PMA Monthly approvals from 2/1/2022 to 2/28/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190002	02/28/2022	PMAO - PMA Origi	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for the Evoke® SCS System. This device is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S270	02/24/2022	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for a software maintenance release for updates to the Model 3300 LATITUDE Programming System software.
P790007/S059	02/22/2022	Y - 135 Review Tra	HANCOCK MODIFIED ORIFICE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P810031/S070	02/16/2022	N - Normal 180 Day	HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for an alternative terminal sterilization modality, ethylene oxide, for the Ophthalmic Viscoelastic Devices (OVDs), Healon® PRO, Healon 5® PRO and Healon GV® PRO, in final finished packaging.
P840001/S500	02/18/2022	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for the use of electronic labeling as a primary medium for distributing Neuromodulation and Pelvic Health product labeling to patients.
P840001/S505	02/01/2022	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for extending the device lifetime of the Model B31060 Connector Plug from 11 to 15 years.
P860004/S378	02/18/2022	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for the use of electronic labeling as a primary medium for distributing Neuromodulation and Pelvic Health product labeling to patients.
P870078/S044	02/22/2022	Y - 135 Review Tra	HANCOCK PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P910001/S114	02/24/2022	S - Special CBE	SPECTRANECTICS CVX-300 EXCIMER LASER	SPECTRANETICS CORP.	Approval for changes being effected (CBE) for Philips Laser System manufacturing verification processes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910077/S187	02/24/2022	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for a software maintenance release for updates to the Model 3300 LATITUDE Programming System software.
P960009/S408	02/18/2022	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for the use of electronic labeling as a primary medium for distributing Neuromodulation and Pelvic Health product labeling to patients.
P960009/S415	02/01/2022	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for extending the device lifetime of the Model B31060 Connector Plug from 11 to 15 years.
P960040/S473	02/24/2022	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for a software maintenance release for updates to the Model 3300 LATITUDE Programming System software.
P970004/S340	02/22/2022	N - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for the InterStim X INS (Model 97800) and its associated software applications (Model A51300, Model A52300).
P970004/S342	02/18/2022	N - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for the use of electronic labeling as a primary medium for distributing Neuromodulation and Pelvic Health product labeling to patients.
P970004/S345	02/22/2022	N - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for multiple uses of the Verify ENS device component in a healthcare facility during the implantation procedure only.
P970031/S064	02/22/2022	Y - 135 Review Tra	MEDTRONIC FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P980040/S144	02/14/2022	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for a manufacturing site located at AMO Groningen BV, Groningen, Groningen, 9728, NX, Netherlands as an alternative manufacturing and sterilization facility for the following with SmartLOAD Delivery Technology: SENSAR 1-Piece IOL, TECNIS 1-Piece IOL, TECNIS OptiBlue 1-Piece IOL and TECNIS Eyhance 1-Piece IOL.
P980043/S069	02/22/2022	Y - 135 Review Tra	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P990064/S077	02/22/2022	Y - 135 Review Tra	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P000054/S062	02/18/2022	N - Normal 180 Day	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for extension of the expiration date from 18 to 24 months for three 1mg drug product lots manufactured at Hospira, Inc. (McPherson, Kansas) and seven 1mg drug product lots manufactured at Wyeth Farma S.A. (Algete, Spain) when stored at 5° and 30°C; addition of a 30 month timepoint to the long-term stability protocol studies performed at 30 ºC ± 2 ºC /75 ± 5% RH and 30 ºC ± 2 ºC /75 ± 5% RH; and discontinuation of testing at the 5°C long-term storage condition (current 5°C lots will continue to the end of the current study).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000058/S081	02/18/2022	N - Normal 180 Day	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for extension of the expiration date from 18 to 24 months for three 1mg drug product lots manufactured at Hospira, Inc. (McPherson, Kansas) and seven 1mg drug product lots manufactured at Wyeth Farma S.A. (Algete, Spain) when stored at 5° and 30°C; addition of a 30 month timepoint to the long-term stability protocol studies performed at 30 ºC ± 2 ºC /75 ± 5% RH and 30 ºC ± 2 ºC /75 ± 5% RH; and discontinuation of testing at the 5°C long-term storage condition (current 5°C lots will continue to the end of the current study).
