PMA Monthly approvals from 3/1/2023 to 3/31/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120003	03/22/2023	PMAO - PMA Origi	ICAST COVERED STENT SYSTEM	ATRIUM MEDICAL CORP.	Approval of The iCAST Covered Stent System. The device is indicated for improving luminal diameter in patients with symptomatic atherosclerotic disease of the native common and/or external iliac arteries up to 110 mm in length, with a reference vessel diameter of 5 to 10 mm.
P170029	03/07/2023	PMAO - PMA Origir	CALCIVIS IMAGING SYSTEM	CALCIVIS LIMITED	Approval for The CALCIVIS Imaging System. The device is intended to be used by dental healthcare professionals on patients (6 years and older) with, or at risk of developing, demineralization associated with caries lesions, on accessible coronal tooth surfaces. The CALCIVIS Imaging System is indicated for use to provide images of active demineralization on tooth surfaces, as an aid to the assessment, diagnosis and treatment planning of demineralization associated with caries lesions.
P200018	03/31/2023	PMAO - PMA Origi	NEURX DIAPHRAGM PACING SYSTEM (DPS)	SYNAPSE BIOMEDICAL, INC.	Approval for the NeuRx DPS® is intended for use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but who lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day. For use only in patients 18 years of age or older.
P210037	03/31/2023	PMAO - PMA Origir	PROSPERA SPINAL CORD STIMULATION (SCS) SYSTEM, RESILIENCE PERCUTANEOUS LEAD, HOMESTREAM REMOTE MANAGEMENT	BIOTRONIK NRO, INC.	Approval for the Prospera Spinal Cord Stimulation (SCS) System, Resilience Percutaneous Lead, HomeStream Remote Management. The Indications for Use (IFU) of the device is as follows: The Prospera spinal cord stimulation (SCS) system is indicated as an aid in the management of chronic, intractable pain in the trunk and/or limbs, which may include unilateral or bilateral pain, resulting from any of the following: 1) Failed Back Syndrome (FBS) or low back syndrome or failed back; 2) Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or; 3) herniated disk; 4) Postlaminectomy pain; 5) Multiple back operations; 6) Unsuccessful disk surgery; 7) Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and; 8) surgical interventions; 9) Peripheral causalgia; 10) Epidural fibrosis; 11) Arachnoiditis or lumbar adhesive arachnoiditis; and 12) Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgiai.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S509	03/14/2023	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval with conditions for Medtronics updated use of third party applications on the CT900 and HH90 devices.
P860003/S109	03/13/2023	Y - 135 Review Tra	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Approval for a new fixture to replace the current leak tester.
P860004/S385	03/14/2023	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval with conditions for Medtronics updated use of third party applications on the CT900 and HH90 devices.
P950020/S133	03/02/2023	R - Real-Time Proc	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Approval for a change to approve an alternate supplier of an equivalent resin used as the middle layer in the tri-layer inner component of your stents¿ delivery system.
P960009/S418	03/14/2023	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval with conditions for Medtronics updated use of third party applications on the CT900 and HH90 devices.
P960058/S157	03/22/2023	R - Real-Time Proc	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Approval for an alternate supplier, and associated design and manufacturing changes, for certain rechargeable batteries used with sound processors of the HiResolution Bionic Ear System.
P970003/S239	03/02/2023	S - Special CBE	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for updates to the warning and precaution sections in the VNS Therapy Physicians Manuals for both Epilepsy and Depression regarding a clearer message directing the reader to view and reference the LivaNova magnetic resonance imaging (MRI) guidelines for any considerations for MRI scans in patients with the VNS Therapy System.
P970003/S240	03/02/2023	S - Special CBE	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for updates to a warning header in the VNS Therapy Physicians Manuals for both Epilepsy and Depression to clarify section about VNS Therapy uses in which safety and effectiveness have not been established.
P970004/S353	03/14/2023	N - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval with conditions for Medtronic¿s updated use of third party applications on the CT900 and HH90 devices.
