PMA Monthly approvals from 7/1/2023 to 7/31/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P220004	07/21/2023	PMAO - PMA Origi	PALMAZ MULLINS XD PULMONARY STENT	CORDIS US CORP.	Approval of the PALMAZ MULLINS XD Pulmonary Stent. The PALMAZ MULLINS XD Pulmonary Stent is indicated for the non-emergency treatment of pulmonary artery stenosis in pediatric patients who are at least 10kg in weight with two ventricle anatomy.
P220014	07/06/2023	PMAO - PMA Origir	CRANISEAL DURAL SEALANT	PRAMAND, LLC	Approval for the CraniSeal Dural Sealant. The device is indicated for use in patients >= 18 years of age as an adjunct to sutured dural repair during cranial surgery to provide watertight closure.
P230002	07/28/2023	PMAO - PMA Origi	MINITOUCH 3.8 ERA SYSTEM (MINITOUCH SYSTEM)	MICROCUBE, LLC	Approval for the Minitouch 3.8 Era System (Minitouch System). This device is indicated for ablation of the endometrial lining of the uterus for the treatment of menorrhagia (heavy menstrual bleeding) due to benign causes in premenopausal women for whom childbearing is complete.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860004/S408	07/14/2023	R - Real-Time Proc	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for a change to the Poly(ethylene) terephthalate (PET) resin material used in the extrusion of monofilament, which is then incorporated into the catheter tubing assembly.
P900056/S208	07/17/2023	R - Real-Time Proc	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for a new packaging configuration for the ROTAPRO Rotational Atherectomy System.
P960009/S454	07/20/2023	R - Real-Time Proc	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for change in maximum length of the Proximal Body Assemblys distance between the connector ring flange to the proximal reflow joint between the connector and lead body tubing from 0.180 inches to 0.193 inches.
P010032/S195	07/27/2023	Y - 135 Review Tra	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval to qualify an alternate site and process improvements for an existing supplier that manufactures components for Abbotts SCS Leads, Extensions and Adapters and DBS Adapters.
P020056/S061	07/12/2023	O - Normal 180 Da	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for including the final results from the BIFS-001 NBIR-Arm Clinical Study in the labeling documents for Natrelle Silicone-Filled Breast Implants and Natrelle INSPIRA Silicone-Filled Breast Implants.
P030011/S064	07/06/2023	O - Normal 180 Da	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for changes to the labeling to reflect the findings of the INTERMACS Companion post-approval Study.

Data as of 08/09/2023 05:16 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030031/S126	07/18/2023	N - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for an indication expansion for the THERMOCOOL SMARTTOUCH Catheter.
P030050/S042	07/11/2023	R - Real-Time Proc	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for revision of the bacterial endotoxin limits and test method for Sculptra finished product and raw materials.
P040044/S094	07/13/2023	R - Real-Time Proc	MATRIX VASCULAR CLOSURE SYSTEM (VSG)	CORDIS US CORPORATIO N	Approval for minor design and material modifications to the deployment button on the Mynx Control Vascular Closure Devices.
P050037/S128	07/12/2023	S - Special CBE	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval to implement a new in-process test for the calcium hydroxyapatite (CaHA) particle manufacturing process.
P050052/S150	07/12/2023	S - Special CBE	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval to implement a new in-process test for the calcium hydroxyapatite (CaHA) particle manufacturing process.
P070004/S027	07/31/2023	Y - 135 Review Tra	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for addition of filter to raw silicone gel material
P070014/S065	07/27/2023	O - Normal 180 Da	LIFESTENT FLEXSTAR & FLEXSTAR XL VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval to update the labeling to include clinical results from the LifeStent Vascular Stent Systems post-approval study (Popliteal Indication)
P100045/S066	07/28/2023	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ABBOTT MEDICAL	Approval for changes to the software and hardware of the CardioMEMS Hospital System.
P100045/S068	07/26/2023	O - Normal 180 Da	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ABBOTT MEDICAL	Approval of the revised protocol as well as Statistical Analysis Plan for the post-approval study (PAS) protocol.
