*New Medical Devices Approved in FY2021*

| Review Category | Approval Date | Approval Date in US Clinical Study Results: Japanese/Foreign | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Classification Term Name | Notes |
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| Robotics, IoT, and other devices (not classified as other categories) | Aug. 6, 2021<br>Total review time: 340 days<br>Regulatory review time: 248 days | -<br>Clinical evaluation report | 1 | Oncotype DX Breast Recurrence Score Program<br>(Exact Sciences K.K.) | Approval | Program 1<br>Software program to support tumor malignancy determination | The application was submitted for marketing approval of a software program to support tumor malignancy determination which outputs a Recurrence Score that assists in determining chemotherapy use based on the RNA expression levels of 21 genes in tumor tissue of hormone receptor-positive, HER2-negative, early-stage invasive breast cancer patients. |
| Orthopedic and Plastic Surgery | Jun. 7, 2021<br>Total review time: 363 days<br>Regulatory review time: 262 days | -<br>Clinical evaluation report | 2 | EpiFix<br>(MiMedx Group, Inc.) | Approval | Medical products 4<br>Tissue-healing promoting material using human amniotic membrane | A tissue-healing promoting material composed of human amniotic membranes intended to promote wound healing in patients with refractory ulcers who have not responded to conventional therapies. The product is made of dried human amniotic/chorionic membranes obtained from the human placenta, prepared by cleaning, drying, and sterilizing, and contains multiple types of amniotic/chorionic membrane-derived extracellular matrix proteins, growth factors, cytokines, etc. A clinical evaluation report primarily consisting of the results of a foreign post-marketing clinical study, a literature review, and an adverse event report was submitted to evaluate the efficacy and safety of the product as a tissue-healing promoting material. |
| Orthopedic and Plastic Surgery | Feb. 17, 2022<br>Total review time: 360 days<br>Regulatory review time: 144 days | Sep. 20, 2018<br>Foreign clinical study results | 3 | RECELL Autologous Cell Harvesting and Non-cultured Cell Suspension Preparation Kit<br>(Cosmotec Co., Ltd.) | Approval | Instrument & apparatus 58<br>Autologous skin cell grafting kit | An autologous skin cell grafting kit intended to produce a non-cultured cell suspension from a skin specimen collected from a patient and promote healing of the wound of acute burn and donor sites. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product. |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | May 13, 2021<br>Total review time: 364 days<br>Regulatory review time: 113 days | Mar. 13, 2020<br>Foreign clinical study results | 4 | ALTO Abdominal Stent Graft System<br>(Endologix LLC) | Approval | Instrument & apparatus 7<br>Aortic stent graft | The application was submitted for marketing approval of a stent graft system for the treatment of abdominal aorta that obtains adhesion to blood vessels by filling polymer. |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | May 26, 2021<br>Total review time: 90 days<br>Regulatory review time: 80 days | Apr. 30, 2014<br>P130008/INSPIRE II UPPER AIRWAY STIMULATOR<br><br>May 5, 2017<br>P130008/S016/INSPIRE UPPER AIRWAY STIMULATOR, MODEL 3028<br>No clinical study results | 5 | Inspire UAS System<br>(Inspire Medical Systems, Inc.) | Change | Instrument & apparatus 12<br>Hypoglossal nerve electrical 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. The application was submitted to add a manufacturing site for sterilization and a programmer cable used for wireless communication between the programmer for physicians and the pulse generator.<br>(A “partial change” application submitted during the post-market performance review period) |

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| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Jun. 8, 2021 | - | 6 | GORE CTAG Thoracic Endoprosthesis (W. L. Gore & Associates, G. K.) | Change | Instrument & apparatus 7 | An aortic stent graft system used for intravascular treatment of thoracic aortic diseases. The application was submitted to add blue pigment to the surgical sutures used of the stent graft and delivery catheter, in order to enhance its identifiability during the manufacturing process, 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).<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 97 days<br>Regulatory review time: 39 days | No clinical study results | | | | Aortic stent graft | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Jun. 17, 2021 | - | 7 | VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.) | Change | Instrument & apparatus 7 | A stent graft system used for the treatment of thoracic aorta. The application was submitted to partially change the raw materials of the delivery system, 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).<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 56 days<br>Regulatory review time: 47 days | No clinical study results | | | | Aortic stent graft | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Jun. 21, 2021 | - | 8 | MR Guided Focused Ultrasound Surgery ExAblate 4000 (InSightec Ltd.) | Change | Instrument & apparatus 12 | A focused ultrasound system intended for focally heating the target and causing focal coagulative necrosis to deliver focused ultrasound energy to the target in the thalamus through the skull. The device is used to alleviate essential tremor and symptoms of Parkinson's disease in patients who are not respond sufficiently to drug therapies. The application was submitted to add components including a patient table and dedicated head coil, due to the addition of the MR device used with the system, to add and make improvements in final confirmation function of the radiation parameter, and to change the evaluation method for the image quality of the MR device used with the system.<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 293 days<br>Regulatory review time: 152 days | No clinical study results | | | | Focused ultrasound system | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Sep. 13, 2021 | - | 9 | Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries) (Medicon, Inc.) | Change | Instrument & apparatus 51 | A balloon-dilating catheter for 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 (excluding those within a stent). The balloon surface of this product is coated with a drug primarily composed of paclitaxel. The application was submitted for deletion of the specification for heavy metal in the drug substance (paclitaxel), 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).<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 98 days<br>Regulatory review time: 71 days | No clinical study results | | | | Catheter for balloon dilatation angioplasty | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Oct. 14, 2021 | May 5, 2019<br>Valiant Thoracic Stent Graft With The Captivia Delivery System (P100040 S038) | 10 | VALIANT Thoracic Stent Graft System (Medtronic Japan Co., Ltd.) | Change | Instrument & apparatus 7 | A stent graft system used for the treatment of thoracic aorta. The application was submitted to add ethylene oxide gas processing to the manufacturing process of stent graft for bioburden reduction.<br>(A "partial change" application submitted during the post-market performance review period) |
| | Total review time: 135 days<br>Regulatory review time: 116 days | No clinical study results | | | | Aortic stent graft | |

