PMA Monthly approvals from 5/1/2023 to 5/31/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130010	05/17/2023	PMAO - PMA Origi	VEGA STEROID-ELUTING ENDOCARDIAL LEADS (VEGA R45, VEGA R52, AND VEGA R58)	MICROPORT CRM USA INC.	Approval for the VEGA Steroid-Eluting Endocardial Leads (VEGA R45, VEGA R52, and VEGA R58).
P210036	05/19/2023	PMAO - PMA Origir	PERCLOT® POLYSACCHARIDE HEMOSTATIC SYSTEM	BAXTER HEALTHCARE CORPRORATION	Approval for the PerClot® Absorbable Hemostatic Powder. The device is indicated in surgical procedures (except neurological and ophthalmic) as an adjunctive hemostatic device to assist when control of suture line bleeding or capillary, venous and arteriolar bleeding by pressure, ligature, and other conventional procedures is ineffective or impractical.
P220013	05/18/2023	PMAO - PMA Origi	TACTIFLEX ABLATION CATHETER, SENSOR ENABLED, TACTISYS QUARTZ EQUIPMENT, TACTISYS QUARTZ, TACTIFLEX RADIOFREQUENCY CABLE, AMPERE RADIOFREQUENCY GENERATOR, COOL POINT PUMP	ABBOTT MEDICAL	Approval for the TactiFle Ablation Catheter, Sensor Enabled. This device is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation and concomitant atrial flutter, when used in conjunction with a compatible RF generator and three-dimensional mapping system.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S213	05/26/2023	R - Real-Time Proc	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval to remove one of the tip stiffness/pressure product design requirements from your internal standard on silicone and polyurethane leads.
P890003/S460	05/16/2023	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for Model SW045 HeartTone device application software.
P930039/S250	05/26/2023	R - Real-Time Proc	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Approval to remove one of the tip stiffness/pressure product design requirements from your internal standard on silicone and polyurethane leads.

Data as of 06/12/2023 04:29 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950029/S127	05/17/2023	N - Normal 180 Day	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Approval for ALIZEA and CELEA pacemakers.
P950029/S132	05/17/2023	N - Normal 180 Day	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Approval for upgrades to the following devices and associated software packages: ALIZEA and CELEA pacemakers, Orchestra Plus and SmartTouch programmer software modules, CPR4 Telemetry head accessory, and the Remote Monitoring System.
P950029/S133	05/17/2023	N - Normal 180 Day	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Approval for upgrades to the ALIZEA and CELEA pacemakers and associated software packages.
P950037/S247	05/11/2023	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for Home Monitoring Service Center version 3.56.0, including the introduction of SmartECG and other software updates.
P960013/S122	05/11/2023	N - Normal 180 Day	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ABBOTT MEDICAL	Approval for the UltiPace Model LPA1231 pacing lead, which incorporates several design and manufacturing modifications to the existing Tendril STS 2088TC lead on the proximal end of the lead.
P980023/S119	05/11/2023	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for Home Monitoring Service Center version 3.56.0, including the introduction of SmartECG and other software updates.
P980040/S156	05/23/2023	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for TECNIS Next-Generation Presbyopia-Correcting (PC) Intraocular lens (IOL) with TECNIS SimplicityTM Delivery System, Model DRN00V which is a design modification of TECNIS Synergy IOL, Model DFR00V.
P980049/S139	05/17/2023	N - Normal 180 Day	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for ALIZEA and CELEA pacemakers.
P980049/S144	05/17/2023	N - Normal 180 Day	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for upgrades to the following devices and associated software packages: ALIZEA and CELEA pacemakers, Orchestra Plus and SmartTouch programmer software modules, CPR4 Telemetry head accessory, and the Remote Monitoring System.
P980049/S145	05/17/2023	N - Normal 180 Day	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Approval for upgrades to the ALIZEA and CELEA pacemakers and associated software packages.
P990018/S009	05/01/2023	R - Real-Time Proc	MENICON Z RIGID GAS PERMEABLE CONTACT LENS	MENICON CO. LTD.	Approval for lens parameters ranges for the central base curve radius, tangential angle and sagittal depth.
P000009/S103	05/11/2023	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for Home Monitoring Service Center version 3.56.0, including the introduction of SmartECG and other software updates.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S164	05/31/2023	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for an alternate design of the garment.
