PMA Monthly approvals from 2/1/2023 to 2/28/2023

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P220009	02/22/2023	PMAO - PMA Origi	STABLEVISC AND TOTALVISC OPHTHALMIC VISCOSURGICAL DEVICE (OVD)	BAUSCH HEALTH COMPANIES, INC.	Approval for the StableVisc Ophthalmic Viscosurgical Device (OVD). StableVisc is indicated for use as a surgical aid in ophthalmic anterior segment procedures including: 1) Extraction of a cataract; and 2) Implantation of an intraocular lens (IOL).

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S098	02/16/2023	S - Special CBE	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for labeling changes to the Instructions for Use for the SURGICEL Family of Absorbable Hemostats and SURGICEL Powder.
P890003/S459	02/08/2023	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for updates to the Alert Management Feature/System for the CareLink network.
P930038/S099	02/09/2023	O - Normal 180 Da	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATIO N	Approval for a sterilization manufacturing site located at the Terumo Elkton Manufacturing Facility, 950 Elkton Blvd., Elkton, Maryland.
P980016/S842	02/08/2023	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updates to the Alert Management Feature/System for the CareLink network.
P980016/S844	02/23/2023	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updates to the hybrid and flashware.
P990009/S070	02/02/2023	N - Normal 180 Day	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Approval to allow kitting an alternate 10 mL FLOSEAL kit configuration, where the human Thrombin vial will be replaced with a vial of recombinant human Thrombin (RECOTHROM).

Data as of 03/28/2023 05:35 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990040/S030	02/28/2023	O - Normal 180 Da	TRUFILL N-BUTYL CYANOACRYLATE LIQUID EMBOLIC SYSTEM	MEDOS INTERNATIONAL SARL	Approval for new manufacturing sites located at: 1) Steris Isomedix Services, 1175 Isuzu Parkway, Grand Prairie, Texas, 75050; 2) Steris Isomedix Services, 7685 St. Andrews Avenue, San Diego, California, 92154; and 3) Sterigenics, 2400 Airport Road, Santa Teresa, New Mexico, 88008. These manufacturing sites will be performing sterilization of the TRUFILL n-BCA Liquid Embolic System.
P010031/S809	02/08/2023	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updates to the Alert Management Feature/System for the CareLink network.
P010031/S810	02/23/2023	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the updates to the hybrid and flashware.
P050019/S035	02/01/2023	R - Real-Time Proc	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for a change to an alternate supplier of an equivalent resin used as the middle layer in the tri-layer inner component of your stent delivery system.
P100013/S025	02/13/2023	O - Normal 180 Da	CORDIS EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS US CORPORATION	Approval for a manufacturing site named Nutek Bravo located at 26545 Corporate Ave, Hayward, CA 94545 USA for sterilization of the EXOSEAL device.
P100016/S009	02/07/2023	N - Normal 180 Day	EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Approval for a new product model, CT LUCIA 621P, which is a design change to the currently approved product CT LUCIA 611P.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100026/S092	02/10/2023	N - Normal 180 Day	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for a revised the RNS System Implanting and Programming Program Qualifications Questionnaire as follows: 1) Provided a list of current diagnostic technologies utilized to identify the seizure onset; 2) Clarified that qualified neurosurgeon(s) are ABNS board-certified or board-eligible and tracking toward certification, with experience in epilepsy surgery procedures and placement of intracranial electrodes; 3) Specified that an established referral relationship is needed to ensure access to neuropsychological testing and mental health services; and 4) Neurologist(s) who is American Board of Psychiatry and Neurology (ABPN) board-certified and is fellowship trained in epilepsy or in clinical neurophysiology, or has experience in the treatment of epilepsy, including selection of antiepileptic medications, interpretation of scalp and intracranial EEG, video EEG monitoring, and selection of patients for epilepsy surgery or neuromodulation devices. 2. Revised the RNS System Programming Physician Qualifications Questionnaire as follows: 1) At least one American Board of Psychiatry and Neurology (ABPN) board-certified neurologist with expertise in epilepsy and in the interpretation of EEG; 2) Established referral relationship with Epilepsy Program qualified to implant and program the RNS System; 3) Local access to urgent or emergent neurosurgical care; and 4) Capability to provide instructions to patient and family members in RNS System use.
P100047/S204	02/13/2023	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the modification of an epoxy used in the HeartWare Ventricular Assist Device (HVAD) controller connectors
P110016/S082	02/24/2023	O - Normal 180 Da	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ABBOTT MEDICAL	Approval of the protocol for the Abbott Ventricular Tachycardia Post Approval Study.
P120011/S023	02/01/2023	O - Normal 180 Da	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for a new manufacturing site at Bentec Medical OpCo, LLC, 1380 E Beamer St. Woodland CA 95776.
P130012/S013	02/07/2023	S - Special CBE	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Approval for changes being effected (CBE) to include revisions and enhancements to the content in the Myopore lead Instructions for Use manual and packaging labeling.
P150003/S088	02/01/2023	N - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for removal of the flushing needle accessory, implementation of the dual chamber pouch for the Synergy Megatron device, and labeling changes for the SYNERGY XD and SYNERGY MEGATRON Everolimus-Eluting Platinum Chromium Coronary Stent System
P150014/S043	02/23/2023	N - Normal 180 Day	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the migration of cobas HBV from cobas 6800/8800 Systems to the cobas 5800 System.