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| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Oct. 26, 2021<br>Total review time: 356 days<br>Regulatory review time: 217 days | Apr. 10, 2013<br>Jetstream SC/XC Atherectomy Catheter/<br>Oct. 19, 2012<br>Jetstream Console/<br>Japanese clinical study results | 11 | Jetstream Atherectomy System<br>(Boston Scientific Japan K.K.) | Approval | Instrument & apparatus 51<br>Atherectomy ablative angioplasty catheter | The application was submitted for marketing approval of a catheter system used to remove hard atherosclerotic disease and stenosis in the superficial femoral artery and/or proximal popliteal artery to facilitate pre-dilation of severely calcified lesions (excluding in-stent restenosis lesions) that do not pass through or are difficult to dilate with a PTA balloon catheter used for pre-dilatation prior to drug-coated balloons. |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Nov. 22, 2021<br>Total review time: 146 days<br>Regulatory review time: 94 days | Feb. 25, 2015<br>VenaSeal Closure System<br>No clinical study results | 12 | VenaSeal Closure System<br>(Covidien Japan Inc.) | Change | Instrument & apparatus 51<br>Vascular embolization prosthesis | A vascular embolization prosthesis to occlude the blood vessel by injecting into the truncal saphenous veins with venous reflux. The application was submitted to change the raw material of the catheter hub and introducer hub and to change the specifications for leakage of the drug solution from the introducer hub.<br>(A "partial change" application submitted during the post-market performance review period) |
| Gastroenterology, Genitourinary and Reproductive Medicine | Jul. 14, 2021<br>Total review time: 161 days<br>Regulatory review time: 101 days | -<br>Clinical evaluation report | 13 | Adacolumn<br>(JIMRO Co., Ltd.) | Change | Instrument & apparatus 7<br>Purifier for blood cell removal | A purifier for blood cell removal 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 add the indication for maintaining remission during the remission phase in patients with refractory ulcerative colitis who have not responded, have not sufficiently responded, or are not amenable to conventional medications. A clinical evaluation report summarizing a Japanese clinical study and the contents of Japanese and foreign clinical literatures, etc. were submitted to evaluate the efficacy and safety of the product for this indication.<br>(A "partial change" application submitted during the post-market performance review period) |
| Gastroenterology, Genitourinary, and Reproductive Medicine | Oct. 13, 2021<br>Total review time: 359 days<br>Regulatory review time: 178 days | Aug. 27, 2015<br>K150786/Rezum System<br>Foreign clinical study results | 14 | Rezum System<br>(Boston Scientific Japan K.K.) | Approval | Instrument & apparatus 29<br>Water vapour delivery system for prostatic tissue | A water vapour delivery system for prostatic tissue indicated for dysuria associated with prostatic hyperplasia. In the system, a needle in the delivery device is inserted into the site of enlarged prostate and the high-temperature water vapour is delivered from the holes of the needle tip. The system uses the thermal energy released from the liquefaction of the water vapour injected from the needle tip, to necrotise the enlarged prostate tissue with time, and improves dysuria. The results of a foreign clinical studies were submitted to evaluate the efficacy and safety of the product. |
| Gastroenterology, Genitourinary and Reproductive Medicine | Feb. 8, 2022<br>Total review time: 776 days<br>Regulatory review time: 520 days | Sep. 28, 2006<br>K060482/CYTORI CELUTION CELL CONCENTRATION DEVICE<br>Japanese clinical study results | 15 | Celution Cell Therapy Kit SUI<br>(Cytori Therapeutics, K.K.) | Approval | Instrument & apparatus 7<br>Adipose tissue separation kit | An adipose tissue separation kit to clean, separate, and process adipose tissue by centrifugation to be administered specific cells and adipose tissue for the treatment of patients who have not responded or have not sufficiently responded to behavioral therapy or drug therapy for mild to moderate male stress urinary incontinence associated with urethral sphincter incompetence secondary to a surgery for prostatic hyperplasia or prostate cancer. The results of Japanese clinical studies were submitted to evaluate the efficacy and safety of the treatment using this product. |

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| Gastroenterology, Genitourinary and Reproductive Medicine | Feb. 8, 2022<br>Total review time: 229 days<br>Regulatory review time: 166 days | Dec. 21, 2017<br>DEN170024/Not described<br>Foreign clinical study results | 16 | AQUABEAM Robotic System (PROCEPT BioRobotics Corporation) | Approval | Instrument & apparatus 12<br>Surgical robot unit | A device to resect an enlarged prostate by inserting a handpiece transurethrally and using a high-pressure water injection of physiological saline. A physician sets a resection plan preoperatively, and the robot system performs treatment following the plan. The application was submitted for marketing approval of a medical device used for resection and removal of prostate tissue of male patients with lower urinary tract symptoms associated with prostatic hyperplasia. |
| Gastroenterology, Genitourinary and Reproductive Medicine | Mar. 28, 2022<br>Total review time: 115 days<br>Regulatory review time: 33 days | Aug. 27, 2015<br>K150786/Rezum System<br>No clinical study results | 17 | Rezum System (Boston Scientific Japan K. K.) | Change | Instrument & apparatus 29<br>Water vapour delivery system for prostatic tissue | A water vapour delivery system for prostatic tissue indicated for dysuria associated with prostatic hyperplasia. In the system, a needle in the delivery device is inserted into the site of enlarged prostate and the high-temperature water vapour is delivered from the holes of the needle tip. The system uses the thermal energy released from the liquefaction of the water vapour injected from the needle tip, to necrotise the enlarged prostate tissue with time, and improves dysuria. The application was submitted to add a model whose a pressure safety valve located at the tip of a tube for injection water is removed. (A “partial change” application). |
| Cardiopulmonary Circulation | Apr. 6, 2021<br>Total review time: 344 days<br>Regulatory review time: 224 days (Review report, etc.) | Aug. 16, 2019<br>Global clinical study results | 18 | CoreValve Evolut R (Medtronic Japan Co., Ltd.) | Change | Instrument & apparatus 7<br>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 of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option" in the treatment for patients with severe symptomatic native aortic valve stenosis (Approval No.: 22800BZX00414000). The application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic valve stenosis who are at low surgical risk were submitted as the clinical study data on the indication expansion.<br>(A “partial change” application submitted during the post-market performance review period) |
| Cardiopulmonary Circulation | Apr. 6, 2021<br>Total review time: 281 days<br>Regulatory review time: 161 days | Aug. 16, 2019<br>Global clinical study results | 19 | Edwards SAPIEN 3 (Edwards Lifesciences Limited) | Change | Instrument & apparatus 7<br>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. This product has been approved as a medical device used for transcatheter aortic valve implantation and transcatheter pulmonary valve replacement (Approval No.: 22800BZX00094000). For the treatment of patients with severe symptomatic native aortic valve stenosis, this product has been approved for the indication of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option." In addition to the indication mentioned above, the application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic valve stenosis who are at low surgical risk were submitted as the clinical study data on the indication expansion.<br>(A “partial change” application submitted during the post-market performance review period) |