P110019/S125	07/20/2023	O - Normal 180 Da	XIENCE SKYPOINT EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval of the revised protocol as well as Statistical Analysis Plan for the post-approval study (PAS) protocol.
P130005/S037	07/28/2023	R - Real-Time Proc	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASC ULAR SYSTEMS, INC.	Approval for a labeling change to include additional language for one of the precautions in the Instructions for Use regarding the availability of surgical backup.
P140009/S081	07/27/2023	Y - 135 Review Tra	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval to qualify an alternate site and process improvements for an existing supplier that manufactures components for Abbotts SCS Leads, Extensions and Adapters and DBS Adapters.
P140018/S037	07/25/2023	R - Real-Time Proc	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for removing the guidewire included in the VenaSeal Closure system and instructing physicians to source a compatible guidewire for the procedure.
P140026/S027	07/20/2023	O - Normal 180 Da	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval of the revised protocol for the ROADSTER 3 post-approval study

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150005/S076	07/17/2023	R - Real-Time Proc	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for software modifications and relevant labeling changes for the RHYTHMIA HDx Mapping System software version v5.0.1.
P150013/S026	07/05/2023	S - Special CBE	PD-L1 IHC 22C3 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval for updates to Instructions for Use and manufacturing quality control technical procedure intended to mitigate nonspecific nuclear staining in formalin-fixed, paraffin-embedded (FFPE) tumor specimens stained with the Negative Control Reagent (NCR) from PD-L1 IHC 22C3 pharmDx.
P150030/S031	07/28/2023	O - Normal 180 Da	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Approval for revisions to device labeling that was updated to include information on the Post-Approval Study (PAS), Long-Term F/u of EU patients PAS, for the R3 Delta Ceramic Hip System
P150031/S056	07/10/2023	R - Real-Time Proc	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for Vercise Neural Navigator 5 software.
P150038/S015	07/18/2023	O - Normal 180 Da	EXABLATE	INSIGHTEC	Approval for a change to the prescribers labeling to include the post-approval study (PAS) results from the 5-year follow-up.
P150048/S073	07/27/2023	O - Normal 180 Da	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for the revised protocol for the post-approval study (PAS), Model 11500A Prospective PAS.
P160026/S039	07/03/2023	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for a material changes to the energy storage capacitor component used in the LIFEPAK 1000 defibrillator.
P160040/S011	07/20/2023	N - Normal 180 Day	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Approval for the LeukoStrat CDx FLT3 Mutation Assay. The device is a PCR-based in vitro diagnostic test designed to detect internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the FLT3 gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia (AML). The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom RYDAPT (midostaurin) treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA (gilteritinib) treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with FLT3-ITD+ AML for whom VANFLYTA (quizartinib) treatment is being considered. The test is for use on the 3500xL Dx Genetic Analyzer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160047/S031	07/28/2023	O - Normal 180 Da	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSURGICAL, INC.	Approval for the site change for Mara Probe manufacturing activities.
P160054/S051	07/03/2023	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for the implementation of various design changes to the Integrated Motor Control printed circuit board assembly used in the HeartMate 3 Left Ventricular Device.
P170019/S040	07/20/2023	O - Normal 180 Da	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for updates to the F1CDx labeling, including updates to the Technical Information document and patient mock reports for F1CDx.
P170023/S015	07/12/2023	R - Real-Time Proc	BULKAMID URETHRAL BULKING SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for an additional Bulkamid Urethral Bulking System packaging configuration.
P180036/S018	07/17/2023	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for modifications of the VESTA/GUARDIO Charger firmware.
P180036/S019	07/21/2023	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for updates to the INTELIO Programmer software.
P180047/S019	07/18/2023	N - Normal 180 Day	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for a change in the conjugate reagent in the LIAISON QuantiFERON TB Gold Plus assay from a lyophilized format to a liquid format.
P200013/S015	07/18/2023	R - Real-Time Proc	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval for a change of the Alinity m HBV Assay to implement a new application specification file containing an improved PCR reagent assembly process that mitigates the potential for overflow at the Alinity m Amplification (AMP) Tray, thus minimizing the potential risk for carryover. The Alinity m HBV Kit package insert is also being updated to reflect the carryover rate using the new application specification file.