P980016/S843	03/07/2023	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for enabling the Optivol 2.0 and Optivol Alert features on the subject devices.
P990056/S039	03/23/2023	N - Normal 180 Day	ELECSYS TOTAL PSA IMMUNOASSAY AND TOTAL PSA CALSET	ROCHE DIAGNOSTICS CORP.	Approval to extend application of the Elecsys total PSA immunoassay onto the cobas e 402 immunoassay analyzer
P000006/S064	03/03/2023	R - Real-Time Proc	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Approval for changes to the packaging to include new or modified components in the prosthesis assembly kits and to reorganize the packaging of these assembly kits, and changes to the instructions for use to accommodate the new assembly kits as well as reorganization of content.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000027/S037	03/23/2023	N - Normal 180 Day	ELECSYS FREE PSA IMMUNOASSAY/CALSET/ CALCHECK	ROCHE DIAGNOSTICS CORP.	Approval to extend application of the Elecsys free PSA immunoassay onto the cobas e 402 immunoassay analyzer
P020024/S067	03/27/2023	O - Normal 180 Da	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for modifications to the Instructions for Use to include the 3-year follow up data on patients enrolled in the ADO II AS Clinical Study (IDE and Continued Access Cohorts).
P040021/S052	03/28/2023	R - Real-Time Proc	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ABBOTT MEDICAL	Approval for modifications to the sewing cuff, suture, and annulus wire components of the valve and a trade name change.
P050047/S083	03/16/2023	N - Normal 180 Day	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for the use of syringes sterilized by X-ray irradiation for Juvéderm Voluma XC, Juvéderm Vollure XC, Juvederm Volbella XC, Juvéderm Ultra, Juvéderm Ultra XC, Juvéderm Ultra Plus, and Juvéderm Ultra Plus XC.
P060006/S105	03/02/2023	R - Real-Time Proc	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a change to approve an alternate supplier of an equivalent resin used as the middle layer in the tri-layer inner component of your stents delivery system.
P070006/S018	03/20/2023	R - Real-Time Proc	T SPOT-TB TEST	OXFORD IMMUNOTEC,LTD.	Approval for [the inclusion of the Allsheng Auto-Pure (AP) 20B and Auto-Pure (AP) 24 for use with the T-Cell Select in the preparation of specimens for use with the T-SPOT.TB test
P080025/S248	03/14/2023	N - Normal 180 Day	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval with conditions for Medtronics updated use of third party applications on the CT900 and HH90 devices.
P100047/S206	03/08/2023	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the use of a different O-ring in the controller connectors.
P110010/S207	03/02/2023	R - Real-Time Proc	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the introduction of an alternative resin material (ReZilok Rx 101) supplied by existing BSC-approved supplier Compounding Solutions.
P110033/S063	03/16/2023	N - Normal 180 Day	JUVEDERM VOLUMA XC	ALLERGAN	Approval for the use of syringes sterilized by X-ray irradiation for Juvéderm Voluma XC, Juvéderm Vollure XC, Juvederm Volbella XC, Juvéderm Ultra, Juvéderm Ultra XC, Juvéderm Ultra Plus, and Juvéderm Ultra Plus XC.
P110042/S179	03/14/2023	O - Normal 180 Da	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a manufacturing site located at Plexus Electronica S. de R.L. de C. V. Paseo del Norte No. 4640 Guadalajara Technology Park Zapopan, Jalisco 45010, Mexico for finished device manufacturing.
