PMA Monthly approvals from 4/1/2021 to 4/30/2021

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200002	04/28/2021	PMAO - PMA Origi	EPI-SENSE GUIDED COAGULATION SYSTEM	ATRICURE, INC.	Approval for the EPi-Sense Guided Coagulation System is intended for the treatment of symptomatic long-standing persistent atrial fibrillation (continuous atrial fibrillation greater than 12 months duration) when augmented in a hybrid procedure with an endocardial catheter listed in the instructions for use, in patients who are refractory or intolerant to at least one Class I and/or III antiarrhythmic drug (AAD); and, in whom the expected benefit from rhythm control outweighs the potential known risks associated with a hybrid procedure such as delayed post-procedure inflammatory pericardial effusions.
P200019	04/22/2021	PMAO - PMA Origi	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS	Approval for the Ventana MMR RxDx Pavel as a CDx for identifying patients with endometrial cancer with dMMR status who may benefit from treatment with Jemperli.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830060/S084	04/16/2021	O - Normal 180 Day	VENTAK AND AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEMS	BOSTON SCIENTIFIC	Approval for a manufacturing site located at Suzhou Jenitek Medical Co., Ltd. (Jenitek), No.70 Emeishan Road, SND, Suzhou, Jiangsu, China for finished device manufacturing.
P870024/S058	04/23/2021	O - Normal 180 Day	FLUOROPERM RGP CONTACT LENSES	COOPERVISION, INC.	Approval for a new manufacturing facility located at Paragon Vision Sciences, Inc., 2120 W Guadalupe Rd. Gilbert, Arizona.
P880047/S040	04/21/2021	S - Special CBE	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Approval for revisions to the Instructions for Use to include an additional precaution for the GYNECARE INTERCEED Absorbable Adhesion Barrier.
P910007/S055	04/22/2021	R - Real-Time Proc	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH).
P950005/S077	04/07/2021	S - Special CBE	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Approval for the addition of warnings from other catheter lines and the clarification of existing warnings and instructions.
P950037/S220	04/30/2021	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for updates to programmer software to versions PSW 2100.U and NEO 2100.U to reduce the number of capacitor reformations and move the timepoint for capacitor reformations from overnight to daytime for various Biotronik implantable cardiac devices.

