PMA Monthly approvals from 12/1/2021 to 12/31/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190022	12/07/2021	PMAO - PMA Origi	4KSCORE TEST	OPKO HEALTH, INC.	Approval for the 4Kscore Test. The 4Kscore Test is an in vitro serum or plasma test that combines the results of four immunoassays (Roche Elecsys total PSA (prostate specific antigen), Roche Elecsys free PSA, intact PSA, and human kallikrein 2) into a single numerical score that also incorporates the following information: a patient¿s age, previous biopsy, and digital rectal exam (DRE). The 4Kscore Test is indicated for use with other patient information as an aid in the decision for prostate biopsy in men 45 years of age and older who have an abnormal age-specific total PSA and/or abnormal DRE. The 4Kscore Test is intended to aid in detection of aggressive prostate cancer (Gleason score >= 7/Gleason Grade Group >= 2) for whom a biopsy would be recommended by a urologist, based on current standards of care before consideration of the 4Kscore Test. A 4Kscore < 5.0 is associated with decreased likelihood of a Gleason score >= 7 on biopsy. Prostate biopsy is required for the diagnosis of cancer. The test is not recommended more than once every 6 months. The test is intended for professional use only, and is performed at a single-site BioReference Laboratories, Inc.
P200035	12/09/2021	PMAO - PMA Origi	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval for the OrganOx metra System. The device is approved for the following indication: The OrganOx metra® is a transportable device intended to be used to sustain donor livers destined for transplantation in a functioning state for a total preservation time of up to 12 hours. The OrganOx metra® device is suitable for liver grafts from donors after brain death (DBD), or liver grafts from donors after circulatory death (DCD) <=40 years old, with <=20 mins of functional warm ischemic time (time from donor systolic blood pressure <50 mmHg), and macrosteatosis <=15%, in a near-physiologic, normothermic and functioning state intended for a potential transplant recipient.
P200041	12/21/2021	PMAO - PMA Origi	SCOREFLEX NC SCORING PTCA CATHETER	ORBUSNEICH MEDICAL (SHENZHEN) CO., LTD.	Approval for the Scoreflex NC Scoring PTCA Catheter. The device is indicated for: Balloon dilatation of a de novo stenotic portion of a coronary artery and in-stent restenosis in coronary arteries in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
P210014	12/13/2021	PMAO - PMA Origi	SLENDER SIROLIMUS-ELUTING CORONARY STENT INTEGRATED DELIVERY SYSTEM AND DIRECT SIROLIMUS-ELUTING CORONARY STENT RAPID EXCHANGE DELIVERY SYSTEM	SVELTE MEDICAL SYSTEMS, INC.	Approval for the SLENDER Sirolimus-Eluting Coronary Stent Integrated Delivery System. The device is indicated for improving coronary artery luminal diameter in patients with symptomatic heart disease due to atherosclerotic lesions <= 24 mm in length in native coronary arteries with >= 2.25 mm to <= 4.00 mm reference vessel diameters, using direct stenting or pre-dilatation interventional techniques. DIRECT Sirolimus-Eluting Coronary Stent Rapid Exchange Delivery System is indicated for improving coronary artery luminal diameter in patients with symptomatic heart disease due to atherosclerotic lesions <= 34 mm in length in native coronary arteries with >= 2.25 mm to <= 4.00 mm reference vessel diameters, using direct stenting or pre-dilatation interventional techniques.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210020	12/03/2021	PMAO - PMA Origi	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Approval of the Optilume® Urethral Drug Coated Balloon. The device is used to treat patients with obstructive urinary symptoms associated with anterior urethral stricture. It is designed to be used in adult males for urethral strictures of less than or equal to 3 cm in length.

Total: 5

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S276	12/09/2021	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	requested approval to remove the re-sterilization instructions in the IFU for the LCS® Total Knee System
P840060/S049	12/02/2021	O - Normal 180 Day	SM-1, CR-1, & GR-1 IOLS	ALCON LABORATORIES	Approval for a manufacturing site located at PT. CIBA VISION Batam located at Jalan Beringin Kav. #204, Batamindo Industrial Park, Muka Kuning Batam Island, 29433 Indonesia for manufacturing, packaging, and sterilization.
P840064/S075	12/03/2021	O - Normal 180 Day	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Approval for the alternate manufacturing sites located are: Lifecore Biomedical, LLC (Site 1) 3515 Lyman Boulevard Chaska, MN 55318 and Lifecore Biomedical, LLC (Site 2) 1245 Lakeview Drive Chaska, MN 55318.
P840064/S076	12/03/2021	O - Normal 180 Day	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Approval for the sterilization site is located at Sterigenics LLC 5725 Harold Gatty Drive, Salt Lake City, UT 84116
P860004/S380	12/21/2021	R - Real-Time Proc	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for minor dimensional modification to the tray for the SynchroMed II Implantable Infusion Pump Kit model number 8637 for the Implantable System.
P860057/S202	12/13/2021	O - Normal 180 Day	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Approval for the manufacturing of the Carpentier-Edwards PERIMOUNT Magna Pericardial Aortic Bioprosthesis (MAGNA Model 3300TFX) at the Edwards Cartago, Costa Rica Facility, limited to cleaning and sterilization of components, bioburden reduction, final assembly, terminal liquid sterilization, and packaging and labeling prior to commercial release.
P880087/S031	12/02/2021	O - Normal 180 Day	KELMAN MULTIFLEX 2 MODELS: MT3-MT7 & MT2U-MT7U	ALCON LABORATORIES	Approval for a manufacturing site located at PT. CIBA VISION Batam located at Jalan Beringin Kav. #204, Batamindo Industrial Park, Muka Kuning Batam Island, 29433 Indonesia for manufacturing, packaging, and sterilization.
P910073/S165	12/23/2021	R - Real-Time Proc	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Approval for minor design changes to the lead terminal component and minor labeling updates
P950022/S142	12/01/2021	O - Normal 180 Day	TVL(TM) LEAD SYSTEM	ABBOTT MEDICAL	Approval for a labeling update to include the findings of the Optisure Post-Approval Study.
P950037/S225	12/09/2021	N - Normal 180 Day	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for updated programmer software designated as NEO 2101.U.
P960013/S118	12/08/2021	N - Normal 180 Day	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ABBOTT MEDICAL	Approval for a design modification to the suture sleeve provided on the Tendril STS Pacing Lead and a new, separately packaged suture sleeve accessory, Model DS2A088.

