PMA Monthly approvals from 3/1/2021 to 3/31/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200025	03/23/2021	PMAO - PMA Origi	CLEARVISC OPHTHALMIC VISCOSURGICAL DEVICE (OVD)	BAUSCH HEALTH	Approval for the ClearVisc Ophthalmic Viscosurgical Device (OVD). ClearVisc 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).
P200029	03/17/2021	PMAO - PMA Origi	THERASPHERE	BOSTON SCIENTIFIC CORPORATIO N	Approval for TheraSphereTM. This device is indicated for use as selective internal radiation therapy (SIRT) for local tumor control of solitary tumors (1-8 cm in diameter), in patients with unresectable hepatocellular carcinoma (HCC), Child-Pugh Score A cirrhosis, well-compensated liver function, no macrovascular invasion, and good performance status.
P200046	03/26/2021	PMAO - PMA Origi	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Approval for the Harmony Transcatheter Pulmonary Valve (TPV) System. This device is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/ or pulmonary regurgitant fraction >= 30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

Total:3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810002/S110	03/17/2021	Y - 135 Review Tra	BILEAFLET-CENTER OPENING CARDIAC VALVE	ST. JUDE MEDICAL, INC.	Approval for a change to the double velour polyester fabric
P840001/S480	03/05/2021	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Approval for an update to the Clinical Summary manual for Medtronic Spinal Cord Stimulation (SCS) Therapy to include data from a post-market randomized controlled trial (RCT) entitled Stimgenics Open-Label, Post Market Study: A Clinical Trial to Study the Effects of Stimgenics Spinal Cord Stimulation (SGX-SCS) Programs in Treating Intractable Chronic Back Pain. There are no changes to indications for use, procedures or devices.
P920015/S252	03/04/2021	R - Real-Time Proc	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Approval for the use of an alternate connector sleeve design configuration for select leads.
P950037/S213	03/08/2021	N - Normal 180 Day	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for the Renamic Neo Programmer and updated software platforms.
P960016/S086	03/12/2021	R - Real-Time Proc	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Approval for minor design changes to a printed circuit board assembly and a change in supplier for the manufacture of the printed circuit board assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000009/S086	03/08/2021	N - Normal 180 Day	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for the Renamic Neo Programmer and updated software platforms.
P000013/S018	03/05/2021	R - Real-Time Proc	TRIDENT SYSTEM	HOWMEDICA OSTEONICS CORP.	Approval for a change in packaging of the Trident Alumina inserts which are part of the Trident Ceramic System. The foam raw material used to manufacture the foam packaging components will change from Opflex Microcell L1900/MC1900 to Vizion 2.0, and the foam packaging component tolerances listed on the foam packaging component drawings will be updated to +/- 0.120 inches to align the drawings with the manufacturing process currently used by the foam packaging component supplier.
P000037/S057	03/04/2021	R - Real-Time Proc	ON-X (R) PROSTHETIC HEART VALVE, MODEL ONXA	ON-X LIFE TECHNOLOGIES, INC.	Approval for changes to the polyester fiber in the suture component.
P010032/S168	03/05/2021	N - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for an update to the Clinician Programmer Application and Patient Controller Application to version 202.0 to include a Remote Care feature that facilitates remote communication between the Clinician Programmer Application and Patient Programmer Application.
P010051/S014	03/11/2021	R - Real-Time Proc	IMMULITE 2000 XPI ANTI-HBC	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Approval for labeling changes as a result of biotin interference testing.
P010053/S013	03/11/2021	R - Real-Time Proc	IMMULITE 2000 XPI ANTI-HBC IMG	SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS, LTD	Approved for labeling changes as a result of biotin interference testing.
P030004/S026	03/18/2021	N - Normal 180 Day	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Approval for a new hub design, pouch material change and labeling changes for the Apollo Onyx Delivery Micro Catheter.
P030031/S109	03/26/2021	O - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval of a revised protocol for the Real-World Experience of Catheter Ablation of Persistent Atrial Fibrillation post-approval study (PAS) protocol.
P030040/S019	03/11/2021	R - Real-Time Proc	ADVIA CENTAUR HBC IGM READYPACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for labeling changes as a result of biotin interference testing.