Data as of 05/14/2021 03:05 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S328	04/09/2021	R - Real-Time Proc	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for minor design change to the foramen needles provided with various InterStim Therapy lead kits and separately packaged kits.
P970051/S203	04/21/2021	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the Model CP1001 and CP1002 Sound Processors, which are additions to the CP1000 series of Sound Processors.
P980007/S044	04/22/2021	R - Real-Time Proc	AXSYM FREE PSA	ABBOTT LABORATORIES	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH).
P980016/S768	04/16/2021	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the addition of through-holes to transformer printed circuit board headers used in CRT-D and ICD devices.
P980023/S105	04/30/2021	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for updates to programmer software to versions PSW 2100.U and NEO 2100.U to reduce the number of capacitor reformations and move the timepoint for capacitor reformations from overnight to daytime for various Biotronik implantable cardiac devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980040/S124	04/28/2021	P - Panel Track	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for TECNIS Synergy Intraocular Lens (Model ZFR00V), TECNIS Synergy Toric II Intraocular Lens (Models ZFW150, ZFW225, ZFW300, and ZFW375), TECNIS Synergy IOL with TECNIS Simplicity Delivery System (Model DFR00V), TECNIS Synergy Toric II IOL with TECNIS Simplicity Delivery System (Models DFW150, DFW225, DFW300 and DFW375). The TECNIS Synergy IOL, Model ZFR00V, is indicated for primary implantation for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy IOL mitigates the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only. The TECNIS Synergy Toric II IOL, Models ZFW150, ZFW225, ZFW300, ZFW375, are indicated for primary implantation for the visual correction of aphakia and for the reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy Toric II IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only. The TECNIS Simplicity Delivery System is used to fold and assist in inserting the TECNIS Synergy IOL which is indicated for primary implantation for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy IOL mitigates the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only. The TECNIS Simplicity Delivery System is used to fold and assist in inserting the TECNIS Synergy Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy Toric II IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.
P980052/S009	04/27/2021	O - Normal 180 Day	TMJ CONCEPTS PATIENT-FITTED TMJ RECONSTRUCTION PROSTHESIS	TMJ CONCEPTS	Approval for heat treatment of surgical instruments by Solar Atmospheres, located at 8606 Live Oak Ave Fontana, CA.
P990025/S062	04/07/2021	S - Special CBE	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for the addition of warnings from other catheter lines and the clarification of existing warnings and instructions.
P000009/S090	04/30/2021	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for updates to programmer software to versions PSW 2100.U and NEO 2100.U to reduce the number of capacitor reformations and move the timepoint for capacitor reformations from overnight to daytime for various Biotronik implantable cardiac devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S463	04/01/2021	O - Normal 180 Day	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for the proposed clinical study summary labeling for the Multiple Point Pacing (MPP) Post Approval Clinical Study
P010031/S728	04/01/2021	O - Normal 180 Day	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for the proposed clinical study summary labeling for the Multiple Point Pacing (MPP) Post Approval Clinical Study.
P010031/S730	04/16/2021	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for the addition of through-holes to transformer printed circuit board headers used in CRT-D and ICD devices.
P010068/S062	04/07/2021	S - Special CBE	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for the addition of warnings from other catheter lines and the clarification of existing warnings and instructions.
P020025/S130	04/08/2021	O - Normal 180 Day	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval for a manufacturing site located at Boston Scientific Corporation, 4100 Hamline Avenue North, Saint Paul, Minnesota, for the manufacturing, distribution, and warehousing activities for the IntellaTip MiFi Filter Module and IntellaTip MiFi Reference Cable.
P030031/S114	04/07/2021	S - Special CBE	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for the addition of warnings from other catheter lines and the clarification of existing warnings and instructions.
P030031/S115	04/07/2021	S - Special CBE	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for the addition of warnings from other catheter lines and the clarification of existing warnings and instructions.
P030047/S041	04/01/2021	S - Special CBE	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS CORP.	Approval for changes to the tip pull test.
P040036/S079	04/07/2021	S - Special CBE	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for the addition of warnings from other catheter lines and the clarification of existing warnings and instructions.
P050023/S154	04/30/2021	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for updates to programmer software to versions PSW 2100.U and NEO 2100.U to reduce the number of capacitor reformations and move the timepoint for capacitor reformations from overnight to daytime for various Biotronik implantable cardiac devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050042/S045	04/22/2021	R - Real-Time Proc	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH).
P050051/S041	04/22/2021	R - Real-Time Proc	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH).
P060011/S026	04/27/2021	R - Real-Time Proc	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Approval for RayOne Spheric IOL Model RAO100C.
P060035/S032	04/22/2021	R - Real-Time Proc	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH).
P070008/S122	04/30/2021	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for updates to programmer software to versions PSW 2100.U and NEO 2100.U to reduce the number of capacitor reformations and move the timepoint for capacitor reformations from overnight to daytime for various Biotronik implantable cardiac devices.
P080023/S034	04/22/2021	R - Real-Time Proc	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH).
P080025/S223	04/09/2021	R - Real-Time Proc	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for minor design change to the foramen needles provided with various InterStim Therapy lead kits and separately packaged kits.