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P970004/S349	12/08/2021	S - Special CBE	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for revisions to physician and patient labeling to align with updated risk management process. The labeling changes include existing precautions elevated to warnings for packaging, single use and effects on other implanted devices.
P970018/S039	12/21/2021	R - Real-Time Proc	BD PREPSTAIN SYSTEM	BD DIAGNOSTIC SYSTEMS	Approval for the minor design changes to the BD Totalys MultiProcessor electronic hardware components, process deck cover, and software modifications to support changes in reagent/waste capacity, operating system, batch types, and service tools.
P970051/S206	12/07/2021	Y - 135 Review Tra	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the introduction of an alternative supplier for components of the following implant devices: CI512, CI522, CI532, ABI541, CI612, CI622, CI624, and CI632.
P980040/S140	12/01/2021	Y - 135 Review Tra	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for changes to lathe cutting and cryotumbling processes and image quality inspection equipment for manufacturing of TECNIS Symfony Toric II OptiBlue Extended Range of Vision Intraocular Lenses.
P980040/S142	12/23/2021	R - Real-Time Proc	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for packaging the TECNIS Symfony OptiBlue Extended Range of Vision (ERV) IOL and the TECNIS Symfony Toric II OptiBlue ERV IOLs with the TECNIS Simplicity Delivery System.
P990071/S047	12/23/2021	N - Normal 180 Day	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Approval for modifications to the design of the device and an alternate supplier/ manufacturer of the device.
P000009/S092	12/09/2021	N - Normal 180 Day	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for updated programmer software designated as NEO 2101.U.
P000015/S046	12/07/2021	Y - 135 Review Tra	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the introduction of an alternative supplier for components of the following implant devices: CI512, CI522, CI532, ABI541, CI612, CI622, CI624, and CI632.
P000046/S030	12/22/2021	O - Normal 180 Day	STAARVISC II	ANIKA THERAPEUTICS, INC.	Approval of the labeling change to update labels of OPHTHALIN® to identify Carl Zeiss Canada Ltd. as a Private Label Manufacturer and Distributor.
P010013/S082	12/09/2021	N - Normal 180 Day	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Approval for changes to two PCBs (the RF power board and the control board) used in the NovaSure RFC model 10, RFC2010-115.
P010014/S098	12/17/2021	R - Real-Time Proc	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for the introduction of a new instructions for use (IFU) for cleaning, disinfection and sterilization of the reusable Oxford Partial Knee instruments.
P010032/S180	12/30/2021	O - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval to add Midwest Sterilization Corporation located at 1204 Lenco Ave. Jackson, Mo 63755 as an alternate ethylene oxide (EO) sterility facility.
P010033/S047	12/13/2021	N - Normal 180 Day	QUANTTFERON-TB GOLD AND TB GOLD-IN-THE-TUBE	QIAGEN	Approval for the following changes to the QuantiFERON®-TB Gold, QuantiFERON®-TB Gold Plus device packge inserts: 1) Removal of the following language from the Warnings and Precautions section from the QuantiFERON®-TB Gold device packge insert: The performance of the USA format of the QFT test has not been extensively evaluated with specimens from the following groups of individuals: I Individuals who have impaired or altered immune functions such as those who have HIV

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P010033/S047	12/13/2021	N - Normal 180 Day	QUANTTFERON-TB GOLD AND TB GOLD-IN-THE-TUBE	QIAGEN	Approval for the following changes to the QuantiFERON®-TB Gold, QuantiFERON®-TB Gold Plus device packge inserts: 1) Removal of the following language from the Warnings and Precautions section from the QuantiFERON®-TB Gold device packge insert: The performance of the USA format of the QFT test has not been extensively evaluated with specimens from the following groups of individuals: I. Individuals who have impaired or altered immune functions, such as those who have HIV infection or AIDS, those who have transplantation managed with immunosuppressive treatment or others who receive immunosuppressive drugs (e.g., corticosteroids, methotrexate, azathioprine, cancer chemotherapy), those who have other clinical conditions, such as diabetes, silicosis, chronic renal failure, and hematological disorders (e.g., leukemia and lymphomas), or those with other specific malignancies (e.g., carcinoma of the head or neck and lung). II. Individuals younger than age 17 years III. Pregnant women 2. Removal of the following language from the Limitations section from the QuantiFERON®-TB Gold Plus device packge insert: The performance of the USA format of the QFT-Plus test has not been extensively evaluated with specimens from the following groups of individuals: -- Individuals who have impaired or altered immune functions, such as those who have HIV infection or AIDS, those who have transplantation managed with immunosuppressive treatment or others who receive immunosuppressive drugs (e.g., corticosteroids, methotrexate, azathioprine, cancer chemotherapy), those who have other clinical conditions, such as diabetes, silicosis, chronic renal failure, and hematological disorders (e.g., leukemia and lymphomas), or those with other specific malignancies (e.g., carcinoma of the head or neck and lung). -- Individuals younger than age 17 years ¿ Pregnant women 3. Addition of the following language to the Summary and Explanation of the Test section of the device package insert of both the QuantiFERON®-TB Gold and QuantiFERON®-TB Gold Plus: Diagnostic testing for Mycobacterium tuberculosis using Interferon Gamma Release Assays should follow applicable published guidelines. QFT has been studied in adults and children identified at higher risk for TB infection, including individuals recently exposure to