P200028/S020	07/21/2023	O - Normal 180 Da	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for a manufacturing site located at Medtronic Ireland, Parkmore Business Park West, Galway, Ireland.
P210005/S005	07/31/2023	O - Normal 180 Da	IC-8 APTHERA INTRAOCULAR LENS (IOL)	ACUFOCUS, INC.	Approval for a manufacturing site located at Bausch & Lomb, 21 N. Park Place Blvd., Clearwater, Florida, 33759 for the following functions: 1) Receiving inspections of device raw materials/ subassemblies 2) Shipping and handling of device raw materials/ subassemblies 3) Lot release and documentation review of finished devices 4) Handling, storage, preservation and distribution of finished devices.
P210027/S002	07/20/2023	O - Normal 180 Da	QDOT MICRO¿ SYSTEM	BIOSENSE WEBSTER, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210040/S001	07/27/2023	S - Special CBE	RESOLUTION CTDX FIRST	RESOLUTION BIOSCIENCE, INC.	Approval for modifications to the Instructions for Use for the Agilent Resolution Sample Collection Kit, a component of the Agilent Resolution ctDx FIRST assay
P220003/S007	07/06/2023	O - Normal 180 Da	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCE S LLC	Approval for the following manufacturing site to conduct ethylene oxide sterilization of the PASCAL Precision Transcatheter Valve Repair System (Models 20000GS, 20000IS, and 20000ISM): Sterigenics, Belgium located at Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers Liege, B-4800 BE.
P220024/S001	07/28/2023	O - Normal 180 Da	LIQUIFIX FIX8 HERNIA MESH FIXATION (HMF) DEVICE, LIQUIFIX PRECISION OPEN HERNIA MESH FIXATION DEVICE	ADVANCED MEDICAL SOLUTIONS LIMITED	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 42

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S104	07/11/2023	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Increase in the number of isopropyl alcohol (IPA) washes to remove water from the oxidized regenerated cellulose (ORC) fabric rolls prior to the drying step.
N970003/S287	07/21/2023	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P820003/S140	07/26/2023	X - 30-Day Notice	VERSATRAX MODEL 7000 UNIVERSAL A-V PULSE GENERATOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer receiving and inspection activities to Medtronic¿s Memphis Manufacturing facility.
P830060/S089	07/21/2023	X - 30-Day Notice	VENTAK AND AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEMS	BOSTON SCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P830061/S217	07/11/2023	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a rework process for monolithic controlled release device packaging at Rice Creek.
P890003/S462	07/26/2023	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Transfer receiving and inspection activities to Medtronic¿s Memphis Manufacturing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S463	07/11/2023	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Implement a rework process for monolithic controlled release device packaging at Rice Creek.
P900056/S209	07/27/2023	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P910007/S062	07/10/2023	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Add a new manufacturing suite.
P910073/S172	07/06/2023	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	New Controlled Environment Area at the BSC Dorado facility.
P910073/S173	07/21/2023	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P910077/S192	07/21/2023	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P920015/S279	07/11/2023	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implement a rework process for monolithic controlled release device packaging at Rice Creek.
P920047/S132	07/27/2023	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P930035/S034	07/21/2023	X - 30-Day Notice	VENTAK(R) P2 SYSTEM	BOSTON SCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P930039/S253	07/11/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Implement a rework process for monolithic controlled release device packaging at Rice Creek.
P950018/S023	07/17/2023	X - 30-Day Notice	PERFLUORON (PURIFIED PERFLUORO-N-OCTANE LIQUID)	ALCON LABORATORIES	Change to the diaphragm valve material.
P950020/S139	07/27/2023	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P950024/S107	07/11/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Implement a rework process for monolithic controlled release device packaging at Rice Creek.
P960004/S103	07/06/2023	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	New Controlled Environment Area at the BSC Dorado facility.
P960004/S105	07/21/2023	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P960006/S056	07/21/2023	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960040/S494	07/07/2023	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Remove an incoming inspection for the presence of Lithium Perchlorate in battery electrolyte.