P090003/S051	04/30/2021	R - Real-Time Proc	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for the use of an alternate strain relief component of the delivery system Y-connector assembly.
P100018/S026	04/13/2021	N - Normal 180 Day	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Approval for design changes to the Pipeline Flex Embolization Device to add a surface modification to the implant.
P100018/S029	04/29/2021	N - Normal 180 Day	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Approval for the inclusion of radial access considerations in the Pipeline Flex Embolization Device labeling.
P100044/S048	04/09/2021	R - Real-Time Proc	PROPEL	INTERSECT ENT	Approval for the change of e-beam sterilization dose for the Propel and Propel Mini Sinus Implants.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100045/S050	04/06/2021	O - Normal 180 Day	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for manufacturing sites located at Midwest Sterilization Corporation, PO BOX 411, 1204 Lenco Avenue, Jackson, Missouri, USA, FEI: 1928237 for Ethylene Oxide Sterilization and Sterigenics US, LLC, 5725 W. Harold Gatty Drive, Salt Lake City, Utah, USA, FEI: 1721676 for Ethylene Oxide Sterilization.
P110029/S034	04/22/2021	R - Real-Time Proc	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH).
P120008/S017	04/22/2021	R - Real-Time Proc	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Approval to modify the ARCHITECT i1000SR probe wash with an alternate wash delivery system (AWDS), and to modify the ARCHITECT i2000SR and Alinity i with Induction Heating (IH)
P130005/S033	04/23/2021	R - Real-Time Proc	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for aminor design change and labeling clarifications.
P140016/S002	04/27/2021	O - Normal 180 Day	ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT	COOK MEDICAL INCORPORATED	Approval for labeling update which incorporates the final 5-year results from the post-approval study for continued follow-up of pivotal and continued access patients enrolled in the premarket study.
P150026/S012	04/06/2021	N - Normal 180 Day	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for the additional of a silicone coating to the inside of the Excalibur balloon.
P160017/S089	04/19/2021	O - Normal 180 Day	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval to introduce the MiniMed 770G System to the post-approval study and to provide protocol updates to meet enrollment requirements.
P160026/S023	04/22/2021	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for minor software and labeling changes
P160029/S008	04/06/2021	R - Real-Time Proc	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Approval for a change in speaker component for the HeartStart FRx, OnSite, and Home Defibrillator devices.
P160042/S015	04/16/2021	S - Special CBE	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for labeling changes to post-market surveillance information of Revanesse Versa, Revanesse Versa+, and Revanesse Lips+.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160055/S015	04/20/2021	N - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for (1) a simplified fixed output beam aperture in place of the current motorized aperture, (2) update to LDD lock-in treatment profile to reduce ocular exposure, (3) update to the Windows 10 operating system, (4) extension of dioptric power range to include +4.0 to +9.0 diopters, (5) introduce an additional UV-A absorber to the anterior portion of the LAL, and (6) updates to manufacturing work instructions, LDD Graphical User Interface (GUI), and user labeling to reflect all modifications.
P170002/S014	04/15/2021	S - Special CBE	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for updated labeling to include adverse events from post market surveillance for RHA 2, RHA 3, and RHA 4
P180025/S009	04/19/2021	N - Normal 180 Day	MANTA VASCULAR CLOSURE DEVICE	ESSENTIAL MEDICAL, INC.	Approval for the addition of an additional depth locator, size 14F, to be packaged separately from the MANTA Vascular Closure Device.
P180028/S005	04/06/2021	R - Real-Time Proc	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Approval for a change in speaker component for the HeartStart FRx, OnSite, and Home Defibrillator devices.
P180032/S005	04/27/2021	S - Special CBE	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Approval for the addition of additional adverse event information and clarification of troubleshooting instructions to the labeling of the instructions for use (IFU-3243 Rev E).
P190015/S009	04/19/2021	R - Real-Time Proc	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Approval for an increase in the labeled shelf life for the straight extension stent-grafts in the TREO Abdominal Stent-Graft System (TREO) product family from 2 years to 3 years.
P190018/S010	04/23/2021	O - Normal 180 Day	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 for new manufacturing facilities located at Alcon Research, LLC, AODC-South, 6065 Kyle Lane, Huntington, WV 25702 and Alcon Research, LLC, AODC-North, 2 Vision Lane, Lesage, WV.
P190025/S004	04/26/2021	R - Real-Time Proc	ALINITY M HCV	ABBOTT MOLECULAR, INC.	Approval for the design change to the access hole diameter of the Alinity m Universal Sample Rack Retention Bar.
P200013/S002	04/26/2021	R - Real-Time Proc	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval for the design change to the access hole diameter of the Alinity m Universal Sample Rack Retention Bar.
P200015/S009	04/16/2021	O - Normal 180 Day	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for the Statistical Analysis Plan (SAP) for the COMPASSION S3 Post-Approval Study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200022/S003	04/01/2021	P - Panel Track	SIMPLIFY® CERVICAL ARTIFICIAL DISC	SIMPLIFY MEDICAL, INC.	Approval for Simplify® Cervical Artificial Disc that is indicated for use in skeletally mature patients for reconstruction of the disc at one or two contiguous levels from C3-C7 following discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (e.g., X-rays, computed tomography (CT), magnetic resonance imaging (MRI)): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. Patients receiving Simplify® Cervical Artificial Disc should have failed at least six weeks of non-operative treatment or demonstrated progressive signs or symptoms despite non-operative treatment prior to implantation. Simplify® Cervical Artificial Disc is implanted via an open anterior approach.
P200039/S001	04/09/2021	O - Normal 180 Day	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for transition to continued follow up study.