P010032/S191	05/10/2023	P - Panel Track	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for expanding the indications to include non-surgical back pain (NSBP) for the tonic and BurstDR stimulation modes, and diabetic peripheral neuropathy (DPN) of the lower extremities for the tonic stimulation mode, for the Prodigy, Proclaim XR, Proclaim Plus, and Externa Spinal Cord Stimulation (SCS) Systems.
P010032/S193	05/05/2023	N - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for the addition of Magnetic Resonance (MR) Conditional labeling to the Tripole (Model 3219), TriCentrus (Model 3292), and Octrode (Model 3189) leads when used with the Eterna Spinal Cord Stimulation (SCS) Implantable Pulse Generator (IPG), and an expansion of the MR scan conditions available for use with the Penta (Model 3228) lead.
P020012/S044	05/19/2023	S - Special CBE	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for revisions to the instructions for use of Bellafill Dermal Filler as a result of postmarket surveillance data.
P020045/S103	05/02/2023	R - Real-Time Proc	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval for the CryoConsole hardware upgrade and software update due to components obsolescence.
P020045/S104	05/31/2023	R - Real-Time Proc	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Approval for an additional CryoConsole configuration (CFN 106E2) that accepts 220V input power and includes additional components to limit peak current during power-up.
P040002/S071	05/08/2023	O - Normal 180 Day	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, LLC	Approval of the protocol for the VQI and VISION EVAR Registry Analysis post-approval study (PAS) protocol.
P040013/S027	05/04/2023	Y - 135 Review Tra	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX	LYNCH BIOLOGICS LLC	Approval for the addition of a Flurotec coating to the piston stopper component in the syringe system of the final finished packaging.
P040024/S135	05/08/2023	P - Panel Track	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for the improvement of infraorbital hollowing in patients over the age of 21.
P040024/S138	05/30/2023	R - Real-Time Proc	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for extension of the expiration dating of Restylane Eyelight to 36 months.
P040050/S013	05/09/2023	O - Normal 180 Day	MACROPLASTIQUE IMPLANTS	UROPLASTY, LLC	Approval for modifying the labeling to reflect the findings of the Macroplastique Real-Time Observation of Safety and Effectiveness (ROSE) Registry.
P050023/S174	05/11/2023	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for Home Monitoring Service Center version 3.56.0, including the introduction of SmartECG and other software updates.
P050047/S087	05/03/2023	S - Special CBE	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for revisions to the clinician labeling and patient labeling of Juvéderm Ultra, Ultra XC, and Ultra Plus XC, Juvéderm Ultra XC, Juvéderm Voluma XC, Juvéderm Vollure XC, Juvéderm Volbella XC, and Juvéderm Volux XC based on the results of postmarket surveillance data.
P070004/S017	05/26/2023	O - Normal 180 Da	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval of the revised protocol for the Post-Approval Study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P070004/S018	05/26/2023	O - Normal 180 Da	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval of the revised protocol for the Post-Approval Study (PAS) protocol.
P070008/S147	05/11/2023	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for Home Monitoring Service Center version 3.56.0, including the introduction of SmartECG and other software updates.
P080004/S046	05/04/2023	Y - 135 Review Tra	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for a reduction in the duration of the heated aeration phase of your existing approved Ethylene Oxide sterilization process.
P090003/S054	05/08/2023	R - Real-Time Proc	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Approval for a design and material changes to the hub component.
P090016/S053	05/18/2023	S - Special CBE	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for revisions to the instructions for use and patient information guides of Belotero Balance and Belotero Balance (+) Lidocaine Dermal Fillers.
P100016/S016	05/09/2023	R - Real-Time Proc	EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Approval for a modification of the injector component of the CT LUCIA 621P.
P100031/S028	05/08/2023	N - Normal 180 Day	ELECSYS ANTI-HBC IMMUNOASSAY & ELECSYS PRECICONTROL ANTI-HBC	ROCHE DIAGNOSTICS CORP.	Approval for the migration of the Elecsys Anti-HBc II Immunoassay and Elecsys PreciControl Anti-HBc to the cobas e 402 immunoassay analyzer.
