PMA Monthly approvals from 5/1/2021 to 5/31/2021

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S038	05/07/2021	S - Special CBE	GELFOAM	PFIZER, INC.	Approval for addition of text to the Instructions for Use regarding CSF retention and hydrocephalus.
P830055/S265	05/10/2021	O - Normal 180 Day	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a manufacturing site located at Johnson & Johnson Medical (DePuy Suzhou) Ltd., No. 299, Changyang Street, Suzhou Industrial Park, Suzhou Jiangsu, China, to manufacture ATTUNE CR and ATTUNE PS Femoral Components of the LCS Total Knee System.
P870076/S026	05/11/2021	S - Special CBE	FALOPE RING BAND AND APPLICATOR SYSTEMS	GYRUS ACMI, INC.	Approval for modifications to the labeling to assure the risks associated with damaged packaging and components identified in the Design Failure Mode and Effects Analysis are addressed in the instructions for use.
P890003/S443	05/05/2021	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for firmware updates (Version M7.6) to the MyCareLink Patient Monitor Model 24950 to enable support for an alternate modem.
P890003/S444	05/27/2021	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for new cardiovascular implantable electronic device (CIED) software applications on the CareLink SmartSync Device Manager.
P910001/S113	05/11/2021	R - Real-Time Proc	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for changing the devices labeling, specifically, the wording of a precaution statement in the Instructions for Use.
P920048/S019	05/21/2021	O - Normal 180 Day	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Approval for a manufacturing site located at 10210 Genetic Center Dr., San Diego, CA 92121 (GCD), for the manufacture of finished, kitted Rapid fFN Cassettes for use in the TLiIQ System.
P950039/S040	05/14/2021	N - Normal 180 Day	THINPREP(R) PROCESSOR, MODEL TP 2000	HOLOGIC, INC.	Approval for the Hologic ThinPrep Genesis Processor.
P960009/S391	05/25/2021	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for the SenSight Directional Lead System and updates to Model A610 DBS Clinician Programmer Application (CPA) Software to version 3.0.
P960009/S397	05/07/2021	R - Real-Time Proc	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for software changes to the Medtronic Model A620 Patient Programmer Application (PPA)which consist of 1) fixing a defect that prevents the software from communicating with certain Model B35200 INSs that have Tel-M IDs containing particular values, 2) updating the impedance test that is used to support the MRI eligibility feature of the A620 PPA, and 3) other minor changes and bug fixes.
P970018/S038	05/20/2021	R - Real-Time Proc	BD PREPSTAIN SYSTEM	BD DIAGNOSTIC SYSTEMS	Approval for (i) a software update for the BD Totalys MultiProcessor and (ii) a revised hardware and software configuration for the BD Totalys SlidePrep.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S774	05/05/2021	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for firmware updates (Version M7.6) to the MyCareLink Patient Monitor Model 24950 to enable support for an alternate modem.
P980016/S775	05/27/2021	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for new cardiovascular implantable electronic device (CIED) software applications on the CareLink SmartSync Device Manager.
P980035/S676	05/05/2021	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for firmware updates (Version M7.6) to the MyCareLink Patient Monitor Model 24950 to enable support for an alternate modem.
P980035/S677	05/27/2021	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for new cardiovascular implantable electronic device (CIED) software applications on the CareLink SmartSync Device Manager.
P990018/S006	05/06/2021	O - Normal 180 Day	MENICON Z RIGID GAS PERMEABLE CONTACT LENS	MENICON CO. LTD.	Approval for addition of the following private label trade names for the Menicon Z Night (tisilfocon A) Contact Lenses for Overnight Wear: ACUVUE® Abiliti Overnight and ACUVUE® Abiliti Overnight Therapeutic Lenses for Myopia Management.
P990081/S044	05/20/2021	R - Real-Time Proc	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.
P000029/S087	05/03/2021	Y - 135 Review Tra	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Approval to remove heavy metals testing at release of raw materials and final finished product.
P010015/S469	05/05/2021	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for firmware updates (Version M7.6) to the MyCareLink Patient Monitor Model 24950 to enable support for an alternate modem.