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P150026/S014	02/24/2023	N - Normal 180 Day	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for changes to the Console of the HeartLight System.
P150031/S052	02/23/2023	R - Real-Time Proc	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval to add a gold colorant to two of the strain reliefs to the Vercise Genus 32-contact IPG.
P160002/S020	02/07/2023	S - Special CBE	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approved for removal of Urothelial Carcinoma (UC) indication from the device intended use statement and labeling.
P160012/S005	02/15/2023	R - Real-Time Proc	LIFEPAK CR® PLUS DEFIBRILLATOR, LIFEPAK EXPRESS® DEFIBRILLATOR, AND CHARGE-PAK® BATTERY CHARGER	PHYSIO-CONTROL. INC.	Approval for a change to the hydrogel formula for the QUIK-PAK Electrodes.
P160013/S010	02/24/2023	O - Normal 180 Day	ORGAN CARE SYSTEM (OCS¿) LUNG SYSTEM	TRANSMEDICS, INC	Approval for revised labeling to reflect the final results of INSPIRE, Lung EXPAND and Lung EXPAND II clinical trials.
P160022/S032	02/17/2023	R - Real-Time Proc	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Approval for clinical and non-clinical changes to the MCU 20.01 software.
P160029/S018	02/16/2023	R - Real-Time Proc	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Approval for a design change to implement a strip of double sided tape to the leading edge of the hydrogel layer of the HS1 SMART pads.
P160031/S004	02/13/2023	R - Real-Time Proc	ASPIRE CRISTALLE DIGITAL BREAST TOMOSYNTHESIS OPTION	FUJIFILM MEDICAL SYSTEMS U.S.A., INC.	Approval for the introduction of a higher dose setting (H-mode) for the DBT option.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160037/S008	02/09/2023	N - Normal 180 Day	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for The BD Onclarity HPV Assay. The device is indicated as a qualitative in vitro test for the detection of Human Papillomavirus in clinician-collected cervical specimens using an endocervical brush/spatula combination or broom and placed in a BD SurePath vial or placed in ThinPrep Pap Test PreservCyt Solution . The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types 16, 18, 31, 45, 51, and 52 while reporting the other HR HPV types in groups (33/58, 35/39/68, and 56/59/66). The BD Onclarity HPV Assay is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with profession medical guidelines, results from prior screening, medical history, and other risk factors. WARNING The BD Onclarity HPV Assay is NOT intended: 1) For use in determining the need for treatment (i.e., excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia. Patients who are HPV 16, 18 and 45 positive should be assessed for the development of high-grade cervical intraepithelial neoplasia according to current practice guidelines; 2) For women who have undergone hysterectomy with removal of the cervix; and 3) For use with samples other than those collected by a clinician using an endocervical brush/spatula combination or broom and placed in the BD SurePath Preservative Fluid Collection Vial or placed in PreservCyt Solution. HPV-negative cancers of the cervix do occur infrequently. In addition, HPV screening is not 100% sensitive for HPV-associated cervical cancer. Use of this device for primary cervical cancer screening should be undertaken after carefully considering the performance characteristics put forth in this label, as well as recommendations of professional guidelines. The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, or who are pregnant, or below age 21, or for the management of transgender individuals.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160037/S012	02/15/2023	R - Real-Time Proc	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for The BD Onclarity HPV Assay. The device is indicated as a qualitative in vitro test for the detection of Human Papillomavirus in clinician-collected cervical specimens using an endocervical brush/spatula combination or broom and placed in a BD SurePath vial or placed in ThinPrep Pap Test PreservCyt Solution . The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types 16, 18, 31, 45, 51, and 52 while reporting the other HR HPV types in groups (33/58, 35/39/68, and 56/59/66). The BD Onclarity HPV Assay is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with profession medical guidelines, results from prior screening, medical history, and other risk factors. WARNING The BD Onclarity HPV Assay is NOT intended: 1) For use in determining the need for treatment (i.e., excisional or ablative treatment of the cervix) in the absence of high-grade cervical dysplasia. Patients who are