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P030009/S105	12/14/2021	Y - 135 Review Tra	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Approval for changing the cleaning method for the extruder tooling used at the Santa Rosa site from a manual cleaning method to an automated cleaning method.
P030053/S051	12/10/2021	N - Normal 180 Day	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval of a product line extension for the MENTOR® MemoryGel® BOOST Moderate Plus Profile Breast Implants, and the MENTOR® MemoryGel® BOOST High Profile Breast Implants.
P030053/S063	12/10/2021	O - Normal 180 Day	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P040045/S117	12/23/2021	Y - 135 Review Tra	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Approval for the implementation of an alternate qualified supplier for one raw material used in the senofilcon A packaging solution and as a processing aid during the post hydration process for VISTAKON® (senofilcon A) Brand Contact Lenses.
P050006/S093	12/21/2021	O - Normal 180 Day	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for IFU modifications to reflect long-term data from the Gore REDUCE Clinical Study as well as other IFU updates.
P050018/S030	12/23/2021	Y - 135 Review Tra	ANGIOSCULPT SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Approval for the addition of a pre-coating plasma treatment step.
P050023/S157	12/09/2021	N - Normal 180 Day	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for updated programmer software designated as NEO 2101.U.
P050050/S020	12/17/2021	S - Special CBE	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	DJO GLOBAL	Approval for addition of a symbol to the package labels of STAR stainless steel instruments.
P060028/S042	12/10/2021	O - Normal 180 Day	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P060037/S073	12/15/2021	O - Normal 180 Day	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Approval to modify the labeling to reflect the findings of the final Post-Approval Study (PAS) report.
P070008/S126	12/09/2021	N - Normal 180 Day	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for updated programmer software designated as NEO 2101.U.
P070026/S088	12/09/2021	S - Special CBE	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for a change to remove suggested methods to re-sterilize products which have been opened (i.e., the sterile barrier breached) but not used during surgery in the Instructions for Use (IFU) for the CERAMAX® Ceramic Total Hip System.

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P080004/S043	12/28/2021	R - Real-Time Proc	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for nine (9) changes to the routine Ethylene Oxide (EO) sterilization process, including: 1) The sterilization equipment used in the routine EO sterilization process; 2) the implementation of a unified set of EO sterilization process parameters for the US marketed products; 3) the lower control limit for EO gas used in the routine EO sterilization process; 4) the method for monitoring EO gas concentration; 5) the frequency of EO sterilant residuals testing; 6) the Process Challenge Device (PCD) used during routine EO sterilization cycles and validation activities; 7) the number of PCDs used during routine EO sterilization cycles and validation activities; 8) the approach used for validation/re-validation activities; and 9) the re-validation cycle.
P080025/S244	12/08/2021	S - Special CBE	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for revisions to physician and patient labeling to align with updated risk management process. The labeling changes include existing precautions elevated to warnings for packaging, single use and effects on other implanted devices.
P090016/S044	12/08/2021	N - Normal 180 Day	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for the removal of protein content as part of release and shelf-life specification of Belotero Balance and Belotero Balance (+) Lidocaine.
P090016/S045	12/08/2021	R - Real-Time Proc	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for a change from traditional sterility testing to parametric release strategy for product release of Belotero Balance (BB) and Belotero Balance + Lidocaine (BBL).
P100010/S118	12/16/2021	O - Normal 180 Day	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval of the protocol for the post-approval study (PAS) protocol.
P110013/S113	12/14/2021	Y - 135 Review Tra	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for changing the cleaning method for the extruder tooling used at the Santa Rosa site from a manual cleaning method to an automated cleaning method.
P110042/S164	12/17/2021	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for software changes for the EMBLEM S-ICD and Programmer SW Application Models 2877 and 3877, and firmware changes for the EMBLEM Pulse Generator.
P120005/S089	12/21/2021	R - Real-Time Proc	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for the modification of the G5 Mobile Android Continuous Glucose Monitoring (CGM) Application software used with the G5 Mobile CGM System.
P120010/S140	12/17/2021	S - Special CBE	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for a labeling update to provide additional clarity on an existing warning for acetaminophen interference to the continuous glucose monitoring (CGM) component of the system.
P120021/S023	12/22/2021	O - Normal 180 Day	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Approval of the revised protocol for the post-approval study (PAS) protocol.
P130008/S069	12/18/2021	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the Model 2580 Sleep Remote as a replacement for the Model 2500 Sleep Remote.