P120016/S029	03/01/2023	N - Normal 180 Day	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Approval for the following changes: 1) Increase in disc deployment diameter from 23F to 25F; 2) Increase in collagen mass from 12 mg to 19 mg; 3) Modifications to certain device components to accommodate the new disc deployment diameter and collagen mass; and 4) Modifications to the Instructions for Use to reflect the changes in device design.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130008/S089	03/20/2023	P - Panel Track	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the Inspire Upper Airway Stimulation (UAS) the device is used to treat a subset of pediatric Down syndrome patients between the age of 13-18 with severe OSA (apnea-hypopnea index [AHI] of greater than or equal to 10 and less than or equal to 50) who: 1) Do not have complete concentric collapse at the soft palate level; 2) Are contraindicated for or not effectively treated by adenotonsillectomy; 3) Have been confirmed to fail, or cannot tolerate positive airway pressure (PAP) therapy despite attempts to improve compliance; and 4) Have followed standard of care in considering all other alternative/adjunct therapies. PAP failure is defined as an inability to eliminate OSA, and PAP intolerance is defined as: a. Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or b. Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).
P130017/S055	03/16/2023	R - Real-Time Proc	COLOGUARD	EXACT SCIENCES CORPORATIO N	Approval for a Cologuard Quick Start Guide (QSG), to be a companion document to the Cologuard Patient Guide, as part of the Cologuard User Interface.
P130021/S132	03/21/2023	S - Special CBE	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Approval for various modifications to the Instructions for Use for the Medtronic Evolut PRO + System and Evolut FX System to add further instructions related to valve frame infolding.
P130030/S075	03/02/2023	R - Real-Time Proc	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Approval for the introduction of an alternative resin material (ReZilok Rx 101) supplied by existing BSC-approved supplier Compounding Solutions.
P140003/S107	03/29/2023	O - Normal 180 Da	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for various modifications to the Instructions for Use to add the final results of the Post-Approval Study (PAS) protocol.
P140031/S143	03/09/2023	N - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Approval for the following manufacturing sites to conduct ethylene oxide sterilization of the Commander Delivery System (Models 9600LDS23, 9750CM23, 9600LDS26, and 9750CM26): (1) Sterigenics, Belgium, located at Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers Liege, B-4800 BE, and (2) STERIS Tullamore, located at IDA Business and Technology Park, Tullamore Offaly, IE R35 X865
P140031/S152	03/08/2023	O - Normal 180 Da	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Approval for a manufacturing site located at Sterile Services Singapore, 47 Jaran Buroh Unit #01-01, Singapore South West, Singapore 619491.
P150003/S090	03/02/2023	R - Real-Time Proc	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Approval for the introduction of an alternative resin material (ReZilok Rx 101) supplied by existing BSC-approved supplier Compounding Solutions.
P150033/S153	03/22/2023	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for material and manufacturing changes to the Micra Scalable Catheter Delivery System Marker Band.
P160039/S008	03/28/2023	N - Normal 180 Day	REMEDE® SYSTEM	RESPICARDIA	Approval for adding MR Conditional labeling for 1.5T and 3T MRI scans to the implantable components of remede System.
P160046/S013	03/01/2023	P - Panel Track	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the VENTANA PD-L1 (SP263) Assay as a companion diagnostic for identifying patients with non-small cell lung carcinoma (NSCLC) with PD-L1 expression of >= 50% tumor cells (TC) for treatment with LIBTAYO.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160048/S021	03/29/2023	P - Panel Track	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for the Eversense® E3 Continuous Glucose Monitoring System for modifying the device to reduce the frequency of calibration.
P160048/S022	03/30/2023	N - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for modifying the Eversense E3 Transmitter, supporting mobile medical application, and the Instructions for Use for consistent use with the modified transmitter.
P160048/S023	03/22/2023	O - Normal 180 Da	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160054/S048	03/07/2023	O - Normal 180 Da	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for various updates to the Instructions for Use to add the final clinical results of Post-Approval Study #1 protocol.
P160055/S024	03/31/2023	N - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for a light adjustable lens (LAL) model LAL+ as a level A modification of the optical design of the original LAL.
P170011/S048	03/31/2023	R - Real-Time Proc	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for changes to the Instructions for Use to include femoral vein access for insertion of the Impella RP Flex.
