New Medical Devices Approved from April to September 2024

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	Aug. 2, 2024 Total review time: 407 days Regulatory review time: 118 days	Approval status related to this change Apr. 11, 2023 K230402/Enroute Transcarotid Neuroprotection System No clinical study results	ENROUTE Transcarotid Neuroprotection System (Silk Road Medical, Inc.)	Change	Instrument & apparatus 51 Central circulatory catheter for trapping embolus	A central circulatory catheter for trapping embolus used to prevent embolization by transcarotid vascular access during carotid angioplasty and stent placement in patients with carotid stenosis. The application was submitted to improve the efficiency of the manufacturing process by consolidating some components of the transcarotid arterial sheath and venous return sheath into single-piece units (A "partial change" application).
Cardiopulmonary Circulation	May. 2, 2024 Total review time: 293 days Regulatory review time: 213 days	Dec. 13, 2023 Global clinical trial	PulseSelect PFA Loop Catheter (Medtronic Japan Co., Ltd.)）	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	A catheter to conduct pulsed field ablation for cardiac electrophysiological mapping and the treatments of patients with drug refractory recurrent symptomatic paroxysmal atrial fibrillation and drug refractory symptomatic persistent atrial fibrillation. (The original product is in the post-market performance review period.
Cardiopulmonary Circulation	May. 2, 2024 Total review time: 293 days Regulatory review time: 252 days	Dec. 13, 2023 Global clinical trial	PulseSelect PFA Generator (Medtronic Japan Co., Ltd.)	Approval	Instrument & apparatus 29 Percutaneous cardiac coagulation/ ablation electrosurgical unit	A pulse generator intended for percutaneous myocardial catheter ablation by the use of pulsed electric fields. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	May. 14, 2024 Total review time: 116 days Regulatory review time: 116 days	- No clinical study results	GORE Cardioform Septal Occluder (W. L. Gore & Associates G.K.)	Change	Medical products 4 Artificial 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. The application was submitted to correct discrepancy in the descriptions of raw materials in the approval document (A "partial change" application).
Cardiopulmonary Circulation	Jul. 24, 2024 Total review time: 254 days Regulatory review time: 128 days	Jun. 1, 2017 Foreign clinical study results	SENTINEL Cerebral Protection System (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 51 Central circulatory catheter for trapping embolus	A distal embolic protection device designed to temporarily place filters at the aortic bifurcation (brachiocephalic artery and left common carotid artery) for capturing and removing substances causing embolization during transcatheter aortic valve replacement (TAVR).
Cardiopulmonary Circulation	Sep. 26, 2024 Total review time: 321 days Regulatory review time: 262 days	Jan. 30, 2024 Foreign clinical study results	FARASTAR Console (Boston Scientific Japan K.K.)	Approval	Instrument & apparatus 29 Percutaneous cardiac coagulation/ ablation electrosurgical unit	A pulse generator for pulsed field ablation procedures used for the treatment of arrhythmia. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	Sep. 26, 2024 Total review time: 321 days Regulatory review time: 229 days	Jan. 30, 2024 Foreign clinical study results	FARAWAVE Catheter (Boston Scientific Japan K. K.)	Approval	Instrument & apparatus 51 Catheter for cardiac ablation	A catheter intended to be used for pulsed field ablation procedure of cardiac tissues and cardiac electrophysiological mapping for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation. (The original product is in the post-market performance review period.)
Cardiopulmonary Circulation	Sep. 27, 2024 Total review time: 351 days Regulatory review time: 197 days	Jun. 29, 2023 Global clinical trial	Aveir LP (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7 Implantable leadless cardiac pacemaker	An implantable electrode integrated cardiac pacemaker intended to be percutaneously placed in the right heart using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. This product has approved as a ventricular leadless pacemaker. The application was submitted to add an atrial leadless pacemaker in the product, and also to add the indications of atrial pacing or dual-chamber pacing that physiologically synchronizes the atria and ventricles (A "partial change" application).