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P130008/S072	12/10/2021	Y - 135 Review Tra	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for updating the final functional test limit for telemetry drive strength used during the manufacture of the Model 2740 Programmer Cable.
P130017/S050	12/13/2021	R - Real-Time Proc	COLOGUARD	EXACT SCIENCES CORPORATIO N	Approval of a design change to modify the hemoglobin stabilization buffer formulation to support extending the specimen stability to 96 hours, and the labeling update to reflect the change.
P140009/S073	12/30/2021	O - Normal 180 Day	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval to add Midwest Sterilization Corporation located at 1204 Lenco Ave. Jackson, Mo 63755 as an alternate ethylene oxide (EO) sterility facility.
P140010/S053	12/17/2021	Y - 135 Review Tra	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for a modified sampling plan for drug content uniformity testing.
P140016/S004	12/22/2021	S - Special CBE	ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT	COOK MEDICAL INCORPORAT ED	Approval for 100% visual QC inspection step for release wires.
P140028/S070	12/23/2021	N - Normal 180 Day	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Approval for the introduction of a 150mm length Eluvia device, reintroduction of 180mm and 200mm Innova devices, and delivery system shaft modifications.
P150001/S093	12/17/2021	S - Special CBE	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for a labeling update to provide additional clarity on an existing warning for acetaminophen interference to the continuous glucose monitoring (CGM) component of the system.
P150004/S053	12/30/2021	O - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval to add Midwest Sterilization Corporation located at 1204 Lenco Ave. Jackson, Mo 63755 as an alternate ethylene oxide (EO) sterility facility.
P150017/S015	12/10/2021	O - Normal 180 Day	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Approval for a manufacturing site located at Building C, 11576 Memphis-Arlington Road, Arlington, Tennessee 38002 as a secondary manufacturing and packaging site of Cartiva SCI devices.
P150019/S064	12/17/2021	S - Special CBE	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for a labeling update to provide additional clarity on an existing warning for acetaminophen interference to the continuous glucose monitoring (CGM) component of the system.
P150028/S006	12/13/2021	N - Normal 180 Day	CHEATHAM PLATINUM (CP) STENT SYSTEM (COVERED CP STENT, COVERED MOUNTED CP STENT, CP STENT, MOUNTED CP STENT)	NUMED, INC.	Approval for the G-Armor Stent Family and includes dimensional design modifications to the currently approved CP Stent Family.
P150029/S037	12/17/2021	S - Special CBE	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Approval for a labeling update to provide additional clarity on an existing warning for acetaminophen interference to the continuous glucose monitoring (CGM) component of the system.

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P150030/S017	12/08/2021	O - Normal 180 Day	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Approval for a manufacturing site located at Synergey Health Daniken AG (a.k.a STERIS), Daniken So, Solothurn, 4658 Switzerland as an alternative vendor for gamma sterilization of the R3TM US Delta Ceramic Liner and R3TM US Delta Ceramic Heads.
P160007/S042	12/17/2021	S - Special CBE	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for approval for a labeling update to provide additional clarity on an existing warning for acetaminophen interference to the continuous glucose monitoring (CGM) component of the system.
P160017/S095	12/17/2021	S - Special CBE	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for approval for a labeling update to provide additional clarity on an existing warning for acetaminophen interference to the continuous glucose monitoring (CGM) component of the system.
P160019/S012	12/09/2021	N - Normal 180 Day	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval to change the serum source for the control and confirmatory reagents from human to sheep for the Elecsys HBsAg Confirmatory Test.
P160043/S049	12/14/2021	Y - 135 Review Tra	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for changing the cleaning method for the extruder tooling used at the Santa Rosa site from a manual cleaning method to an automated cleaning method.
P160045/S027	12/01/2021	N - Normal 180 Day	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGI ES CORPORATIO N	Approval to expand the intended use of the Oncomine Dx Target Test to include a companion diagnostic indication for the detection of EGFR exon 20 insertion mutations in non-small cell lung cancer patients who may benefit from treatment with RYBREVANT (amivantamab-vmjw).
P170002/S012	12/22/2021	P - Panel Track	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for the RHA® Redensity is indicated for injection into the dermis and superficial dermis of the face, for the correction of moderate to severe dynamic perioral rhytids, in adults aged 22 years or older.
P170003/S024	12/16/2021	O - Normal 180 Day	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval of the revised protocol for the New Enrollment Post Approval Study Registry.
P170027/S006	12/09/2021	O - Normal 180 Day	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180011/S046	12/23/2021	N - Normal 180 Day	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the introduction of a 150mm length Eluvia device, reintroduction of 180mm and 200mm Innova devices, and delivery system shaft modifications.
P180036/S011	12/16/2021	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for software changes to the Optimizer Smart Mini firmware.
P180037/S008	12/16/2021	R - Real-Time Proc	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval for a change in configuration of the J1 joint of the delivery system.
P180050/S001	12/17/2021	N - Normal 180 Day	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval to add an alternate implantable pulse generator Model 2104 and associated Model 9010 Programmer System software.

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P190008/S007	12/17/2021	Y - 135 Review Tra	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Approval for a modified sampling plan for drug content uniformity testing.
P190023/S003	12/13/2021	Y - 135 Review Tra	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Approval to add a new bovine pericardial tissue supplier.
P200015/S011	12/16/2021	P - Panel Track	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent. The device is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.
P200049/S002	12/09/2021	O - Normal 180 Day	AMPLATZER¿ AMULET ¿ LEFT ATRIAL APPENDAGE OCCLUDER	ABBOTT MEDICAL	Approval of the revised protocol for the post-approval study (PAS) protocol.