P170027/S008	03/09/2023	Y - 135 Review Tra	THEROX DOWNSTREAM SYSTEM	ZOLL CIRCULATION, INC.	Approval of the refurbishment process for DS-2 Consoles meant to be used in the TherOx DownStream System
P170030/S023	03/22/2023	N - Normal 180 Day	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval for an update to the specification for the maximum allowed post-dilatation diameter for the 3.5 mm and 4.0 mm stent designs from 4.5 mm to 5.0 mm and updates to the dual antiplatelet therapy recommendation in the Instructions for Use for both the Orsiro and Orsiro Mission Stent Systems.
P170034/S008	03/14/2023	R - Real-Time Proc	HYDRUS MICROSTENT	IVANTIS, INC. WHOLLY-OWNED SUBSIDIARY OF ALCON RESEARCH, LLC	Approval for a modification to the 30-Pack Shipping Container.
P170038/S011	03/03/2023	Y - 135 Review Tra	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval for the addition of a supplier for the molded components of the CentriMag pump, the upper and lower housing, rotor bottom and impeller.
P180002/S022	03/25/2023	O - Normal 180 Da	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval for modifications to the protocol including an increase in study sites from 10 to 15 and minor clarification changes.
P180036/S016	03/21/2023	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for design changes to the GUARDIO/VESTA charger power supply.
P190019/S011	03/24/2023	Y - 135 Review Tra	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Approval to adjust the existing weld and trim equipment and process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190019/S018	03/02/2023	R - Real-Time Proc	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Approval for a change to an alternate supplier of an equivalent resin used as the middle layer in the tri-layer inner component of your stents delivery system.
P190032/S009	03/08/2023	O - Normal 180 Day	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval for Waiver of Condition of Approval (CoA) for Contrived Sample Functional Characterization (CSFC) study for F1 Liquid CDx.
P200006/S004	03/08/2023	O - Normal 180 Da	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE, INC.	Approval for Waiver of Condition of Approval (CoA) for Contrived Sample Functional Characterization (CSFC) study for F1 Liquid CDx.
P200015/S026	03/09/2023	N - Normal 180 Day	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for the following manufacturing sites to conduct ethylene oxide sterilization of the Commander Delivery System (Models 9600LDS23, 9750CM23, 9600LDS26, and 9750CM26): (1) Sterigenics, Belgium, located at Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers Liege, B-4800 BE, and (2) STERIS Tullamore, located at IDA Business and Technology Park, Tullamore Offaly, IE R35 X865
P200015/S034	03/03/2023	O - Normal 180 Da	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval of the revised protocol for the post-approval study protocol.
P200016/S002	03/08/2023	O - Normal 180 Day	FOUNDATIONONE LIQUID CDX	FOUNDATION MEDICINE, INC.	Approval for Waiver of Condition of Approval (CoA) for Contrived Sample Functional Characterization (CSFC) study for F1 Liquid CDx.
P200022/S010	03/15/2023	N - Normal 180 Day	SIMPLIFY® CERVICAL ARTIFICIAL DISC	NUVASIVE, INC.	Approval for the manufacturing site transfer for the Simplify® Cervical Artificial Disc.
P200028/S016	03/13/2023	O - Normal 180 Day	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for a manufacturing site located at 7000 Central Ave., N.E., Minneapolis, MN 55432.
P200036/S005	03/13/2023	R - Real-Time Proc	ECOIN PERIPHERAL NEUROSTIMULATOR	VALENCIA TECHNOLOGIES CORPORATION	Approval for a modification to the printed circuit board assembly component of the External Controller, a reduction in the number of External Controller and its associated accessories (adaptors, radios, and antennas) included in the kit to one, and changes to the External Controller labeling (i.e., minor clarifications and to reflect the change in kit components).