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	Sep. 19, 2024 Total review time: 174 days Regulatory review time: 137 days	- No clinical study results	HemeSight Analysis Program (Otsuka Pharmaceutical Co., Ltd.)	Approval	Program 1 Software for gene variants analysis (for cancer genome profiling)	The application was submitted for marketing approval of software for gene variants analysis that outputs genomic profiles summarizing hematological malignancy-related variant information, using, as input information, the base sequence data obtained by the sequence analysis of tumor and normal specimen-derived DNA and tumor specimen-derived RNA from patients with hematological malignancies or similar diseases. The output genomic profiles are used for diagnosis, selection of treatment methods, and investigation of prognosis predictions for hematological malignancies and similar disease, based on the "Guidelines for Genomic Testing of Hematological Malignancies" established by the Japanese Society of Hematology, etc.

Improved Medical Devices (With Clinical Data) Approved from April to September 2024

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)	Jun. 10, 2024	License date: Jul. 21, 2009 License No.: K091645 License date: Jun. 21, 2016 License No.: K160209 License date: Jun. 11, 2020 License No.: K201117 Brand name: Gold Anchor Number of units shipped: Conventional needle (approved product): 61,894 New needle (proposed product): 36,181	Gold Anchor Marker (GA Japan Company, Inc.)	Change	Medical products 4	A serrated gold wire to be implanted in the body to create an identification maker that can be visualized on film or digital imaging during radiation therapy. It is an implantable lesion identification marker used for locating and delineating malignant tumors in the lung, prostate, liver, pancreas, and breast in the trunk of the body. The application was submitted to add the kidney and uterus to the indications and change the shapes and measurements of the needle components (A “partial change” application).
	Total review time: 180 days Regulatory review time: 109 days	Clinical evaluation report			Implantable lesion identification marker	
Robotics, IoT, and other devices (not classified as other categories)	Aug. 28, 2024	Date of license: May 26, 2017 License No.: K171294 Brand name: da Vinci X Surgical System, Model IS4200 Number of units shipped: --	da Vinci X Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, gynecology, and head and neck surgery (limited to transoral surgery), to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal placement, ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of breast surgery (limited to nipple-sparing mastectomy) and additional concomitant devices (A “partial change” application).
	Total review time: 488 days Regulatory review time: 331 days	Clinical evaluation report			Surgical robot unit	
Robotics, IoT, and other devices (not classified as other categories)	Aug. 28, 2024	Date of license: Mar. 28, 2014 License No.: K131861 Brand name: da Vinci Surgical System, Model IS4000 Number of units shipped: No description	da Vinci Xi Surgical System (Intuitive Surgical G.K.)	Change	Instrument & apparatus 12	A device to assist surgeons' manipulation of endoscopic surgical instruments during endoscopic surgery in the areas of general digestive surgery, thoracic surgery, cardiac surgery (limited to intracardiac surgical operations under cardiac arrest), urology, gynecology, and head and neck surgery (limited to transoral surgery), to hold tissues or foreign matters, perform incisions, blunt/sharp dissection, proximal placement, ligation, incision/coagulation using high-frequency current, suturing and operation, and insertion/delivery of surgical accessories. The application was submitted for the additional indication of breast surgery (limited to nipple-sparing mastectomy) and additional concomitant devices (A “partial change” application).
	Total review time: 485 days Regulatory review time: 328 days	Clinical evaluation report			Surgical robot unit	
Robotics, IoT, and other devices (not classified as other categories)	Sep. 9, 2024	No actual data	Radiopharmaceutical Synthesis Device MPS200Aβ (Sumitomo Heavy Industries, Ltd.)	Change	Instrument & apparatus 10	A radioactive compound synthesizing facility used for the semi-automated preparation of a radioisotope labeled compound, florbetapir (18F) injection used for positron emission tomography. The application was submitted to add patients suspected of having mild cognitive impairment due to Alzheimer's disease (MCI due to AD) to the indications of florbetapir (18 F) injection (A “partial change” application).