P010012/S548	02/24/2022	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for a software maintenance release for updates to the Model 3300 LATITUDE Programming System software.
P010047/S065	02/09/2022	O - Normal 180 Day	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Approval for labeling changes.
P020012/S039	02/17/2022	N - Normal 180 Day	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for a change in the syringe body from 1.0mL to 1.5mL, modified tray packaging, and a change in syringe cap lubricant.
P020036/S045	02/25/2022	N - Normal 180 Day	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	Approval for a new delivery system to allow use with a transradial approach.
P020045/S098	02/18/2022	O - Normal 180 Day	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval to expand the indication for use statement for the Freezor and Freezor Xtra Cardiac Cryoablation Catheters for use with pediatric patients.
P030005/S215	02/24/2022	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for a software maintenance release for updates to the Model 3300 LATITUDE Programming System software.
P030031/S125	02/01/2022	R - Real-Time Proc	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for an extension of the ThermoCool SmartTouch (ST) and ThermoCool SmartTouch SF (STSF) finished device shelf life from one to three years.
P030047/S043	02/11/2022	S - Special CBE	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS US CORPORATIO N	Approval for labeling updates.
P040036/S087	02/01/2022	R - Real-Time Proc	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for an extension of the ThermoCool SmartTouch (ST) and ThermoCool SmartTouch SF (STSF) finished device shelf life from one to three years.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050027/S028	02/04/2022	N - Normal 180 Day	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System. The device is for use in combination with the optical imaging drug Cysview® (hexaminolevulinate hydrochloride) for Intravesical Solution is indicated for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy for the detection of non-muscle invasive bladder cancer, including carcinoma in situ (CIS), in patients suspected or known to have the lesion on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for bladder cancer.
P050053/S053	02/18/2022	N - Normal 180 Day	INFUSE BONE GRAFT	MEDTRONIC INC.	Approval for extension of the expiration date from 18 to 24 months for three 1mg drug product lots manufactured at Hospira, Inc. (McPherson, Kansas) and seven 1mg drug product lots manufactured at Wyeth Farma S.A. (Algete, Spain) when stored at 5° and 30°C; addition of a 30 month timepoint to the long-term stability protocol studies performed at 30 ºC ± 2 ºC /75 ± 5% RH and 30 ºC ± 2 ºC /75 ± 5% RH; and discontinuation of testing at the 5°C long-term storage condition (current 5°C lots will continue to the end of the current study).
P080004/S042	02/28/2022	O - Normal 180 Day	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for a manufacturing site located at HOYA Lamphun Ltd., 75/2 Moo 4, Tambol Banklang, Amphur Muang, Lamphun 51000, Thailand. Specifically, the approval is for machining, polishing, inspection, assembly, and primary packaging (pre-sterilization) of raw material buttons.
P080011/S131	02/01/2022	O - Normal 180 Day	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for a new private label trade name.
P080025/S235	02/22/2022	N - Normal 180 Day	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for the InterStim X INS (Model 97800) and its associated software applications (Model A51300, Model A52300).
P080025/S237	02/18/2022	N - Normal 180 Day	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for the use of electronic labeling as a primary medium for distributing Neuromodulation and Pelvic Health product labeling to patients.
P080025/S240	02/22/2022	N - Normal 180 Day	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for multiple uses of the Verify ENS device component in a healthcare facility during the implantation procedure only.
P080032/S019	02/18/2022	O - Normal 180 Day	ALAIR BRONCHIAL THERMOPLASTY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for updating the labeling to include the results of the post approval study RESCUE 3.
P100018/S035	02/08/2022	R - Real-Time Proc	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Approval for changes to the hypotube composition specification and full-length tensile strength specifications for the Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology.
P100022/S040	02/02/2022	R - Real-Time Proc	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK IRELAND, LTD.	Approval for an additional active pharmaceutical ingredient supplier.
P100042/S032	02/25/2022	R - Real-Time Proc	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval to support the addition of the optional use of an automated dishwasher (Miele Dishwasher) to wash Panther Trax shuttle shields, sample racks, and storage racks used with the Aptima HPV assays.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100045/S056	02/18/2022	P - Panel Track	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for the CardioMEMS HF System. The device is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.