P100046/S016	05/19/2023	S - Special CBE	ATRICURE SYNERGY ABLATION SYSTEM	ATRICURE INC.	Approval for labeling changes for the Multifunctional Ablation Generator (MAG).
P110015/S009	05/19/2023	N - Normal 180 Day	GASTRIC EMPTYING BREATH TEST (GEBT)	ADVANCED BREATH DIAGNOSTICS	Approval for the addition of an updated model of Gas Isotope Ratio Mass Spectrometer (GIRMS) for use in analyzing 13C/12C ratios in breath samples as part of your approved 13C-Spirulina Gastric Emptying Breath Test (GEBT)
P110033/S059	05/11/2023	P - Panel Track	JUVEDERM VOLUMA XC	ALLERGAN	Approval for SKINVIVE by JUVÉDERM® injectable gel, indicated for intradermal injection to improve facial skin smoothness of the cheeks in adults over the age of 21.
P110033/S069	05/03/2023	S - Special CBE	JUVEDERM VOLUMA XC	ALLERGAN	Approval for revisions to the clinician labeling and patient labeling of Juvéderm Ultra, Ultra XC, and Ultra Plus XC, Juvéderm Ultra XC, Juvéderm Voluma XC, Juvéderm Vollure XC, Juvéderm Volbella XC, and Juvéderm Volux XC based on the results of postmarket surveillance data.
P130008/S096	05/19/2023	O - Normal 180 Da	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval of the protocol for the post-approval study (PAS) protocol.
P130013/S052	05/11/2023	N - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval to add an alternative imaging modality option, intracardiac echocardiography (ICE), to the Instructions for Use (IFU) for use during the implant procedure. Additionally, you proposed updating the IFU with new clinical data, updating the Indications for Use to align with current practice, as well as streamline the IFU, Pouch Label, Spine Label, Carton Label, Patient Guide and Patient Implant Card in accordance with current labeling procedures.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130022/S048	05/12/2023	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for use of an alternate battery component, the Contego 440, for the IPG3000 device model of the Senza HFX iQ System.
P140004/S030	05/11/2023	R - Real-Time Proc	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Approval for Labeling and Packaging changes
P150036/S068	05/04/2023	R - Real-Time Proc	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval to extend the shelf life of the Edwards INTUITY Delivery System packaging trays from 2 to 4 years and to implement for a 4-year packaging shelf life and new peel strength test specifications for the inner and outer packaging trays.
P160013/S012	05/09/2023	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS) LUNG SYSTEM	TRANSMEDICS, INC	Approval for a change to the wireless monitor of the OCS Lung System, including replacing the obsolete display panel with an updated panel, replacing the existing CCFL backlight driver with an LED backlight driver, updating the Wireless Monitor PCBA with minor component updates.
P170002/S022	05/12/2023	N - Normal 180 Day	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval to update the labeling to allow RHA®2, RHA®3 and RHA®4 to be injected with a blunt tip cannula (25G x 2) as well as a needle.
P170019/S037	05/26/2023	O - Normal 180 Da	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval of the clinical protocol entitled Statistical Analysis Plan for Real-World Evidence Study Supporting FoundationOne®CDx as a Companion Diagnostic for Entrectinib in Non-Small Cell Lung Cancer Patients with ROS1 Fusions.
P170019/S044	05/26/2023	O - Normal 180 Da	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval of the clinical protocol entitled Statistical Analysis Plan for F1CDx Clinical Bridging Study of Entrectinib Efficacy for NTRK
P180051/S003	05/09/2023	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS) HEART SYSTEM	TRANSMEDICS, INC.	Approval for a change to the wireless monitor of the OCS Lung System, including replacing the obsolete display panel with an updated panel, replacing the existing CCFL backlight driver with an LED backlight driver, updating the Wireless Monitor PCBA with minor component updates.
P190002/S012	05/05/2023	N - Normal 180 Day	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for changes which include: 1) Modification of the implanted pulse generator (IPG) without changes to delivered therapy; 2) Modification of the external Closed-Loop Stimulator (eCLS) to be consistent with the new IPG features and to replace obsolete components; 3) Firmware and Software changes to: a. Simplify use of Clinical Software, b. Improve usability and user interface during programming, and c. Improve traceability. 4) Change from Surface Pro 4 to Surface Pro 6 as hardware platform for the Clinical Interface due to obsolescence; and 5) Minor labelling updates to reflect the proposed changes to the IPG, firmware, and software.