	Total review time: 195 days Regulatory review time: 154 days	Clinical evaluation report			Radioactive compound synthesizing facilities	
Orthopedic and Plastic Surgery	Jun. 24, 2024	-	Lymmity (Techno Takatsuki Co., Ltd.)	Approval	Instrument & apparatus 12	A pneumatically-powered sequential device for stimulating lymph flow to reduce edema in patients with lymphedema by applying pneumatic compression to the affected limb and trunk. The product consists of a main unit with a built-in actuator and sleeves that compress the affected limb and trunk. As clinical evaluation data, a clinical evaluation report summarizing the literature research data on a foreign clinical study of intermittent pneumatic compression therapy with a similar product was submitted.
	Total review time: 346 days Regulatory review time: 266 days	Clinical evaluation report			Pneumatically-powered sequential device for stimulating lymph flow	

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	May 23, 2024 Total review time: 315 days Regulatory review time: 192 days	Sep. 25, 2000 P990040/TRUFILL n-butyl cyanoacrylate (n-BCA) Liquid Embolic System Clinical evaluation report	TRUFILL n-BCA Liquid Embolic System (Johnson & Johnson K.K.)	Approval	Instrument & apparatus 51 Central circulatory intravascular embolization prosthesis	A central circulatory intravascular embolization prosthesis is used as an embolic agent for vascular embolization in cases where embolization is needed before surgical removal of cerebral arteriovenous malformation refractory to non-surgical approaches or in dural arteriovenous fistula that is difficult to treat sufficiently with transvenous embolization, etc. A clinical evaluation report summarizing the literature research data, etc. on the efficacy and safety of this product was submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jun. 19, 2024 Total review time: 266 days Regulatory review time: 141 days	- Japanese clinical study results	Medilizer AGD System (Bolt Medical, Inc.)	Approval	Instrument & apparatus 51 Cerebrovascular guiding assist device	A cerebrovascular guiding assist device used to deliver an endovascular treatment device to a target lesion. The product is used in cases where the delivery of endovascular treatment devices including catheters is difficult by traditional methods due to vascular tortuosity, etc. The results of clinical studies conducted in Japan were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Jul. 29, 2024 Total review time: 391 days Regulatory review time: 197 days	Jan. 20, 2023 K222848/No description Foreign clinical study results	pRESET Stent Retriever (phenox Limited)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy that is intended for use to restore blood flow by removing clots from the intracranial blood vessel in patients with acute ischemic stroke (in principle, within 8 hours from the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) or who failed to restore blood flow with the t-PA therapy. The results of foreign clinical studies were submitted.
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Aug. 8, 2024 Total review time: 146 days Regulatory review time: 126 days	[Type IIIc] Dec. 2022 k222808/Penumbra System (Reperfusion Catheter RED 43) [Type IIb] Nov. 2011 k113163/Penumbra System MAX [Type IIIb] Nov. 2011 k113163/Penumbra System MAX Clinical evaluation report	Penumbra System 4 (Medico's Hirata Inc.)	Approval	Instrument & apparatus 51 Catheter for central circulatory embolectomy	A catheter for central circulatory embolectomy used for revascularization for patients with acute ischemic stroke (in principle, within 8 hours of the onset) who are ineligible for intravenous tissue plasminogen activator (t-PA) therapy or who failed in revascularization with the t-PA therapy. A clinical evaluation report summarizing the contents of Japanese and foreign clinical literature, etc. was submitted to evaluate the efficacy and safety of ADAPT.