P110042/S167	02/24/2022	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a software maintenance release for updates to the Model 3300 LATITUDE Programming System software.
P120002/S020	02/25/2022	N - Normal 180 Day	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS US CORPORATION	Approval for a new delivery system to allow use with a transradial approach.
P120007/S029	02/25/2022	R - Real-Time Proc	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval to support the addition of the optional use of an automated dishwasher (Miele Dishwasher) to wash Panther Trax shuttle shields, sample racks, and storage racks used with the Aptima HPV assays.
P130021/S056	02/22/2022	Y - 135 Review Tra	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P140004/S027	02/08/2022	O - Normal 180 Day	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Approval for the sterilization site change have been reviewed and are acceptable.
P140017/S013	02/22/2022	Y - 135 Review Tra	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P150012/S120	02/24/2022	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for a software maintenance release for updates to the Model 3300 LATITUDE Programming System software.
P150013/S024	02/08/2022	S - Special CBE	PD-L1 IHC 22C3 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval for the removal of the gastric or gastroesophageal junction (GEJ) adenocarcinoma indication from the device labeling.
P150048/S056	02/22/2022	Y - 135 Review Tra	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for the removal of the leak test from the lot release testing process for the KONECT RESILIA Aortic Valved Conduit manufactured at the Irvine, CA facility.
P160024/S011	02/11/2022	R - Real-Time Proc	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Approval for modifying the materials of the packaging sterile barrier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160042/S013	02/08/2022	R - Real-Time Proc	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for a change in syringe for Revanesse Versa, Revanesse Versa+, and Revanesse Lips+.
P160048/S016	02/10/2022	P - Panel Track	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for the Eversense® E3 Continuous Glucose Monitoring System for expanding the indications for use and modifying the sensor design to allow use for up to 180 days.
P160054/S042	02/16/2022	R - Real-Time Proc	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval to introduce a standalone packaging configuration for the HeartMate 3¿ Apical Cuff Holding Tool.
P170006/S007	02/22/2022	Y - 135 Review Tra	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Approval for a change in formulation of detergent used in the manufacturing process of the device.
P170008/S038	02/10/2022	N - Normal 180 Day	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for the addition of the 2.25mm diameter EluNIR stent system to the approved EluNIR matrix
P170019/S029	02/18/2022	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order to expand the intended use of FoundationOne®CDx (F1CDx) to include a companion diagnostic (CDx) indication for the detection of microsatellite instability High (MSI-H) status in patients with solid tumors who may benefit from treatment with KEYTRUDA® (pembrolizumab).
P170025/S017	02/25/2022	R - Real-Time Proc	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Approval to support the addition of the optional use of an automated dishwasher (Miele Dishwasher) to wash Panther Trax shuttle shields, sample racks, and storage racks used with the Aptima HPV assays.
P170030/S019	02/18/2022	Y - 135 Review Tra	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval for the introduction of semi-automated optimized spray coating equipment and additional stent holders for the drug coating process
P180027/S006	02/15/2022	R - Real-Time Proc	FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM	MICROVENTION, INC.	Approval for a design change to the introducer sheath from a single-ended taper to a double-ended taper for the FRED System and FRED X System 3.5 to 5.5 mm stents.
P180046/S044	02/01/2022	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to extend the shelf life of the Surgical Tool Kit to 36 months.
P190006/S044	02/01/2022	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to extend the shelf life of the Surgical Tool Kit to 36 months.
P190014/S006	02/10/2022	N - Normal 180 Day	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	Approval of an upgraded version of MyChoice CDx (version 2) due to reagent change to the device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190018/S012	02/14/2022	O - Normal 180 Day	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 RESEARCH, LTD.	Approval for additional manufacturing sites at Alcon Research, LLC (AODC-South) located at 6065 Kyle Lane Huntington, West Virginia and Alcon Research, LLC (AODC-North) located at 2 Vision Lane Lesage, West Virginia. The AODC-South facility performs the Injection Moulding through the Cosmetic Inspection manufacturing steps and the AODC-North facility performs the Pouching & Barseal through the Overwrap steps of the manufacturing process, as well as sterilization and distribution.
P200006/S001	02/03/2022	O - Normal 180 Day	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE, INC.	Approval of the clinical protocol entitled Statistical Analysis Plan Expanded Validation Study for the Efficacy of Rucaparib in Ovarian Cancer based on F1L CDx.