Total: 76

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S271	12/23/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Re-order the low voltage pulse generator Top Attach/Test manufacturing process steps.
N970003/S272	12/21/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Add alternate nitrile gloves to be used in the manufacturing operations at BSC-Clonmel.
P810002/S115	12/09/2021	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ABBOTT MEDICAL	Use of a new detergent in the manufacture of the valves cuff fabric component.
P830061/S200	12/07/2021	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P840001/S503	12/03/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Replacement of current Underfill Dispense System (Asymtek Axiom X-1020) with a new system (Asymtek Spectrum II) at Medtronic Tempe Campus (MTC).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S504	12/15/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Revision to the manufacturing execution system used in several facilities for the subject devices.
P850089/S159	12/07/2021	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P860004/S382	12/03/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Replacement of current Underfill Dispense System (Asymtek Axiom X-1020) with a new system (Asymtek Spectrum II) at Medtronic Tempe Campus (MTC).
P860004/S383	12/15/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Revision to the manufacturing execution system used in several facilities for the subject devices.
P890003/S450	12/07/2021	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P890055/S078	12/06/2021	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Change in the supplier of components of the Intera 3000 pump.
P900061/S167	12/07/2021	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P910007/S056	12/06/2021	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Replace a sterile with a non-sterile bulk container for a kit component.
P910007/S057	12/15/2021	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Change a raw material supplier.
P910071/S018	12/02/2021	X - 30-Day Notice	ADATOMED SILICONE OIL OP5000	BAUSCH & LOMB	Update the dry heat sterilization equipment for ADATO® SIL-OL 5000 prefilled syringe.
P920015/S261	12/07/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P920015/S263	12/13/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Add a visual inspection for selected components at Medtronic Rice Creek (Fridley, MN).
P930014/S140	12/21/2021	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Change in the microbiological test method for determination of pre-sterilization bioburden, and a change in the organism used to determine the bioburden enumeration correction factor.
P930029/S070	12/07/2021	X - 30-Day Notice	ATAKR(TM) RFCA SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.

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P930039/S234	12/07/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P950020/S114	12/06/2021	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Add an additional blade bonding cell.
P950020/S115	12/06/2021	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Addition of a new cleanroom in building 2 (under the same FDA establishment inspection number).
P950024/S101	12/07/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P950037/S231	12/22/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Introduce automated options for Header Milling and Header Polishing.
P960009/S413	12/03/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Replacement of current Underfill Dispense System (Asymtek Axiom X-1020) with a new system (Asymtek Spectrum II) at Medtronic Tempe Campus (MTC).
P960009/S414	12/15/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Revision to the manufacturing execution system used in several facilities for the subject devices.
P960040/S474	12/21/2021	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Add alternate nitrile gloves to be used in the manufacturing operations at BSC-Clonmel.
P970004/S346	12/03/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Replacement of current Underfill Dispense System (Asymtek Axiom X-1020) with a new system (Asymtek Spectrum II) at Medtronic Tempe Campus (MTC).
P970004/S347	12/01/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	New HDPE (High Density Polyethylene) resin suppliers.
P970004/S348	12/15/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Revision to the manufacturing execution system used in several facilities for the subject devices.
P970054/S020	12/21/2021	X - 30-Day Notice	BIOTRIN PARVOVIRUS B19 IGG	DIASORIN	Subcontract manufacturing equipment cleaning processes.
P970055/S022	12/21/2021	X - 30-Day Notice	BIOTRIN PARVOVIRUS IGM EIA (V619IMUS)	DIASORIN	Subcontract manufacturing equipment cleaning processes.
P980007/S045	12/06/2021	X - 30-Day Notice	AXSYM FREE PSA	ABBOTT LABORATORIES	Replace a sterile with a non-sterile bulk container for a kit component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980007/S046	12/15/2021	X - 30-Day Notice	AXSYM FREE PSA	ABBOTT LABORATORIES	Change a raw material supplier.
P980016/S798	12/07/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P980016/S799	12/17/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a new inspection method to the capacitor manufacturing process for ICDs and CRT-Ds.
P980016/S800	12/09/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new electrostatic discharge handling tray used in manufacturing at Medtronic's internal supplier - Medtronic Tempe Campus.
P980016/S801	12/21/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the inspection of the device connector and to add clarifications to the process instructions.
P980023/S110	12/20/2021	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Update the sampling rate for process monitoring tensile tests on select manufacturing processes.
P980035/S696	12/07/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P980035/S697	12/09/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement a new electrostatic discharge handling tray used in manufacturing at Medtronic's internal supplier - Medtronic Tempe Campus.
P980035/S698	12/17/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modifications to the Seam Welding & Tack Welding processes at Medtronic Singapore Operations.