P030049/S016	03/11/2021	R - Real-Time Proc	ADVIA CENTAUR HBSAG READY PACK REAGENTS/ CONFIRMATORY READY PACK REAGENTS/QUALITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for labeling changes as a result of biotin interference testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030056/S019	03/11/2021	R - Real-Time Proc	ADVIA CENTAUR HCV READY PACK REAGENTS, ADVIA CENTAUR HCV QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for labeling changes as a result of biotin interference testing.
P040004/S019	03/11/2021	R - Real-Time Proc	ADVIA CENTAUR HBC TOTAL READYPACK REAGENTS/ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for labeling changes as a result of biotin interference testing.
P040014/S042	03/12/2021	R - Real-Time Proc	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Approval for minor design changes to a printed circuit board assembly and a change in supplier for the manufacture of the printed circuit board assembly.
P040029/S017	03/30/2021	O - Normal 180 Day	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	Approval for model name additions to the Euclid Systems Orthokeratology (tisilfocon A) Contact Lenses for Overnight Wear
P040042/S048	03/12/2021	R - Real-Time Proc	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Approval for minor design changes to a printed circuit board assembly and a change in supplier for the manufacture of the printed circuit board assembly.
P050023/S148	03/08/2021	N - Normal 180 Day	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for the Renamic Neo Programmer and updated software platforms.
P060011/S025	03/26/2021	N - Normal 180 Day	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Approval for the RayOne EMV, Model RAO200E, which is a preloaded intraocular lens (IOL) injector system extending the RayOne family of one-piece IOLs that incorporate an optical modification.
P060019/S050	03/12/2021	R - Real-Time Proc	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Approval for minor design changes to a printed circuit board assembly and a change in supplier for the manufacture of the printed circuit board assembly.
P070008/S116	03/08/2021	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 the Renamic Neo Programmer and updated software platforms.
P080004/S036	03/01/2021	N - Normal 180 Day	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for the Hoya ezSert injector system.
P080012/S069	03/02/2021	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for a minor software changes to address three minor issues with the Patient Therapy controller REF 12860.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100034/S025	03/09/2021	O - Normal 180 Day	NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT	NOVOCURE GMBH	Approval for a manufacturing site, Flex-Romania, located at Calea Torontalului, DN 6, Km 5,7, Timisoara, Romania 300668 to manufacture the INE Transducer Arrays in the Optune System.
P100034/S027	03/09/2021	O - Normal 180 Day	NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT	NOVOCURE GMBH	Approval for a manufacturing site, A.L. Electronics LTD, located at 24 Giron Abraham Street, Yehud, Israel 56217, to manufacture the INE Transducer Arrays in the Optune System.
P100039/S011	03/11/2021	R - Real-Time Proc	ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for labeling changes as a result of biotin interference testing.
P100045/S047	03/12/2021	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for a replacement liquid crystal display (LCD) in the Patient Electronics System.
P100047/S176	03/30/2021	S - Special CBE	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval of an update to an existing in process inspection procedure of the impeller at Medtronic.
P110008/S013	03/31/2021	O - Normal 180 Day	COFLEX® INTERLAMINAR TECHNOLOGY	SURGALIGN SPINE TECHNOLOGIES, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P110016/S073	03/12/2021	R - Real-Time Proc	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for minor design changes to a printed circuit board assembly and a change in supplier for the manufacture of the printed circuit board assembly.
P110041/S011	03/11/2021	R - Real-Time Proc	ADVIA CENTAUR HBSAGII	SIEMENS CORP.	Approval for labeling changes as a result of biotin interference testing.
P130008/S063	03/12/2021	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for: 1) Updates to the System Implant Manual to include an alternative implant technique for the sensing lead; and 2) Updates to the MRI Guidelines in conjunction with the update to the System Implant Manual
P130013/S038	03/24/2021	Y - 135 Review Tra	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for a change in composition to the detergent that is used in the cleaning of the subject device during its manufacturing process
P130020/S004	03/23/2021	N - Normal 180 Day	SENOCLAIRE	GE HEALTHCARE	Approval of the algorithm updates of the Synthetized 2D image called V-Preview for the Senographe Pristina 3D and SenoClaire.