HPV 16, 18 and 45 positive should be assessed for the development of high-grade cervical intraepithelial neoplasia according to current practice guidelines; 2) For women who have undergone hysterectomy with removal of the cervix; and 3) For use with samples other than those collected by a clinician using an endocervical brush/spatula combination or broom and placed in the BD SurePath Preservative Fluid Collection Vial or placed in PreservCyt Solution. HPV-negative cancers of the cervix do occur infrequently. In addition, HPV screening is not 100% sensitive for HPV-associated cervical cancer. Use of this device for primary cervical cancer screening should be undertaken after carefully considering the performance characteristics put forth in this label, as well as recommendations of professional guidelines. The use of this test has not been evaluated for the management of women with prior ablative or excisional therapy, or who are pregnant, or below age 21, or for the management of transgender individuals.
P160040/S012	02/06/2023	R - Real-Time Proc	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Approval for replacing NEBuffer 3.1, containing bovine serum albumin, with NEBuffer r3.1, containing recombinant (non-bovine) albumin in the LeukoStrat® CDx FLT3 Mutation Assay kit configuration.
P160042/S018	02/15/2023	R - Real-Time Proc	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for the change to a one needle PVC tray for holding the final gel product for Revanesse Versa 1.0 mL, Revanesse Versa 1.2 mL, Revanesse Versa+ with Lidocaine 1.0 mL, Revanesse Versa+ with Lidocaine 1.2 mL, Revanesse Lips + with Lidocaine 1.0 mL, Revanesse Lips+ with Lidocaine 1.2 mL.
P160045/S038	02/01/2023	O - Normal 180 Da	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval to update the user guide for the Oncomine Dx Target Test to include the results of the supplemental clinical data submitted in the Post-Approval Study (PAS) Protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160055/S027	02/16/2023	O - Normal 180 Da	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180046/S054	02/07/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for a labeling expansion to '1.5T MRI conditional' for the Axonics Sacral Neuromodulation System in two clinical scenarios: 1) abandoned lead fragment (i.e., no implanted pulse generator in the body); and 2) a broken lead connected with an intact, rechargeable, implanted pulse generator.
P180047/S021	02/01/2023	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for a new system configuration featuring internal canisters for the supply of liquids (System Liquid, Wash Buffer, Cleaning solution) and changing from LIAISON XS software version 1.4.9 to software version 1.5.2, in order to support the new hardware components.
P190006/S054	02/07/2023	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval for labeling expansion to '1.5T MRI conditional' for the Axonics Sacral Neuromodulation System in two clinical scenarios: 1) abandoned lead fragment (i.e., no implanted pulse generator in the body) and 2) a broken lead connected with an intact, rechargeable, implanted pulse generator.
P190012/S002	02/15/2023	O - Normal 180 Da	SPATZ3 ADJUSTABLE BALLOON SYSTEM	SPATZ FGIA INC.	Approval for adding a new in-house cleanroom to the Spatz manufacturing site at Ha-Tidhar 2 St. Ra¿anana.
P200013/S010	02/21/2023	R - Real-Time Proc	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval to release software version 1.7.1 in the US.
P200015/S033	02/22/2023	S - Special CBE	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for various revisions to the Instructions for Use for the SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent to provide additional instruction on deployment of the prestent and extend the recapture limit from 50% to 65%.
P200020/S003	02/17/2023	O - Normal 180 Da	SBL-3 MULTIFOCAL INTRAOCULAR LENS	LENSTEC, INC.	Approval for the commercial name change from SBL-3 to ClearView 3.
P200035/S005	02/14/2023	R - Real-Time Proc	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval for the addition of a Quick Reference Guide (QRG) as a supplement to existing labeling for the OrganOx metra System.
P200039/S009	02/02/2023	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 the final results of your continued follow up study.
P210022/S003	02/21/2023	R - Real-Time Proc	ALINITY M CMV	ABBOTT MOLECULAR, INC.	Approval to release software version 1.7.1 in the US.
P210027/S001	02/24/2023	N - Normal 180 Day	QDOT MICRO¿ SYSTEM	BIOSENSE WEBSTER, INC.	Approval for software and hardware modifications to the nGEN Generator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement