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P980050/S136	12/07/2021	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P990004/S051	12/21/2021	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change to the Electron beam (E-beam) equipment located at the current E-beam contract sterilization site for the SURGIFOAM® Absorbable Gelatin Dental Sponge, the SURGIFOAM® Absorbable Gelatin Hemorrhoidectomy Sponge, and the SURGIFOAM® Absorbable Gelatin Powder.
P990009/S068	12/10/2021	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Addition of an alternate bottom web film for the non-contacting packaging of the Gelatin Syringe and Thrombin pouches in the 5mL and 10 mL Floseal Hemostatic Matrix device.
P990038/S032	12/21/2021	X - 30-Day Notice	DIASORIN ETI MAK-2 PLUS ASSAY	DIASORIN, INC.	Subcontract manufacturing equipment cleaning processes.
P990041/S031	12/21/2021	X - 30-Day Notice	DIASORIN ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Subcontract manufacturing equipment cleaning processes.
P990042/S028	12/21/2021	X - 30-Day Notice	DIASORIN ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Subcontract manufacturing equipment cleaning processes.
P990043/S032	12/21/2021	X - 30-Day Notice	DIASORIN ETI-EBK PLUS ASSAY	DIASORIN, INC.	Subcontract manufacturing equipment cleaning processes.
P990044/S029	12/21/2021	X - 30-Day Notice	DIASORIN ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Subcontract manufacturing equipment cleaning processes.
P990045/S029	12/21/2021	X - 30-Day Notice	DIASORIN ETI-AB-COREK PLUS ASSAY	DIASORIN, INC.	Subcontract manufacturing equipment cleaning processes.
P000006/S060	12/22/2021	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	New ethylene oxide sterilization process and chamber at the current sterilization provider, Steris AST.
P000021/S044	12/20/2021	X - 30-Day Notice	DIMENSION(R) RXL PSA FLEX(R) REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Addition of an Alternate Supplier for the Lens and Mirror components used in Photometer Assembly on the Dimension Family of Instruments.
P010003/S039	12/09/2021	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Changes to the resin used to manufacture a portion of the syringe extender tips and a reduction in the shelf life of the finished device.
P010012/S549	12/21/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add alternate nitrile gloves to be used in the manufacturing operations at BSC-Clonmel.
P010015/S486	12/07/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S487	12/09/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement a new electrostatic discharge handling tray used in manufacturing at Medtronic's internal supplier - Medtronic Tempe Campus.
P010030/S156	12/03/2021	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Alternate supplier of the response buttons used in the LifeVest 4000 and HWD 1000 monitors.
P010031/S764	12/07/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P010031/S765	12/17/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a new inspection method to the capacitor manufacturing process for ICDs and CRT-Ds.
P010031/S766	12/09/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new electrostatic discharge handling tray used in manufacturing at Medtronic's internal supplier - Medtronic Tempe Campus.
P010031/S767	12/21/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the inspection of the device connector and to add clarifications to the process instructions.
P010054/S041	12/16/2021	X - 30-Day Notice	ELECSYS ANTI-HBS	ROCHE DIAGNOSTICS CORP.	Improve and expand manufacturing of kit components.
P020004/S186	12/16/2021	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Add a new manufacturing line for the GORE EXCLUDER AAA Endoprosthesis and GORE EXCLUDER Iliac Branch Endoprosthesis.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020027/S039	12/20/2021	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTRIDGE AND DIMENSION T/F PSA CALIBRATOR FOR DIMENSION RXL AND XPAND SYSTEMS	SIEMENS HEALTHCARE DIAGNOSTICS	Addition of an Alternate Supplier for the Lens and Mirror components used in Photometer Assembly on the Dimension Family of Instruments.
P030005/S216	12/23/2021	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Re-order the low voltage pulse generator Top Attach/Test manufacturing process steps.
P030005/S217	12/21/2021	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Add alternate nitrile gloves to be used in the manufacturing operations at BSC-Clonmel.
P030017/S349	12/14/2021	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Use of a new controlled environment area at the Boston Scientific Corporation Dorado Puerto Rico facility.
P030036/S133	12/07/2021	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P040012/S063	12/08/2021	X - 30-Day Notice	ACCULINK CAROTID STENT SYSTEM AND RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	Update to the on-line sampling plan and the implementation of process monitoring alerts.
P040021/S048	12/16/2021	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ABBOTT MEDICAL	Discontinuation of passive monitoring procedures in ISO Class 7 and 8 cleanrooms.
P040024/S128	12/09/2021	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Addition of a new supplier for ready-to-use solutions used in the manufacturing of Restylane, Restylane-L, Restylane Lyft with Lidocaine, Perlane, and Restylane Silk.
P040024/S129	12/14/2021	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Addition of an alternate supplier of phosphoric acid solution for the manufacturing of Restylane-L®, Restylane Lyft® with Lidocaine and Restylane® Silk.
P040024/S130	12/14/2021	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Addition of an alternate supplier of phosphate buffer solution for the manufacturing of Restylane® and Perlane®.
P040037/S149	12/03/2021	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Relocation of manufacturing of the graft tube component and related Quality control activities from the Medical West facility to the Woody Springs facility.
P040038/S039	12/08/2021	X - 30-Day Notice	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Supplier and manufacturing changes to the Exit Port Molding (EPM) component of the XACT Carotid Stent System.
P040044/S090	12/13/2021	X - 30-Day Notice	MATRIX VASCULAR CLOSURE SYSTEM (VSG)	CORDIS US CORPORATION	Change to the method used for finished device pouching for the MynxGrip and Mynx Control VCDs.