P130022/S036	03/06/2021	N - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for the Senza Bluetooth Trial system which consists of the following components: Bluetooth Trial Stimulator (TSM), Bluetooth Patient Remote (PTR), and Updated Clinician Programmer Software (PS). Accessory kits that support the Senza Bluetooth Trial system consist of the Trial Stimulator Pouch kit, Extra battery kit and the Magnet kit.
P130022/S037	03/01/2021	O - Normal 180 Day	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for addition of OSCOR Caribe located at Santo Domingo Este, Dominican Republic as a secondary manufacturing site for the Percutaneous Leads of the Senza neuromodulation system. Pro-Tech Design & Manufacturing Inc. and Steris-Isomedix Services will continue to perform final packaging and sterilization, respectively.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130026/S068	03/12/2021	R - Real-Time Proc	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for minor design changes to a printed circuit board assembly and a change in supplier for the manufacture of the printed circuit board assembly.
P140003/S074	03/10/2021	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for labeling updates to revise the Instructions for Use and the High-Risk PCI Patient Brochure.
P140003/S076	03/12/2021	Y - 135 Review Tra	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for a new environmentally controlled manufacturing room at the same manufacturing facility.
P140009/S064	03/05/2021	N - Normal 180 Day	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for an update to the Clinician Programmer Application and Patient Controller Application to version 202.0 to include a Remote Care feature that facilitates remote communication between the Clinician Programmer Application and Patient Programmer Application.
P140025/S014	03/03/2021	N - Normal 180 Day	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for inclusion of an indication for LORBRENA ((lorlatinib). The device will be marketed under the trade name VENTANA ALK (D5F3) CDx Assay and is indicated for:VENTANA ALK (D5F3) CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark XT or BenchMark ULTRA automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), or ALECENSA® (alectinib) or LORBRENA® (lorlatinib). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.
P140026/S017	03/30/2021	S - Special CBE	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for changes to the tip pull test.
P150003/S071	03/19/2021	O - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval of the protocol for the post-approval study (PAS) protocol.
P150004/S043	03/05/2021	N - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for an update to the Clinician Programmer Application and Patient Controller Application to version 202.0 to include a Remote Care feature that facilitates remote communication between the Clinician Programmer Application and Patient Programmer Application.
P150005/S062	03/03/2021	O - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at 4100 Hamline Avenue North, St. Paul, Minnesota 55112 to perform manufacturing, repair, distribution and warehousing activities for the MetriQ Pump.
P160055/S014	03/17/2021	Y - 135 Review Tra	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for the introduction of an alternate mixing method used in the silicone mixing process for the RxSight Light Adjustable Lens (LAL).
P160055/S017	03/10/2021	O - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170011/S027	03/12/2021	Y - 135 Review Tra	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a new environmentally controlled manufacturing room at the same manufacturing facility.
P170032/S001	03/29/2021	O - Normal 180 Day	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, 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
P170043/S008	03/03/2021	O - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATION	Approval of the revised PAS protocol, IG2M-105-PASN to include the modified device version, Model G2-W
P180001/S002	03/31/2021	O - Normal 180 Day	ZENITH DISSECTION ENDOVASCULAR SYSTEM	WILLIAM COOK EUROPE APS	Approval of the labeling updates for the post-approval study (PAS) protocol.
P180029/S030	03/30/2021	O - Normal 180 Day	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval of revised protocols to truncate follow-up for the post-approval studies (PAS) protocol.
P190018/S009	03/15/2021	R - Real-Time Proc	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval to expand dioptric-power range to 6.0 D - 34.0 D for Clareon PanOptix Trifocal Hydrophobic IOL (CNWTT0), Clareon PanOptix Trifocal UV Absorbing IOL (CCWTT0), and Clareon PanOptix Trifocal Hydrophobic IOL models CNWTT3-CNWTT6, as well as approval for Clareon PanOptix Toric Trifocal Hydrophobic IOL with the AutonoMe Automated Preloaded Delivery Device (CNATT3-CNATT6).