Total: 58

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S079	04/01/2021	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Change of ink used for the inline printing on SURGICEL® product cartons at Ethicon SARL in Neuchatel, Switzerland.
N970003/S261	04/02/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Implement the Global Labeling System version 3.0 at select locations.
N970003/S262	04/30/2021	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Update test software to include an additional Bill of Materials check for all pulse generator devices.
P810025/S041	04/07/2021	X - 30-Day Notice	AMVISC(R)	BAUSCH & LOMB, INC.	Changes to component supplier and packaging modification for rubber plunger stopper.
P830026/S083	04/02/2021	X - 30-Day Notice	COSMOS(TM) SYSTEM	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830060/S085	04/02/2021	X - 30-Day Notice	VENTAK AND AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEMS	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P840001/S485	04/06/2021	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Modification to the Implantable Neurostimulator (INS) devices weld monitoring method from a manual peel test to an automated pull test.
P840068/S055	04/02/2021	X - 30-Day Notice	DELTA PACEMAKER SYS; VIGOR DDD MODEL 950	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P850010/S096	04/28/2021	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Replacement of a packaging sealer, which has reached end of its life, with an identical model, at the Collagen Manufactunng Center (CMC) located at Plainsboro, NJ.
P860004/S371	04/01/2021	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implement ionic contamination monitoring to the SynchroMed II Infusion Pump.
P880047/S039	04/01/2021	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Change of ink used for the inline printing on GYNECARE INTERCEED¿ product cartons at Ethicon SARL in Neuchatel, Switzerland.
P880086/S318	04/09/2021	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Adjust sample size for bacterial endotoxin testing.
P890055/S077	04/13/2021	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Change in the firms responsible for receiving and inspection activities for the barbed connector and tapered catheter components, cleaning and passivating of the barbed connector component, and packaging, sealing, and labeling of the barbed connector and tapered catheter components for the Intera 3000 Hepatic Artery Infusion Pump.
P890061/S024	04/02/2021	X - 30-Day Notice	VENTAK P 1600 AICD AND 2830 SOFTWARE MODULE	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P900009/S046	04/14/2021	X - 30-Day Notice	SONIC ACCELERATED FRACTURE HEALING SYSTEM MODEL 2A	BIOVENTUS LLC	Use an additional supplier for the ultrasound gel provided with the EXOGEN Ultrasound Bone Healing System.
P910018/S030	04/29/2021	X - 30-Day Notice	LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2).	KANEKA PHARMA AMERICA CORP.	Change in sterility tests for the SULFLUX KP-05 Plasma Separator.
P910023/S436	04/09/2021	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Adjust sample size for bacterial endotoxin testing.
P910073/S160	04/02/2021	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910077/S183	04/02/2021	X - 30-Day Notice	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P920048/S020	04/29/2021	X - 30-Day Notice	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Addition of a manufacturing site at 10210 Genetic Center Dr., San Diego, CA (GCD) for the manufacture of critical components of the Rapid fFN for the TLiIQ System, namely the control kit, calibrators and other internal use-only components.
P930014/S135	04/22/2021	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Add an alternate supplier for a raw material (i.e. initiator) used in the manufacturing process.
P930027/S025	04/28/2021	X - 30-Day Notice	IMMULITE SYSTEMS PSA & THIRD GENERATION PSA REAGENTS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Modify resin used in manufacture of test unit cap/body.
P930035/S031	04/02/2021	X - 30-Day Notice	VENTAK(R) P2 SYSTEM	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P930036/S016	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Moving manufacturing of Atellica IM analyzer¿s component/subassembly named Autoloader to an internal supplier.
P930039/S225	04/27/2021	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	MCRD and sleeve head bonding process and inspection updates
P940031/S079	04/02/2021	X - 30-Day Notice	VIGOR(TM) DR PACEMAKER SYSTEM	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P950001/S029	04/02/2021	X - 30-Day Notice	SELUTE STEROID ELUTING ENDOCARDIAL LEAD MODELS 4185 & 4285	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P950005/S078	04/28/2021	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	New ethylene oxide (EO) sterilization cycle (J&J Consolidated Cycle 1) at the Steris IsoMedix Services (Steris SD) facility in San Diego, CA.
P950005/S079	04/27/2021	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Procedure to repackage and relabel products with secondary packaging damage.
P950021/S024	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Moving manufacturing of Atellica IM analyzer¿s component/subassembly named Autoloader to an internal supplier.
P950022/S138	04/09/2021	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Adjust sample size for bacterial endotoxin testing.
P950034/S052	04/01/2021	X - 30-Day Notice	SEPRAFILM(TM) (HAL-F (TM)) BIORESORBABLE MEMBRANE	BAXTER HEALTHCARE CORPORATION	Change to the clean hold time of a vessel used in the manufacturing process of Seprafilm Adhesion Barrier.

