXRT Clinical evaluation report	Radiation Dermatitis Film-forming Material StrataXRT (Toyo Medic Co., Ltd.)	Approval	Medical products 4 Local control hydrogel dressing	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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 28, 2022 Total review time: 260 days Regulatory review time: 77 days	- Clinical evaluation report	Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.)	Change	Instrument & apparatus 51 Catheter for balloon dilatation angioplasty	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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 26, 2022 Total review time: 268 days Regulatory review time: 124 days	- Japanese clinical trial results	PENTAS Stent (PENTAS Inc.)	Approval	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 29, 2022 Total review time: 154 days Regulatory review time: 131 days	(Approved size) Mar, 2014 P120020/Supera Peripheral Stent System (LV size) May 2021 P120020, S026/Supera Peripheral Stent System Clinical evaluation report	Supera Stent (Abbott Medical Japan LLC.)	Change	Instrument & apparatus 7 Vascular stent	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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Sep. 27, 2022 Total review time: 179 days Regulatory review time: 100 days	Aug. 2021 Not described/RelayPro Thoracic Stent Graft System Foreign clinical study results	RelayPro Thoracic Stent Graft System (Terumo Corporation)	Change	Instrument & apparatus 7 Aortic stent graft	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.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Oct. 12, 2022 Total review time: 512 days Regulatory review time: 215 days	May 18, 2015 P140026/ENROUTE Transcarotid Stent System Foreign clinical study results	ENROUTE Transcarotid Stent System (Silk Road Medical, Inc.)	Approval	Instrument & apparatus 7 Carotid artery stent	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.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Gastroenterology, Genitourinary, and Reproductive Medicine	Jul. 4, 2022 Total review time: 193 days Regulatory review time: 144 days	- Clinical evaluation report	Niti-S EUS-BD System (Century Medical, Inc.)	Approval	Instrument & apparatus 51 Transgastric biliary drainage stent	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.
Gastroenterology, Genitourinary, and Reproductive Medicine	Sep. 9, 2022 Total review time: 528 days Regulatory review time: 135 days	Sep. 29, 2010 (Proposed product: Jan. 23, 2018)/ Not described/C2 Cryo Ballon Ablation System Clinical evaluation report	C2 CryoBalloon Ablation System (HOYA Corporation)	Approval	Instrument & apparatus 31 General-purpose cryosurgical unit	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.
Dentistry and Oral Medicine	Sep. 9, 2022 Total review time: 247 days Regulatory review time: 193 days	- Japanese clinical study results	Apajet (Sangi Co., Ltd.)	Approval	Instrument & apparatus 60 Tooth surface coating spray device	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.
Ophthalmology and Otorhinolaryngology	Jun. 2, 2022 Total review time: 269 days Regulatory review time: 191 days	Nov. 21, 2016 Foreign clinical study results	WaveLight EX 500 (Alcon Japan Ltd.)	Change	Instrument & apparatus 31 Ophthalmic corneal surgery laser system	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).
Ophthalmology and Otorhinolaryngology	Sep. 6, 2022 Total review time: 253 days Regulatory review time: 157 days	- Foreign and Japanese clinical study results	FINEVISION HP (Beaver-Visitec International Japan K.K.)	Approval	Instrument & Multifocal posterior chamber lens	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.
Ophthalmology and Otorhinolaryngology	Sep. 20, 2022 Total review time: 267 days Regulatory review time: 192 days	- Japanese clinical study results	Avansee Preload1P Toric (Kowa Company, Ltd.)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	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.
Ophthalmology and Otorhinolaryngology	Oct. 11, 2022 Total review time: 224 days Regulatory review time: 169 days	- Foreign clinical study results	Airy One Day (HOYA Corporation)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	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} $(cm^2/sec)\cdot(mLO_2/[mL \times mmHg])$.
Ophthalmology and Otorhinolaryngology	Oct. 11, 2022 Total review time: 224 days Regulatory review time: 169 days	- No clinical study results	hoyaONE treasured (HOYA Corporation)	Approval	Instrument & apparatus 72 Single-use colored vision corrective contact lens	A product with multiple brand name of "Airy One Day."