P200039/S010	03/22/2023	R - Real-Time Proc	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for the addition of an alternate Field Programmable Gate Array (FPGA) component and minor Control Logic Board (CLB) design modifications.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200045/S002	03/07/2023	P - Panel Track	RELAYPRO THORACIC STENT-GRAFT SYSTEM	BOLTON MEDICAL, INC.	Approval of the RelayPro Thoracic Stent Graft System for treatment of all lesions of the descending thoracic aorta. The RelayPro Thoracic Stent-Graft System is indicated for the endovascular repair of all lesions of the descending thoracic aorta in patients having appropriate anatomy, including: 1) Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories; 2) Non-aneurysmal aortic neck diameter in the range of 20 to 42 mm (fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers) or proximal and distal landing zones with diameters between 19 to 42 mm (traumatic aortic injuries); 3) Non-aneurysmal proximal aortic neck lengths (fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers) or landing zones (traumatic aortic injuries) of: a. 15 mm for the 22 to 28 mm device diameters (Bare Stent Configuration) b. 20 mm for the 30 to 38 mm device diameters (Bare Stent Configuration) c. 25 mm for the 40 to 46 mm device diameters (Bare Stent Configuration) d. 25 mm for the 22 to 38 mm device diameters (Non-Bare Stent Configuration) e. 30 mm for the 40 to 46 mm device diameters (Non-Bare Stent Configuration) 4) Non-aneurysmal distal aortic neck lengths (fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers) of: a. 25 mm for the 24 to 38 mm device diameters b. 30 mm for the 40 to 46 mm device diameters 5) Non-aneurysmal distal landing zone of 20 mm for traumatic aortic injuries (22 to 46mm device diameters) and dissections (24 to 46mm device diameters) The RelayPro Thoracic Stent-Graft System (NBS configuration) is indicated for the endovascular distal extension of the Thoraflex Hybrid device.

Total: 59

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810002/S117	03/28/2023	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ABBOTT MEDICAL	New supplier of polishing media used in mechanical heart valve manufacturing.
P810002/S118	03/31/2023	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ABBOTT MEDICAL	Supplier change to resin material for use in manufacturing the sewing cuff fabric of the VAVGJ valved conduit.
P810031/S074	03/13/2023	X - 30-Day Notice	HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Changes to the seal strength test method to align the method with current FDA-recognized industry standard ISO 11607-1.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S214	03/28/2023	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change the Crimp Core component inspection from a manual to an automatic process at Lake Region Medical.
P830063/S025	03/29/2023	X - 30-Day Notice	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Changing the transfer of the molding activity of the female luer lock 5.5 (current part number: 9200973400, new part number: 60023196) that is present on the Prismaflex TPE 2000 set, from HMC, a third-party supplier to the Baxter manufacturing plant Malta.
P840001/S537	03/17/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Move its material milling and molding operations for the silicone components of the Pocket adaptor from the Trelleborg-Delano facility to the Trelleborg-Paso Robles facility.
P840001/S538	03/16/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Transfer the cleaning of the Contact Multi-Beam Welded (referred to as MBC) component from Medtronic Rice Creek to the Villalba facility to ensure product availability and increase capacity and flexibility at the Villalba site.
P840064/S079	03/29/2023	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Reduction in the aeration phase of your existing approved Ethylene Oxide sterilization process.
P850089/S164	03/28/2023	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change the Crimp Core component inspection from a manual to an automatic process at Lake Region Medical.
P860004/S405	03/09/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of endotoxin mitigation measures for incoming components at MDT, by changing water supply source.
P890047/S060	03/29/2023	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Reduction in the aeration phase of your existing approved Ethylene Oxide sterilization process.
P910001/S118	03/21/2023	X - 30-Day Notice	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Alternate packaging material supplier.
P910018/S035	03/01/2023	X - 30-Day Notice	LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2).	KANEKA PHARMA AMERICA CORP.	Change in quality control testing for the Liposorber LA-15 System regarding a change of gas chromatograph (GC) equipment for measurement of residual propanol.
P930039/S249	03/09/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Make improvements to the Top Hat surrogate process.
P950020/S135	03/10/2023	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Change the in-process monitoring online sampling plan for extruded components at the Galway manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950020/S136	03/09/2023	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Change to a blade bonding process parameter.