Total: 56

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S078	03/31/2021	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Addition of a duplicate dehumidifier unit for SURGICEL® Absorbable Hemostats manufacturing at the Ethicon SARL, Neuchatel Switzerland site
N970012/S185	03/16/2021	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Manufacturing change to include the addition of an inspection of the Kink Resistant Tubing cylinder angle.
P820033/S014	03/03/2021	X - 30-Day Notice	PLASMAFLO OP-05 W(A) ASAHI PLASMA SEPARATOR	ASAHI KASEI MEDICAL CO., LTD.	Change in the sterilization test method performed at the 3-month sterilization dose audit for the Plasmaflo OP-05W(A).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S193	03/04/2021	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process change relating to raw material at a supplier.
P830061/S194	03/29/2021	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Relocate the final packaging operations and select processing and equipment.
P840064/S074	03/03/2021	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Introduction of Lifecore Biomedical, LLC Site 2 as a additional quality control laboratory for release and stability chemistry testing of the VISCOAT and PROVISC Ophthalmic Viscosurgical Devices, as well as the DUOVISC Ophthalmic Viscoelastic System.
P850089/S154	03/04/2021	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process change relating to raw material at a supplier.
P860004/S369	03/25/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	New supplier of the jewel bearing and plug stone subcomponents of the SynchroMed II motor subassembly.
P860004/S370	03/31/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Automating the manual process of updating preloaded Data Flash Image (DFI) that manages battery performance for the FOB component.
P890003/S442	03/04/2021	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Process change relating to raw material at a supplier.
P890047/S057	03/03/2021	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Introduction of Lifecore Biomedical, LLC Site 2 as a additional quality control laboratory for release and stability chemistry testing of the VISCOAT and PROVISC Ophthalmic Viscosurgical Devices, as well as the DUOVISC Ophthalmic Viscoelastic System.
P900061/S164	03/04/2021	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process change relating to raw material at a supplier.
P920015/S253	03/04/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Process change relating to raw material at a supplier.
P920015/S254	03/29/2021	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Relocate the final packaging operations and select processing and equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930039/S223	03/04/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Process change relating to raw material at a supplier.
P930039/S224	03/29/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Relocate the final packaging operations and select processing and equipment.
P950009/S024	03/29/2021	X - 30-Day Notice	AUTOPAP(R) 300 QC AUTOMATIC PAP SCREENER/QC SYSTEM	BD DIAGNOSTICS	Component replacement with the like-for-like objective lens.
P950024/S098	03/04/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Process change relating to raw material at a supplier.
P950029/S131	03/10/2021	X - 30-Day Notice	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Update the in-process treatment of the pacemaker headers and the final cleaning process for pacemakers and their screwdriver accessory.
P960009/S398	03/31/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Automating the manual process of updating preloaded Data Flash Image (DFI) that manages battery performance for the FOB component.
P960030/S073	03/18/2021	X - 30-Day Notice	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ST. JUDE MEDICAL	Implementation of MCRD component manufacturing process improvements and changes associated with the optimized drug release/elution test method for Isoflex leads.
P970004/S330	03/31/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Automating the manual process of updating preloaded Data Flash Image (DFI) that manages battery performance for the FOB component.
P970051/S204	03/26/2021	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Add an automated magnet detector to verify the presence of the magnet before the implant is released.
P980016/S769	03/04/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process change relating to raw material at a supplier.
P980016/S770	03/03/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Automate the Contact Assembly manufacturing process.
P980016/S771	03/08/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of receiving and incoming inspection activities for a device component from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company Junco site and the FedEx/3PL facility in Guaynabo, Puerto Rico.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S772	03/25/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add inspection steps to the manufacturing process for batteries used in the Polaris family of devices.
P980016/S773	03/03/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Replace the Boiling Heptane Surface Treatment with a Vacuum Plasma Surface Treatment.
P980016/S776	03/12/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	New supplier for the 6-inch wafer bumping process.
P980016/S777	03/16/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update Final Visual Inspection criteria for hybrids at Medtronic Tempe Campus.
P980035/S671	03/03/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Automate the Contact Assembly manufacturing process.
P980035/S672	03/08/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Transfer of receiving and incoming inspection activities for a device component from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company Junco site and the FedEx/3PL facility in Guaynabo, Puerto Rico.
P980035/S674	03/25/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add Medtronic Puerto Rico Operations Company, Juncos internal laboratory as an alternate to perform viable test for compressed air monitoring.
P980035/S675	03/03/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Replace the Boiling Heptane Surface Treatment with a Vacuum Plasma Surface Treatment.
P980035/S678	03/12/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	New supplier for the 6-inch wafer bumping process.

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P980035/S680	03/29/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Relocate the final packaging operations and select processing and equipment.
P980040/S131	03/08/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Additional image quality manufacturing process step for the TECNIS Symfony Toric II OptiBlue ERV IOLs, Models ZXW50, ZXW225, ZXW300, ZXW375 manufactured at the AMO Groningen B.V. facility.
P980040/S132	03/23/2021	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Change to the manufacturing process of the TECNIS Symfony Optiblue ERV IOL, Model ZXR00V, at the Puerto Rico facility.
P980050/S132	03/04/2021	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Process change relating to raw material at a supplier.
P010013/S083	03/30/2021	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Consolidation of inspection test steps to reduce any over-manipulation of the devices in the manufacturing process and modification of the current inspection sampling method for the Array Liner and Array Sewing Assembly of the NovaSure Gen 4.1 devices from a defined sampling size to a credit sampling method.
P010015/S466	03/04/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Process change relating to raw material at a supplier.
P010015/S467	03/03/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Automate the Contact Assembly manufacturing process.
P010015/S468	03/08/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Transfer of receiving and incoming inspection activities for a device component from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company Junco site and the FedEx/3PL facility in Guaynabo, Puerto Rico.
P010015/S471	03/12/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	New supplier for the 6-inch wafer bumping process.
P010031/S731	03/04/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process change relating to raw material at a supplier.