P210007/S001	02/16/2022	R - Real-Time Proc	VIVISTIM® SYSTEM	MICROTRANS PONDER, INC.	Approval for updating the Wireless Transmitter from Model 2000 to Model 2100 to accommodate an obsolete part and accompanying changes to the software (SAPS Model 4001) and Implantable Pulse Generator (Model 1001)
P210020/S003	02/03/2022	O - Normal 180 Day	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 68

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P820003/S139	02/16/2022	X - 30-Day Notice	VERSATRAX MODEL 7000 UNIVERSAL A-V PULSE GENERATOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the dose substantiation method for the 5846 disposable safety patient cables.
P820033/S015	02/08/2022	X - 30-Day Notice	PLASMAFLO OP-05 W(A) ASAHI PLASMA SEPARATOR	ASAHI KASEI MEDICAL CO., LTD.	Use of new equipment for the EVOH coating process, and the hollow fiber (HF) drying process to increase the hollow fiber drying capacity.
P830055/S280	02/24/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Additional facility location for current supplier of Pentaerythritol tetrakis[3-(3,5-di tertiary butyl-4-hydroxyphenyl) propionate] powder used in AOX bar stock material.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S281	02/18/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of a new Final Cleanline for Poly Product and the movement of process steps from one building to a second building under the same establishment and address for several Knee components.
P830061/S204	02/28/2022	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the final packaging process to improve the process and to reduce potential nonconformance.
P840001/S508	02/04/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Addition of Integer as an alternate supplier for the Intellis Implantable Neurostimulator (INS) Titanium Shield Assembly component.
P840001/S510	02/17/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Update to the visual inspection requirements of the Intellis flex circuit laser solder joint print specification and process qualification in order to align with the sponsors current Neurostimulator designs including the elimination of the solder joint visual inspection requirements for the Component Side of the flex.
P840001/S511	02/26/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Process change to the final clean process used in the manufacturing of hybrids and to make operational/procedural changes related to the final clean process at the internal supplier, Medtronic Tempe Campus.
P860004/S386	02/26/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Process change to the final clean process used in the manufacturing of hybrids and to make operational/procedural changes related to the final clean process at the internal supplier, Medtronic Tempe Campus.
P900056/S197	02/25/2022	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P900066/S015	02/02/2022	X - 30-Day Notice	PERFLUOROPROPANE	AIRGAS THERAPEUTICS LLC	Change to the firms manufacturing procedure and method of manufacturing.
P920015/S266	02/28/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Updates to the final packaging process to improve the process and to reduce potential nonconformance.
P920047/S126	02/22/2022	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Relocation of multiple ablation catheter family subassembly manufacturing processes within the Heredia, Costa Rica campus.
P920047/S127	02/25/2022	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P920048/S021	02/28/2022	X - 30-Day Notice	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Move of a suppliers manufacturing facility for a critical raw material (i.e., ascites fluid containing A137 mouse monoclonal antibodies) of the Rapid fFN for the TLiIQ System.
P930039/S237	02/25/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Modify the deburring process and cleaning process of the tip electrode and electrode ring components supplied by Heraeus.
P930039/S239	02/28/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Updates to the final packaging process to improve the process and to reduce potential nonconformance.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950020/S116	02/25/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P960009/S420	02/26/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Process change to the final clean process used in the manufacturing of hybrids and to make operational/procedural changes related to the final clean process at the internal supplier, Medtronic Tempe Campus.
P960009/S421	02/25/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Allow the use of additional products in the paperless chart recorder system: Sterilization Automated Release (StAR) System.
P970004/S354	02/26/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Process change to the final clean process used in the manufacturing of hybrids and to make operational/procedural changes related to the final clean process at the internal supplier, Medtronic Tempe Campus.
P970004/S355	02/25/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Allow the use of additional products in the paperless chart recorder system: Sterilization Automated Release (StAR) System.
P980003/S093	02/25/2022	X - 30-Day Notice	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P980016/S805	02/22/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates the accept/reject criteria for anode shifting and spacer non-conformances and addition of pictures and descriptions of defect codes.
P980016/S806	02/17/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a wafer fabrication facility location and other process changes at the 2nd and 1st tier suppliers for hybrid components.
