PMA Monthly approvals from 9/1/2022 to 9/30/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P220003	09/14/2022	PMAO - PMA Origi	PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM	EDWARDS LIFESCIENCES LLC	Approval for the PASCAL Precision Transcatheter Valve Repair System. This device is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation (MR >= 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S109	09/22/2022	N - Normal 180 Day	ACUVUE CONTACT LENS	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Approval for a change to the material of the lens container closure (foil lidstock) for VISTAKON® (etafilcon A) and (senofilcon A) Brand Contact Lenses.
P860004/S387	09/02/2022	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for a change in the formulation of the resin used in the plastic hub component (Styrene-Butadiene Copolymer), and replacement of the current Urethane Acrylate adhesive (Dymax 1136-M) with another Urethane Acrylate adhesive (Dymax 1405-M-UR-SC), which is used to attach the cannula to the hub.
P860004/S397	09/16/2022	S - Special CBE	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling updates for the Targeted Drug Delivery (TDD) Therapy labeling.
P880086/S325	09/30/2022	R - Real-Time Proc	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Approval for the Merlin@home transmitter software model EX2000 v9.0 and cybersecurity enhancements.
P900056/S200	09/02/2022	Y - 135 Review Tra	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for changes to incoming inspection activities and a supplier change.
P910023/S447	09/30/2022	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for the Merlin@home transmitter software model EX2000 v9.0 and cybersecurity enhancements.
P950005/S084	09/09/2022	N - Normal 180 Day	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Approval for software and hardware modifications for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR, and CELSIUS catheters).

Data as of 10/31/2022 04:05 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S368	09/23/2022	R - Real-Time Proc	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for a change to update the pinch flash requirement on a distal section of the lead body assemblies and loosening the outer diameter (OD) tolerance on a proximal section of the lead body assemblies.
P970013/S091	09/30/2022	R - Real-Time Proc	MICRONY PACEMAKERS	ABBOTT MEDICAL	Approval for the Merlin@home transmitter software model EX2000 v9.0 and cybersecurity enhancements.
P970029/S040	09/01/2022	S - Special CBE	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Approval for the addition of chassis grounding resistance and chassis leakage current tests to the service manual for use after repair, maintenance, and installation activities.
P970051/S212	09/26/2022	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for modifications to the Nucleus SmartNav System resulting in version 2.0 of the software.
P990025/S069	09/09/2022	N - Normal 180 Day	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for software and hardware modifications for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR, and CELSIUS catheters).
P990034/S043	09/16/2022	S - Special CBE	MEDTRONIC ISOMED INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling updates for the Targeted Drug Delivery (TDD) Therapy labeling.
P990081/S047	09/30/2022	P - Panel Track	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody for expanding the indications to include testing for breast cancer patients who are eligible for treatment with ENHERTU®.
P010068/S069	09/09/2022	N - Normal 180 Day	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Approval for software and hardware modifications for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR, and CELSIUS catheters).
P030031/S127	09/09/2022	N - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Approval for software and hardware modifications for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR, and CELSIUS catheters).
P030035/S191	09/30/2022	R - Real-Time Proc	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Approval for the Merlin@home transmitter software model EX2000 v9.0 and cybersecurity enhancements.
P030054/S401	09/30/2022	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for the Merlin@home transmitter software model EX2000 v9.0 and cybersecurity enhancements.
P040036/S089	09/09/2022	N - Normal 180 Day	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for software and hardware modifications for the nGEN Generator (compatible with the THERMOCOOL, NAVISTAR, and CELSIUS catheters).
P040045/S127	09/22/2022	N - Normal 180 Day	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Approval for a change to the material of the lens container closure (foil lidstock) for VISTAKON® (etafilcon A) and (senofilcon A) Brand Contact Lenses.
P050037/S115	09/02/2022	Y - 135 Review Tra	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for the implementation of a different blender into the Calcium Hydroxylapatite (CaHA) particle manufacturing process.
P050052/S136	09/02/2022	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the implementation of a different blender into the Calcium Hydroxylapatite (CaHA) particle manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080011/S141	09/19/2022	O - Normal 180 Da	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for the following new private label brand names: Ethos AquaTech Monthly XR and Ethos AquaTech Monthly XR for astigmatism
P080025/S263	09/23/2022	R - Real-Time Proc	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a change to update the pinch flash requirement on a distal section of the lead body assemblies and loosening the outer diameter (OD) tolerance on a proximal section of the lead body assemblies.