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| Cardiopulmonary Circulation | Apr. 7, 2021 | Oct. 27, 2016<br>510K (K160121)/CorPath GRX System<br>Mar. 1, 2018<br>510K (K173806)/CorPath GRX System: RoR added | 20 | CorPath GRX System<br>(Corindus, Inc.) | Change | Instrument & apparatus 51 | Remote catheter manipulation equipment to be installed in a cardiac catheterization room to manipulate and hold guiding catheters, guidewires, rapid exchange balloon dilatation catheters for coronary angioplasty, and rapid exchange coronary stent catheters that are used for percutaneous coronary intervention. The application was submitted for an additional function to make several movements with this device (such as rotation and back and forward movement), which are commonly required when a guidewire and a therapeutic catheter are inserted to the lesion by a physician.<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 208 days<br>Regulatory review time: 111 days | No clinical study results | | | | Catheter manipulation equipment for use in the cardiac and central circulatory system | |
| Cardiopulmonary Circulation | May 13, 2021 | Dec. 27, 2018 | 21 | Edwards SAPIEN 3<br>(Edwards Lifesciences Limited) | Change | Instrument & apparatus 7 | A prosthetic cardiac valve system used for transcatheter valve implantation. The system mainly consists of a bovine pericardium-derived bioprosthetic valve and a delivery catheter system that is used to deploy the bioprosthetic valve at the valve position. The application was submitted to add a bioprosthetic valve model in which the height of the outer skirt and the type of the cloth were changed in order to maintain the prevention of paravalvular regurgitation.<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 286 days<br>Regulatory review time: 191 days | No clinical study results | | | | Transcatheter bovine cardiac valve | |
| Cardiopulmonary Circulation | Jun. 17, 2021 | May 8, 2020 | 22 | HeartLight Endoscopic Ablation System<br>(Japan Lifeline Co., Ltd.) | Change | Instrument & apparatus 51 | A balloon-type laser ablation catheter with an endoscope to treat drug-resistant recurrent symptomatic paroxysmal atrial fibrillation. The application was submitted to add a model with a laser autorotation mode (RAPID mode) in order to shorten procedure time. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the additional model.<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 351 days<br>Regulatory review time: 169 days (Review report, etc.) | Foreign clinical study results | | | | Catheter for cardiac ablation | |
| Cardiopulmonary Circulation | Jun. 30, 2021 | Jan. 8, 2016 | 23 | Perceval Bioprosthetic Valve<br>(LivaNova Canada Corp.) | Change | Instrument & apparatus 7 | A bovine pericardium valve designed to replace a diseased native aortic valve or a malfunctioning prosthetic aortic valve via open-heart surgery. The application was submitted to change the transportation time for bovine pericardium.<br>(A “partial change” application submitted during the post-market performance review period) |
| | Total review time: 159 days<br>Regulatory review time: 145 days | No clinical study results | | | | Bovine pericardium valve | |
| Cardiopulmonary Circulation | Jul. 29, 2021 | Jan. 15, 2020 | 24 | Micra Transcatheter Pacing System<br>(Medtronic Japan Co., Ltd.) | Change | Instrument & apparatus 7 | An implantable electrode-integrated cardiac pacemaker intended to be percutaneously placed in the right ventricle using a catheter. Patients in whom the device is implanted may undergo limited MRI examinations only if the patients meet the set requirements. The application was submitted to mainly add a model with an atrioventricular synchronization function. The results of foreign clinical studies were submitted as clinical evaluation data.<br>(A "partial change" application submitted during the post-market performance review period) |
| | Total review time: 314 days<br>Regulatory review time: 197 days | Foreign clinical study results | | | | Implantable leadless cardiac pacemaker | |

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| Cardiopulmonary Circulation | Jul. 29, 2021<br>Total review time: 269 days<br>Regulatory review time: 248 days | Sep. 19, 2019<br>P130021S059/Medtronic Evolut PRO+ System<br>Global clinical study results | 25 | Evolut PRO+ System<br>(Medtronic Japan Co., Ltd.) | Change | Instrument & apparatus 7<br>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 of "patients who are not eligible for surgery and for whom the treatment with this device is considered as their best therapeutic option" in the treatment for patients with severe symptomatic native aortic stenosis (Approval No.: 30200BZX00272000). The application was submitted to expand the indication for patients who are eligible for surgery. The results of a global clinical study in patients with severe symptomatic native aortic stenosis who are at a low surgical risk were submitted as the clinical study data on the indication expansion. |
| Cardiopulmonary Circulation | Aug. 23, 2021<br>Total review time: 266 days<br>Regulatory review time: 116 days | Mar. 26, 2021<br>Global clinical study results | 26 | Harmony Transcatheter Pulmonary Valve Replacement System<br>(Medtronic Japan Co., Ltd.) | Approval | Instrument & apparatus 7<br>Transcatheter porcine pericardial valve | A transcatheter porcine pericardial valve used in patients with severe pulmonary regurgitation who have a medical history of surgical repair of the right ventricular outflow tract or transcatheter intervention (balloon valvuloplasty) and for whom pulmonary valve replacement is clinically required. The results of a global clinical study were submitted to evaluate the efficacy and safety of the product. |
| Cardiopulmonary Circulation | Oct. 26, 2021<br>Total review time: 971 days<br>Regulatory review time: 192 days | Nov. 2017<br>P170008/EluNIR Ridaforolimus Eluting Coronary Stent System<br>Foreign and Japanese clinical study results | 27 | EluNIR Drug-Eluting Stent<br>(Medinol Ltd.) | Approval | Instrument & apparatus 7<br>Coronary stent | A coronary stent used for the treatment of patients with symptomatic heart disease who have de novo native coronary artery lesions (a lesion length of 42 mm or less) with a reference vessel diameter of 2.50-4.25 mm. The results of foreign and Japanese clinical studies were submitted to evaluate the efficacy and safety of the product. |
| Cardiopulmonary Circulation | Oct. 27, 2021<br>Total review time: 111 days<br>Regulatory review time: 36 days | Jan. 27, 2021<br>No clinical study results | 28 | Edwards SAPIEN 3<br>(Edwards Lifesciences Limited) | Change | Instrument & apparatus 7<br>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 a manufacturing site and to modify the descriptions in the manufacturing method column.<br>(A "partial change" application submitted during the post-market performance review period) |
| Cardiopulmonary Circulation | Jan. 17, 2022<br>Total review time: 145 days<br>Regulatory review time: 93 days | -<br>No clinical study results | 29 | AMPLATZER PFO Occluder<br>(Abbott Medical Japan LLC.) | Change | Medical products 4<br>Prosthetic material for artificial cardiac membrane | A percutaneous transcatheter closure device of a patent foramen ovale (PFO) intended to close PFO in patients with a history of cryptogenic cerebral infarction in whom the existence of PFO is determined to be related to the onset of cerebral infarction. The device is used to reduce the risk of recurrence of cerebral infarction. The application was submitted to change the left atrial disc, size of 30 mm and add a model in which the occluder is connected to the delivery cable in advance (A “partial change” application). |
| Cardiopulmonary Circulation | Jan. 17, 2022<br>Total review time: 292 days<br>Regulatory review time: 223 days | -<br>Foreign clinical study results | 30 | Navitor Transcatheter Aortic Valve Implantation System<br>(Abbott Medical Japan LLC.) | Approval | Instrument & apparatus 7<br>Transcatheter bovine cardiac valve | A self-expandable percutaneous aortic bioprosthetic valve system for a percutaneous aortic valve replacement used in symptomatic patients with severe aortic valve stenosis attributed to calcification and degeneration of the native aortic valve cusps, who are not eligible for surgery and of which this treatment is considered as their best therapeutic option. This product consists of a self-expanding bioprosthetic valve, delivery system, and loading system. As clinical evaluation data, the results of foreign clinical studies were submitted. |