P010015/S470	05/27/2021	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for new cardiovascular implantable electronic device (CIED) software applications on the CareLink SmartSync Device Manager.
P010031/S736	05/05/2021	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for firmware updates (Version M7.6) to the MyCareLink Patient Monitor Model 24950 to enable support for an alternate modem.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S737	05/27/2021	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for new cardiovascular implantable electronic device (CIED) software applications on the CareLink SmartSync Device Manager.
P020055/S024	05/20/2021	R - Real-Time Proc	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.
P030009/S103	05/21/2021	S - Special CBE	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P030031/S118	05/13/2021	O - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval of an updated and finalized protocol for the Real-World Experience of Catheter Ablation of Persistent Atrial Fibrillation post-approval study (PAS)
P030050/S032	05/18/2021	O - Normal 180 Day	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for updated labeling to reflect the incidence rate of adverse events through year three of the post approval study for SCULPTRA Aesthetic
P040021/S046	05/28/2021	S - Special CBE	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ST. JUDE MEDICAL, INC.	Approval for labeling changes related to future valve-in-valve procedures.
P060022/S026	05/04/2021	N - Normal 180 Day	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS,MODEL ADAPT	BAUSCH & LOMB, INC.	Approval for changes to the packaging of preloaded Akreos intraocular lens models AO60 and MI60.
P060035/S031	05/14/2021	Y - 135 Review Tra	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORI ES	Approval to process improvements and scale-up of components for kit production.
P070014/S060	05/19/2021	Y - 135 Review Tra	LIFESTENT FLEXSTAR & FLEXSTAR XL VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval an alternate supplier for the primary and secondary sheath components of the LifeStent Vascular Stent Systems.
P080004/S031	05/21/2021	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., 725 Moo 4, Tambol Banklang, Amphur Muagn, Lamphun 5100, Thailand. HOYA Lamphun Ltd. processes will be limited to machining, polishing, inspecting, assembly, and primary packaging (pre-sterilization) of intraocular lenses (IOLs) and injector cartridges.
P100014/S024	05/03/2021	Y - 135 Review Tra	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Approval to remove heavy metals testing at release of raw materials and final finished product.
P100016/S007	05/13/2021	Y - 135 Review Tra	EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Approval for changes in manufacturing with installation of new equipment and process accessories for machining, tumbling, assembly, and inspection for 3-piece intraocular lens models CT LUCIA 202 and CT LUCIA 602.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100021/S091	05/21/2021	S - Special CBE	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P100021/S092	05/28/2021	O - Normal 180 Day	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval to provide supplemental data from the ANCHOR Registry from an additional 60 subjects treated for short neck infrarenal aneurysms to provide support long-term safety and effectiveness data on the short neck indication.
P100026/S085	05/24/2021	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for minor updates to the RNS® Tablet. NeuroPace is requesting approval for addition of Mobile Device Management (MDM) capability on the tablet platform as well as changes to the login requirements for accessing the NeuroPace Programmer Application on the tablet.
P100027/S034	05/20/2021	R - Real-Time Proc	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.
P100034/S028	05/24/2021	O - Normal 180 Day	NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT	NOVOCURE GMBH	Approval for a manufacturing site, Synergy Health Däniken AG (Steris), located at Hogenweidstrasse 6, CH-4658, Daniken, Switzerland. This site is a sterilization facility used to sterilize the INE Transducer Arrays in the Optune System.
P100040/S047	05/21/2021	S - Special CBE	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P110013/S111	05/21/2021	S - Special CBE	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P110019/S113	05/13/2021	N - Normal 180 Day	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for increased post dilatation diameters and changes to the delivery system.
P110027/S012	05/28/2021	P - Panel Track	THERASCREEN KRAS RGQ PCR KIT	QIAGEN GMBH	Approval for expanding the indication to aid in the identification of non-small cell lung cancer patients whose tumors harbor KRAS G12C mutations and may benefit from treatment with LUMAKRA (sotorasib).
P110033/S053	05/28/2021	P - Panel Track	JUVEDERM VOLUMA XC	ALLERGAN	Approval for JUVEDERM VOLBELLA XC for expanding the indications to include the improvement of infraorbital hollowing in adults over the age of 21.