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P950037/S219	04/01/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Introduce in-house production of the outer wiring bands for headers for Edora, Evity, Entira, and Enticos devices.
P950037/S221	04/14/2021	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Implement automated equipment for the pickling process used for wiring bands.
P960004/S093	04/02/2021	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P960006/S051	04/02/2021	X - 30-Day Notice	SWEET TIP(R) RX STEROID ELUTING LEAD	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P960009/S399	04/06/2021	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Modification to the Implantable Neurostimulator (INS) devices weld monitoring method from a manual peel test to an automated pull test.
P960013/S117	04/09/2021	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Adjust sample size for bacterial endotoxin testing.
P960030/S074	04/09/2021	X - 30-Day Notice	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ST. JUDE MEDICAL	Adjust sample size for bacterial endotoxin testing.
P960040/S462	04/02/2021	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P960040/S463	04/30/2021	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Update test software to include an additional Bill of Materials check for all pulse generator devices.
P960058/S152	04/23/2021	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Change in colorant sub-supplier for production of cable material used in the connection between the sound processor and headpiece.
P960058/S153	04/29/2021	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Implantation of Assemble-to-Order process functionality within the ERP (Enterprise Resource Planning) system.
P970004/S331	04/06/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Modification to the Implantable Neurostimulator (INS) devices weld monitoring method from a manual peel test to an automated pull test.
P970004/S332	04/09/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Addition of a test application to the DistributionCenter Sorter Tool (DCST) for Model 97810 InterStim Micro.

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P970013/S086	04/09/2021	X - 30-Day Notice	MICRONY PACEMAKERS	ST. JUDE MEDICAL, INC.	Adjust sample size for bacterial endotoxin testing.
P980016/S778	04/08/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add a new laser welder for battery assemblies and updated tooling.
P980016/S779	04/12/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Process changes for the use of the dadet used in feedthrough assembly.
P980016/S781	04/16/2021	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Replace IC testing equipment at a subassembly supplier.
P980035/S679	04/12/2021	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Process changes for the use of the dadet used in feedthrough assembly.
P980044/S055	04/15/2021	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture SUPARTZ FX and VISCO-3 for the purpose of manufacturing an investigational drug substance
P990004/S047	04/30/2021	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Change to the irradiation service location for the dose audit samples.
P990025/S063	04/28/2021	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	New ethylene oxide (EO) sterilization cycle (J&J Consolidated Cycle 1) at the Steris IsoMedix Services (Steris SD) facility in San Diego, CA.
P990025/S064	04/27/2021	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Procedure to repackage and relabel products with secondary packaging damage.
P990046/S058	04/22/2021	X - 30-Day Notice	ATS OPEN PIVOT BILEAFLET HEART VALVE	MEDTRONIC ATS MEDICAL, INC.	Implementation of a new graphite cutting method.
P990055/S023	04/27/2021	X - 30-Day Notice	BAYER IMMUNO 1 COMPLEXED PSA ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Moving manufacturing of Atellica IM analyzer¿s component/subassembly named Autoloader to an internal supplier.
P990071/S048	04/28/2021	X - 30-Day Notice	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	New ethylene oxide (EO) sterilization cycle (J&J Consolidated Cycle 1) at the Steris IsoMedix Services (Steris SD) facility in San Diego, CA.

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P990071/S049	04/27/2021	X - 30-Day Notice	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Procedure to repackage and relabel products with secondary packaging damage.
P000054/S065	04/05/2021	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Modification to the cleaning process used in manufacture of the absorbable collagen sponge component of the INFUSE bone graft product.
P000058/S084	04/05/2021	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Modification to the cleaning process used in manufacture of the absorbable collagen sponge component of the INFUSE bone graft product.
P010007/S014	04/28/2021	X - 30-Day Notice	IMMULITE/IMMULITE 1000 AFP AND IMMULITE 2000/ IMMULITE 2500 AFP	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Modify resin used in manufacture of test unit cap/body.
P010012/S533	04/02/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Implement the Global Labeling System version 3.0 at select locations.
P010012/S534	04/28/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Acceptance to duplicate five lead subassembly manufacturing processes.
P010012/S535	04/09/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Clarify the terminal pin welding fixture loading process instruction.
P010012/S536	04/30/2021	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Update test software to include an additional Bill of Materials check for all pulse generator devices.
P010015/S472	04/12/2021	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Process changes for the use of the dadet used in feedthrough assembly.