P950037/S245	03/09/2023	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Automate manufacturing processes for the Edora family of IPGs and CRT-Ps.
P960009/S447	03/17/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Move its material milling and molding operations for the silicone components of the M930340A001 Pocket adaptor from the Trelleborg-Delano facility to the Trelleborg-Paso Robles facility.
P960009/S448	03/16/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Transfer the cleaning of the Contact Multi-Beam Welded (referred to as MBC) component from Medtronic Rice Creek to the Villalba facility to ensure product availability and increase capacity and flexibility at the Villalba site.
P960009/S449	03/10/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Update process monitoring controls (sample sizes and control limits) as part of the implementation of Statistical Process Control (SPC) program at Medtronic Vascular.
P980016/S849	03/14/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the software configuration file on battery laser welder equipment.
P980016/S851	03/24/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Change the sub-tier suppliers of inspection and packaging of the Tel M component used in hybrid manufacturing.
P980035/S742	03/09/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement an automated vision system in the Blister Packaging process.
P980040/S157	03/06/2023	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Modification to the endotoxin extraction method used during endotoxin testing of intraocular lenses manufactured at the AMO Groningen manufacturing site, and packaged in either the TECNIS Simplicity Delivery System or the daisywheel packaging configuration.
P010031/S815	03/14/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the software configuration file on battery laser welder equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S816	03/24/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Change the sub-tier suppliers of inspection and packaging of the Tel M component used in hybrid manufacturing.
P030031/S131	03/10/2023	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Alternate sub-tier supplier for a component on the catheter printed circuit board (PCB).
P030036/S142	03/28/2023	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Change the Crimp Core component inspection from a manual to an automatic process at Lake Region Medical.
P030045/S007	03/02/2023	X - 30-Day Notice	INTRASTENT DOUBLESTRUT STENT	MEDTRONIC VASCULAR INC	Addition of an extruder, balloon former and balloon stretcher.
P040036/S093	03/10/2023	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Alternate sub-tier supplier for a component on the catheter printed circuit board (PCB).
P040037/S157	03/16/2023	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Additional analytical test laboratory and approval of a heparin coating related supplier site change.
P040037/S158	03/16/2023	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Additional ovens used for delivery system component manufacturing at a supplier.
P040043/S134	03/08/2023	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Specification update to allow consistency of the manufacturing process across device sizes for the GORE TAG Thoracic Endoprosthesis and the GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System.
P040045/S130	03/22/2023	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Qualification of an additional production line, with changeover capability.
P050017/S021	03/16/2023	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK IRELAND, LTD.	Alternative supplier of an adhesive used in the manufacture of the delivery system.
P050019/S037	03/10/2023	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Change the in-process monitoring online sampling plan for extruded components at the Galway manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060006/S106	03/08/2023	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate raw material supplier used in forming stents.
P060037/S084	03/24/2023	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change a biological indicator (BI) for hydrogen peroxide gas plasma sterilization process utilized to sterilize the NexGen LPS-Flex/LPS Mobile Bearing Knee System, Cross-linked Polyethylene Prolong Articular Surface components.
P060040/S090	03/21/2023	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Addition of second tier supplier for polyester mesh used in apical sewing ring.
P070006/S019	03/27/2023	X - 30-Day Notice	T SPOT-TB TEST	OXFORD IMMUNOTEC,LTD.	Changes to the incoming QC method for one of the components in a Reagent kit.
P070008/S145	03/09/2023	X - 30-Day Notice	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Automate manufacturing processes for the Edora family of IPGs and CRT-Ps.
P080006/S175	03/17/2023	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Transfer of component extrusion lines from the Santa Rosa facility to the Medtronic Danvers facility.
P090003/S055	03/08/2023	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Alternate raw material supplier used in forming stents.
P090013/S326	03/09/2023	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Make improvements to the Top Hat surrogate process.