P960040/S495	07/20/2023	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Change the high voltage capacitor rivet slot width dimensional inspection method.
P960040/S496	07/21/2023	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P970051/S219	07/14/2023	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Changes to the coating material and deposition process used on electrode molding tools.
P980003/S096	07/27/2023	X - 30-Day Notice	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P980007/S051	07/10/2023	X - 30-Day Notice	AXSYM FREE PSA	ABBOTT LABORATORIES	Add a new manufacturing suite.
P980016/S862	07/17/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Relocation of the distribution center sorter tool.
P980035/S752	07/03/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modifications to the plasma cleaning process and associated inspections.
P980035/S753	07/17/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Relocation of the distribution center sorter tool.
P980035/S754	07/13/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of high capacitance procedural changes at a secondary supplier.
P990046/S066	07/19/2023	X - 30-Day Notice	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Change to a sub-tier supplier of a Teleflex suture component used on the Open Pivot Aortic Valved Graft (AVG).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000029/S096	07/11/2023	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Replacement of the current inkjet printer used for printing the Unique Device Identifier (UDI) 2D-barcode on the device carton with a new printer and vision system that will print both the UDI 2D-barcode and associated batch information on the device carton.
P010012/S572	07/06/2023	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	New Controlled Environment Area at the BSC Dorado facility.
P010012/S573	07/07/2023	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Remove an incoming inspection for the presence of Lithium Perchlorate in battery electrolyte.
P010012/S574	07/20/2023	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Change the high voltage capacitor rivet slot width dimensional inspection method.
P010012/S575	07/21/2023	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P010015/S522	07/13/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of high capacitance procedural changes at a secondary supplier.
P010015/S523	07/17/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Relocation of the distribution center sorter tool.
P010031/S828	07/17/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Relocation of the distribution center sorter tool.
P010032/S199	07/21/2023	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Utilize previously validated Cycle 59 parameters in chamber 6 to the alternate chamber 13 to increase chamber capacity for sterilizing the same Abbott neuromodulation products.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020025/S140	07/27/2023	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P020036/S049	07/27/2023	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS US CORPORATION	Reduction of ethylene oxide concentration for the sterilization cycle.
P030005/S232	07/21/2023	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P030047/S047	07/27/2023	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS US CORPORATION	Reduction of ethylene oxide concentration for the sterilization cycle.
P030054/S409	07/19/2023	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Add an alternate supplier for the filtered feedthrough assembly used in CRT-D devices.
P040037/S159	07/21/2023	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Upgraded manufacturing equipment to be used for an additional endoprosthesis assembly manufacturing line.
P040037/S160	07/05/2023	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate supplier of the outer foil packaging of the following devices: GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE VIABAHN VBX Balloon Expandable Endoprosthesis and GORE TAG Thoracic Branch Endoprosthesis.
P040037/S161	07/18/2023	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Removal of post-deployment visual and deployment force quality control inspection steps for the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface.
P050018/S032	07/07/2023	X - 30-Day Notice	ANGIOSCULPT SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Alternate supplier for a catheter component.
P050047/S089	07/28/2023	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Improve the dialysis and homogenization (mixing) steps of the Juvéderm manufacturing process.
P050051/S054	07/10/2023	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Add a new manufacturing suite.
P060006/S107	07/27/2023	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P060035/S039	07/10/2023	X - 30-Day Notice	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Add a new manufacturing suite.
P080006/S177	07/11/2023	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Implement a rework process for monolithic controlled release device packaging at Rice Creek.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080023/S041	07/10/2023	X - 30-Day Notice	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Add a new manufacturing suite.
P090013/S328	07/11/2023	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Implement a rework process for monolithic controlled release device packaging at Rice Creek.
P100014/S034	07/11/2023	X - 30-Day Notice	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Replacement of the current inkjet printer used for printing the Unique Device Identifier (UDI) 2D-barcode on the device carton with a new printer and vision system that will print both the UDI 2D-barcode and associated batch information on the device carton.
P100042/S035	07/07/2023	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Modify a QC testing method for process improvement.