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| Cardiopulmonary Circulation | Mar. 14, 2022<br>Total review time: 171 days<br>Regulatory review time: 53 days | Feb. 17, 2021<br>No clinical study results | 31 | Edwards SAPIEN 3<br>(Edwards Lifesciences Limited) | Change | Instrument & apparatus 7<br>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 extend the shelf life of the bioprosthetic valve from 2 years to 3 years.<br>(A "partial change" application submitted during the post-market performance review period) |
| Cardiopulmonary Circulation | Mar. 23, 2022<br>Total review time: 170 days<br>Regulatory review time: 141 days | Jan. 27, 2020<br>No clinical study results | 32 | HeartMate 3 Left Ventricular Assist System<br>(Thoratec Corporation) | Change | Instrument & apparatus 7<br>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 HeartMate Touch monitor, etc. developed as an alternative to a component system monitor.<br>(A "partial change" application submitted during the post-market performance review period) |
| Cardiopulmonary Circulation | Mar. 23, 2022<br>Total review time: 111 days<br>Regulatory review time: 91 days | -<br>No clinical study results | 33 | HeartMate 3 Left Ventricular Assist System<br>(Thoratec Corporation) | Change | Instrument & apparatus 7<br>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 of an outflow graft with bend relief, etc.<br>(A "partial change" application submitted during the post-market performance review period) |
| Cardiopulmonary Circulation | Mar. 28, 2022<br>Total review time: 363 days<br>Regulatory review time: 162 days | Feb. 12, 2021<br>Foreign and Japanese clinical study results | 34 | IVL Generator<br>(Shockwave Medical, Inc.) | Approval | Instrument & apparatus 29<br>Driving unit for angioplasty athelectomy catheter | A generator used to disrupt severely calcified *de novo* coronary artery lesions. As clinical evaluation data, the results of foreign clinical studies and Japanese studies were submitted. |
| Cardiopulmonary Circulation | Mar. 28, 2022<br>Total review time: 363 days<br>Regulatory review time: 156 days | Feb. 12, 2021<br>Foreign and Japanese clinical study results | 35 | $C^2$ Coronary IVL Catheter<br>(Shockwave Medical, Inc.) | Approval | Instrument & apparatus 51<br>Atherectomy ablative angioplasty catheter | A catheter used to disrupt severely calcified *de novo* coronary artery lesions. As clinical evaluation data, the results of foreign clinical studies and Japanese studies were submitted. |

*Improved Medical Devices (With Clinical Data) Approved in FY 2021*

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| Robotics, IoT, and other devices (not classified as other categories) | Apr. 21, 2021<br>Total review time: 246 days<br>Regulatory review time: 110 days | Jun. 12, 2020<br>Foreign clinical study results | 1 | FreeStyle Libre 2<br>(Abbott Japan LLC) | Approval | Instrument & apparatus 20<br>Glucose monitor system | The application was submitted for marketing approval of a glucose monitor system that continuously measures glucose levels in the interstitial fluid. The monitored fluctuation patterns of the glucose level are displayed on the screen. |
| Robotics, IoT, and other devices (not classified as other categories) | Sep. 17, 2021<br>Total review time: 340 days<br>Regulatory review time: 267 days | Sep. 1, 2020<br>Foreign clinical study results | 2 | Medtronic MiniMed 700 Series<br>(Medtronic Japan Co., Ltd.) | Approval | Instrument & apparatus 74<br>Portable insulin infusion pump | The application was submitted for marketing approval of a glucose monitoring system used for continuous subcutaneous infusion of basal insulin at a selectable rate and bolus infusion of insulin at a selectable dose. |
| Robotics, IoT, and other devices (not classified as other categories) | Oct. 27, 2021<br>Total review time: 359 days<br>Regulatory review time: 274 days | -<br>Foreign clinical study results | 3 | Octopal R Pulse Oximeter DMO-8000<br>(Nihon Kohden Corporation) | Approval | Instrument & apparatus 21<br>Pulse oximeter | This application was submitted for marketing approval of a pulse oximeter that has a function of measuring patients' vital signs (percutaneous arterial oxygen saturation, carboxyhemoglobin concentration, methemoglobin concentration, and pulse rate), displaying them on the screen, and issuing an alarm. |
| Robotics, IoT, and other devices (not classified as other categories) | Oct. 28, 2021<br>Total review time: 211 days<br>Regulatory review time: 128 days | Oct. 26, 2012<br>Cyberknife M6 System<br>Clinical evaluation report | 4 | CyberKnife M6 Series<br>(Accuray Japan K.K.) | Change | Instrument & apparatus 9<br>Stereotactic radiotherapy accelerator system | A cyber knife intended to be used for non-incisional surgery with high-energy X-ray stereotactic irradiation through the acquisition of a treatment plan and images of lesions requiring radiotherapy, such as head and neck (including intracranial region), cerebral arteriovenous malformation, and arteriovenous malformation of trunk and spinal cord. The application was submitted to add trigeminal neuralgia whose pain is difficult to control with drug therapy to the indication of this product (A "partial change" application). There is no change in the specifications, and change and addition of components of this product in this application. |
| Robotics, IoT, and other devices (not classified as other categories) | Oct. 28, 2021<br>Total review time: 210 days<br>Regulatory review time: 127 days | Jul. 14, 1999<br>CyberKnife Radiosurgery System<br>Clinical evaluation report | 5 | CyberKnife Radiosurgery System<br>(Accuray Japan K.K.) | Change | Instrument & apparatus 9<br>Stereotactic radiotherapy accelerator system | A cyber knife intended to be used for non-incisional surgery with high-energy X-ray stereotactic irradiation through the acquisition of a treatment plan and images of lesions requiring radiotherapy, such as head and neck (including intracranial region), cerebral arteriovenous malformation, and arteriovenous malformation of trunk and spinal cord. The application was submitted to add trigeminal neuralgia whose pain is difficult to control with drug therapy to the indication of this product (A "partial change" application). There is no change in the specifications, and change and addition of components of this product in this application. |

| Review Category | Approval Date | Approval Date in US Clinical Study Results: Japanese/Foreign | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Classification Term Name | Notes |
|---|---|---|---|---|---|---|---|
| Robotics, IoT, and other devices (not classified as other categories) | Jan. 7, 2022 | Nov. 16, 2018<br>K180881/HemoSphere advanced monitor, hemoSphere pressure cable<br><br>May 21, 2019<br>K183646/Acumen hypotension prediction index-EV1000 clinical platform, Acumen hypotension prediction index-hemosphere advanced monitoring platform, Acumen hypotension prediction index-hemosphere advanced monitoring platform-pressure<br><br>Aug. 29, 2019<br>K190205/HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module<br><br>Number of units shipped (total): Approximately 2500 units | 6 | Acumen HPI System<br>(Edwards Lifesciences Limited) | Approval | Instrument & apparatus 21 | The application was submitted for marketing approval of a multiparameter monitor to measure hemodynamics such as thermodilution cardiac output and arterial pressure-based cardiac output and to collect and monitor various biological information. |
| | Total review time: 266 days<br>Regulatory review time: 201 days | Foreign clinical study results | | | | Multiparameter monitor | |
| Robotics, IoT, and other devices (not classified as other categories) | Jan. 20, 2022 | None | 7 | ait<br>(Peace of Mind Co., Ltd.) | Approval | Instrument & apparatus 12 | The application was submitted for marketing approval of an alternating magnetic field therapy device used to relieve pain by transcutaneously irradiating 2 types of alternating magnetic fields and stimulating the nerves. |
| | Total review time: 269 days<br>Regulatory review time: 225 days | Japanese clinical study results | | | | Alternating magnetic field therapy device | |
| Orthopedic and Plastic Surgery | Jun. 16, 2021 | - | 8 | TNS Alloy Stem<br>(Mizuho Corporation) | Approval | Medical products 4 | A femoral component for hip prosthesis used for total hip replacement or prosthesis replacement in patients with hip joint functional disorders including osteoarthritis, rheumatoid arthritis and necrosis of the femoral head. The product has only a direct fixation type of femoral stem, and is used with an approved stem head. The product is made from Ti-Nb-Sn alloy, and obtains elastic gradient from proximal to distal by thermal processing of the base material. The results of a Japanese clinical study designed as a single-arm, open-label, multicenter study were submitted to evaluate the improvement in JOA hip score after surgery as efficacy and malfunctions and adverse events as safety. |
| | Total review time: 266 days<br>Regulatory review time: 147 days | Japanese clinical study results | | | | Femoral component for hip prosthesis | |
| Orthopedic and Plastic Surgery | Dec. 13, 2021 | - | 9 | Motiva Breast Implants<br>(Establishment Labs S.A.) | Approval | Medical products 4 | A gel-filled mammary prosthesis made of a silicone gel used for breast reconstruction or augmentation in adult women to restore or form the shape of a breast. This product contains SmoothSilk Series implant and SmoothSilk Ergonomix Series implant as components, both of which are round in shape and have a smooth surface finish. A clinical evaluation report consisting of data related to foreign clinical study and clinical publications was submitted to prove there are not unacceptable risks of product-specific adverse events. |
| | Total review time: 269 days<br>Regulatory review time: 124 days | Clinical evaluation report | | | | Gel-filled mammary prosthesis | |
| Orthopedic and Plastic Surgery | Feb. 10, 2022 | Jul. 15, 2015 | 10 | Phototherapy Device for Pigmentary Skin Disease Nordlys<br>(Syneron Candela K.K.) | Approval | Instrument & apparatus 12 | A phototherapy device for skin diseases used to treat benign superficial skin pigmentary disease by thermal action of continuous spectral light from visible to infrared rays using intense pulsed light. A clinical evaluation report summarizing clinical literatures, etc. on the previous generation product of this device and similar products of other companies was submitted to evaluate the improvement effect on pigmentary disease and the acceptability of anticipated adverse events for the efficacy. |
| | Total review time: 182 days<br>Regulatory review time: 144 days | Clinical evaluation report | | | | Phototherapy device for skin diseases | |