P090016/S052	03/31/2023	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Replacing the manually-controled Ligacon systems with the automated qualified Transfer Machine during gel filtration of Belotero Balance® Dermal Filler.
P100009/S053	03/30/2023	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	New incoming inspection test method and pre-conditioning procedure for the Leaf Spring component used in the MitraClip Systems.
P100010/S137	03/06/2023	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATHLP	Addition of alternate injection mold equipment for the Arctic Front Advance Catheter Tip.
P100018/S039	03/16/2023	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Repackage and relabel the Pipeline Flex Embolization Device with Shield Technology at Medtronic Inc, -Swinnea, 4340 Swinnea Road, Memphis, Tennessee, 38118.
P100021/S112	03/02/2023	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Internal facility transfer of component extrusion and secondary annealing operations.
P100021/S113	03/17/2023	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changes to temporary packaging and pallet configuration during the bioburden reduction process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100022/S041	03/16/2023	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK IRELAND, LTD.	Alternative supplier of an adhesive used in the manufacture of the delivery system.
P100040/S056	03/17/2023	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changes to temporary packaging and pallet configuration during the bioburden reduction process.
P100046/S015	03/23/2023	X - 30-Day Notice	ATRICURE SYNERGY ABLATION SYSTEM	ATRICURE INC.	Alternative epoxy backfilling process to be used on the overmolded insulators found on the sterile OSL2 and OLL2 handpieces.
P100047/S208	03/03/2023	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of an in-process inspection to the controller assembly procedure.
P110005/S013	03/10/2023	X - 30-Day Notice	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Changes to methods for routine sterility and endotoxin monitoring per USP <71> and USP <85>.
P110010/S208	03/15/2023	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the particulates testing model.
P110010/S209	03/10/2023	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change the in-process monitoring online sampling plan for extruded components at the Galway manufacturing site.
P110035/S069	03/21/2023	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the rinse and dry steps in the stent wetline process.
P130006/S096	03/16/2023	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Additional analytical test laboratory and approval of a heparin coating related supplier site change.
P130006/S097	03/16/2023	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Additional ovens used for delivery system component manufacturing at a supplier.
P130008/S094	03/08/2023	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Notification of the addition of three laser weld stations to be used in the manufacturing of the Inspire Model 3028 IPG
P130013/S058	03/29/2023	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Implement upgraded Implant Loading Stations used to attach the WATCHMAN FLX Implant to the Delivery Sheath.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140028/S077	03/21/2023	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update the rinse and dry steps in the stent wetline process.
P140031/S153	03/22/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Transfer of the tube extrusion process for the balloon component from Irvine to Draper facility.
P140031/S154	03/30/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	New Flex Shaft subassembly supplier for use in the Edwards Commander Delivery System.
P150001/S105	03/13/2023	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Manufacturing change to expand the welding parameters used when manufacturing the pump case assembly. The pump case assembly is a component of the MiniMed 630G, MiniMed 670G, and MiniMed 770G systems.
P150003/S091	03/15/2023	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the particulates testing model.
P150003/S092	03/10/2023	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change the in-process monitoring online sampling plan for extruded components at the Galway manufacturing site.
P150011/S027	03/02/2023	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	CORCYM CANADA CORP.	Removal of an in-process inspection demonstrated to be redundant by qualification.
P150012/S141	03/01/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add an alternate supplier of the helix component used the manufacture of INGEVITY and INGEVITY+ lead.
P150030/S032	03/30/2023	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Implementation of a new manufacturing cell (AC1) for the manufacturing of R3 Acetabular shells at Smith & Nephew Aurora, Leamington Spa, UK facility.
P150033/S165	03/01/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement updates to the Accelerometer Activity Test software for the Micra AV Transcatheter Pacing System.
P160003/S016	03/03/2023	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Device inspection and annealing processes.
P160017/S109	03/13/2023	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Manufacturing change to expand the welding parameters used when manufacturing the pump case assembly. The pump case assembly is a component of the MiniMed 630G, MiniMed 670G, and MiniMed 770G systems.