Total: 44

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S099	02/16/2023	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Validation of a new reactor for the oxidation of the oxidized regenerated cellulose used in the manufacturing of SURGICEL SNOW.
N12159/S100	02/28/2023	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Adding a duplicate cutter equipment for increasing manufacturing capacity due to the transfer of Neuchatel Surgicel fabric and Interceed device manufacturing to Ethicon, LLC, San Lorenzo in Puerto Rico.
N970012/S195	02/10/2023	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Supplier change of the traction suture due to the original supplier leaving the medical market.
P810006/S102	02/23/2023	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Replacement of the current stainless-steel AT basket/paddle with a modular polyethylene/ stainless steel AT basket to improve ergonomics and reduce wear particles as a result of paddle motion at the Integra LifeSciences Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, NJ 08536.
P830055/S303	02/01/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change from etching Cobalt Chrome products with Red yttrium aluminum garnet (YAG) Laser using ink to Green Beam Laser without ink at the DePuy Orthopaedics, Inc., Warsaw, IN manufacturing site.
P830055/S304	02/09/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change to the polish process step for components of the LCS® Total Knee System manufactured at the DePuy Orthopedics, Inc., manufacturing site located in Warsaw, IN, which introduces an alternate polishing belts from new suppliers to the in-process polishing step due to supply chain shortages of the current belts.
P830055/S305	02/06/2023	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change in inspection frequency after the CNC machining manufacturing step in the Suzhou manufacturing site.
P830061/S212	02/17/2023	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a sub-tier supplier for Platinum/Iridium powder used in electrode tips.
P840001/S536	02/02/2023	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implement manufacturing process changes at an external supplier in order to manufacturing different sized TBC series tantalum capacitors.
P840062/S087	02/23/2023	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Replacement of the current stainless-steel AT basket/paddle with a modular polyethylene/ stainless steel AT basket to improve ergonomics and reduce wear particles as a result of paddle motion at the Integra LifeSciences Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, NJ 08536.