| Review Category | Approval Date | Approval Date in US Clinical Study Results: Japanese/Foreign | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Classification Term Name | Notes |
|---|---|---|---|---|---|---|---|
| Orthopedic and Plastic Surgery | Mar. 14, 2022 | Mar. 26, 2014<br>REGENETEN Implant<br>Jul. 12, 2013<br>Tendon Staple<br>Aug. 29, 2013<br>Bone Staple, Staple Delivery Set<br>Dec. 22, 2011<br>Tendon Marker<br>Dec. 22, 2011<br>Tendon Guide | 11 | REGENETEN Implant<br>(Smith & Nephew KK) | Approval | Medical products 4 | A collagen containing absorbable tendon regeneration material that manages and protects tendons with oriented collagen fibers that act as a scaffold for tendon tissue, in order to promote repair of a cuff injury site without substantial loss of tissue. A clinical evaluation report organizing the results of non-GCP-compliant foreign clinical studies and clinical literatures, etc. was submitted to evaluate the facts that this product contributes to the repair of the cuff such as a tendency towards increased tendon thickness and that the risks associated with the use of this product are acceptable for the efficacy. |
| | Total review time: 391 days<br>Regulatory review time: 183 days | Clinical evaluation report | | | | Collagen-containing absorbable tendon regeneration material | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Apr. 23, 2021 | May 4, 2020 | 12 | TREO Abdominal Stent Graft System<br>(Terumo Corporation) | Approval | Instrument & apparatus 7 | An aortic stent graft indicated for the intravascular treatment of infrarenal abdominal aortic aneurysm that satisfies the specific anatomical conditions. The results of a single-arm clinical study conducted in the US were submitted to evaluate the efficacy and safety of the product. |
| | Total review time: 263 days<br>Regulatory review time: 118 days | Foreign clinical study results | | | | Aortic stent graft | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Jun. 2, 2021 | - | 13 | LUNAWAVE<br>(Terumo Corporation) | Change | Instrument & apparatus 12 | An optical coherence tomography (OCT) imaging system to perform intravascular optical coherence tomography (OCT), connected to the dedicated intravascular optical tomographic catheter, "FastView" (Approval No.: 22500BZX00057000). The application was submitted to add an indication for the arteries of the lower limb in addition to the current indication for the coronary arteries. |
| | Total review time: 187 days<br>Regulatory review time: 115 days | Japanese clinical study results | | | | Optical coherence tomography (OCT) imaging system | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Jun. 2, 2021 | - | 14 | FastView<br>(Terumo Corporation) | Change | Instrument & apparatus 51 | An intravascular optical tomographic catheter to perform intravascular optical coherence tomography (OCT), connected to the dedicated OCT imaging system, "LUNAWAVE" (Approval No.: 22500BZX00058000). The application was submitted to add an indication for the arteries of the lower limb in addition to the current indication for the coronary arteries. |
| | Total review time: 187 days<br>Regulatory review time: 109 days | Japanese clinical study results | | | | Intravascular optical tomographic catheter | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Oct. 28, 2021 | May 4, 2015<br>ERBECRYO2/K151041 | 15 | ERBE CRYO2<br>(Amco Inc.) | Change | Instrument & apparatus 31 | A cryosurgery unit used for tissue biopsy or removal of foreign matters by cooling/freezing the bronchus, bronchial peripheral tissues, or foreign matters in the bronchus by touching with the probe tip cooled by high-pressure carbon dioxide. The application was submitted to add removal of airway obstruction in patients in whom a tumor obstructs the central airway and who require immediate airway securing to the intended use (A “partial change” application). |
| | Total review time: 255 days<br>Regulatory review time: 61 days | Clinical evaluation report | | | | General-purpose cryosurgical unit | |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Nov. 29, 2021 | - | 16 | RelayPro Thoracic Stent Graft System<br>(Terumo Corporation) | Approval | Instrument & apparatus 7 | The application was submitted for marketing approval of an arterial stent graft used for the endovascular treatment of descending thoracic aortic aneurysm. The product was designed based on the company’s approved product "Relay Plus Thoracic Stent Graft System" (Approval No. 22500BZX00160000) and for which different stent graft types were added and the delivery system was improved. The results of physicochemical characterization tests, biological safety test, durability test, animal test, and clinical studies were submitted to secure the application content. |
| | Total review time: 301 days<br>Regulatory review time: 201 days | Global clinical study results | | | | Aortic stent graft | |