P120020/S026	05/12/2021	N - Normal 180 Day	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Approval for adding new device sizes to the product line.
P130013/S042	05/21/2021	O - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval of the protocol for the post-approval study (PAS) protocol.
P130021/S092	05/21/2021	S - Special CBE	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130022/S034	05/21/2021	O - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for the addition of an alternative site, Cirtec Medical Corporation Free Zone Coyol, Building 11 Costa Rica CR 20101, as a back up to the primary site Cirtec Medical, formerly known as Stellar, Brooklyn Park, MN for the manufacturing of the percutaneous lead components to accommodate higher volume manufacturing.
P130022/S040	05/10/2021	N - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for MR conditional labeling for the Surpass-C surgical leads used with the Senza Spinal Cord Stimulation System
P130022/S041	05/10/2021	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a new 0.016 curved stylet with 22 degree band angle to be marketed with the Senza Spinal Cord Stimulation (SCS) System. This stylet will replace 0.012 curved stylet with 30 degree angle which is being discontinued.
P140010/S060	05/21/2021	S - Special CBE	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P140018/S025	05/21/2021	S - Special CBE	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P140025/S015	05/20/2021	R - Real-Time Proc	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.
P140031/S125	05/13/2021	P - Panel Track	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System. The device is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality >= 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).
P150033/S095	05/05/2021	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for firmware updates (Version M7.6) to the MyCareLink Patient Monitor Model 24950 to enable support for an alternate modem.
P150033/S096	05/27/2021	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for new cardiovascular implantable electronic device (CIED) software applications on the CareLink SmartSync Device Manager.
P150033/S105	05/21/2021	S - Special CBE	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P160002/S014	05/20/2021	R - Real-Time Proc	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.

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P160022/S028	05/19/2021	O - Normal 180 Day	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 CORPORATION	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160042/S014	05/07/2021	N - Normal 180 Day	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for the increase in syringe volume from 1.0 mL to 1.2 mL of Revanesse Lips+.
P160043/S047	05/21/2021	S - Special CBE	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.
P160046/S009	05/20/2021	R - Real-Time Proc	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.
P170008/S024	05/21/2021	N - Normal 180 Day	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for extension of the shelf-life from two to three years
P170019/S021	05/28/2021	N - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval to expand the intended use of FoundationOne CDx (F1CDx) to include a companion diagnostic indication for FGFR2 fusion/rearrangements in patients with Cholangiocarcinoma who may benefit from treatment with Truseltiq (infigratinib).
P180046/S024	05/19/2021	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for 1.5T and 3T MRI RF Extremity Coil Conditional Labeling on the Axonics Sacral Neuromodulation System.
P190006/S024	05/19/2021	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for 1.5T and 3T MRI RF Extremity Coil Conditional Labeling on the Axonics Sacral Neuromodulation System.
P190008/S014	05/21/2021	S - Special CBE	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190024/S003	05/20/2021	R - Real-Time Proc	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.
P190031/S002	05/20/2021	R - Real-Time Proc	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for the dispenser resin replacement used in the injection molding process for six (6) dispenser parts.
P200010/S001	05/21/2021	P - Panel Track	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval order for extending the label claim to include an indication for RYBREVANT (amivantamab) in non-small cell lung cancer patients with EGFR exon 20 insertions.
P200010/S002	05/28/2021	P - Panel Track	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval of Guardant360 CDx for expanding the indications for use to include the companion diagnostic claim to identify non-small cell lung cancer patients with KRAS G12C mutation for treatment with LUMAKRASTM (sotorasib).
P200022/S005	05/28/2021	O - Normal 180 Day	SIMPLIFY® CERVICAL ARTIFICIAL DISC	NUVASIVE, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P200022/S006	05/26/2021	O - Normal 180 Day	SIMPLIFY® CERVICAL ARTIFICIAL DISC	NUVASIVE, INC.	Approval of changes to the previously approved PAS protocol for the post-approval study (PAS) protocol.
P200028/S003	05/25/2021	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for modifications to the circuitry of the RF Generator, modifications to the RF Generator Front Panel Board, and an update to the RF Generator software.