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P010030/S147	04/26/2021	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Updates to the manufacturing of the belt connector plate inside the LifeVest 4000 and HWD 1000 Monitors.
P010031/S740	04/08/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a new laser welder for battery assemblies and updated tooling.
P010031/S741	04/12/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process changes for the use of the dadet used in feedthrough assembly.
P010031/S743	04/16/2021	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Replace IC testing equipment at a subassembly supplier.
P010032/S174	04/23/2021	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Addition of an alternate second tier supplier of a MLCC capacitor component used in the manufacture of Orion family implantable pulse generator (IPG) devices.
P010068/S063	04/28/2021	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	New ethylene oxide (EO) sterilization cycle (J&J Consolidated Cycle 1) at the Steris IsoMedix Services (Steris SD) facility in San Diego, CA.
P010068/S064	04/27/2021	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Procedure to repackage and relabel products with secondary packaging damage.
P020004/S181	04/15/2021	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Upgrades to wire processing equipment.
P020036/S044	04/01/2021	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Implementing recertification procedures for returned stents.
P020056/S053	04/10/2021	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Addition of new ovens used in the manufacturing process of NATRELLE Silicone-Filled Breast Implants.

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P030005/S207	04/02/2021	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Implement the Global Labeling System version 3.0 at select locations.
P030005/S208	04/30/2021	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Update test software to include an additional Bill of Materials check for all pulse generator devices.
P030017/S343	04/23/2021	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of two new reflow ovens to the manufacturing process for the Printed Circuit Board Assemblies (PCBAs) of the Implantable Pulse Generator (IPG) and External Trial Stimulator (ETS).
P030031/S116	04/28/2021	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	New ethylene oxide (EO) sterilization cycle (J&J Consolidated Cycle 1) at the Steris IsoMedix Services (Steris SD) facility in San Diego, CA.
P030031/S117	04/27/2021	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Procedure to repackage and relabel products with secondary packaging damage.
P030035/S185	04/09/2021	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Adjust sample size for bacterial endotoxin testing.
P030040/S020	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR HBC IGM READYPACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Moving manufacturing of Atellica IM analyzers component/subassembly named Autoloader to an internal supplier.
P030047/S042	04/01/2021	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS CORP.	Implementing recertification procedures for returned stents.
P030050/S036	04/28/2021	X - 30-Day Notice	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Moving the processes of filling, freeze drying, and capping into alternate cleanrooms.
P030054/S391	04/09/2021	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Adjust sample size for bacterial endotoxin testing.
P030056/S020	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR HCV READY PACK REAGENTS, ADVIA CENTAUR HCV QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Moving manufacturing of Atellica IM analyzers component/subassembly named Autoloader to an internal supplier.
P040002/S067	04/08/2021	X - 30-Day Notice	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, LLC	Supplier and manufacturing changes for the suture material used in the AFX Endovascular AAA System.

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P040004/S020	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR HBC TOTAL READYPACK REAGENTS/ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Moving manufacturing of Atellica IM analyzers component/subassembly named Autoloader to an internal supplier.
P040020/S098	04/22/2021	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Add an alternate supplier for a raw material (i.e. initiator) used in the manufacturing process.
P040027/S087	04/15/2021	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Upgrades to wire processing equipment.
P040036/S080	04/28/2021	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	New ethylene oxide (EO) sterilization cycle (J&J Consolidated Cycle 1) at the Steris IsoMedix Services (Steris SD) facility in San Diego, CA.
P040036/S081	04/27/2021	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Procedure to repackage and relabel products with secondary packaging damage.
P040037/S144	04/15/2021	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Upgrades to wire processing equipment.
P040043/S125	04/08/2021	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of a manufacturing aid during the Stent Graft Constraining step of the GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System.
P040043/S126	04/15/2021	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Upgrades to wire processing equipment.
P050006/S092	04/15/2021	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Upgrades to wire processing equipment.
P050046/S031	04/02/2021	X - 30-Day Notice	ACUITY STEERABLE LEAD SYSTEM	GUIDANT CORP.	Implement the Global Labeling System version 3.0 at select locations.
P050050/S018	04/19/2021	X - 30-Day Notice	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	STRYKER CORPORATION	Due to the breakage of the original grinding machine, the old grinding machine is no longer able to function and therefore needs to be replaced.
P050053/S056	04/06/2021	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Modification to the cleaning process used in manufacture of the absorbable collagen sponge component of the INFUSE bone graft product.
P060005/S013	04/28/2021	X - 30-Day Notice	IMMULITE / IMMULITE 1000 AND IMMULITE 2000 FREE PSA ASSAYS	SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS LIMITED	Modify resin used in manufacture of test unit cap/body.