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P040045/S123	12/08/2021	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Qualification of an existing production line for ACUVUE® OASYS MULTIFOCAL (senofilcon A) Contact Lenses.
P050019/S033	12/10/2021	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Addition of alternative degreaser and grinding emulsion used to manufacturing delivery system components.
P050042/S046	12/06/2021	X - 30-Day Notice	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Replace a sterile with a non-sterile bulk container for a kit component.
P050042/S047	12/15/2021	X - 30-Day Notice	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Change a raw material supplier.
P050051/S044	12/06/2021	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Replace a sterile with a non-sterile bulk container for a kit component.
P050051/S045	12/15/2021	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Change a raw material supplier.
P060035/S033	12/06/2021	X - 30-Day Notice	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Replace a sterile with a non-sterile bulk container for a kit component.
P060035/S034	12/15/2021	X - 30-Day Notice	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Change a raw material supplier.
P060039/S109	12/07/2021	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P070008/S133	12/22/2021	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.	Introduce automated options for Header Milling and Header Polishing.
P080006/S165	12/07/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P080006/S167	12/17/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Update the Pull Test Monitoring parameters used to monitor special manufacturing process in leads manufacturing.
P080011/S136	12/10/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Installation and qualification of two new lab equipment at the CooperVision facility located in Juana Diaz, Puerto Rico.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080023/S035	12/06/2021	X - 30-Day Notice	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Replace a sterile with a non-sterile bulk container for a kit component.
P080023/S036	12/15/2021	X - 30-Day Notice	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Change a raw material supplier.
P080025/S241	12/03/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Replacement of current Underfill Dispense System (Asymtek Axiom X-1020) with a new system (Asymtek Spectrum II) at Medtronic Tempe Campus (MTC).
P080025/S242	12/01/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	New HDPE (High Density Polyethylene) resin suppliers.
P080025/S243	12/15/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Revision to the manufacturing execution system used in several facilities for the subject devices.
P090013/S317	12/07/2021	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P100010/S122	12/14/2021	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P100013/S023	12/15/2021	X - 30-Day Notice	CORDIS EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS US CORPORATION	Change in the method used in the determination of the E-beam dosage and the loading configuration used during sterilization of the EXOSEAL® Vascular Closure Device (VCD).
P100018/S036	12/27/2021	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Relocation of the distal bump wire supplier, Creganna Medical, from the manufacturing location in Tualatin, Oregon, to Wilsonville, Oregon.
P100021/S097	12/17/2021	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of corrective actions and associated process improvements for all spindle tubing assemblies based on root cause investigation for inadequate welding issue.
P100021/S098	12/20/2021	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Add a verification fixture to ensure use of the correct stent stop assembly size in the manufacturing of the Endurant Stent Graft System.
P100026/S089	12/16/2021	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Add an existing NeuroPace supplier as an alternate supplier to manufacture the PEEK Connector Cover part of the Connector Cover Assemblies and Connector Cover Kits for the RNS Neurostimulators (Model RNS-320 and RNS-300M) and to manufacture this part by injection molding rather than by the current machining process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100029/S045	12/16/2021	X - 30-Day Notice	ST JUDE MEDICAL TRIFECTA VALVE	ABBOTT MEDICAL	Discontinuation of passive monitoring procedures in ISO Class 7 and 8 cleanrooms.
P100030/S016	12/09/2021	X - 30-Day Notice	ARTERX SURGICAL SEALANT	BAXTER HEALTHCARE CORPORATION	Additional location for quarterly dose audits for the Preveleak device.
P100040/S050	12/10/2021	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Manufacturing changes to be implemented by the first-tier supplier (Phillips) of stent stop components for the delivery system of Valiant Captivia.
P110001/S017	12/08/2021	X - 30-Day Notice	RX HERCULINK ELITE RENAL STENT SYSTEM	ABBOTT VASCULAR	Update to the on-line sampling plan and the implementation of process monitoring alerts.
P110029/S035	12/06/2021	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Replace a sterile with a non-sterile bulk container for a kit component.
P110029/S036	12/15/2021	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Change a raw material supplier.
P110042/S166	12/29/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add a sensor to battery manufacturing equipment to prevent device defects.
P110042/S168	12/21/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add alternate nitrile gloves to be used in the manufacturing operations at BSC-Clonmel.
P120008/S018	12/06/2021	X - 30-Day Notice	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Replace a sterile with a non-sterile bulk container for a kit component.
P120008/S019	12/17/2021	X - 30-Day Notice	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Change a raw material supplier.
P120014/S012	12/20/2021	X - 30-Day Notice	BIOMERIEUX THXID BRAF ASSAY KIT	BIOMERIEUX, INC.	Transfer of manufacturing site location for a critical component.
P120017/S029	12/07/2021	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130006/S088	12/03/2021	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Relocation of manufacturing of the graft tube component and related Quality control activities from the Medical West facility to the Woody Springs facility.
P130014/S013	12/17/2021	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Additional production apparatus for Polyethylene (PEG) Sebacate (SB-1 setup) that is used in the chemical synthesis of PEG Sebacate.
P130021/S106	12/01/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Automation of an in-process inspection of the delivery catheter system.
P130021/S107	12/16/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Establishment of an in-process shelf life for fixed tissue placed in storage.
P130024/S042	12/02/2021	X - 30-Day Notice	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Removal of a process documentation step for the vacuum drying process when no deviations from process parameters are identified during the automated cycle, to reduce redundancy.
P140008/S023	12/21/2021	X - 30-Day Notice	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Manufacturing changes to the sheath assembly procedures.
P140010/S063	12/09/2021	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Addition of a new workstep.
P140018/S030	12/09/2021	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implementation of SAP Manufacturing Intelligence Integration (Mii) software for use in manufacturing of the VenaSeal Closure System.
P140028/S072	12/15/2021	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Re-pelletize the resin for a delivery system component.
P140029/S044	12/09/2021	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Addition of a new supplier for ready-to-use solutions used in the manufacturing of Restylane Refyne, Restylane Defyne, Restylane Kysse, and Restylane Contour
P150003/S080	12/16/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Remove residual solvent testing as a batch release requirement.
P150003/S081	12/17/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Introduction of updated glassware for particulate evaluation.
P150005/S068	12/10/2021	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Addition of a new piece of equipment at the supplier to automate the current manual process used to decore the braided subassembly.