P200028/S004	05/28/2021	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for the addition of the DiamondTemp Generator Connection Box E (Model: CEDTGCB100) device to the DiamondTemp Ablation System.
P200028/S006	05/19/2021	S - Special CBE	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for a correction to the catheter diameter in the device labels and labeling.
P200029/S001	05/14/2021	O - Normal 180 Day	THERASPHERE	BOSTON SCIENTIFIC CORPORATIO N	Approval of the protocol for the post-approval study (PAS) protocol.
P200046/S002	05/21/2021	S - Special CBE	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Approval for additional verification of the date of manufacture and use by date for devices undergoing rework activities.

Total: 77

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S263	05/06/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Remove dwells from laser weld process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S264	05/10/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.
N970012/S187	05/27/2021	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Process change to add a new Kink Resistant Tubing (KRT) Fabrication Machine System.
P830055/S266	05/05/2021	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change in cleaning agent formulation for in-process cleaning and final-cleaning process of LCS Total Knee System.
P830060/S086	05/10/2021	X - 30-Day Notice	VENTAK AND AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEMS	BOSTON SCIENTIFIC	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.
P840001/S487	05/06/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Use of an alternate component supplier Meier Tool & Engineering, Inc. for the platinum iridium electrodes used in SCS Leads, Models 39286, 39565, 977C165, 977C190, 977C265, & 977C290. Meier Tool & Engineering, Inc. will form the electrodes using progressive die instead of manual blank/form die. Vanishing Oil 101 will be used in the manufacturing process. Meier Tool & Engineering, Inc. will SQM Inspect the product and Medtronic Villalba will SQM Verify the product.
P860004/S372	05/03/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of a new Servo Press machine at Brunk Industries, Inc to manufacture the SynchroMed II Pump (SMII) Inner Shield (P/N M955170A001) for the SynchroMed Infusion System.
P860004/S373	05/04/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of additional detection controls for the pump tube O-ring assembly processes for the SynchroMed Infusion System and the Implantable System for Remodulin.
P870076/S027	05/19/2021	X - 30-Day Notice	FALOPE RING BAND AND APPLICATOR SYSTEMS	GYRUS ACMI, INC.	Update to sterilization parameters for the reduction of gas concentration in the ethylene oxide (EO) sterilization process.
P910073/S161	05/10/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.
P910077/S184	05/10/2021	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.
P930035/S032	05/10/2021	X - 30-Day Notice	VENTAK(R) P2 SYSTEM	BOSTON SCIENTIFIC	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.
P930039/S226	05/26/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Addition of removal process for Loose foreign material/adhesive on helix electrodes.
P960004/S094	05/10/2021	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.
P960006/S052	05/10/2021	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960016/S087	05/18/2021	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Changes to a resin as a result of transferring resin manufacturing from the current supplier manufacturing site in LaPorte, TX to a new supplier manufacturing site in Avon, OH.
P960040/S464	05/06/2021	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Remove dwells from laser weld process.
P980016/S782	05/06/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Acceptance to incorporate two robots into the component manufacturing process at a Medtronic component supplier.
P980016/S783	05/18/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Acceptance to implement a new degreasing process at their component suppliers.
P980035/S681	05/18/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Acceptance to implement a new degreasing process at their component suppliers.
P980035/S682	05/21/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Second manufacturing line for shield assemblies at an existing supplier.
P980040/S134	05/04/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Addition of two raw material suppliers for nut and pushrod components of TECNIS Simplicity Delivery System in the AMO Groningen manufacturing facility.
P980044/S056	05/24/2021	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture SUPARTZ FX and VISCO-3 for the purpose of the manufacturing the intermediate of Gel-One.
P000053/S120	05/27/2021	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Manufacturing process change to add a Kink Resistant Tubing (KRT) fabrication machine, 5.0.
P010012/S537	05/06/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Remove dwells from laser weld process.

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P010012/S538	05/10/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.
P010015/S473	05/18/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Acceptance to implement a new degreasing process at their component suppliers.
P010030/S148	05/17/2021	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Change in the application of a surface coating finish on the Printed Circuit Boards (PCBs) used in the LifeVest Model 4000 electrode belt therapy electrodes.