P980016/S807	02/25/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a vapor degreaser rework and process improvements.
P980035/S704	02/28/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to the final packaging process to improve the process and to reduce potential nonconformance.
P980035/S705	02/25/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of a vapor degreaser rework and process improvements.

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P980037/S087	02/09/2022	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Modification of a core pin and cooling pin for supplied components.
P980040/S145	02/17/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Update the tolerance ranges of the Haptic Blocker/ Haptic Cup that are manufacturing processing aids for applicable toric intraocular lenses.
P000054/S066	02/17/2022	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Change in the packaging suppliers machine equipment.
P000058/S085	02/17/2022	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Change in the packaging suppliers machine equipment.
P010015/S492	02/25/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of a vapor degreaser rework and process improvements.
P010031/S771	02/22/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates the accept/reject criteria for anode shifting and spacer non-conformances and addition of pictures and descriptions of defect codes.
P010031/S772	02/17/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a wafer fabrication facility location and other process changes at the 2nd and 1st tier suppliers for hybrid components.
P010031/S773	02/25/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a vapor degreaser rework and process improvements.
P010032/S184	02/17/2022	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Additional heat sealer (Accu Seal 6400 series) for use in the Plano facility.
P020004/S187	02/22/2022	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.

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P020004/S188	02/11/2022	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Replicating a manufacturing line for the GORE EXCLUDER AAA Endoprosthesis Contralateral Leg subassembly at an existing manufacturing facility.
P020025/S134	02/22/2022	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Relocation of multiple ablation catheter family subassembly manufacturing processes within the Heredia, Costa Rica campus.
P020025/S135	02/25/2022	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P030036/S135	02/25/2022	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the deburring process and cleaning process of the tip electrode and electrode ring components supplied by Heraeus.
P040027/S090	02/22/2022	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.
P040037/S150	02/22/2022	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.
P040043/S130	02/22/2022	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.
P050006/S098	02/22/2022	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.
P050037/S113	02/02/2022	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Testing laboratory change for the incoming material testing and a testing method change for the metallic impurities.
P050052/S134	02/02/2022	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Testing laboratory change for the incoming material testing and a testing method change for the metallic impurities.
P050053/S057	02/18/2022	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Change in the packaging suppliers machine equipment.
P060006/S103	02/25/2022	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P060037/S077	02/10/2022	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Relocation of some manufacturing steps and in-process cleaning steps for Fluted Mobile Stemable Tray Set Screw, which is a sub-component of NexGen LPS Mobile Knee Fluted Stem Mobile Knee Precoat Tibial Baseplate.
P070008/S135	02/28/2022	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.	Additional IS4 connector housing supplier for the Sentus QP leads.

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P070026/S090	02/14/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Movement of manufacturing steps and equipment to a 2nd building within the same establishment and address and introduction of a new clean room and additional new assets.
P070026/S091	02/22/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Introduction of a new spray dry asset at a contract manufacturer.
P080011/S138	02/16/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Manufacture of Biofinity Energys on Biofinity Line 6 at the CooperVision Manufacturing, Ltd. facility in Hamble, UK.
P080025/S249	02/26/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Make a process change to the final clean process used in the manufacturing of hybrids and to make operational/procedural changes related to the final clean process at the internal supplier, Medtronic Tempe Campus.
P080025/S250	02/25/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Allow the use of additional products in the paperless chart recorder system: Sterilization Automated Release (StAR) System.
P080030/S023	02/18/2022	X - 30-Day Notice	GLAUKOS ISTENT TRABECULAR BYPASS STENT MODEL GTS100R/L	GLAUKOS, CORPORATION	Change to the sampling plan for Limulus Amebocyte Lysate (LAL) endotoxin testing.
P100021/S100	02/07/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Removal of a third tier supplier from the manufacturing of Endurant Stent Graft System, Endurant II Stent Graft System, Endurant II AUI Stent Graft System and Endurant IIs Stent Graft System.
P100021/S101	02/24/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of temporary visual inspection for sorting finished Endurant devices within scope of a field corrective action.
P100039/S014	02/16/2022	X - 30-Day Notice	ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Manufacturing process change for kit components.