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P150012/S121	12/23/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Re-order the low voltage pulse generator Top Attach/Test manufacturing process steps.
P150012/S122	12/21/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add alternate nitrile gloves to be used in the manufacturing operations at BSC-Clonmel.
P150030/S018	12/20/2021	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Change to conveyor system used during gamma irradiation terminal sterilization.
P150031/S047	12/14/2021	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Use of a new controlled environment area at the Boston Scientific Corporation Dorado Puerto Rico facility.
P150033/S127	12/07/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.9.
P150033/S129	12/09/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement a new electrostatic discharge handling tray used in manufacturing at Medtronic's internal supplier - Medtronic Tempe Campus.
P160019/S013	12/16/2021	X - 30-Day Notice	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS, INC.	Improve and expand manufacturing of kit components.
P160054/S041	12/20/2021	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Addition of an alternate supplier for a component of the HeartMate 3 Left Ventricular Assist Device.
P170003/S025	12/02/2021	X - 30-Day Notice	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Removal of a process documentation step for the vacuum drying process when no deviations from process parameters are identified during the automated cycle, to reduce redundancy.
P170007/S010	12/22/2021	X - 30-Day Notice	DUROLANE	BIOVENTUS LLC	Additional sterility testing laboratory.
P170030/S020	12/09/2021	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Implementation of the reorganization of lot release changes.
P170032/S010	12/20/2021	X - 30-Day Notice	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Change in bacterial endotoxin test sampling plan and to update the manufacturing procedure to conduct bacterial endotoxin testing prior to device sterilization.
P180001/S003	12/15/2021	X - 30-Day Notice	ZENITH DISSECTION ENDOVASCULAR SYSTEM	WILLIAM COOK EUROPE APS	Change to the delivery system trigger-wire coating facility and updates to the acceptance criteria used in testing of the trigger wires.
P180011/S048	12/15/2021	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Re-pelletize the resin for a delivery system component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180038/S007	12/21/2021	X - 30-Day Notice	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Subcontract manufacturing equipment cleaning processes.
P180038/S008	12/27/2021	X - 30-Day Notice	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Changes allowing harmonization of product QC workflows.
P180038/S009	12/17/2021	X - 30-Day Notice	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Automate a portion of a manual packaging process.
P180039/S006	12/21/2021	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Subcontract manufacturing equipment cleaning processes.
P180039/S007	12/27/2021	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Changes allowing harmonization of product QC workflows.
P180039/S008	12/17/2021	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Automate a portion of a manual packaging process.
P180045/S004	12/21/2021	X - 30-Day Notice	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Subcontract manufacturing equipment cleaning processes.
P180045/S005	12/27/2021	X - 30-Day Notice	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Changes allowing harmonization of product QC workflows.
P180045/S006	12/17/2021	X - 30-Day Notice	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Automate a portion of a manual packaging process.
P180046/S045	12/28/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Removal of the X-ray inspection step from receiving inspection for the Tined Lead.
P180047/S012	12/21/2021	X - 30-Day Notice	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Subcontract manufacturing equipment cleaning processes.

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P180047/S013	12/17/2021	X - 30-Day Notice	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Automate a portion of a manual packaging process.
P180048/S004	12/21/2021	X - 30-Day Notice	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Subcontract manufacturing equipment cleaning processes.
P180048/S005	12/27/2021	X - 30-Day Notice	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Changes allowing harmonization of product QC workflows.
P180048/S006	12/17/2021	X - 30-Day Notice	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Automate a portion of a manual packaging process.
P180049/S004	12/21/2021	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Subcontract manufacturing equipment cleaning processes.
P180049/S005	12/27/2021	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Changes allowing harmonization of product QC workflows.
P180049/S006	12/17/2021	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Automate a portion of a manual packaging process.
P190006/S045	12/28/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Removal of the X-ray inspection step from receiving inspection for the Tined Lead
P190008/S017	12/09/2021	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Addition of a new workstep.

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P190018/S014	12/01/2021	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Reduce Clareon Intraocular Lenses (IOLs) dimensional inspection from 100% to a sampling plan for non-toric models.
P190018/S015	12/21/2021	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Change in the microbiological test method for determination of pre-sterilization bioburden, and a change in the organism used to determine the bioburden enumeration correction factor.

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P190018/S016	12/22/2021	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Reduction of the Clareon Intraocular Lenses (IOLs) plan view inspection from a 100% inspection to a statistical sampling plan in Alcon Ireland facility.
P190018/S017	12/28/2021	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Modifications to the sampling plan for edge thickness.
P190023/S004	12/16/2021	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Discontinuation of passive monitoring procedures in ISO Class 7 and 8 cleanrooms.
P190034/S001	12/16/2021	X - 30-Day Notice	ELECSYS ANTI-HBS II, PRECICONTROL ANTI-HBS, ANTI-HBS CALCHECK	ROCHE DIAGNOSTICS	Improve and expand manufacturing of kit components.
P200030/S006	12/16/2021	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Add a manufacturing line for the Graft Attach and Stent Graft Crush manufacturing process for the GORE EXCLUDER Conformable AAA Endoprosthesis (EXCC) device.

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P200037/S003	12/17/2021	X - 30-Day Notice	ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM	KESTRA MEDICAL TECHNOLOGIES, INC.	Change to a supplier of the silver-plating process of the ECG electrode.
P200046/S006	12/16/2021	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Establishment of an in-process shelf life for fixed tissue placed in storage.

Total:170