P090016/S034	09/07/2022	O - Normal 180 Da	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval of an alternative contract manufacturer for secondary packaging operations and finished product warehousing and distribution of Belotero Balance.
P100045/S063	09/15/2022	O - Normal 180 Da	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ABBOTT MEDICAL	Approval of the protocol for the post-approval study (PAS) protocol.
P100047/S196	09/30/2022	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for a modification to the HVAD Battery configuration mode and changes to the Battery Pack Final Tester software
P100047/S200	09/08/2022	O - Normal 180 Da	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for various updates to the Instructions for Use to add the final clinical results of the post-approval studies entitled Newly Enrolled (HW-PAS-01) Training Program (HeartWare-PAS-02), and Cont F/u of HW004-A ENDURANCE.
P110013/S117	09/29/2022	O - Normal 180 Da	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for updated labeling for the the Resolute Onyx Zotarolimus-Eluting Coronary Stent System electronic Instructions for Use (eIFU) to reflect the long-term data from The RESOLUTE ONYX CTO Post-Approval Study.
P110019/S122	09/14/2022	R - Real-Time Proc	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval to extend the shelf life for the XIENCE Sierra and XIENCE Skypoint Everolimus-Eluting Coronary Stent System from 24 to 36 months and minor labeling changes for the XIENCE Sierra, Skypoint, and Alpine Everolimus-Eluting Coronary Stent System.
P130008/S085	09/12/2022	R - Real-Time Proc	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the modification of the main button of the Model 2580 patient remote to be slightly smaller.
P130013/S043	09/02/2022	N - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for the addition of dual antiplatelet therapy (DAPT) as an alterative post-implant antithrombotic medication regimen.
P130022/S043	09/30/2022	O - Normal 180 Da	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a manufacturing site located at Nevro Medical S.R.L. Building 28-C, Coyol Free Zone Park C.R. El Coyol, Alajuela Costa Rica, 20101 to manufacture IPG, charger and patient remotes.
P140031/S145	09/23/2022	O - Normal 180 Da	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval of the protocol for the post-approval study (PAS) protocol.
P140033/S075	09/30/2022	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for the Merlin@home transmitter software model EX2000 v9.0 and cybersecurity enhancements.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150009/S008	09/21/2022	O - Normal 180 Da	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Approval for service life expansion to 6 years.
P150030/S014	09/09/2022	Y - 135 Review Tra	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Approval for an alternative process to mask the device during the Vacuum Plasma Spray (VPS) coating process for the POLARSTEM Stems.
P150048/S065	09/08/2022	O - Normal 180 Da	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Costa Rica Cartago (Zona Franca La Lima, De La Entrada De Pequeno Mundo 100 Mts Oeste Y 200 Mts Sur Finca 31 Y 32 Guadalupe Cartago 30106 CR) for subassembly of bioprosthetic heart valves.
P160043/S058	09/15/2022	P - Panel Track	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for the Resolute Onyx and Onyx Frontier Zotarolimus-Eluting Coronary Stent Systems. The device is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus or high bleeding risk, with symptomatic ischemic heart disease due to de novo lesions of length <= 35 mm in native coronary arteries with reference vessel diameters of 2.0 mm to 5.0 mm. In addition, the Resolute Onyx and Onyx Frontier Zotarolimus-Eluting Coronary Stent Systems are indicated for treating de novo chronic total occlusions and non-left main bifurcation lesions utilizing the provisional bifurcation stenting technique.
P160043/S060	09/29/2022	O - Normal 180 Da	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for updated labeling for the the Resolute Onyx Zotarolimus-Eluting Coronary Stent System electronic Instructions for Use (eIFU) to reflect the long-term data from The RESOLUTE ONYX CTO Post-Approval Study.
P160045/S031	09/21/2022	P - Panel Track	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval to expand the intended use of the Oncomine Dx Target Test to include a companion diagnostic indication for the detection of the identification of RET fusions in NSCLC patients, RET mutations in medullary thyroid cancer (MTC) patients and RET fusions in thyroid cancer (TC) patients who may benefit from RETEVMO® (selpercatinib).
P160045/S037	09/19/2022	R - Real-Time Proc	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval for the revised DNA and RNA controls (DNA Control v3 and RNA Control v2) for the Oncomine Dx Target Test
P160053/S005	09/13/2022	N - Normal 180 Day	MAGTRACETM AND SENTIMAG(R) MAGNETIC LOCATIZATION SYSTEM	ENDOMAGNETICS LTD.	Approved for using new Gen 3 and Gen 3T Sentimag detectors to detect Magtrace, addition of CIDEX OPA as a high level disinfectant for disinfecting Sentimag Gen 3 and Gen 3T detectors, and addition of certain low temperature sterilization systems for certain cycles for sterilization of Sentimag Gen 3 and Gen 3T detectors.