P190005/S002	05/16/2023	N - Normal 180 Day	ELECSYS ANTI-HBE, PRECICONTROL ANTI-HBE	ROCHE DIAGNOSTICS	Approval for use of the Elecsys Anti-HBe with the cobas e 402 immunoassay analyzer.
P190028/S008	05/16/2023	R - Real-Time Proc	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Approval for: Assay Specific Analytical Package (ASAP) updated from version 12.1.1 to version 12.2.1 within core system software v1.4.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190032/S005	05/03/2023	P - Panel Track	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval to include a companion diagnostic indication for EGFR exon 20 insertions in patients with non-small cell lung cancer who may benefit from treatment with EXKIVITY® (mobocertinib).
P200002/S005	05/19/2023	S - Special CBE	EPI-SENSE GUIDED COAGULATION SYSTEM	ATRICURE, INC.	Approval for labeling changes for the Multifunctional Ablation Generator (MAG).
P200010/S013	05/08/2023	R - Real-Time Proc	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval for sourcing one of the Sample Preparation Kit reagents, which is used in Guardant360 CDx assay from a new vendor.
P200028/S017	05/24/2023	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for changes to the raw materials used in the formulation of an adhesive used in DiamondTemp catheter manufacturing.
P200031/S003	05/09/2023	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS) LIVER	TRANSMEDICS, INC.	Approval for a change to the wireless monitor of the OCS Lung System, including replacing the obsolete display panel with an updated panel, replacing the existing CCFL backlight driver with an LED backlight driver, updating the Wireless Monitor PCBA with minor component updates.
P200039/S011	05/08/2023	O - Normal 180 Da	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for updated labeling to include post approval study results.
P210001/S008	05/26/2023	O - Normal 180 Da	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Approval of PAS that was submitted to comply with the condition of approval #1 which required providing data to support the analytical sensitivity of the VENTANA MMR RxDx Panel for the solid tumor indication.
P210003/S004	05/08/2023	N - Normal 180 Day	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Approval for the Migration of the Abbott ARCHITECT HBsAg Next Qualitative and ARCHITECT HBsAg Next Confirmatory assay to the ARCHITECT i1000SR System.
P210032/S007	05/02/2023	N - Normal 180 Day	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Approval for an expansion of the indications for use and modifications to the Instructions for Use of the Gore TAG Thoracic Branch Endoprosthesis (TBE Device).
P220003/S009	05/31/2023	O - Normal 180 Da	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Approval for a sterilization site located at the STERIS, Synergy Health Ireland Limited Facility, IDA Business & Technology Park, Sragh Industrial Estate, Tullamore, Co. Offaly, R35 X865 Ireland for the sterilization of the PASCAL Precision Transcatheter Valve Repair System including the PASCAL Precision implant system (Models 20000IS and 20000ISM) and the PASCAL Precision guide sheath (Model 20000GS).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P220003/S010	05/30/2023	O - Normal 180 Da	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Approval for a manufacturing site located at the Edwards Limerick Facility, Edwards Lifesciences Ireland, National Technology Park, Castletroy, Limerick Ireland V9431X5 for the manufacturing of the PASCAL Precision Transcatheter Valve Repair System including the PASCAL Precision implant system (Models 20000IS and 20000ISM) and the PASCAL Precision guide sheath (Model 20000GS).

Total: 64

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S041	05/16/2023	X - 30-Day Notice	GELFOAM	PFIZER, INC.	Change of a new nitrogen flowmeter and a change in the in-process brick dimensions.
N970003/S284	05/11/2023	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Updates to the header inspection performed during the Header Overmolding process to identify material discontinuities.
N970003/S285	05/01/2023	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Add a new Controlled Environment Area (CEA) Level VIII and a new CEA Level IX for pulse generator and implantable cardiac monitor battery manufacturing.
N970003/S286	05/08/2023	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Modifications to the pin gauge color coding and number of devices used in the pin gauge device inspection process.
P810006/S104	05/11/2023	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room.
P810006/S105	05/10/2023	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Qualification of a new purified water tank.