P010030/S149	05/17/2021	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Relocation of automated electrical functional testing of the Printed Circuit Assemblies (PCAs) to the supplier.
P010031/S744	05/06/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Acceptance to incorporate two robots into the component manufacturing process at a Medtronic component supplier.
P010031/S745	05/18/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Acceptance to implement a new degreasing process at their component suppliers.
P020012/S038	05/14/2021	X - 30-Day Notice	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Implementation of a new chromatography equipment for hydroxyproline/collagen content and lidocaine hydrochloride content in-process and lot release quality control testing.
P030005/S209	05/06/2021	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Remove dwells from laser weld process.

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P030009/S102	05/11/2021	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Transfer of component extrusion manufacturing operations from the Santa Rosa to the Danvers site.
P030017/S345	05/13/2021	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add an alternate semi-automated process for the final packaging activities for the sterile-packaged Implantable Pulse Generators at the Boston Scientific Clonmel Ireland facility.
P030045/S006	05/07/2021	X - 30-Day Notice	INTRASTENT DOUBLESTRUT STENT	MEDTRONIC VASCULAR INC	New sterilization cycle with a reduced EO concentration using Chamber 31 and Chamber 32 at contract sterilizer.
P040014/S044	05/04/2021	X - 30-Day Notice	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Change to the flux used during soldering.
P040042/S050	05/04/2021	X - 30-Day Notice	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Change to the flux used during soldering.
P040043/S127	05/04/2021	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	New quality control test equipment for testing of the catheter hubs of the Conformable GORE TAG Thoracic Endoprosthesis (CTAG) catheters.
P040043/S128	05/04/2021	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate manufacturing process, using a second-generation equipment, to manufacture a sleeve component for the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System Device.
P060001/S032	05/07/2021	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	New sterilization cycle with a reduced EO concentration using Chamber 31 and Chamber 32 at contract sterilizer.
P060019/S052	05/04/2021	X - 30-Day Notice	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Change to the flux used during soldering.
P060019/S053	05/18/2021	X - 30-Day Notice	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Changes to a resin as a result of transferring resin manufacturing from the current supplier manufacturing site in LaPorte, TX to a new supplier manufacturing site in Avon, OH.
P070026/S081	05/05/2021	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change in cleaning agent formulation for in-process cleaning and final cleaning processes of CERAMAX® Ceramic Total Hip System.
P080004/S040	05/07/2021	X - 30-Day Notice	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Removal of the ethylene oxide ink indicator on individual sterilization pouches of fully preloaded intraocular lens devices, and replacement with an ethylene oxide indicator sticker that will be attached to the sterilization tray during batch sterilization.
P080011/S127	05/06/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Manufacture of Biofinity Toric Multifocal lenses on an additional Biofinity production line.
P080011/S128	05/20/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Manufacture of Biofinity XR Toric Lenses with additional cylinder powers on Biofinity Line 20.

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P080020/S043	05/26/2021	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture SUPARTZ FX and VISCO-3 for the purpose of the manufacturing the intermediate of Gel-One.
P080032/S018	05/27/2021	X - 30-Day Notice	ALAIR BRONCHIAL THERMOPLASTY SYSTEM	BOSTON SCIENTIFIC CORP.	Replacing components of an extrusion line.
P100010/S115	05/13/2021	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Additional manufacturing line at the Villalba, Puerto Rico site.
P100026/S086	05/07/2021	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the Automatic Test Equipment (ATE) hardware, software and database to improve yield of components of the RNS Neurostimulators.
P100047/S179	05/24/2021	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Alternate manufacturer to provide the 3mL syringes used during the manufacturing process for the HeartWare HVAD System.
P110002/S030	05/05/2021	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Increased storage time of the Mobi-C® implant endplates in the existing clean room at Viant from 2 months to 12 months.
P110009/S030	05/05/2021	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Increased storage time of the Mobi-C® implant endplates in the existing clean room at Viant from 2 months to 12 months.
P110010/S192	05/12/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate GPC Column for analytical chemistry.
P110010/S193	05/27/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the incoming verification of the active pharmaceutical ingredient (API) everolimus.