| Review Category | Approval Date | Approval Date in US Clinical Study Results: Japanese/Foreign | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Classification Term Name | Notes |
|---|---|---|---|---|---|---|---|
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Nov. 30, 2021<br>Total review time: 179 days<br>Regulatory review time: 125 days | -<br>Clinical evaluation report | 17 | Wire for Lymphatic Vessels (TRS Co., Ltd.) | Approval | Instrument & apparatus 51<br>Non-vascular guidewire | The application was submitted for marketing approval of a non-vascular guidewire used to be inserted into the lymphatic vessels to confirm their courses, locations, etc. in lymphatic-venous anastomosis for treatment of lymphoedema. A clinical evaluation report summarizing literatures, etc. on lymphatic-venous anastomosis at the sites where this product is expected to be used was submitted. |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Mar. 2, 2022<br>Total review time: 485 days<br>Regulatory review time: 145 days | -<br>Clinical evaluation report | 18 | Histoacryl (B. Braun Aesculap Japan Co., Ltd.) | Change | Instrument & apparatus 51<br>Central circulatory intravascular embolization prosthesis | The application was submitted to add the indication regarding vascular embolization for hemostasis, prevention of bleeding, alleviation of symptoms, etc. (A "partial change" application). A clinical evaluation report summarizing the contents of Japanese and foreign literatures, etc. was submitted to evaluate the efficacy and safety of the product. |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Mar. 2, 2022<br>Total review time: 243 days<br>Regulatory review time: 106 days | -<br>Clinical evaluation report | 19 | NEOVEIL (GUNZE LIMITED) | Change | Medical products 4<br>Absorbable tissue reinforcement material | The application was submitted to add reinforcement of defective and fragile parts in organs/tissue, and prevent of air leakage. (A "partial change" application). A clinical evaluation report summarizing literatures, etc. related to the results of use of this product in defective and fragile parts in organs and tissue was submitted. |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Mar. 28, 2022<br>Total review time: 364 days<br>Regulatory review time: 144 days | Dec. 22, 2020<br>PMA approved/GORE EXCLUDER Conformable AAA Endoprosthesis<br>Foreign clinical study results | 20 | GORE Excluder Conformable AAA Stent Graft System (W. L. Gore & Associates G.K.) | Approval | Instrument & apparatus 7<br>Aortic stent graft | An aortic stent graft used for the intravascular treatment of infrarenal abdominal aortic aneurysm (including aneurysms extending from the abdominal aorta to the iliac artery) that satisfies the specific anatomical requirements. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product. |
| Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry | Mar. 28, 2022<br>Total review time: 238 days<br>Regulatory review time: 83 days | -<br>Foreign clinical study results | 21 | EIT Monitor PulmoVista 500 (Draeger Japan Ltd.) | Approval | Instrument & apparatus 21<br>Respiratory function measuring system | The application was submitted for marketing approval of a respiratory function measuring system which displays information on changes in lung volume and local distribution in the internal electrode surface by measuring the biological impedance distribution in the chest using electric impedance tomography technology. This product displays the tomographic image data related to impedance changes in real time and analyzes the data. |
| Gastroenterology, Genitourinary and Reproductive Medicine | May 26, 2021<br>Total review time: 321 days<br>Regulatory review time: 167 days | Nov. 22, 2011<br>Clinical evaluation report | 22 | RENASYS Abdominal Kit (Smith & Nephew KK) | Approval | Medical products 4<br>Open abdominal wound dressing kit | The application was submitted for marketing approval of a dressing kit intended to facilitate early closure of the peritoneum. The product provides the protection of abdominal contents from external environment, efficient drainage, suppression of inflammation, and alleviation of edema by covering the organs inside the abdomen and applying controlled negative pressure in the case where open abdominal wounds are accompanied by exposure of abdominal organs and also abdominal closure by primary suture is difficult. The product consists of an organ protective layer, form filler, drape, and soft port. An approved product, “RENASYS Wound Therapy System” is used in combination with the product for negative pressure control. |

| Review Category | Approval Date | Approval Date in US<br>Clinical Study Results:<br>Japanese/Foreign | No. | Brand Name<br>(Applicant Company) | New Approval/<br>Partial Change | Classification<br>Term Name | Notes |
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| Gastroenterology, Genitourinary, and Reproductive Medicine | Oct. 27, 2021<br>Total review time: 245 days<br>Regulatory review time: 147 days | -<br>Japanese clinical study results | 23 | Tenaleaf<br>(GUNZE LIMITED) | Approval | Medical products 4<br>Absorbable adhesion-prevention dressing | A sheet-type absorbable adhesion-prevention dressing to reduce the frequency, extent, and severity of postoperative adhesions in patients undergoing surgery of abdominal or pelvic cavity. The product becomes gel by absorbing water in the damaged site or abdominal cavity, prevents formation of fibrin networks in the damaged site and surrounding tissues as a physical barrier, and exerts an adhesion-reducing effect. |
| Gastroenterology, Genitourinary, and Reproductive Medicine | Dec. 24, 2021<br>Total review time: 228 days<br>Regulatory review time: 118 days | -<br>Clinical evaluation report | 24 | Cool-tip RFA System E Series<br>(Covidien Japan Inc.) | Change | Instrument & apparatus 29<br>Radiofrequency ablation system | A radiofrequency ablation system used for coagulating and ablating tissues. The application was submitted to add the followings to the intended use of this product: "small-diameter renal malignant tumor" as well as "pulmonary malignant tumor," "malignant bone tumor," "osteoid osteoma," "pelvic malignant tumor," and "soft tissue tumors that developed in the extremities, thoracic cavity, and abdominal cavity" that are ineligible for or refractory to standard therapy (A “partial change” application). A clinical evaluation report based on Japanese and foreign clinical literatures, etc. was submitted to evaluate the efficacy and safety of the product. |
| Dentistry and Oral Medicine | Jul. 14, 2021<br>Total review time: 226 days<br>Regulatory review time: 161 days | -<br>Japanese clinical study results | 25 | Opalescence GO<br>(ULTRADENT PRODUCTS, INC.) | Approval | Instrument & apparatus 62<br>Drug-containing dental tooth surface cleaner auxiliary material | A drug-containing dental tooth surface cleaner auxiliary material whose ready-made tray is pre-filled with 6% hydrogen peroxide. This product is used by patients on their teeth at home, etc., under the management of a dentist. The results of a Japanese clinical study designed as a multicenter, open-label controlled study were submitted to evaluate the efficacy and safety of the product. |
| Ophthalmology and Otorhinolaryngology | May 11, 2021<br>Total review time: 242 days<br>Regulatory review time: 189 days | Jun. 2, 2020<br>Foreign clinical study results | 26 | Bausch & Lomb Aqualox One Day UV Shin<br>(Bausch & Lomb Japan Co., Ltd.) | Approval | Instrument & apparatus 72<br>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 (kalifilcon A) with a moisture content of 55% and an oxygen permeability (Dk) of 107 x $10^{-11}$ ($cm^2$/sec)·($mLO_2$/[mL x mmHg]). |
| Ophthalmology and Otorhinolaryngology | Jun. 11, 2021<br>Total review time: 248 days<br>Regulatory review time: 163 days | -<br>Japanese clinical study results | 27 | 2 Week Fresh View S<br>(Rohto Pharmaceutical Co., Ltd.) | Approval | Instrument & apparatus 72<br>Reusable colored vision corrective contact lens | The application was submitted for marketing approval of daily wear, reusable colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (toufilcon B) with a moisture content of 50% and an oxygen permeability (Dk) of 91×$10^{-11}$ (cm2/sec)·($mLO_2$/[mL x mmHg]). |
| Ophthalmology and Otorhinolaryngology | Oct. 14, 2021<br>Total review time: 269 days<br>Regulatory review time: 129 days | -<br>Japanese clinical study results | 28 | 1day SD01H-S<br>(SEED Co., Ltd.) | Approval | Instrument & apparatus 72<br>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 68% and an oxygen permeability (Dk) of 60 x $10^{-11}$ ($cm^2$/sec)·($mLO_2$/[mL × mmHg]). |
| Ophthalmology and Otorhinolaryngology | Dec. 17, 2021<br>Total review time: 267 days<br>Regulatory review time: 135 days | Dec. 31, 2013<br>Clinical evaluation report | 29 | Nasaleze<br>(Nasaleze Limited) | Approval | Medical products 4<br>Home-use nasal mucosal protector | The application was submitted for marketing approval of a home-use nasal mucosal protector used for alleviation of symptoms associated with allergic rhinitis (sneezing, runny nose, and stuffy nose). |