P830055/S307	05/19/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Removal of the duplicate inspections from different steps of the manufacturing process for the LCS Total Knee System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S215	05/23/2023	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modification to the sampling plan for viable air and surface testing.
P840001/S541	05/04/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Addition of an automatic process monitoring station for batteries manufactured at Medtronic Energy and Component Center (MECC).
P840062/S089	05/11/2023	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room.
P840062/S090	05/10/2023	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Qualification of a new purified water tank.
P850010/S107	05/11/2023	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Manufacturing changes including modifications to two ISO 7 Collagen Packaging Cleanrooms and the associated Gowning Room.
P850010/S108	05/10/2023	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Qualification of a new purified water tank.
P850048/S059	05/25/2023	X - 30-Day Notice	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY	BECKMAN COULTER, INC.	Revision of conjugate pooling and prefill/postfill testing specifications utilized in the Access Hybritech PSA Assay
P850064/S050	05/31/2023	X - 30-Day Notice	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Replace the Thermistor Inspection Fixtures with an upgraded design. This change would increase the ease and efficiency of performing incoming inspections of the 3¿ thermistors (P/N 00234) and 58 thermistors (P/N 00235) which are components in the Patient Circuit used in the LifePulse HFV Systems. The new Inspection Fixtures will not affect the safety or effectiveness of the Patient Circuit or the LifePulse HFV.
P860004/S407	05/04/2023	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Addition of an automatic process monitoring station for batteries manufactured at Medtronic Energy and Component Center (MECC).
P860047/S035	05/31/2023	X - 30-Day Notice	HYDROXYPROPYLMETHYL CELLULOSE 20MG/ML	BAUSCH & LOMB, INC.	Change to an alternative syringe barrel manufacturing site used for the OcuCoat OVD.
P880086/S328	05/01/2023	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Alternate supplier to provide the identical header components for the connector block components used in ICDs and pacemakers.
P880086/S329	05/23/2023	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Addition of a new electrical test and modification of an existing device-level manufacturing test.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900056/S207	05/10/2023	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Replace aging production molds and update inspection activities for the components.
P910001/S119	05/04/2023	X - 30-Day Notice	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Second supplier for the molded Proximal Coupler and Strain Relief components.
P910023/S453	05/01/2023	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Alternate supplier to provide the identical header components for the connector block components used in ICDs and pacemakers.
P920015/S276	05/17/2023	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implementation of three fixtures in the annealing process.
P930039/S251	05/23/2023	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Modification to the sampling plan for viable air and surface testing.
P950020/S138	05/05/2023	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Adding another automated processing unit.
P960009/S451	05/04/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Addition of an automatic process monitoring station for batteries manufactured at Medtronic Energy and Component Center (MECC).
P960040/S491	05/11/2023	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Updates to the header inspection performed during the Header Overmolding process to identify material discontinuities.
P960040/S492	05/01/2023	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Add a new Controlled Environment Area (CEA) Level VIII and a new CEA Level IX for pulse generator and implantable cardiac monitor battery manufacturing.
P960042/S071	05/04/2023	X - 30-Day Notice	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM & LASER SHEATH	SPECTRANETICS (PHILIPS)	Second supplier for the molded Proximal Coupler and Strain Relief components.
P970004/S380	05/04/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Addition of an automatic process monitoring station for batteries manufactured at Medtronic Energy and Component Center (MECC).
P970004/S381	05/05/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Add an alternate applicator sponge manufacturer (sub- tier supplier) for Medtronic Model 309201.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S854	05/16/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement the micro-CT scanning process for finished batteries at the MECC site.
P980016/S855	05/17/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Remove a redundant visual inspection during the Resistance Spot Welding (RSW) process at MECC.
P980035/S746	05/23/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modification to the sampling plan for viable air and surface testing.
P990075/S056	05/24/2023	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Implementation of a new rubber processing mill
P000025/S125	05/05/2023	X - 30-Day Notice	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Qualification of alternative capacitors from an additional supplier for use in the cochlear implant electrical assembly.
P000039/S077	05/02/2023	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Addition of two (2) sterilization chambers at the Steris Costa Rica facility to sterilize the subject devices.
P010012/S568	05/11/2023	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Updates to the header inspection performed during the Header Overmolding process to identify material discontinuities.