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P070008/S123	04/14/2021	X - 30-Day Notice	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Implement automated equipment for the pickling process used for wiring bands.
P070026/S080	04/30/2021	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Additional inspection equipment (i.e., Zeiss Contura, DE1093 coordinate measurement machine/CMM) as an additional inspection asset to be used with the current measurement equipment to inspect critical features of the Summit Hip Stem components.
P080011/S124	04/06/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Modification of automated inspection system distortion tolerance.
P080011/S125	04/15/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Introduction of Biofinity XR Toric extended range product to cover additional sphere powers on Biofinity MTO Line 2.
P080011/S126	04/22/2021	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Modification in the packaging sampling plan and QA Final audit inspection regime performed post-autoclave for the Biofinity products.
P080020/S042	04/15/2021	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture Gel-One for the purpose of manufacturing an investigational drug substance.
P080025/S226	04/06/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Modification to the Implantable Neurostimulator (INS) devices weld monitoring method from a manual peel test to an automated pull test.
P080025/S227	04/09/2021	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Addition of a test application to the DistributionCenter Sorter Tool (DCST) for Model 97810 InterStim Micro.
P080027/S039	04/20/2021	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Manufacturing process improvements.
P090024/S010	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR HBEAG ASSAY AND QUALITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS	Moving manufacturing of Atellica IM analyzers component/subassembly named Autoloader to an internal supplier.
P100021/S090	04/15/2021	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changing the current pouch sealer with an upgraded pouch sealer.
P100039/S012	04/13/2021	X - 30-Day Notice	ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Implement two additional tiers of standards identical to the approved standard used in manufacturing.
P100039/S013	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Moving manufacturing of Atellica IM analyzers component/subassembly named Autoloader to an internal supplier.
P100040/S046	04/15/2021	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changing the current pouch sealer with an upgraded pouch sealer.

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P100045/S051	04/22/2021	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Replacement of fan component used in CardioMEMS I3 Patient Electronic System (PES).
P110010/S191	04/22/2021	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Alternative process to allow for the automation of top assembly process steps for the manufacture of stent delivery catheters.
P110035/S066	04/07/2021	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Automate a process used to stretch a delivery system liner material.
P110041/S012	04/27/2021	X - 30-Day Notice	ADVIA CENTAUR HBSAGII	SIEMENS CORP.	Moving manufacturing of Atellica IM analyzers component/subassembly named Autoloader to an internal supplier.
P110042/S153	04/02/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Implement the Global Labeling System version 3.0 at select locations.
P110042/S155	04/02/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add an alternate supplier for the Grade 1 Titanium raw material used in manufacturing of the EMBLEM S-ICD case halves component.
P110042/S156	04/30/2021	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Update test software to include an additional Bill of Materials check for all pulse generator devices.
P120002/S019	04/01/2021	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS CORP.	Implementing recertification procedures for returned stents.
P130006/S083	04/15/2021	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Upgrades to wire processing equipment.
P130008/S064	04/09/2021	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Replace a component on the sensor capsule burn-in fixture and increase the sensor capsule burn-in fixture capacity.
P130014/S011	04/16/2021	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Addition of a glove box for storage and handling of the two precursor solutions of the Adherus sealant.
P130017/S046	04/12/2021	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Changes required for manufacturing scale-up of a device component.

