New Medical Devices Approved from April to June 2023

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 29, 2023 Total review time: 53 days Regulatory review time: 39 days	- No clinical study results	Jetstream Atherectomy System (Boston Scientific Japan K.K.)	Change	Instrument & apparatus 51 Atherectomy ablative angioplasty catheter	An atherectomy ablative angioplasty catheter that is percutaneously inserted into the peripheral blood vessel to cut, crush, and suck the lesion by rotating the tip of the catheter. The application was submitted to add a raw material of the catheter (A "partial change" application).
Cardiopulmonary Circulation	May 8, 2023 Total review time: 199 days Regulatory review time: 148 days	Sep. 19, 2019 Foreign and Japanese 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 position of the aortic valve. The device has been approved for the indication of severe symptomatic native aortic stenosis or treatment in patients with symptomatic valvular disease due to dysfunction of a surgically placed bioprosthetic aortic valve who are not receiving chronic dialysis. The application was submitted to expand the indication for patients on chronic dialysis with these findings for whom surgery cannot be performed (A “partial change” application).
Cardiopulmonary Circulation	May 11, 2023 Total review time: 867 days Regulatory review time: 510 days	- Japanese clinical study results	Paravalvular Leak Closure Set (Japan Lifeline Co., Ltd.)	Approval	Medical products 4 Artificial pericardial prosthesis	A set consisting of an occluder, pusher, and loader intended to be used for percutaneous closure of a defect hole for prosthetic paravalvular regurgitation.
Cardiopulmonary Circulation	Jun. 12, 2023 Total review time: 56 days Regulatory review time: 56 days	- No clinical study results	MitraClip NT System (Abbott Medical Japan LLC)	Change	Instrument & apparatus 7 Percutaneous repair system for mitral valve coaptation failure	Percutaneous repair system for mitral valve coaptation failure is intended to reduce mitral regurgitation (MR) by coapting the anterior and posterior leaflets of the mitral valve using a percutaneously inserted clip. The application was submitted to add a raw material, falling under a “specified partial change” based on “Acceleration of Procedure for Specified Change for Medical Devices” (PFSB/ELD/OMDE Notification No. 1110001 dated on November 10, 2008). (A “partial change” application submitted during the post-market performance review period)

Improved Medical Devices (With Clinical Data) Approved from April to June 2023

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	Jun. 12, 2023	Apr. --, 2004 K033801/KyphX HV-R Jul. --, 2004 K041584/KyphX HV-R Aug. --, 2010 K093828/KyphX HV-R Apr. --, 2015 K150460/KYPHON HV-R Aug. --, 2016 K160983/KYPHON HV-R May --, 2018 K180700/KYPHON HV-R	KYPHON BKP Bone Cement HV-R (Medtronic Sofamor Danek Co., Ltd.)	Change	Medical products 4	An orthopedic bone cement used to restore the vertebral height of the fractured vertebral body and to relieve pain in patients with vertebral fracture due to osteoporosis, multiple myeloma, or metastatic bone tumor. The application was submitted to add the indication of simultaneous treatment of multiple vertebral bodies, to delete the indications restricted to primary osteoporosis and acute spinal compression fracture, and to add the indication for patients who are considered unlikely to respond to conservative therapy, in the case to use the medical device for vertebral fracture due to osteoporosis (A “partial change” application).
	Total review time: 252 days Regulatory review time: 175 days	Clinical evaluation report			Orthopedic bone cement	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 3, 2023	Nov. 27, 2018 −/VASCADE MVP® Venous Vascular Closure System	VASCADE MVP (Haemonetics Japan G.K.)	Approval	Medical products 4	The application was submitted for marketing approval of an absorbable topical hemostatic material with collagen used for hemostasis at the femoral venous access site following percutaneous catheterization. As clinical evaluation data, the results of foreign clinical studies were submitted.
	Total review time: 264 days Regulatory review time: 116 days	Foreign clinical study results			Absorbable topical hemostatic material with collagen	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 20, 2023	Sep. 2012 K121917/CAT/SEP 3 & 5 May 2015 K142870/CAT/SEP 6 & 8 Jul. 2016 K161523/CAT/SEP 6 & 8 May 2018 K180939/Aspiration Tubing	INDIGO System (Penumbra, Inc.)	Approval	Instrument & apparatus 51	The application was submitted for marketing approval of catheter for central circulatory embolectomy used to aspirate thrombus from a peripheral artery or vein. A clinical evaluation report summarizing foreign clinical studies and the contents of foreign literatures was submitted as clinical evaluation data.
	Total review time: 115 days Regulatory review time: 50 days	Clinical evaluation report			Catheter for central circulatory embolectomy	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	Apr. 25, 2023	-	Envi-SR Retriever for Mechanical Thrombectomy (NeuroVasc Technologies, Inc.)	Approval	Instrument & apparatus 51	A catheter for central circulatory embolectomy intended for use to restore blood flow in patients with acute ischemic stroke in whom intravenous tissue plasminogen activator (tPA) therapy is not indicated or fails to achieve reperfusion. As clinical evaluation data, the results of clinical studies conducted in Japan were submitted.
	Total review time: 207 days Regulatory review time: 119 days	Japanese clinical study results			Catheter for central circulatory embolectomy	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 8, 2023	Jun. 15, 2004 K040835/XenoSure Bioligic Patch	Bovine Pericardium Patch XenoSure (LeMaitre Vascular G.K.)	Change	Instrument & apparatus 7	A bovine pericardial patch used for repair or procedure of femoral artery, femoral vein, and carotid artery. The application was submitted to add an indication for carotid artery (A “partial change” application). The clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted as clinical evaluation data.
	Total review time: 269 days Regulatory review time: 156 days	Clinical evaluation report			Bovine pericardial patch	
Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry	May 29, 2023	Apr. 2022 −/Thoraflex Hybrid	Thoraflex Hybrid (Terumo Corporation)	Approval	Instrument & apparatus 7	An aortic stent graft and gelatin coated vascular graft used for surgical repair in patients with aneurysms or dissections of the aortic arch and descending aorta. The aortic stent graft and gelatin coated vascular graft are sutured and integrated in advance for the purpose of simplifying the procedure. The results of foreign clinical studies were submitted as clinical evaluation data.
	Total review time: 320 days Regulatory review time: 194 days	Foreign clinical study results			Aortic stent graft	