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P010031/S732	03/03/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Automate the Contact Assembly manufacturing process.
P010031/S733	03/08/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of receiving and incoming inspection activities for a device component from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company Junco site and the FedEx/3PL facility in Guaynabo, Puerto Rico.
P010031/S734	03/25/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add inspection steps to the manufacturing process for batteries used in the Polaris family of devices.
P010031/S735	03/03/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Replace the Boiling Heptane Surface Treatment with a Vacuum Plasma Surface Treatment.
P010031/S738	03/12/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New supplier for the 6-inch wafer bumping process.
P010031/S739	03/16/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update Final Visual Inspection criteria for hybrids at Medtronic Tempe Campus.
P020004/S180	03/25/2021	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an FEP formulation change by a sub-tier supplier in the manufacturing of Conformable GORE® TAG® Thoracic Endoprosthesis (CTAG Device), GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL SYSTEM (CMDS Device) and GORE® EXCLUDER® Iliac Branch Endoprosthesis Iliac Bifurcated Component (IBE IBC Device).

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P020045/S094	03/17/2021	X - 30-Day Notice	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Additional inspection criteria for components during manufacturing.
P020047/S074	03/24/2021	X - 30-Day Notice	MULTI-LINK VISION/MINI/8 CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Change to the sub-assembly stent inspection process to increase manufacturing efficiency.
P030009/S100	03/12/2021	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P030031/S113	03/02/2021	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Add an additional supplier for the Pebax 40D Tubing Fluid Lumen component.
P030036/S130	03/04/2021	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process change relating to raw material at a supplier.
P030054/S390	03/18/2021	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Implementation of MCRD component manufacturing process improvements and changes associated with the optimized drug release/elution test method for Isoflex leads.
P040014/S043	03/24/2021	X - 30-Day Notice	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Addition of an alternative bacterial endotoxin test method.
P040027/S084	03/04/2021	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate manufacturing site to produce the ultra-thin walled component of the GORE VIATORR TIPS Endoprosthesis and GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion.
P040027/S085	03/04/2021	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Implementation of a change from a manual inspection method to an automated inspection method for in-process verification of GORE® VIATORR® TIPS Endoprosthesis and GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion.
P040036/S078	03/02/2021	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Add an additional supplier for the Pebax 40D Tubing Fluid Lumen component.
P040042/S049	03/24/2021	X - 30-Day Notice	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Addition of an alternative bacterial endotoxin test method.

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P040043/S124	03/25/2021	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an FEP formulation change by a sub-tier supplier in the manufacturing of Conformable GORE® TAG® Thoracic Endoprosthesis (CTAG Device), GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL SYSTEM (CMDS Device) and GORE® EXCLUDER® Iliac Branch Endoprosthesis Iliac Bifurcated Component (IBE IBC Device).
P050010/S023	03/15/2021	X - 30-Day Notice	PRODISC -L TOTAL DISC REPLACEMENT DEVICE	CENTINEL SPINE, LLC	Change to eliminate redundant quality control method regarding endplate coating thickness.
P050028/S084	03/09/2021	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Move the manufacturing site of critical sub-assembly.
P050050/S017	03/15/2021	X - 30-Day Notice	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	STRYKER CORPORATIO N	Change in sub-suppliers for the citric passivation steps for the STAR Pin Tube (727-0001-01) and the STAR Pin Tube Cap (727-0001-02) components.
P060019/S051	03/24/2021	X - 30-Day Notice	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Addition of an alternative bacterial endotoxin test method.
P060030/S085	03/09/2021	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Move the manufacturing site of critical sub-assembly.
P060039/S106	03/04/2021	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Process change relating to raw material at a supplier.
P060040/S079	03/21/2021	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Addition of 5 alternate components from alternate second tier suppliers for the HeartMate 3 System Controller PCBAs, one of which is a shared component with the HeartMate II System Controller PCBA.
P070006/S016	03/22/2021	X - 30-Day Notice	T SPOT-TB TEST	OXFORD IMMUNOTEC,L TD.	Scale up of batch size for device components.
P070015/S148	03/24/2021	X - 30-Day Notice	XIENCE AND PROMUS EVEROLIMUS ELUTING CORONARY STENT SYSTEMS	ABBOTT VASCULAR INC.	Change to the sub-assembly stent inspection process to increase manufacturing efficiency.
P080006/S158	03/04/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Process change relating to raw material at a supplier.
P080006/S159	03/11/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Add Rice Creek and Pace Analytical to perform testing of silicon material.
P080006/S160	03/25/2021	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Update the process parameter of a current Laser Weld machine.
P080007/S024	03/23/2021	X - 30-Day Notice	BARD E-LUMINEXX VASCULAR STENT	BARD PERIPHERAL VASCULAR, INC.	Addition of a new laser for welding radiopaque markers to the stent.
P080011/S123	03/02/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Introduction of a new autoclave.