P100045/S067	07/19/2023	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ABBOTT MEDICAL	Implement new alternate laser equipment for the manufacturing of the CardioMEMS PA Sensor.
P100047/S212	07/07/2023	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Improvements to the Loctite application manufacturing process of the HVAD Controllers.
P110010/S211	07/27/2023	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P110019/S127	07/14/2023	X - 30-Day Notice	XIENCE SKYPOINT EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Implementation of automated weighing machinery for the pre-coated stents.
P110029/S045	07/10/2023	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Add a new manufacturing suite.
P110033/S076	07/06/2023	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Duplicate mixer to be used during the manufacturing process for Skinvive by Juvéderm.
P110042/S185	07/06/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	New Controlled Environment Area at the BSC Dorado facility.
P110042/S186	07/07/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Remove an incoming inspection for the presence of Lithium Perchlorate in battery electrolyte.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110042/S187	07/20/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change the high voltage capacitor rivet slot width dimensional inspection method.
P110042/S188	07/21/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P120002/S024	07/27/2023	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS US CORPORATION	Reduction of ethylene oxide concentration for the sterilization cycle.
P120003/S001	07/12/2023	X - 30-Day Notice	ICAST COVERED STENT SYSTEM	ATRIUM MEDICAL CORP.	Change to equipment used in the polymer extrusion water quenching process.
P120008/S024	07/10/2023	X - 30-Day Notice	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Add a new manufacturing suite.
P130006/S098	07/21/2023	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Upgraded manufacturing equipment to be used for an additional endoprosthesis assembly manufacturing line.
P130006/S099	07/05/2023	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate supplier of the outer foil packaging of the following devices: GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE VIABAHN VBX Balloon Expandable Endoprosthesis and GORE TAG Thoracic Branch Endoprosthesis.
P130006/S100	07/18/2023	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Removal of post-deployment visual and deployment force quality control inspection steps for the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface.
P130012/S014	07/07/2023	X - 30-Day Notice	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Supplier change for the coils used in the Myopore Pacing Lead.
P130021/S140	07/28/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Alternate sub-tier supplier for adhesives used in the delivery and loading systems.
P130021/S141	07/25/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Extension of shelf-life for a suture component in the 23mm size of the Evolut Transcatheter Aortic Valve (TAV) product family.
P130030/S076	07/27/2023	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P140009/S085	07/21/2023	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Utilize previously validated Cycle 59 parameters in chamber 6 to the alternate chamber 13 to increase chamber capacity for sterilizing the same Abbott neuromodulation products.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140017/S024	07/27/2023	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Alternative sub-tier supplier for raw material used in the Harmony valve sutures.
P140030/S016	07/20/2023	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Addition of an alternative EPCD used to release products from the sterilization cycle and a reduction in sample size for in-process diameter inspection.
P140031/S159	07/06/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Outsource the laser cutting process of the SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valve main, inner, and PVL skirt components.
P150004/S062	07/21/2023	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Utilize previously validated Cycle 59 parameters in chamber 6 to the alternate chamber 13 to increase chamber capacity for sterilizing the same Abbott neuromodulation products.
P150005/S078	07/27/2023	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility
P150012/S147	07/06/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	New Controlled Environment Area at the BSC Dorado facility.
P150012/S148	07/21/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Streamline the bacterial endotoxin testing (BET) method for all items submitted to the Arden Hills Microbiology Lab to one test method.
P150030/S034	07/11/2023	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Change for the replacement of two manufacturing machine centers with a new manufacturing machine at Smith & Nephew Orthopaedics AG (SNOAG), Switzerland.
P150033/S175	07/17/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Relocation of the distribution center sorter tool.
P150033/S176	07/11/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement a rework process for monolithic controlled release device packaging at Rice Creek.
P150038/S027	07/27/2023	X - 30-Day Notice	EXABLATE	INSIGHTEC	Add a second engraving machine.
P150038/S028	07/27/2023	X - 30-Day Notice	EXABLATE	INSIGHTEC	Change to allow fully automated assembly of the coil isolation board PCB layout.