Gastroenterology, Genitourinary and Reproductive Medicine	Jun. 24, 2024 Total review time: 312 days Regulatory review time: 169 days	Initial: Sep. 29, 2010/ CryoBalloon Ablation System Proposed product: Jan. 23, 2018 C2 CryoBalloon Ablation System Japanese clinical study results	C2 CryoBalloon Ablation System (HOYA Corporation)	Change	Instrument & apparatus 31 General-purpose cryosurgical unit	A general-purpose cryosurgical unit intended for endoscopic cryoablation of lesion tissue. This product has already been approved for use in patients with "endoscopically-unresectable, recurrent Barrett's esophageal lesion associated with dysplasia or noninvasive adenocarcinoma that has arisen from residual diseased tissue or in/around the scar after endoscopic resection." The application was submitted to add the indication of “endoscopically-unresectable, recurrent esophageal squamous cell carcinoma that has arisen from residual diseased tissue or in/around the scar after endoscopic resection” (A “partial change” application).
Gastroenterology, Genitourinary and Reproductive Medicine	Sep. 2, 2024 Total review time: 242 days Regulatory review time: 122 days	None Japanese clinical study results	Zeostent HG (Zeon Medical Inc.)	Approval	Instrument & apparatus 51 Transgastric biliary drainage stent	A transgastric biliary drainage stent designed to create an anastomotic site between the gastrointestinal wall (stomach) and the bile duct in endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) for use as a drainage pathway. The product consists of a self-expanding stent with a hook-shaped anchor at the gastric wall-side distal end and a delivery system.

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	Jun. 3, 2024 Total review time: 270 days Regulatory review time: 138 days	- Japanese clinical study results	SEERS (Menicon Co., Ltd.)	Approval	Medical products 4 Ophthalmic material for maintaining visibility	The application was submitted for marketing approval of an ophthalmic material for maintaining visibility during open surgery to treat glaucoma. The product is a prefilled syringe loaded with synthetic peptide in a clear gel formulation, which is applied to the area of observation or treatment to ensure a clear operative field and help with observation and treatment.
Ophthalmology and Otorhinolaryngology	Jun. 6, 2024 Total review time: 252 days Regulatory review time: 137 days	Aug. 10, 2018 /P170034/Hydrus Microstent Foreign clinical study results	Hydrus Glaucoma Microstent (Alcon Japan Ltd.)	Approval	Medical products 4 Intraocular drain	The application was submitted for marketing approval of a stent and its delivery system used simultaneously during cataract surgery to lower intraocular pressure in patients with mild to moderate open-angle glaucoma.
Ophthalmology and Otorhinolaryngology	Jun. 19, 2024 Total review time: 265 days Regulatory review time: 144 days	- Japanese clinical study results	PODEYE Toric (Beaver-Visitec International Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens	The application was submitted for marketing approval of a posterior chamber lens with cylindrical refractivity to be implanted in the posterior chamber of the eye to replace a cloudy crystalline lens and restore vision.
Ophthalmology and Otorhinolaryngology	Jul. 11, 2024 Total review time: 265 days Regulatory review time: 119 days	- Clinical evaluation report	iStent inject Trabecular Micro-Bypass System (Glaukos Corporation)	Change	Medical products 4 Heparin-coated drain for intraocular	A stent and the injector used for lowering intraocular pressure in patients with mild to moderate open-angle glaucoma. The application was submitted to expand the indications by adding the use of the product alone to the conventional indications for simultaneous use in cataract surgery, and to add a new type of injector (A "partial change" application).
Ophthalmology and Otorhinolaryngology	Aug. 2, 2024 Total review time: 224 days Regulatory review time: 162 days	- Foreign clinical study results	TECNIS PureSee Extended Depth of Focus IOL Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter.
Ophthalmology and Otorhinolaryngology	Aug. 2, 2024 Total review time: 224 days Regulatory review time: 162 days	- Foreign clinical study results	TECNIS PureSee Toric Extended Depth of Focus IOL Simplicity (AMO Japan K.K.)	Approval	Instrument & apparatus 72 Posterior chamber lens with inserter	The application was submitted for marketing approval of a posterior chamber lens with inserter.