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P080025/S225	03/31/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Automating the manual process of updating preloaded Data Flash Image (DFI) that manages battery performance for the FOB component.
P080026/S024	03/05/2021	X - 30-Day Notice	ABBOTT REALTIME HBV ASSAY	ABBOTT MOLECULAR, INC.	Addition of alternative testing location for a device component.
P090013/S314	03/04/2021	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Process change relating to raw material at a supplier.
P100009/S039	03/09/2021	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Semi-automation of the mandrel removal manufacturing step for the Delivery Catheter shaft.
P100010/S113	03/03/2021	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Changes to the final inspection test methods for the Balloon Outer Diameter and Pushbutton Clearance.
P100017/S024	03/05/2021	X - 30-Day Notice	ABBOTT REALTIME HCV, ABBOTT REALTIME HCV AMPLIFICATION REAGENT KIT, ABBOTT REALTIME HVC CONTROL KIT, ABBOTT REALTIME HCV	ABBOTT MOLECULAR, INC.	Addition of alternative testing location for a device component.
P100021/S087	03/02/2021	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Use of an electronic Manufacturing Execution System (MES) to replace the current paper-based device history record (DHR).
P100021/S088	03/12/2021	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P100040/S044	03/02/2021	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Use of an electronic Manufacturing Execution System (MES) to replace the current paper-based device history record (DHR).
P100040/S045	03/12/2021	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P100045/S048	03/09/2021	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Manufacturing parameter changes to the UV curing process.
P100047/S175	03/11/2021	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Introducing a new solder machine used for the assembly of HVAD power adapters.
P110005/S008	03/15/2021	X - 30-Day Notice	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Change in volume measurement process.
P110010/S189	03/05/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the incoming verification of the active pharmaceutical ingredient.

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P110010/S190	03/24/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the acceptance criteria for the population of white phase precipitate present in platinum chromium alloys (PCA) tubing.
P110013/S108	03/12/2021	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P110015/S007	03/16/2021	X - 30-Day Notice	GASTRIC EMPTYING BREATH TEST (GEBT)	ADVANCED BREATH DIAGNOSTICS	Changes to the quality control process used during the manufacture of the 13C-Spirulina substrate. The substrate is a component of the GEBT.
P110016/S074	03/24/2021	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Addition of an alternative bacterial endotoxin test method.
P110019/S116	03/24/2021	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change to the sub-assembly stent inspection process to increase manufacturing efficiency.
P110035/S065	03/03/2021	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate facility for a nitinol tubing supplier.
P110037/S055	03/09/2021	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Move the manufacturing site of critical sub-assembly.
P120012/S019	03/05/2021	X - 30-Day Notice	ABBOTT REALTIME HCV GENOTYPE II, ABBOTT REALTIME HCV GENOTYPE II CONTROL KIT, URACIL-N-GLYCOSYLASE (UNG)	ABBOTT MOLECULAR	Addition of alternative testing location for a device component.
P120014/S011	03/10/2021	X - 30-Day Notice	BIOMERIEUX THXID BRAF ASSAY KIT	BIOMERIEUX, INC.	Qualification of rooms to support manufacturing activities.
P120017/S027	03/04/2021	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Process change relating to raw material at a supplier.
P130009/S113	03/19/2021	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add low ethylene oxide concentration sterilization process (Cycle 335) for sterilization of THV devices.