P110013/S110	05/11/2021	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion manufacturing operations from the Santa Rosa to the Danvers site.
P110016/S075	05/04/2021	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Change to the flux used during soldering.
P110016/S076	05/18/2021	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Changes to a resin as a result of transferring resin manufacturing from the current supplier manufacturing site in LaPorte, TX to a new supplier manufacturing site in Avon, OH.

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P110023/S032	05/07/2021	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	New sterilization cycle with a reduced EO concentration using Chamber 31 and Chamber 32 at contract sterilizer.
P130013/S044	05/17/2021	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Add an additional inspection method for the WATCHMAN FLX weld measurements.
P130021/S090	05/11/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Transfer of component extrusion manufacturing operations from the Santa Rosa to the Danvers site.
P130026/S071	05/18/2021	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Changes to a resin as a result of transferring resin manufacturing from the current supplier manufacturing site in LaPorte, TX to a new supplier manufacturing site in Avon, OH.
P130026/S073	05/21/2021	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Software changes to the non-product test systems including an update to the operating systems and the introduction of digitally validated records and signatures.
P140026/S018	05/05/2021	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Implementing recertification procedures for returned stents.
P140030/S013	05/06/2021	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Modification to the ethylene oxide sterilization parameters.
P140032/S069	05/03/2021	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Implementation of a new Servo Press machine at Brunk Industries, Inc to manufacture the SynchroMed II Pump (SMII) Inner Shield (P/N M955170A001) for the SynchroMed Infusion System.
P140032/S070	05/04/2021	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Implementation of additional detection controls for the pump tube O-ring assembly processes for the SynchroMed Infusion System and the Implantable System for Remodulin.
P150002/S010	05/26/2021	X - 30-Day Notice	INCRAFT(R) AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Implementation of a change in raw material and its supplier for the body of the Stopcock-Luer Cap Assembly of INCRAFT AAA Stent Graft delivery system.
P150003/S074	05/27/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update to the incoming verification of the active pharmaceutical ingredient (API) everolimus.
P150003/S075	05/18/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update to the final stent cleaning equipment and process.
P150012/S110	05/06/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Remove dwells from laser weld process.
P150012/S111	05/10/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add a new pallet sterilization chamber at the Arden Hills facility to increase sterilization capacity.

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P150031/S042	05/13/2021	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add an alternate semi-automated process for the final packaging activities for the sterile-packaged Implantable Pulse Generators at the Boston Scientific Clonmel Ireland facility.
P150033/S106	05/27/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modifications to the battery assembly cell stack process.
P160003/S013	05/06/2021	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Modification to the ethylene oxide sterilization parameters.
P160025/S011	05/06/2021	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Modification to the ethylene oxide sterilization parameters.
P160038/S020	05/21/2021	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Replacement of a flow cell component supplier.
P160043/S046	05/11/2021	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion manufacturing operations from the Santa Rosa to the Danvers site.
P170002/S017	05/26/2021	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Changing the precision of the analytical testing performed during receiving inspection of the needles of RHA2, RHA3 and RHA4 dermal fillers.
P170007/S009	05/25/2021	X - 30-Day Notice	DUROLANE	BIOVENTUS LLC	Change in the air monitoring sampling plan.
P170030/S016	05/06/2021	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Modification to the ethylene oxide sterilization parameters.
P180011/S042	05/12/2021	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate GPC Column for analytical chemistry.
P180027/S004	05/25/2021	X - 30-Day Notice	FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM	MICROVENTION, INC.	Conversion of a two-step UV glue process into a 1-step UV glue process for the Flow Re-Direction Endoluminal Device (FRED) System.
P180046/S037	05/25/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Contract manufacturer¿s addition of the hermetic welding system.
P190006/S037	05/25/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Contract manufacturer¿s addition of the hermetic welding system.
P200026/S001	05/07/2021	X - 30-Day Notice	ABRE VENOUS SELF-EXPANDING STENT SYSTEM	MEDTRONIC VASCULAR, INC.	New sterilization cycle with a reduced EO concentration using Chamber 31 and Chamber 32 at contract sterilizer.

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