Ophthalmology and Otorhinolaryngology	Sep. 19, 2024 Total review time: 269 days Regulatory review time: 169 days	- Japanese clinical study results	Acriva Trinova Pro (Wakamoto Pharmaceutical Co., Ltd.)	Approval	Instrument & apparatus 72 Multifocal posterior chamber lens	The application was submitted for marketing approval of a multifocal posterior chamber lens which is used to correct near, intermediate and far vision of an aphakic eye and reduce spectacle dependence.
Ophthalmology and Otorhinolaryngology	Sep. 30, 2024 Total review time: 854 days Regulatory review time: 353 days	Jul. 3, 2019 K190589/OSI100, Osia SP, (Osia System) Nov. 15, 2019 K191921/OSI200, Osia 2 SP (Osia System/Osia 2 System) Foreign clinical study results	Osia System (Nihon Cochlear Co., Ltd.)	Approval	Instrument & apparatus 73 Implantable bone-conduction hearing aid	The application was submitted for marketing approval of an implantable bone-conduction hearing aid to improve the ability to hear environmental sounds and speech sounds in patients with hearing impairment who have normal bone conduction thresholds or mild impairment at least in one ear.

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	Apr. 22, 2024 Total review time: 130 days Regulatory review time: 111 days	May 2, 2017 Clinical evaluation report	RESONATE ICD Series (Boston Scientific Japan K. K.)	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 model with a function to provide indicators related to the changes in the patient's biological information (HeartLogic function) as per the section 3 in the "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 and PSEHB/SD Notification No. 1117-1 dated on November 17, 2017)" (A "partial change" application).
Cardiopulmonary Circulation	Jun. 12, 2024 Total review time: 160 days Regulatory review time: 145 days	- Japanese clinical study results	Kaneka Cutting Balloon Catheter CO-R1 (Kaneka Corporation)	Approval	Instrument & apparatus 51 Catheter for coronary balloon dilatation angioplasty	A balloon catheter used to dilate coronary stenosis that is difficult to dilate with a conventional balloon catheter. The balloon has integrated blades along its surface.
Cardiopulmonary Circulation	Jun. 18, 2024 Total review time: 82 days Regulatory review time: 44 days	- Clinical evaluation report	POLARx Cryoablation Balloon Catheter (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 51 Catheter for cardiac ablation	A balloon catheter used for cryoablation of cardiac tissue. The application was submitted to add "the treatment of drug-resistant, symptomatic, persistent atrial fibrillation" to the existing intended use (the treatment of drug-refractory, recurrent, symptomatic, paroxysmal arterial fibrillation) and "compatibility with electric powered injectors" to the specifications related to performance and safety (A "partial change" application).
Cardiopulmonary Circulation	Jun. 18, 2024 Total review time: 230 days Regulatory review time: 182 days	Oct. 1, 2022 Foreign registry	SelectSecure Lead (Medtronic Japan Co., Ltd.)	Change	Instrument & apparatus 7 Implantable endocardial pacemaker electrode/lead	The device is an implantable endocardial pacemaker electrode/lead. 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 left bundle branch area pacing to its intended use (A "partial change" application).
Cardiopulmonary Circulation	Jun. 19, 2024 Total review time: 257 days Regulatory review time: 180 days	- Performance evaluation study results using existing medical information in Japan	CardiMax FCP-9900Ai System (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 21 Multi-function electrocardiograph	A multi-functional electrocardiograph intended for ECG with at least 12 leads including limb leads and chest leads. The device was developed based on "CardiMax FCP-9900 System" (Certification No.: 301ADBZX00034000). The change is addition of a function that estimates the possibility of paroxysmal atrial fibrillation occurring in the past 2 years.