| Review Category | Approval Date | Approval Date in US Clinical Study Results: Japanese/Foreign | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Classification Term Name | Notes |
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| Ophthalmology and Otorhinolaryngology | Dec. 20, 2021<br>Total review time: 264 days<br>Regulatory review time: 190 days | -<br>Foreign clinical study results | 30 | Total 14<br>(Alcon Japan Ltd.) | Approval | Instrument & apparatus 72<br>Reusable colored vision corrective contact lens | The application was submitted for marketing approval of daily wear, reusable colored vision corrective contact lens, which is intended to be used for visual correction. The lens is composed of silicone hydrogel (Lehfilcon A) with a moisture content of 55% and an oxygen permeability (Dk) of 123 x $10^{-11}$ ($cm^2$/sec)·($mLO_2$/[mL × mmHg]). |
| Ophthalmology and Otorhinolaryngology | Feb. 24, 2022<br>Total review time: 269 days<br>Regulatory review time: 114 days | -<br>Foreign clinical study results | 31 | Preserflo MicroShunt Glaucoma Drainage System Core Kit<br>(Santen Pharmaceutical Co., Ltd.) | Approval | Medical products 4<br>Intraocular drain | The application was submitted for marketing approval of an intraocular drain used to reduce intraocular pressure in patients with glaucoma whose intraocular pressure can not be sufficiently reduced by treatments including drug and laser therapies. |
| Cardiopulmonary Circulation | Apr. 27, 2021<br>Total review time: 270 days<br>Regulatory review time: 155 days | May 30, 2008<br>K063727/IMPELLA 2.5<br>Apr. 15, 2009<br>K083111/IMPELLA 5.0<br>Sep. 6, 2012<br>K112892/IMPELLA CP<br>Mar. 22, 2018<br>P140003_S026/IMPELLA CP SmartAssist (CP-Op)<br>Clinical evaluation report | 32 | Impella Circulatory Assist Pump Catheter<br>(Abiomed, Inc.) | Change | Instrument & apparatus 51<br>Controler for temporary non-roller type cardiac support blood pump | A catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through femoral artery or axillary/subclavian artery and placed in the left ventricle. This device removes blood directly from the left ventricle and sends the blood from the catheter into the ascending aorta. The application was submitted to add a procedure for inserting the device through the axillary/subclavian artery as a part of the usage of the product, a model in which the shape and raw material of the pigtail at the tip of the Impella CP and CP-Op were changed, and a raw material of the lure connector on the branch connector line in the set for purge. A clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted to evaluate the safety of the procedure for inserting the device through the axillary/subclavian artery. |
| Cardiopulmonary Circulation | Jun. 17, 2021<br>Total review time: 261 days<br>Regulatory review time: 103 days | May 28, 2019<br>Foreign clinical study results | 33 | GORE Cardioform ASD Occluder<br>(W. L. Gore & Associates G.K.) | Approval | Medical products 4<br>Artifitial pericardial prosthesis | An artifitial pericardial prosthesis used to percutaneously close ostium secundum atrial septal defect. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product. |
| Cardiopulmonary Circulation | Jul. 21, 2021<br>Total review time: 250 days<br>Regulatory review time: 102 days | -<br>Foreign clinical study results | 34 | POLARx Cryoablation Balloon Catheter<br>(Boston Scientific Japan K.K.) | Approval | Instrument & apparatus 51<br>Catheter for cardiac ablation | A balloon catheter used for cryoablation of cardiac tissue in the treatment of drug-refractory, recurrent, symptomatic, paroxysmal atrial fibrillation. The results of foreign clinical studies were submitted to evaluate the efficacy and safety of the product. |
| Cardiopulmonary Circulation | Aug. 26, 2021<br>Total review time: 269 days<br>Regulatory review time: 175 days | Jan. 28, 2021<br>Foreign clinical study results | 35 | DiamondTemp Ablation Catheter<br>(Medtronic Japan Co., Ltd.) | Approval | Instrument & apparatus 51<br>Catheter for cardiac ablation | An electrode catheter to be used for conducting cardiac electrophysiological mapping, and percutaneous cardiac ablation with high-frequency current for the treatment of patients with drug-resistant recurrent symptomatic paroxysmal atrial fibrillation and common type atrial flutter. The results of foreign clinical studies were submitted as clinical evaluation data . |
| Cardiopulmonary Circulation | Oct. 5, 2021<br>Total review time: 256 days<br>Regulatory review time: 181 days | -<br>Global clinical study results | 36 | Ultimaster Nagomi<br>(Terumo Corporation) | Approval | Instrument & apparatus 7<br>Coronary stent | A stent system consisting of a drug-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have de novo native coronary artery lesions (a lesion length of 45 mm or less) with a reference vessel diameter of 2.25-4.0 mm, and a delivery catheter used to implant a stent to the target lesion. The results from a subgroup analysis of global clinical study data using the previous generation product of this product “Ultimaster” (Approval No.: 22700BZX00224000) were submitted to evaluate the efficacy and safety of this product. |