P010012/S569	05/01/2023	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add a new Controlled Environment Area (CEA) Level VIII and a new CEA Level IX for pulse generator and implantable cardiac monitor battery manufacturing.
P010029/S034	05/12/2023	X - 30-Day Notice	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUT ICALS, INC.	Removal of package integrity testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S820	05/16/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement the micro-CT scanning process for finished batteries at the MECC site.
P010031/S821	05/17/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Remove a redundant visual inspection during the Resistance Spot Welding (RSW) process at MECC.
P010032/S197	05/04/2023	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Implement an alternative to batch testing for bacterial endotoxin testing performed at the Plano, TX facility for Proclaim DRG and Eterna IPGs.
P030005/S229	05/11/2023	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Updates to the header inspection performed during the Header Overmolding process to identify material discontinuities.
P030005/S230	05/01/2023	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Add a new Controlled Environment Area (CEA) Level VIII and a new CEA Level IX for pulse generator and implantable cardiac monitor battery manufacturing.
P030005/S231	05/08/2023	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Modifications to the pin gauge color coding and number of devices used in the pin gauge device inspection process.
P030017/S360	05/17/2023	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Supplier Meier Tool & Engineering, Inc. to move its manufacturing facility for the 32 Paddle Lead Disc Electrodes and Slotted Paddle Disc Electrodes used to manufacture the Artisan and CoverEdge Leads to a new site.
P030017/S361	05/12/2023	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Remove the Verify Multi-lumen Tube Length step currently performed at the BSC Dorado manufacturing site during the assembly of the 15cm Precision M8 Adapter, Precision M8 Trial Adapter, and Vercise M8 Adapter of the Spinal Cord Stimulator (SCS) and Deep Brain Stimulation (DBS) systems.
P030017/S362	05/15/2023	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add an additional Controlled Environment Area (CEA F) to expand existing manufacturing clean room space at the Boston Scientific Dorado Puerto Rico facility to be used for the manufacturing of Boston Scientific Neuromodulation (BSN) Spinal Cord Stimulator and Deep Brain Stimulator Leads products.

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P030031/S132	05/03/2023	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Addition of two sub-tier suppliers for a PCB component used in Thermocool Smarttouch (ST) and Thermocool Smarttouch SF (STSF) Catheters.
P030035/S194	05/01/2023	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Alternate supplier to provide the identical header components for the connector block components used in ICDs and pacemakers.
P030035/S195	05/23/2023	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Addition of a new electrical test and modification of an existing device-level manufacturing test.
P040013/S028	05/31/2023	X - 30-Day Notice	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX	LYNCH BIOLOGICS LLC	Change to a larger mixing vessel/clamp and an additional stoppering box, to the existing manufacturing line.
P040034/S037	05/24/2023	X - 30-Day Notice	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Changing the quantification test method for determining elemental impurities present in one of the raw materials.
P040036/S094	05/03/2023	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Addition of two sub-tier suppliers for a PCB component used in Thermocool Smarttouch (ST) and Thermocool Smarttouch SF (STSF) Catheters.
P040045/S131	05/17/2023	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of a raw material manufacturing site, from an existing supplier.
P050027/S031	05/05/2023	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Change in supplier of three subassembly components used in the Karl Storz PDD System.
P050037/S124	05/04/2023	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Re-establish Site 100 as a secondary location for manufacturing.
P050038/S041	05/24/2023	X - 30-Day Notice	ARISTA AH ABSORBABLE HEMOSTAT	DAVOL, INC.	Use of reclaimed Stainless Steel (SS) tubes to manufacture Arista AH FlexiTip XL-R Applicator.
P050052/S146	05/04/2023	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Re-establish Site 100 as a secondary location for manufacturing.
P060028/S048	05/24/2023	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Implementation of a new rubber processing mill
P070026/S105	05/02/2023	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Introduction of an automated dry-blasting system at the DePuy Ireland manufacturing facility.
P070026/S106	05/19/2023	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Removal of the duplicate inspections from different steps of the manufacturing process for the LCS Total Knee System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080013/S026	05/24/2023	X - 30-Day Notice	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Changing the quantification test method for determining elemental impurities present in one of the raw materials.
P080025/S275	05/04/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Addition of an automatic process monitoring station for batteries manufactured at Medtronic Energy and Component Center (MECC).