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P130014/S010	03/05/2021	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Replacement of four ovens for drying glassware.
P130017/S047	03/17/2021	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Manufacturing changes to a tube assembly.
P130017/S048	03/25/2021	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Transfer of scaled-up manufacturing processes and testing methods to a previously approved manufacturing facility.
P130021/S086	03/02/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Use of an electronic Manufacturing Execution System (MES) to replace the current paper-based device history record (DHR).
P130021/S087	03/12/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P130021/S089	03/24/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Introduction of an additional pre-heating workstep to the manufacturing of the 18Fr delivery system.
P130029/S009	03/23/2021	X - 30-Day Notice	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Addition of a new laser for welding radiopaque markers to the stent.
P130030/S072	03/24/2021	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Update the acceptance criteria for the population of white phase precipitate present in platinum chromium alloys (PCA) tubing.
P140009/S066	03/05/2021	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Supplier manufacturing update to the Deep Brain Stimulation Multilead Trial Cable printed circuit board depanel process, label format, and solder and flux material.
P140010/S056	03/02/2021	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Use of an electronic Manufacturing Execution System (MES) to replace the current paper-based device history record (DHR).
P140010/S058	03/12/2021	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P140018/S022	03/22/2021	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Change to the External Process Challenge Device (EPCD) used in device sterilization.

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P140018/S023	03/02/2021	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Use of an electronic Manufacturing Execution System (MES) to replace the current paper-based device history record (DHR).
P140028/S067	03/03/2021	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of an alternate facility for a nitinol tubing supplier.
P140029/S036	03/03/2021	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Introduction of a new equipment to perform automated assembly and sealing of the blister packaging during manufacturing.
P140031/S127	03/19/2021	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Add low ethylene oxide concentration sterilization process (Cycle 335) for sterilization of THV devices.
P140031/S128	03/31/2021	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Height increase and assembly adjustments for the laser cut main skirt component.
P140032/S067	03/25/2021	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	New supplier of the jewel bearing and plug stone subcomponents of the SynchroMed II motor subassembly.
P150003/S070	03/05/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the incoming verification of the active pharmaceutical ingredient.
P150003/S072	03/24/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update the acceptance criteria for the population of white phase precipitate present in platinum chromium alloys (PCA) tubing.
P150011/S022	03/17/2021	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	New sub-supplier for sutures used in Perceval devices.
P150033/S093	03/03/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Automate the Contact Assembly manufacturing process.
P150033/S097	03/16/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update Final Visual Inspection criteria for hybrids at Medtronic Tempe Campus.
P150033/S099	03/26/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement SAP Manufacturing Intelligence Integration Scan Verify software.
P150048/S052	03/23/2021	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Transfer of KONECT AVC final assembly from one building to another building within the Irvine, CA facility.

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P160015/S010	03/09/2021	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Eliminate redundant shock testing during manufacture of the AED Plus.
P160015/S011	03/18/2021	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Update the existing HiPot test fixture.
P160021/S030	03/25/2021	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Change to heparin activity lot release acceptance criteria.
P160021/S031	03/31/2021	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Changes to the balloon delivery system tubing extrusion and hub bonding processes.
P160022/S026	03/18/2021	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	Update the existing HiPot test fixture.
P160022/S027	03/26/2021	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	Introduction of a new Automatic Optical Inspection (AOI) machine used during PCBA manufacturing at the supplier.

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P160026/S024	03/19/2021	X - 30-Day Notice	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Replacement of the washing system used during capacitor manufacturing.
P160029/S010	03/10/2021	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Inspection changes for components and subassemblies used to build AEDs.
P160036/S002	03/11/2021	X - 30-Day Notice	HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM	DT MEDTECH LLC	Introduction of a new robotic system at Marle Orthopaedics SAS (approved supplier of DT MedTech). The new robotic system will replace the existing robotic system which is used to manufacture components for the Hintermann Series H3 Total Ankle Replacement System.
P160043/S044	03/12/2021	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P160044/S003	03/05/2021	X - 30-Day Notice	ABBOTT REALTIME CMV	ABBOTT MOLECULAR	Addition of alternative testing location for a device component.
P160054/S034	03/21/2021	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATIO N	Addition of 5 alternate components from alternate second tier suppliers for the HeartMate 3 System Controller PCBAs, one of which is a shared component with the HeartMate II System Controller PCBA.
P160054/S035	03/23/2021	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATIO N	Transfer the final Motor Cap to Motor Housing laser weld from one welder system to another.
P160055/S018	03/19/2021	X - 30-Day Notice	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Addition of a second source supplier for a contact lens accessory used with the LDD and an expansion of the contact lens accessory packaging to hold three devices.
P170002/S013	03/19/2021	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Declare the change of analytical laboratory in charge of the assay of sodium hyaluronate (NaHA) content in the finished products at the release step for RHA2, RHA3, and RHA4.
P170005/S003	03/03/2021	X - 30-Day Notice	ABBOTT REALTIME IDH2	ABBOTT MOLECULAR INC.	Addition of alternative testing location for a device component.
P170008/S033	03/31/2021	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Update to the sampling plan for the securement force testing for additional stent sizes.
P170027/S003	03/26/2021	X - 30-Day Notice	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Change to the catheter qualification process.
P170027/S004	03/29/2021	X - 30-Day Notice	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Single use packaging design for the fully assembled one-piece Console.