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. 25, 2023	-	Filtrap (Nipro Corporation)	Change	Instrument & apparatus 51	A basket catheter set that is temporarily placed in the blood vessel to capture or remove intravascular foreign matters such as floating thrombus and blood clots. The application was submitted to add the intended use of capture or removal of substances causing embolization during percutaneous coronary intervention in patients with acute coronary syndrome in whom a large amount of plaque at a high risk for distal embolization was found in the native coronary lesions on intravascular imaging (A “partial change” application).
	Total review time: 827 days Regulatory review time: 485 days	Clinical evaluation report			Central circulatory catheter for trapping embolus	
Cardiopulmonary Circulation	Apr. 26, 2023	-	OSYPKA TMA (Heiwa Bussan Co., Ltd.)	Approval	Instrument & apparatus 7	A wire-type cardiac electrode that is connected to the external pacemaker "OSYPKA DefiPace" (Approval No.: 30500BZX00068000) for temporary cardiac pacing after open heart surgery. When the product is placed in both atria, biatrial pacing and cardioversion for atrial fibrillation can be performed.
	Total review time: 295 days Regulatory review time: 181 days	Clinical evaluation report			Extracorporeal pacemaker electrode wire	
Cardiopulmonary Circulation	May 29, 2023	-	External Ventricular Assist Device EVAD (Sun Medical Technology Research Corp.)	Approval	Instrument & apparatus 7	A single-use extracorporeal assistant artificial cardiac pump used to maintain normal systemic circulation including the heart itself and improve cardiac insufficiency in patients with severe heart failure exceeding the limit of treating with conventional medication or existing assisted circulation (such as intra-aortic balloon pumping or venoarterial bypass) due to severe heart failure or cardiogenic shock. The device consists of the internal components of the inflow cuff and outflow graft, external components such as the cannula carrying blood into and from the body, blood pump, and controller, and accessories. They are identical to those of the company's approved product "implantable Ventricular Assist System EVAHEART" (Approval No.: 22200BZX00939000) except for the cannula and tunneler.
	Total review time: 935 days Regulatory review time: 240 days	Clinical evaluation report			Single-use extracorporeal assistant artificial cardiac pump	
Program	May 23, 2023	1) IRNF Version 2.0 License date: Oct. 22, 2021 License No.: K212516 Brand name: IRNF App Number of units shipped: -- 2) IRNF Version 1.0 License date: Sep. 11, 2020 License No.: DEN180042 Brand name: Irregular Rhythm Notification Feature Number of units shipped: 397,800 (2018), 4499,700 (2019), 3922,500 (2020)	Apple's Irregular Rhythm Notification Feature (Apple Inc.)	Change	Program 1	A home-use program that analyzes pulse rate data, detects irregular heartbeats suggestive of atrial fibrillation and notifies the user. The application was submitted to change the requirements for the platform to install the product and the classification algorithms to classify irregular heartbeats (A “partial change” application). Data on the platform study under the changed platform requirements and data on validation of the algorithm were submitted. Also, a clinical evaluation report summarizing the contents of foreign clinical literatures, etc. was submitted as data related to results of clinical study results.
	Total review time: 323 days Regulatory review time: 84 days	Clinical evaluation report			Software for home use heart rate monitor	

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.