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Ophthalmology and Otorhinolaryngology	Dec. 21, 2022 Total review time: 337 days Regulatory review time: 177 days	Jul. 26, 2021 510(k) LTF K193500 and DEN200028/OptiLight System Foreign clinical study results	OptiLight M22 IPL model (Lumenis Be Japan K.K.)	Approval	Instrument & apparatus 12 Xenon beam light therapy unit	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.
Cardiopulmonary Circulation	May 30, 2022 Total review time: 161 days Regulatory review time: 105 days	Jun. 18, 2021 Foreign clinical study results	Arctic Front Advance Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	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.
Cardiopulmonary Circulation	May 30, 2022 Total review time: 161 days Regulatory review time: 105 days	Dec. 17, 2010 Foreign clinical study results	Freezor MAX Cryoablation Catheter (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	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.
Cardiopulmonary Circulation	Jun. 9, 2022 Total review time: 224 days Regulatory review time: 135 days	Aug. 2015 ReDS Wearable System/K150095 Feb. 2019 ReDS System/K180479 Clinical evaluation report	ReDS Pro System (Century Medical, Inc.)	Approval	Instrument & apparatus 21 Electromagnetic component analyzer	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.
Cardiopulmonary Circulation	Aug. 2, 2022 Total review time: 260 days Regulatory review time: 86 days	- Japanese clinical study results	M-DES Coronary Stent (Nipro Corporation)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.5-4.25 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.
Cardiopulmonary Circulation	Aug. 19, 2022 Total review time: 435 days Regulatory review time: 166 days	Apr. 12, 2019 510(k):K183599/Makoto Intravascular Imaging System, TVC-MC10/TVC-MC10i Dualpro IVUS + NIRS Imaging Catheter, TVC-C195-42 Foreign clinical study results	TVC NIRS Catheter (Goodman Co., Ltd.)	Approval	Instrument & apparatus 51 Central circulation system intravascular near-infrared catheter	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.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	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	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	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	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	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	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
Cardiopulmonary Circulation	Oct. 14, 2022 Total review time: 128 days Regulatory review time: 114 days	Mar. 13, 2019 P050023/S125/Acticor 7 DR-T ProMRI / Acticor 7 VR-T ProMRI Clinical evaluation report	Acticor 7 ICD ProMRI (Biotronik Japan, Inc.)	Change	Instrument & apparatus 12 Automatic implantable defibrillator	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).
Cardiopulmonary Circulation	Oct. 18, 2022 Total review time: 263 days Regulatory review time: 155 days	Dec. 13, 2021 SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System and DIRECT Sirolimus Eluting Coronary Stent Rapid Exchange Delivery System/P210014 Global clinical trial	Svelte Sirolimus-eluting Coronary Stent System (Svelte Medical Systems, Inc.)	Approval	Instrument & apparatus 7 Coronary stent	A stent system consisting of a sirolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo native coronary artery lesion (a lesion length of 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.
Program	Nov. 11, 2022 Total review time: 193 days Regulatory review time: 104 days	Date of license: Oct. 8, 2020 License No.: K201525 Brand name: ECG App Number of units shipped: 92,900 (2020), 16.4 million (2021) Clinical evaluation report	Apple's ECG App (Apple Inc.)	Change	Program 1 Software for home use electrocardiograph	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.
Cardiopulmonary Circulation	Nov. 25, 2022 Total review time: 224 days Regulatory review time: 58 days	- Japanese clinical study results	Agent Paclitaxel-coated Balloon Catheter (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Catheter for coronary balloon dilatation angioplasty	A catheter for coronary balloon dilatation angioplasty used to inhibit restenosis in revascularization for coronary in-stent restenosis and de novo coronary lesions.
Cardiopulmonary Circulation	Dec. 20, 2022 Total review time: 265 days Regulatory review time: 105 days	Mar. 31, 2022 Foreign and Japanese clinical study results	Aveir LP (Abbott Medical Japan LLC)	Approval	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	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.
Program	Jun. 2, 2022 Total review time: 98 days Regulatory review time: 47 days	- Clinical evaluation report	COVID-19 Pneumonia Analysis Program SCO-PA01 (Canon Medical Systems Corporation)	Approval	Program 1 Software for diagnostic X-ray imaging system workstation	The application was submitted for marketing approval of a computer detection support software which processes the image information of the lungs obtained from the X-ray computed tomography system, and is used to present reference information on the possibility of containing characteristic findings of COVID-19 pneumonia in the CT image when performing the image diagnosis of pneumonia.

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification Term Name	Notes
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)	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 from April to December 2022

Review Category	Approval Date	Approval Date in US Clinical Study Results: Japanese/Foreign	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 Total review time: 225 days Regulatory review time: 185 days	- No clinical study results	Reprocessed Flowtron ACS900 (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 12 Reprocessed cuff for pneumatically-powered massager	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).
Orthopedic and Plastic Surgery	Aug. 17, 2022 Total review time: 294 days Regulatory review time: 227 days	- No clinical study results	Reprocessed Saw Blade S (HOGY) (HOGY MEDICAL CO., LTD.)	Approval	Instrument & apparatus 40 Reprocessed single-use surgical saw	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.
Gastroenterology, Genitourinary and Reproductive Medicine	Jun. 7, 2022 Total review time: 211 days Regulatory review time: 106 days	- No clinical study results	Reprocessed Trocar E (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 49 Reprocessed single-use trocar sleeve	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).
Gastroenterology, Genitourinary, and Reproductive Medicine	Aug. 19, 2022 Total review time: 141 days Regulatory review time: 125 days	- No clinical study results	Reprocessed V-pipe (HOGY) (HOGY MEDICAL CO., LTD.)	Change	Instrument & apparatus 25 Reprocessed single-use natural orifices endoscopic dilator	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).
Cardiopulmonary Circulation	Jun. 7, 2022 Total review time: 442 days Regulatory review time: 295 days	May 8, 2019 No clinical study results	Reprocessed Intracardiac Ultrasound Catheter V (Stryker Japan) (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Remanufactured central circulatory intravascular ultrasound catheter	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).
Cardiopulmonary Circulation	Sep. 1, 2022 Total review time: 505 days Regulatory review time: 285 days	Jul. 9, 2008 No clinical study results	Reprocessed Steerable Electrode Catheter (Stryker Japan) (Stryker Japan K.K.)	Approval	Instrument & apparatus 51 Reprocessed cardiac catheter-tip electrode	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.

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.