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P170041/S005	03/03/2021	X - 30-Day Notice	ABBOTT REALTIME IDH1	ABBOTT MOLECULAR, INC.	Addition of alternative testing location for a device component.
P180011/S041	03/03/2021	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate facility for a nitinol tubing supplier.
P180028/S007	03/10/2021	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Inspection changes for components and subassemblies used to build AEDs.
P180034/S004	03/16/2021	X - 30-Day Notice	TACK ENDOVASCULAR SYSTEM (6F)	PHILIPS IMAGE GUIDED THERAPY CORPORATION	Alternate supplier for the tip component of the delivery system.
P180035/S007	03/26/2021	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Introduction of new reduced quality control sampling plan for lens dry process along with new inspection software.
P180035/S008	03/26/2021	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Introducing an alternative supplier of sealer heads used in the blister sealing process.
P180046/S030	03/01/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change the manufacturing process method for the hole in the PNE Lead stylet handle from being drilled/machined through the molded handle to molding the hole directly into the handle.
P180046/S031	03/02/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	1. Changes to manufacturing instructions for a critical device component at a contract manufacturer; 2. New inspection procedures for a critical device component; and 3. Changes made to the temperature sensor calibration of a critical device component.
P180046/S032	03/04/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Updates to quality control procedures and supporting manufacturing equipment.
P180046/S033	03/16/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Qualification of Heraeus Medical Components as an alternate supplier of the Axonics Leads.
P180046/S034	03/25/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Updates related to the pre-cutting of the polyurethane extrusion and a change in the color of the ETFE insulation for the Percutaneous Extension component.

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P190006/S030	03/01/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Change the manufacturing process method for the hole in the PNE Lead stylet handle from being drilled/machined through the molded handle to molding the hole directly into the handle.
P190006/S031	03/02/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	1. Changes to manufacturing instructions for a critical device component at a contract manufacturer; 2. New inspection procedures for a critical device component; and 3. Changes made to the temperature sensor calibration of a critical device component.
P190006/S032	03/04/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Updates to quality control procedures and supporting manufacturing equipment.
P190006/S033	03/16/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Qualification of Heraeus Medical Components as an alternate supplier of the Axonics Leads.
P190006/S034	03/25/2021	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Updates related to the pre-cutting of the polyurethane extrusion and a change in the color of the ETFE insulation for the Percutaneous Extension component.
P190008/S011	03/02/2021	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Use of an electronic Manufacturing Execution System (MES) to replace the current paper-based device history record (DHR).
P190008/S013	03/12/2021	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Implementation of new product label and component verification software for use on manufacturing lines in Medtronic Ireland.
P190019/S007	03/15/2021	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Addition of four stretchers.
P190024/S004	03/29/2021	X - 30-Day Notice	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Modification of a method for preparing qualified samples used in QC testing.
P190025/S005	03/05/2021	X - 30-Day Notice	ALINITY M HCV	ABBOTT MOLECULAR, INC.	Addition of alternative testing location for a device component.
P200013/S003	03/05/2021	X - 30-Day Notice	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Addition of alternative testing location for a device component.

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P200013/S004	03/08/2021	X - 30-Day Notice	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Addition of alternative testing location for a device component.
P200015/S008	03/19/2021	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Add low ethylene oxide concentration sterilization process (Cycle 335) for sterilization of THV devices.
P200028/S001	03/08/2021	X - 30-Day Notice	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Changes to the visual inspection methodology and acceptance criteria for a laser welding process.
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