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P130021/S091	04/29/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Automation of the bioburden reduction process.
P130021/S093	04/29/2021	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Modification of the patency inspection on the outer member sub-assembly of the delivery catheter system.
P140009/S068	04/23/2021	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Addition of an alternate second tier supplier of a MLCC capacitor component used in the manufacture of Orion family implantable pulse generator (IPG) devices.
P140010/S059	04/27/2021	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Change component manufacturing sites and other minor process control changes.
P140029/S037	04/14/2021	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Changes in the dialysis procedure for the manufacturing of Restylane Kysse to permit parallel dialysis of two batches of the same product at the same time.
P140029/S038	04/13/2021	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Revision of the criteria for the visual inspection of filled and sterilized syringes performed during manufacturing.
P140030/S012	04/23/2021	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Implementation of the reorganization of the lot release changes.
P140032/S068	04/01/2021	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Implement ionic contamination monitoring to the SynchroMed II Infusion Pump.
P140033/S066	04/09/2021	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Adjust sample size for bacterial endotoxin testing.
P150003/S073	04/29/2021	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Extension in the expiry of the drug coating solution used for the SYNERGY product family.
P150004/S046	04/23/2021	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Addition of an alternate second tier supplier of a MLCC capacitor component used in the manufacture of Orion family implantable pulse generator (IPG) devices.
P150012/S107	04/02/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Implement the Global Labeling System version 3.0 at select locations.
P150012/S108	04/02/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Update the automated Terminal Crimp System software used on INGEVITY MRI pace/sense leads.

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P150012/S109	04/30/2021	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Update test software to include an additional Bill of Materials check for all pulse generator devices.
P150031/S041	04/23/2021	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of two new reflow ovens to the manufacturing process for the Printed Circuit Board Assemblies (PCBAs) of the Implantable Pulse Generator (IPG) and External Trial Stimulator (ETS).
P150033/S100	04/14/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement MESWeb for manufacturing traceability for battery production lines for Micra devices.
P150033/S101	04/15/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the Titan final functioning tester for Micra Transcatheter Pacing Systems.
P150033/S103	04/02/2021	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update laser weld inspection criteria and processing at Medtronic's Swiss Manufacturing Operations.
P150048/S053	04/15/2021	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Implementation of an automated solution mixing, storage, and distribution system for RESILIA solutions.
P160003/S012	04/23/2021	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Implementation of the reorganization of the lot release changes.
P160025/S010	04/23/2021	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Implementation of the reorganization of the lot release changes.
P160026/S025	04/27/2021	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 for the LifePack 1000 Defibrillator.
P160029/S011	04/19/2021	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Change to the audio production test manufacturing specification performed during the Final Acceptance Test.

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P160047/S022	04/12/2021	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Process change from manual force fitting of polymer tubing to expansion of polymer tubing ends prior to assembly.
P160047/S023	04/21/2021	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Change to the manufacturing process for the slide collar tips that replaces a multi-step fabrication process with the use of an injection molded component to form the tips.
P160047/S024	04/19/2021	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Change to the supply chain for manufacturing of the Mara Console to add additional qualified suppliers for components used in its assembly.
P160054/S036	04/28/2021	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Addition of a new test fixture for the HeartMate 3 Left Ventricular Device.
P160055/S019	04/01/2021	X - 30-Day Notice	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Introduction of an alternate Tyvek package heat sealer to meet increased manufacturing capacity.
P170002/S015	04/26/2021	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Change to the location of temperature sensors and biological indicators during the sterilization process qualification.
P170002/S016	04/30/2021	X - 30-Day Notice	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Change to the sodium hydroxide control at receiving inspection to add a specification.
P170008/S034	04/07/2021	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Introduction of new measuring equipment for dimensional verification of the delivery system.
P170008/S035	04/16/2021	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Introduction of an automated ablation method for the hypotube components.
P170024/S007	04/27/2021	X - 30-Day Notice	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Changes to the braid component incoming inspection to remove redundant inspections and accept a Certificate of Conformance/Certificate of Analysis from the supplier.
P170030/S015	04/23/2021	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Implementation of the reorganization of the lot release changes.
P170035/S012	04/08/2021	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Adding an alternate supplier of a monomer component for the Ultra® (samfilcon A) product family.

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P180003/S004	04/15/2021	X - 30-Day Notice	BIOMIMICS 3D VASCULAR STENT SYSTEM	VERYAN MEDICAL LTD.	Change to a packaging film material.
P190018/S011	04/22/2021	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Add an alternate supplier for a raw material (i.e. initiator) used in the manufacturing process.
P190019/S008	04/20/2021	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATIO N	Implementation of additional analytical equipment for residual solvents batch release testing.
P190019/S009	04/01/2021	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATIO N	Implementation of new manufacturing equipment.
P200030/S002	04/15/2021	X - 30-Day Notice	GORE EXCLUDER CONFORMABLE AAA ENDOPROSTHESIS (CEXC)	W. L. GORE AND ASSOCIATES, INC.	Upgrades to wire processing equipment.
P200046/S001	04/06/2021	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Implementation of product label and component verification software for use during device manufacturing.
Total: 158					