P160021/S037	03/16/2023	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Additional analytical test laboratory and approval of a heparin coating related supplier site change.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160022/S033	03/24/2023	X - 30-Day Notice	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATIO N	Automate the manual process of liquid gel weight verification for the electrodes.
P160033/S009	03/23/2023	X - 30-Day Notice	POWERHEART® G5 AED, POWERHEART® AED G3 PLUS, AND POWERHEART® AED G3	ZOLL MEDICAL CORPORATIO N	Additional of a conformal coating to portions of the printed circuit board.
P160042/S020	03/22/2023	X - 30-Day Notice	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGI ES INC.	Change to the stopper, which is a component of the syringe system of the 1.0 and 1.2mL configurations of Revanesse Versa, Revanesse Versa+ with Lidocaine, and Revanesse Lips+ with Lidocaine.
P160043/S065	03/23/2023	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Remove the requirement to complete non-stability indicating tests as part of the annual stability studies for the Resolute Onyx and Onyx Frontier Zotarolimus-Eluting Coronary Stent Systems.
P160047/S029	03/13/2023	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSUR GICAL, INC.	Addition of a water vapor probe test during the manufacturing process to enhance the reliability of the device.
P160049/S020	03/21/2023	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETI CS CORP.	Alternate packaging material supplier.
P170008/S042	03/01/2023	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Improvements to the Deionized Water (DI) circulation system.
P170008/S043	03/20/2023	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Replacement of the laser unit component in the laser cutting/welding machine.
P170029/S001	03/23/2023	X - 30-Day Notice	CALCIVIS IMAGING SYSTEM	CALCIVIS LIMITED	Replace the drug substance manufacturing wash step buffer component of Triton X-100 with Ecosurf SA-9 at the 3P Biopharmaceuticals facility located in Navarra, Spain.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170030/S027	03/03/2023	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Device inspection and annealing processes.
P180011/S054	03/21/2023	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the rinse and dry steps in the stent wetline process.
P180035/S016	03/22/2023	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Introduction of a new high volume impression strip blister tool.
P180046/S065	03/02/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a progressive stamping die machine by a manufacturing supplier.
P190006/S065	03/02/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of a progressive stamping die machine by a manufacturing supplier.
P190018/S023	03/09/2023	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON LABORATORIES, LLC	Transition from 100-percent to reduced inspection for edge thickness.
P190030/S002	03/23/2023	X - 30-Day Notice	ACTASTIM-S SPINE FUSION STIMULATOR	THERAGEN, INC.	Distribute the device incorporating the alternative battery.
P200013/S013	03/31/2023	X - 30-Day Notice	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Change the temperature and time manufacturing process parameters for kit components.
P200015/S035	03/22/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Transfer of the tube extrusion process for the balloon component from Irvine to Draper facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200015/S036	03/30/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	New Flex Shaft subassembly supplier for use in the Edwards Commander Delivery System.
P200023/S004	03/16/2023	X - 30-Day Notice	ZILVER VENA VENOUS SELF-EXPANDING STENT	COOK IRELAND LTD.	Alternative supplier of an adhesive used in the manufacture of the delivery system.
P200028/S015	03/01/2023	X - 30-Day Notice	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Changes to the maximum sterilization pallet load configuration for DiamondTemp Irrigation Tubing Set and DiamondTemp Catheter-to-RF Generator Cable.
P200030/S011	03/14/2023	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Relocate and upgrade equipment for base tube manufacturing.
P210022/S004	03/31/2023	X - 30-Day Notice	ALINITY M CMV	ABBOTT MOLECULAR, INC.	Change the temperature and time manufacturing process parameters for kit components.
P210032/S008	03/16/2023	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Additional analytical test laboratory and approval of a heparin coating related supplier site change.
P220003/S006	03/03/2023	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Add an alternate supplier for various titanium components used in the PASCAL Precision Ace Implant System.

Total: 100