Cardiopulmonary Circulation	Aug. 2, 2024 Total review time: 219 days Regulatory review time: 140 days	- Foreign registry	COMBO Plus Coronary Stent (Orbusneich Medical K. K.)	Change	Instrument & apparatus 7 Murine antibody-coated coronary stent	A coronary stent system consists of a drug-eluting stent used to treat patients with ischemic heart disease and a delivery catheter to deploy a stent to the stenosed lesion. A murine-derived anti-CD34 antibody and sirolimus are coated on the stent surface of the device. The application was submitted to add stent sizes (A "partial change" application).
Cardiopulmonary Circulation	Aug. 26, 2024 Total review time: 242 days Regulatory review time: 196 days	- Performance evaluation study results using existing medical information in Japan	CardiMax FCP-9800Ai (Fukuda Denshi Co., Ltd.)	Approval	Instrument & apparatus 21 Multi-function electrocardiograph	A multi-functional electrocardiograph intended for ECG with 12 leads including limb leads and chest leads. The device was developed based on the "CardiMax FCP-9800" (Certification No.: 303ADBZX00038000). The change is addition of a function that estimates the possibility of paroxysmal atrial fibrillation occurring in the past 2 years.

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	May 8, 2024 Total review time: 398 days Regulatory review time: 320 days	License date: Jun. 3, 2022 License number: K213971 Brand name: Atrial Fibrillation History Feature Foreign clinical study results	Apple's Atrial Fibrillation History Feature (Apple Inc.)	Approval	Program 1 Software for home use heart rate monitor	The application was submitted for marketing approval of a software for home use heart rate monitor. The device is used to analyze pulse rate data to identify episodes suggestive of atrial fibrillation, and to provide users with the estimated percentage of time that the heart showed the signs of atrial fibrillation in the past relative to the time wearing the Apple Watch.
Program	Aug. 2, 2024 Total review time: 368 days Regulatory review time: 149 days	- Performance evaluation study results using existing medical information in Japan	Endoscopic Surgery Support Program SurVis-Hys (Jmees Inc.)	Approval	Program 1 Supporting software for surgical image recognition	The application was submitted for marketing approval of supporting software for surgical image recognition. This software assists surgeons with image recognition by processing image data obtained from an endoscopy system and highlighting candidate areas of the ureter and bladder during surgery.
Program	Aug. 23, 2024 Total review time: 333 days Regulatory review time: 196 days	None Japanese clinical study	RST Calculation Program (HeartLab, Inc.)	Approval	Program 1 Software for analysis of body motion information	Software for analysis of body motion information used to provide an index related to respiratory stability by analyzing nocturnal body motion data. The present application for marketing approval of the product was submitted based on the "Concept of two-step approval of Software as a Medical Device for disease diagnosis" described in the "Handling of two-step approval based on the characteristics of Software as a Medical Device" (PSB/MDED Notification No. 1116-2 dated November 16, 2023).
Program	Aug. 26, 2024 Total review time: 270 days Regulatory review time: 167 days	Sep. 13, 2024 Foreign clinical study results	Apple's Sleep Apnea Notification Feature (Apple Inc.)	Approval	Program 1 Software for analysis of home use body motion information	The application was submitted for marketing approval of software for analysis of home use body motion information that analyzes wrist motion data from the built-in accelerometer of the Apple Watch to detect any irregular breathing suggestive of sleep apnea and notifies the user of it.
Program	Sep. 30, 2024 Total review time: 241 days Regulatory review time: 99 days	Sep. 12, 2024 Foreign clinical study results	Apple's hearing assist Feature (Apple Inc.)	Approval	Program 1 Software for home use hearing assist fitting	The application was submitted for marketing approval of software for home use hearing assist fitting that allows the user to configure the sound amplification-related settings for hearing aid based on the input audiogram results.
Program	Sep. 30, 2024 Total review time: 122 days Regulatory review time: 61 days	- Clinical evaluation report	Apple's hearing check feature (Apple Inc.)	Approval	Program 1 Software for home use audiometry device	The application was submitted for marketing approval of software for home use audiometry device used to notify the user of the possibility of hearing loss by performing air conduction audiometry.

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.