| Review Category | Approval Date | Approval Date in US<br>Clinical Study Results:<br>Japanese/Foreign | No. | Brand Name<br>(Applicant Company) | New Approval/<br>Partial Change | Classification<br>Term Name | Notes |
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| Cardiopulmonary Circulation | Oct. 21, 2021<br>Total review time: 262 days<br>Regulatory review time: 224 days | -<br>Clinical evaluation report | 37 | SATAKE HotBalloon Catheter<br>(Toray Industries, Inc.) | Change | Instrument & apparatus 51<br>Catheter for cardiac ablation | A balloon ablation catheter utilizing a high frequency current. The application was submitted to add drug-resistant recurrent symptomatic persistent atrial fibrillation to the conventional intended use (drug-resistant recurrent symptomatic paroxysmal atrial fibrillation) (A "partial change" approval application). A clinical evaluation report summarizing the contents of Japanese and foreign clinical literatures, etc. was submitted to secure the application content. |
| Cardiopulmonary Circulation | Nov. 22, 2021<br>Total review time: 270 days<br>Regulatory review time: 139 days | Sep. 24, 2019<br>None/IMPELLA 5.5<br>Clinical evaluation report | 38 | Impella 5.5 SmartAssist<br>(Abiomed, Inc.) | Approval | Instrument & apparatus 51<br>Controler for temporary non-roller type cardiac support blood pump | A catheter-based blood pump that assists systemic circulation in patients with drug resistant acute heart failure, such as cardiogenic shock, can be inserted through axillary/subclavian artery and placed in the left ventricle. This device removes blood directly from the left ventricle and sends the blood from the catheter into the ascending aorta. The product is concomitantly used with a dedicated driving device “Impella Controller” (Approval No.: 22800BZX00031000). This product was developed with the aim of limiting the insertion site to the axillary/subclavian artery according to the clinical needs, increasing the circulatory support flow, and reducing the size of the catheter pump based on the approved "Impella Circulatory Assist Pump Catheter" (Approval No.: 228000BZI00032000). A clinical evaluation report summarizing the contents of clinical literatures, etc. was submitted as the data for clinical evaluation of the product. |
| Cardiopulmonary Circulation | Jan. 25, 2022<br>Total review time: 147 days<br>Regulatory review time: 100 days | Mar. 11, 2022<br>Foreign clinical study results | 39 | XIENCE Skypoint Drug-Eluting Coronary Stent System<br>(Abbott Medical Japan LLC.) | Change | Instrument & apparatus 7<br>Coronary stent | A stent system consisting of an everolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary artery lesion (a lesion length of 32 mm or less) with a reference vessel diameter of 2.25-5.25 mm, and a delivery catheter used to implant the stent to the site of stenosis. The application was submitted to add stent sizes of 4.50 mm and 5.00 mm in diameter (A “partial change” application). As clinical evaluation data, the results of foreign clinical studies were submitted. |
| Cardiopulmonary Circulation | Feb. 15, 2022<br>Total review time: 251 days<br>Regulatory review time: 125 days | Apr. 28, 2017<br>Number unknown/Resolute Onyx Zotarolimus-Eluting Coronary Stent System<br>Global clinical study results | 40 | Resolute Onyx Coronary Stent System<br>(Medtronic Japan Co., Ltd.) | Change | Instrument & apparatus 7<br>Coronary stent | A drug-eluting stent system used for the treatment of patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 35 mm or less) with a reference vessel diameter of 2.25-4.2 mm. The application was submitted to expand the maximum diameter of a stent by 0.25 mm, extend the shelf life, and add results of the clinical study in which the period of dual antiplatelet therapy (DAPT) after the implantation of this product was set for 1 month to the Clinical Studies section of the package insert (A “partial change” application). The results of a global clinical study were submitted as clinical evaluation data. |
| Cardiopulmonary Circulation | Feb. 15, 2022<br>Total review time: 251 days<br>Regulatory review time: 125 days | Apr. 28, 2017<br>Number unknown/Resolute Onyx Zotarolimus-Eluting Coronary Stent System<br>Global clinical study results | 41 | Resolute Onyx SV Coronary Stent System<br>(Medtronic Japan Co., Ltd.) | Change | Instrument & apparatus 7<br>Coronary stent | A drug-eluting stent system used for the treatment of patients with symptomatic ischemic cardiac disease who have a new coronary artery lesion (a lesion length of 27 mm or less) that have a reference vessel diameter of 2.0-2.25 mm and are considered as dissection of the blood vessel or acute or impending coronary occlusion associated with angioplasty. The application was submitted to expand the maximum diameter of a stent by 0.25 mm, extend the shelf life, and add results of the clinical study in which the period of dual antiplatelet therapy (DAPT) after the implantation of this product was set for 1 month to the Clinical Studies section of the package insert (A “partial change” application). The results of a global clinical study were submitted as clinical evaluation data. |

| Review Category | Approval Date | Approval Date in US Clinical Study Results: Japanese/Foreign | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Classification Term Name | Notes |
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| Cardiopulmonary Circulation | Feb. 24, 2022<br>Total review time: 239 days<br>Regulatory review time: 113 days | Nov. 4, 2021<br>Foreign clinical study results | 42 | TactiCath SE Irrigation Catheter (Abbott Medical Japan LLC.) | Change | Instrument & apparatus 51<br>Catheter for cardiac ablation | An electrode catheter to be used for conducting cardiac electrophysiological mapping, and percutaneous catheter ablation with high-frequency current. The application was submitted to add the treatment of drug-resistant symptomatic persistent atrial fibrillation to the conventional intended use (treatment of drug-resistant symptomatic paroxysmal atrial fibrillation and common atrial flutter) (A “partial change” application). As clinical evaluation data, the results of foreign clinical studies were submitted. |
| Cardiopulmonary Circulation | Mar. 31, 2022<br>Total review time: 489 days<br>Regulatory review time: 147 days | -<br>Foreign clinical study results | 43 | BioFreedom Ultra Drug-coated Stent (Biosensors Japan Co., Ltd.) | Approval | Instrument & apparatus 7<br>Coronary stent | A stent system consisting of a biolimus-eluting stent used for the treatment of patients with symptomatic ischemic heart disease who have a de novo coronary artery lesion (a lesion length of 33 mm or less) with a reference vessel diameter of 2.5-4.0 mm and a delivery catheter used to implant the stent to the site of stenosis. As clinical evaluation data, the results of foreign clinical studies were submitted. |
| Program | May 26, 2021<br>Total review time: 65 days<br>Regulatory review time: 35 days | -<br>Clinical evaluation report | 44 | COVID-19 Pneumonia Image Analysis Program FS-AI693 (FUJIFILM Corporation) | Approval | Program 1<br>Software for general-purpose 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. |
| Program | Dec. 24, 2021<br>Total review time: 60 days<br>Regulatory review time: 44 days | -<br>Clinical evaluation report | 45 | HOPE LifeMark-CAD Pneumonia Image Analysis Program for COVID-19 (Fujitsu Japan Limited) | Approval | Program 1<br>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. |

*Reprocessed Single-Use Medical Devices Approved in FY2021*

| Review Category | Approval Date | Approval Date in US Clinical Study Results: Japanese/Foreign | No. | Brand Name (Applicant Company) | New Approval/ Partial Change | Classification Term Name | Notes |
|---|---|---|---|---|---|---|---|
| Robotics, IoT, and other devices (not classified as other categories) | Sep. 17, 2021<br>Total review time: 171 days<br>Regulatory review time: 155 days | -<br>No clinical study results | 1 | Reprocessed Flowtron ACS900 (HOGY)<br>(HOGY MEDICAL CO., LTD.) | Change | Instrument & apparatus 12<br>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 add a collection container of the original medical device and change the manufacturing site (A “partial change” application). |
| Robotics, IoT, and other devices (not classified as other categories) | Dec. 24, 2021<br>Total review time: 267 days<br>Regulatory review time: 231 days | -<br>No clinical study results | 2 | Reprocessed cuff C (HOGY)<br>(HOGY MEDICAL CO., LTD.) | Approval | Instrument & apparatus 12<br>Reprocessed cuff for pneumatically-powered massager | Reprocessed single-use medical device originating from the component of “SCD 700 Series” (Certification No.: 223AABZX00029000), which is a cuff for a pneumatically-powered massager used to prevent venous thrombosis by promoting venous blood circulation. |
| Gastroenterology, Genitourinary and Reproductive Medicine | Aug. 26, 2021<br>Total review time: 217 days<br>Regulatory review time: 171 days | -<br>No clinical study results | 3 | Reprocessed V-pipe (HOGY)<br>(HOGY MEDICAL CO., LTD.) | Change | Instrument & apparatus 25<br>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 extend the storage period before cleansing (A “partial change” application). |
| Gastroenterology, Genitourinary and Reproductive Medicine | Aug. 26, 2021<br>Total review time: 150 days<br>Regulatory review time: 113 days | -<br>No clinical study results | 4 | Reprocessed Trocar E (HOGY)<br>(HOGY MEDICAL CO., LTD.) | Change | Instrument & apparatus 49<br>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 extend the storage period before cleansing (A “partial change” application). |

***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<br>・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<br>・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<br>・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.***