P080025/S276	05/05/2023	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Add an alternate applicator sponge manufacturer (sub- tier supplier) for Medtronic Model 309201.
P090029/S017	05/24/2023	X - 30-Day Notice	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Change to the verification dose experiment testing schedule.
P100009/S054	05/03/2023	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Alternative raw material sub-suppliers for adhesives used in the delivery system.
P110016/S083	05/02/2023	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ABBOTT MEDICAL	Addition of two (2) sterilization chambers at the Steris Costa Rica facility to sterilize the subject devices.
P110042/S182	05/12/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change the annealing process of the EMBLEM S-ICD pulse generator case halves to align with industry standards.
P110042/S183	05/11/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Updates to the header inspection performed during the Header Overmolding process to identify material discontinuities.
P110042/S184	05/01/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add a new Controlled Environment Area (CEA) Level VIII and a new CEA Level IX for pulse generator and implantable cardiac monitor battery manufacturing.
P130026/S085	05/02/2023	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Addition of two (2) sterilization chambers at the Steris Costa Rica facility to sterilize the subject devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140010/S072	05/04/2023	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER AND IN.PACT 018 PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER	MEDTRONIC INC.	Addition of balloon shaping and weld dimension verification steps.
P140010/S073	05/22/2023	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER AND IN.PACT 018 PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON CATHETER	MEDTRONIC INC.	Changes to the welding process of the catheter subassembly of the IN.PACT Admiral PTA DCB.
P140031/S156	05/18/2023	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add an alternate inspection site for the Edwards SAPIEN 3 and Edwards SAPIEN 3 Ultra transcatheter heart valves frames.
P140033/S079	05/01/2023	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Alternate supplier to provide the identical header components for the connector block components used in ICDs and pacemakers.
P140033/S080	05/23/2023	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Addition of a new electrical test and modification of an existing device-level manufacturing test.
P150003/S095	05/05/2023	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Adding another automated processing unit.
P150004/S060	05/04/2023	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Implement an alternative to batch testing for bacterial endotoxin testing performed at the Plano, TX facility for Proclaim DRG and Eterna IPGs.
P150012/S142	05/11/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Updates to the header inspection performed during the Header Overmolding process to identify material discontinuities.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S143	05/01/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Add a new Controlled Environment Area (CEA) Level VIII and a new CEA Level IX for pulse generator and implantable cardiac monitor battery manufacturing.
P150012/S144	05/08/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Modifications to the pin gauge color coding and number of devices used in the pin gauge device inspection process.
P150012/S145	05/17/2023	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Introduction of a digital microscope to verify removal of medical adhesive during the Drug Collar Bonding manufacturing process.
P150031/S057	05/12/2023	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Remove the Verify Multi-lumen Tube Length step currently performed at the BSC Dorado manufacturing site during the assembly of the 15cm Precision M8 Adapter, Precision M8 Trial Adapter, and Vercise M8 Adapter of the Spinal Cord Stimulator (SCS) and Deep Brain Stimulation (DBS) systems.
P150031/S058	05/15/2023	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add an additional Controlled Environment Area (CEA F) to expand existing manufacturing clean room space at the Boston Scientific Dorado Puerto Rico facility to be used for the manufacturing of Boston Scientific Neuromodulation (BSN) Spinal Cord Stimulator and Deep Brain Stimulator Leads products.
P150033/S168	05/04/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the end cap welder monitoring equipment at Medtronic Swiss Operations.
P150033/S169	05/04/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement an automated process monitoring station for the burn-in test system used during medium rate battery manufacturing at MECC.
P150033/S170	05/09/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the plasma cleaning rework process step in the Manufacturing Execution System (MES) for Micra devices.
P150033/S171	05/09/2023	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Transfer Extrusion Line 17 to Medtronic Danvers.
P160015/S015	05/23/2023	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Automate the manual process of the Velcro cutting process.

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P160022/S034	05/23/2023	X - 30-Day Notice	X SERIES®, R SERIES®, AED PRO®, AED 3 BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER BATTERY PACK, SUREPOWER II BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 BATTERY PACK, SUREPOWER CHARGER, AND SUREPOWER SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Automate the manual process of the Velcro cutting process.