P110010/S200	02/10/2022	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternative contract testing laboratory to carry out confirmatory testing on Everolimus for the SYNERGY and PROMUS devices.
P110010/S202	02/25/2022	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P130006/S089	02/22/2022	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.

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P130008/S077	02/02/2022	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Notification of additional raw material suppliers.
P130008/S078	02/11/2022	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Notification of introducing a multi-cavity mold to manufacture Model 2580 patient remote buttons.
P130014/S014	02/14/2022	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Shift in the tolerance range for the Nozzle-Insert component of the Adherus AutoSpray Dural Sealant.
P130021/S108	02/09/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Alternative manufacturing site for a sub-tier supplier and addition of an antioxidant to the raw material used for a component of the delivery system.
P130030/S073	02/25/2022	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P140009/S075	02/17/2022	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Additional heat sealer (Accu Seal 6400 series) for use in the Plano facility.
P140017/S020	02/02/2022	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	New cleanroom area for various manufacturing processes at an existing site.
P140018/S031	02/17/2022	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	New sub-tier supplier for the crude n-butyl cyanoacrylate used in the VenaSeal Closure System.
P140019/S006	02/16/2022	X - 30-Day Notice	I-FACTOR PEPTIDE ENHANCED BONE GRAFT	CERAPEDICS, LLC	Modification to the endotoxin test plan.
P150003/S083	02/10/2022	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of an alternative contract testing laboratory to carry out confirmatory testing on Everolimus for the SYNERGY and PROMUS devices.
P150004/S055	02/17/2022	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Additional heat sealer (Accu Seal 6400 series) for use in the Plano facility.
P150005/S069	02/22/2022	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Relocation of multiple ablation catheter family subassembly manufacturing processes within the Heredia, Costa Rica campus.
P150005/S070	02/25/2022	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P150033/S133	02/01/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modify the final function test at Medtronic Swiss Manufacturing Operations.

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P150033/S134	02/25/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modify the deburring process and cleaning process of the tip electrode and electrode ring components supplied by Heraeus.
P150033/S135	02/25/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implementation of a vapor degreaser rework and process improvements.
P160021/S033	02/22/2022	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.
P170002/S020	02/24/2022	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Removal of in-process control (IPC) tests for pH at dialysis and rheology at filling during the manufacturing of RHA 2, RHA 3, and RHA 4
P170030/S021	02/23/2022	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Using an alternative vacuum oven for the annealing of the drug-coated Orsiro and Orsiro Mission Stents.
P170043/S012	02/18/2022	X - 30-Day Notice	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Change to the sampling plan for Limulus Amebocyte Lysate (LAL) endotoxin testing.
P180031/S004	02/07/2022	X - 30-Day Notice	NEUROFORM ATLAS® STENT SYSTEM	STRYKER NEUROVASCULAR	Three changes to the non-patient contacting introducer sheath component of the Neuroform Atlas Stent System: 1) sheath manufacturing to be outsourced to an external supplier; 2) change from a three- to two-step manufacturing process; and 3) tip length specification simplification and change of the nominal length.
P180046/S050	02/10/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Reduction in the bakeout time for the IPG hermetic enclosure.
P190006/S050	02/10/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Reduction in the bakeout time for the IPG hermetic enclosure.
P190019/S012	02/22/2022	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Manufacturing equipment and inspection process change.
P190019/S013	02/25/2022	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Introduction of parametric release for the BSC2000-2 Ethylene Oxide Sterilization Cycle at the BSC Coventry, RI Facility.
P200010/S007	02/28/2022	X - 30-Day Notice	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Relocation of the manufacturing room for a component/control material.
P200022/S008	02/09/2022	X - 30-Day Notice	SIMPLIFY® CERVICAL ARTIFICIAL DISC	NUVASIVE, INC.	Changes to the location of a mid-process inspection of device components due to acquisition and transfer of ownership.
P200026/S004	02/11/2022	X - 30-Day Notice	ABRE VENOUS SELF-EXPANDING STENT SYSTEM	MEDTRONIC VASCULAR, INC.	Add an alternate test facility for hydrogen content testing of the nitinol tubing.

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P200030/S007	02/22/2022	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Removal of cytotoxicity and infrared spectroscopy inspections for incoming components.

Total: 93