P150038/S029	07/21/2023	X - 30-Day Notice	EXABLATE	INSIGHTEC	Change to the Exablate Neuro manufacturing process which involves the addition of a water recycling system for dicing machines.
P150038/S030	07/21/2023	X - 30-Day Notice	EXABLATE	INSIGHTEC	Adding a contract manufacturer for the assembly of the head coils and membranes, and adding a label with serial number on the coils for warehouse goods tracking.
P150038/S031	07/27/2023	X - 30-Day Notice	EXABLATE	INSIGHTEC	Change to the Exablate Neuro manufacturing process to allow use of pre-owned systems and system components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150048/S072	07/12/2023	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCE S, LLC.	Reduction of the seal strength process specification for the foil pouch of the KONECT RESILIA Aortic Valved Conduit.
P160017/S111	07/06/2023	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of an alternate manufacturing site for the sensor fabrication process for the Guardian 4 Sensor (G4S). The G4S is a component of the MiniMed 780G System.
P160021/S040	07/13/2023	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Use of two new heparin coating machines.
P160021/S041	07/05/2023	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate supplier of the outer foil packaging of the following devices: GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE VIABAHN VBX Balloon Expandable Endoprosthesis and GORE TAG Thoracic Branch Endoprosthesis.
P160025/S017	07/20/2023	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Addition of an alternative EPCD used to release products from the sterilization cycle and a reduction in sample size for in-process diameter inspection.
P160047/S032	07/27/2023	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	COOPERSURGICAL, INC.	Modifications to the AutoCalibration Unit used in the manufacturing process.
P170002/S023	07/05/2023	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Transfer of approved products from Teoxane S.A. Geneva, Switzerland to Teoxane Meyrin, Switzerland following packaging but before completion of Quality Control batch release.
P170008/S045	07/20/2023	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Replacement of the color component of the transition outer which is part of EluNIR's delivery system transition shaft.
P170043/S016	07/13/2023	X - 30-Day Notice	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Adoption of an Acceptable Quality Limit (AQL) sampling plan of 0.65 for the Hammer Cam component manufactured by Micron.
P170043/S017	07/14/2023	X - 30-Day Notice	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Addition of iMark Molding (Woodwille, WI) as an alternative supplier for the Hammer Cam component used in the manufacture of the Glaukos iStent inject® W Trabecular Micro-Bypass System (model G2-W).
P180032/S013	07/17/2023	X - 30-Day Notice	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Modification to the manufacturing process for the subject device. This change is the implementation of updated manufacturing software and associated fixtures that automate some existing manual processes.
P190019/S022	07/27/2023	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Change to the PLC software/control system for a sterilization chamber at the Boston Scientific Corporation (BSC) Coventry Rhode Island facility

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200015/S042	07/06/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Outsource the laser cutting process of the SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valve main, inner, and PVL skirt components.
P200028/S021	07/19/2023	X - 30-Day Notice	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Transferring the final pack-to-order (PTO) process to a new location due to the closure of existing facility and creating a new automated final functional test for the RF Generator component at the new location.
P200029/S005	07/26/2023	X - 30-Day Notice	THERASPHERE	BOSTON SCIENTIFIC CORPORATION	Supplier changes within the production of Loctite 4307 which is used in the manufacturing of the TheraSphere Administration Set manufactured by CEA.
P210003/S008	07/10/2023	X - 30-Day Notice	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Add a new manufacturing suite.
P210032/S010	07/05/2023	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate supplier of the outer foil packaging of the following devices: GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE VIABAHN VBX Balloon Expandable Endoprosthesis and GORE TAG Thoracic Branch Endoprosthesis.
P210037/S001	07/20/2023	X - 30-Day Notice	PROSPERA SPINAL CORD STIMULATION (SCS) SYSTEM, RESILIENCE PERCUTANEOUS LEAD, HOMESTREAM REMOTE MANAGEMENT	BIOTRONIK NRO, INC.	Introduction of an imaging process system which automatically determines the offset for the start position a the laser seam welding process for the Prospera Implantable Pulse Generator (IPG).

Total: 114