P160025/S016	05/23/2023	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Alternate suppliers for catheter components and a change in extrusion speed.
P160037/S016	05/17/2023	X - 30-Day Notice	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Change the manufacturing of a critical assay component.
P160043/S068	05/01/2023	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Reducing the sampling size for the Fourier Transform Infrared Spectroscopy (FTIR) and Appearance testing for the polymers.
P160048/S024	05/10/2023	X - 30-Day Notice	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Addition of a new supplier for a critical component of the Eversense E3 Transmitter. The transmitter is a component of the Eversense Continuous Glucose Monitoring System.
P160049/S021	05/23/2023	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Balloon processing changes.
P160055/S029	05/18/2023	X - 30-Day Notice	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Option to sterilize the Light Adjustable Lens (LAL) device a second time by Ethylene Oxide (2x EO sterilization).
P170008/S044	05/09/2023	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Replacing the vacuum oven used as part of EluNIR's delivery system manufacturing process of assembling markers on the distal inner shaft tube.
P170022/S002	05/22/2023	X - 30-Day Notice	PYLOPLUS UBT SYSTEM	ARJ MEDICAL INC.	Moving some packaging activities to another building (under same FEI#) and a vendor change for a critical kit component.
P170032/S013	05/22/2023	X - 30-Day Notice	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Addition of an alternate supplier of components used for the printed circuit board assembly of the Woven EndoBridge (WEB) Detachment Controller (WDC-2) of the WEB Aneurysm Embolization System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180046/S068	05/16/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change in the manufacturing process regarding the method of surface texturing, leak testing, and cleaning.
P190006/S068	05/16/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change in the manufacturing process regarding the method of surface texturing, leak testing, and cleaning.
P190008/S023	05/04/2023	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Addition of balloon shaping and weld dimension verification steps.
P190008/S024	05/22/2023	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Changes to the welding process of the catheter subassembly of the IN.PACT Admiral PTA DCB.
P190017/S011	05/11/2023	X - 30-Day Notice	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Implementation of three process improvement changes.
P190018/S024	05/31/2023	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON LABORATORIES, LLC	Add all Clareon models to the Semi-Automated Welding System (SAWS) for the welding of wafers.
P190023/S015	05/10/2023	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Increase the individual leaflet thickness measurement allowances and to automate the valve level leaflet thickness matching.

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P200002/S006	05/25/2023	X - 30-Day Notice	EPI-SENSE GUIDED COAGULATION SYSTEM	ATRICURE, INC.	Expansion of the current manufacturing campus for the CSK-2060 to include an additional building located at 7555B Innovation Way, Mason, OH 45040 and an update to a pouch sealing test method.
P200010/S014	05/16/2023	X - 30-Day Notice	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Add component manufacturing at Guardants facility.
P200015/S038	05/18/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Add an alternate inspection site for the Edwards SAPIEN 3 and Edwards SAPIEN 3 Ultra transcatheter heart valves frames.
P200015/S039	05/30/2023	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Residual testing for the 20 kg weight classification in the pulmonic population for an alternative ethylene oxide sterilization cycle.
P200037/S008	05/25/2023	X - 30-Day Notice	ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM	KESTRA MEDICAL TECHNOLOGIES, INC.	Updates to test limit changes for a circuit on the AFE PCBA board.
P200046/S016	05/23/2023	X - 30-Day Notice	HARMONY TPV SYSTEM	MEDTRONIC, INC.	Addition of eddy current testing to check for nitinol wire surface defects at a nitinol wire sub-tier supplier.
P200049/S005	05/02/2023	X - 30-Day Notice	AMPLATZER AMULET LEFT ATRIAL APPENDAGE OCCLUDER	ABBOTT MEDICAL	Addition of two (2) sterilization chambers at the Steris Costa Rica facility to sterilize the subject devices.
P210006/S004	05/26/2023	X - 30-Day Notice	THORAFLEX HYBRID	VASCUTEK LTD.	Increase the number of Thoraflex Hybrid device samples that undergo the elevated aeration step at a time.
P220003/S008	05/11/2023	X - 30-Day Notice	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Additional supplier for the Guide Sheath Shaft component of the PASCAL Precision Guide Sheath (Model 2000GS).

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