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P850010/S105	02/23/2023	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Replacement of the current stainless-steel AT basket/paddle with a modular polyethylene/ stainless steel AT basket to improve ergonomics and reduce wear particles as a result of paddle motion at the Integra LifeSciences Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, NJ 08536.
P850064/S049	02/06/2023	X - 30-Day Notice	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Notice of Change to the Patient Box Burn-In Fixture used during manufacturing and servicing of the LifePulse High Ventilator, specifically the Patient Box. The Patient Box Burn-In Fixture is used to burn in the Patient Boxes when a ventilator is not being burned-in at the same time.
P880047/S054	02/28/2023	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Adding a duplicate cutter equipment for increasing manufacturing capacity due to the transfer of Neuchatel Surgicel fabric and Interceed device manufacturing to Ethicon, LLC, San Lorenzo in Puerto Rico.
P880086/S327	02/10/2023	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Automate parts of the battery welding process to increase battery production capacity.
P900033/S104	02/07/2023	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Modification to The Clean Compressed Air Distribution System.
P900033/S105	02/23/2023	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Replacement of the current stainless-steel AT basket/paddle with a modular polyethylene/ stainless steel AT basket to improve ergonomics and reduce wear particles as a result of paddle motion at the Integra LifeSciences Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, NJ 08536.
P900056/S204	02/02/2023	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Additional supplier for a switch component.
P910023/S449	02/21/2023	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Add an alternate supplier of aluminum foil for high-voltage capacitors anodes currently manufactured at Abbott¿s Liberty, SC capacitor manufacturing site.
P910023/S450	02/10/2023	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Update the manufacturing electrical test requirement and lower limit to increase manufacturing yields for ICD and CRT-D devices.
P910023/S452	02/10/2023	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Automate parts of the battery welding process to increase battery production capacity.
P920015/S275	02/17/2023	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Add a sub-tier supplier for Platinum/Iridium powder used in electrode tips.
P930021/S030	02/03/2023	X - 30-Day Notice	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Addition of a second supplier, Eurofins BioPharma Product Testing Sweden AB, for sterility testing (release testing).
P950008/S017	02/22/2023	X - 30-Day Notice	SILIKON 1000	ALCON	Add Alcon Laboratories, Inc., the Fort Worth North (FWN) quality control (QC) lab, as a testing location for finished device and device component resistivity testing.
P960009/S446	02/02/2023	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Implement manufacturing process changes at an external supplier in order to manufacturing different sized TBC series tantalum capacitors.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970003/S238	02/07/2023	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Introduce a new resistance welding system and associated parameter changes utilized in the production of the VNS Therapy System Implantable Pulse Generators.
P980016/S847	02/03/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement manufacturing process updates at a capacitor supplier.
P980016/S848	02/06/2023	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modification to a rework connector adhesive process at Medtronic Swiss Operations.
P980035/S739	02/03/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement manufacturing process updates at a capacitor supplier.
P980035/S740	02/06/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modification to a rework connector adhesive process at Medtronic Swiss Operations.
P980035/S741	02/16/2023	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement minor modifications to the final packaging process.
P000006/S066	02/15/2023	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Manufacturing change to a new connector cage mold to reduce the wear and tear on the device.
P000053/S129	02/23/2023	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the machining process.
P010015/S513	02/03/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement manufacturing process updates at a capacitor supplier.
P010015/S514	02/06/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modification to a rework connector adhesive process at Medtronic Swiss Operations.
P010015/S515	02/06/2023	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Updates to the material supplier and associated component specification and BOM of the guidewire clip accessory used to prevent unwanted dislocation of the guidewire during implantation.

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P010031/S813	02/03/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement manufacturing process updates at a capacitor supplier.
P010031/S814	02/06/2023	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modification to a rework connector adhesive process at Medtronic Swiss Operations.
P010047/S068	02/07/2023	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Change water quality inspection method from Oxidized Substances test to Total Organic Carbon test.
P020004/S194	02/13/2023	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Relocate and upgrade equipment for base tube manufacturing.
P030035/S193	02/10/2023	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Automate parts of the battery welding process to increase battery production capacity.
P030039/S028	02/23/2023	X - 30-Day Notice	COSEAL SURGICAL SEALANT	BAXTER BIO SCIENCE	Change in location of residuals testing.
P030040/S022	02/06/2023	X - 30-Day Notice	ADVIA CENTAUR HBC IGM READYPACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Implement second and third tier standards with more robust QC testing.
P030054/S403	02/21/2023	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Add an alternate supplier of aluminum foil for high-voltage capacitors anodes currently manufactured at Abbott¿s Liberty, SC capacitor manufacturing site.
P030054/S404	02/10/2023	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Update the manufacturing electrical test requirement and lower limit to increase manufacturing yields for ICD and CRT-D devices.
P030054/S406	02/10/2023	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Automate parts of the battery welding process to increase battery production capacity.
P040027/S093	02/13/2023	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Relocate and upgrade equipment for base tube manufacturing.
P040033/S037	02/22/2023	X - 30-Day Notice	BIRMINGHAM HIP RESURFACING (BHR) SYSTEM	SMITH & NEPHEW, INC.	Addition of a more time-efficient laser maker to the laser marking process for the Birmingham Hip Resurfacing System including moving the laser marking operation earlier in the manufacturing process flow.
P040034/S036	02/16/2023	X - 30-Day Notice	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCE S CORPORATIO N	Changing the test method from the oxidizable substances test to the total organic carbon test for the water for injection and changing the high-performance liquid chromatography test method to determine the purity of trilysine.

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P040037/S156	02/13/2023	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Relocate and upgrade equipment for base tube manufacturing.
P040043/S133	02/13/2023	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Relocate and upgrade equipment for base tube manufacturing.
P050017/S020	02/22/2023	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK IRELAND, LTD.	Alternate supplier for a component of external process challenge device.
P050023/S172	02/13/2023	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Modifications to the module test of the short circuit protection function.
P060004/S004	02/16/2023	X - 30-Day Notice	MEL 80 EXCIMER LASER SYSTEM	CARL ZEISS MEDITEC, INC.	Change the coating of the d24 VIS Window component of the laser.
P060004/S005	02/16/2023	X - 30-Day Notice	MEL 80 EXCIMER LASER SYSTEM	CARL ZEISS MEDITEC, INC.	Change the glue used on the Fluence Test Card.
P060011/S033	02/27/2023	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Update the software used with the optical test instruments to evaluate the depth of focus of the proposed EMV IOLs.
P060039/S113	02/06/2023	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Updates to the material supplier and associated component specification and BOM of the guidewire clip accessory used to prevent unwanted dislocation of the guidewire during implantation.
P070014/S064	02/02/2023	X - 30-Day Notice	LIFESTENT FLEXSTAR & FLEXSTAR XL VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	New supplier for a delivery system wheel sub-assembly.
P070026/S104	02/09/2023	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Introduction of alternate polishing belts from new suppliers due to supply chain shortages.
P080006/S174	02/06/2023	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Updates to the material supplier and associated component specification and BOM of the guidewire clip accessory used to prevent unwanted dislocation of the guidewire during implantation.
P080011/S154	02/15/2023	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Implementation of a replacement viscometer at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080013/S025	02/16/2023	X - 30-Day Notice	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Changing the test method from the oxidizable substances test to the total organic carbon test for the water for injection and changing the high-performance liquid chromatography test method to determine the purity of trilysine
P100010/S136	02/28/2023	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Transfer of the Arctic Front family of Cardiac Cryoablation Catheters and its Manual Retraction Kit Accessory (20MRK) from Medtronic's Montreal facility to Medtronic's Tijuana Mexico facility in addition to the implementation of manufacturing changes and minor updates to the packaging design.

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P100018/S038	02/28/2023	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Use of additional validated equipment for sealing the pouch of the Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology.
P100026/S093	02/17/2023	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the Automated Test Equipment hardware, software and database to improve the yield of components used in the production of the RNS Neurostimulators.
P100047/S205	02/02/2023	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Add an in-process quality inspection step to the manufacturing of the external battery charger.
P100047/S207	02/15/2023	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Add in-process inspection steps to Driveline Splice Kit assembly.
P110033/S068	02/28/2023	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Implementation of additional duplicate manufacturing equipment for the Juvéderm® Volux XC.
P110042/S180	02/21/2023	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replace a manual temperature and time chart recorder with a new automated MDI system.
P130006/S095	02/13/2023	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Relocate and upgrade equipment for base tube manufacturing.
P130021/S130	02/01/2023	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Implementation of a change in the sub-tier suppliers of sutures used in the manufacturing of the Evolut R, PRO, PRO+, and FX Transcatheter Aortic Valve (TAV).
P130029/S012	02/17/2023	X - 30-Day Notice	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Implementation of an additional stent cutting laser.
P140028/S076	02/16/2023	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Additional ovens used for delivery system component manufacturing at a supplier.
P140033/S078	02/10/2023	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Automate parts of the battery welding process to increase battery production capacity.
P150016/S023	02/07/2023	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Change water quality inspection method from Oxidized Substances test to Total Organic Carbon test.
P150030/S029	02/12/2023	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Introduction of an additional furnace for the heat-treating process of ANTHOLOGY stems.

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P150030/S030	02/12/2023	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Introduction of additional equipment to apply the closing seal of the 3rd peel pouch (protective packaging) for SL-Plus and POLARSTEM stems.
P150036/S067	02/14/2023	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Removal of the coating step to have uncoated malleable handles for the INTUITY delivery system.
P160013/S011	02/23/2023	X - 30-Day Notice	ORGAN CARE SYSTEM (OCS¿) LUNG SYSTEM	TRANSMEDICS, INC	Expand the clean room area at the existing manufacturing facility.
P160035/S032	02/17/2023	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Transfer of the cannula coating manufacturing process from supplier to Berlin Heart.
P160037/S015	02/27/2023	X - 30-Day Notice	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Add an alternative tube and plate filling method.
P160038/S025	02/17/2023	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Modification of an internal QC process.
P160045/S040	02/10/2023	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Remove an incoming Quality Control (QC) test for raw materials.
P160054/S052	02/16/2023	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	One-time use of an alternate formulation for the Outer Diameter epoxy used in the manufacturing of the hermetic motor assembly of the HeartMate 3 Left Ventricular Assist Device.
P170019/S041	02/24/2023	X - 30-Day Notice	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Modification of reagent QC procedures.
P170042/S012	02/02/2023	X - 30-Day Notice	COVERA¿ VASCULAR COVERED STENT	C.R. BARD, INC	New supplier for a delivery system wheel sub-assembly.
P180011/S053	02/16/2023	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Additional ovens used for delivery system component manufacturing at a supplier.
P180037/S012	02/02/2023	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	New supplier for a delivery system wheel sub-assembly.
P180046/S064	02/01/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change the hermetic welding process parameters for the IPG Model 4101
P180051/S002	02/23/2023	X - 30-Day Notice	ORGAN CARE SYSTEM (OCS) HEART SYSTEM	TRANSMEDICS, INC.	Expand the clean room area at the existing manufacturing facility.

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P190006/S064	02/01/2023	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change the hermetic welding process parameters for the IPG Model 4101
P190021/S004	02/16/2023	X - 30-Day Notice	REACTIV8 IMPLANTABLE NEUROSTIMULATION SYSTEM	MAINSTAY MEDICAL LIMITED	Qualification of a commercially-available, equivalent programmer laptop for the ReActiv8 Implantable Neurostimulation System.
P190023/S012	02/07/2023	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	changes to the controlled access environments (CAE) for the Portico and Navitor Transcatheter Heart Valves
P200023/S003	02/22/2023	X - 30-Day Notice	ZILVER VENA VENOUS SELF-EXPANDING STENT	COOK IRELAND LTD.	Alternate supplier for a component of external process challenge device.
P200031/S002	02/23/2023	X - 30-Day Notice	ORGAN CARE SYSTEM (OCS¿) LIVER	TRANSMEDICS, INC.	Expand the clean room area at the existing manufacturing facility.
P200037/S007	02/21/2023	X - 30-Day Notice	ASSURE WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) SYSTEM	KESTRA MEDICAL TECHNOLOGIES, INC.	Updates to specification limits for in-process testing required to accommodate a change to a resistor value on the user interface PCBA.
P200046/S014	02/15/2023	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Introduce the Optimized PCA Sterilization Cycle for sterilization of the Harmony delivery catheter and loading systems.
P200046/S015	02/12/2023	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Various modifications to the Harmony Delivery Catheter System (DCS) outer shaft subassembly manufacturing process.
P210032/S006	02/13/2023	X - 30-Day Notice	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Relocate and upgrade equipment for base tube manufacturing.

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