P170018/S014	09/27/2022	R - Real-Time Proc	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Approval for a new packaging design, which will include new corrugated cardboard packaging components to replace the current packaging components.
P170019/S038	09/27/2022	S - Special CBE	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approved removal of the companion diagnostic indication for FoundationOne® CDx (FICDx) to identify patients with ovarian cancer harboring BRCA1 or BRCA2 alterations for treatment with rucaparib.
P180001/S006	09/01/2022	R - Real-Time Proc	ZENITH DISSECTION ENDOVASCULAR SYSTEM	WILLIAM COOK EUROPE APS	Approval for a design change to the introduction system green release knob of the Cook Zenith Dissection Endovascular System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180034/S006	09/29/2022	Y - 135 Review Tra	TACK ENDOVASCULAR SYSTEM (6F)	PHILIPS IMAGE GUIDED THERAPY CORPORATIO N	Approval for an alternate supplier for the delivery system.
P180036/S014	09/06/2022	O - Normal 180 Da	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for revision to exclusion criteria in the Optimizer SMART PAS protocol.
P190027/S003	09/29/2022	Y - 135 Review Tra	TACK ENDOVASCULAR SYSTEM (4F, 1.5-4.5MM)	PHILIPS IMAGE GUIDED THERAPY CORPORATIO N (FORMERLY INTACT)	Approval for an alternate supplier for the delivery system.
P190032/S006	09/21/2022	S - Special CBE	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval for the formatting and updates to the Specimen Instructions document, the technical labeling, and the mock patient reports for FoundationOne® Liquid CDx.
P190032/S007	09/21/2022	S - Special CBE	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approved removal of the companion diagnostic indication for F1Liquid CDx to identify patients with ovarian cancer harboring BRCA1 or BRCA2 alterations for treatment with rucaparib.
P200006/S002	09/21/2022	S - Special CBE	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE, INC.	Approval for the formatting and updates to the Specimen Instructions document, the technical labeling, and the mock patient reports for FoundationOne® Liquid CDx.
P200016/S001	09/21/2022	S - Special CBE	FOUNDATIONONE LIQUID CDX	FOUNDATION MEDICINE, INC.	Approval for the formatting and updates to the Specimen Instructions document, the technical labeling, and the mock patient reports for FoundationOne® Liquid CDx.
P200020/S001	09/16/2022	O - Normal 180 Da	SBL-3 MULTIFOCAL INTRAOCULAR LENS	LENSTEC, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P200031/S001	09/19/2022	O - Normal 180 Da	ORGAN CARE SYSTEM (OCS¿) LIVER	TRANSMEDIC S, INC.	Approval of revised device labeling to reflect the final results of the OCS Liver PROTECT Continuation Post-Approval Study.
P200039/S007	09/01/2022	R - Real-Time Proc	SHOCKWAVE INTRAVASCULAR LITHOTRIPSY (IVL) SYSTEM WITH SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY (IVL) CATHETER	SHOCKWAVE MEDICAL, INC.	Approval for a modification to your generator enclosure.
P210005/S001	09/20/2022	O - Normal 180 Da	IC-8 APTHERA INTRAOCULAR LENS (IOL)	ACUFOCUS, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P210005/S002	09/20/2022	O - Normal 180 Da	IC-8 APTHERA INTRAOCULAR LENS (IOL)	ACUFOCUS, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210006/S003	09/29/2022	R - Real-Time Proc	THORAFLEX¿ HYBRID	VASCUTEK LTD.	Approval for an increase in the labeled shelf life for the Thoraflex Hybrid device from 2 years to 55 months.
P210020/S006	09/29/2022	O - Normal 180 Da	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.

Total: 60

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S276	09/27/2022	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Implement an automatic handling system for the helium leak test process.
N970012/S192	09/01/2022	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Process change to the Global Labeling System version 3.0 software and infrastructure from the current Minnetonka Labeling System.
P830055/S295	09/01/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Automation of an in-process cleaning process for the removal of buffing compounds from products under the LCS® Total Knee System.
P830061/S208	09/15/2022	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Minor updates for manufacturing and inspection processes for the Monolithic Controlled Release Devices.
P840001/S523	09/01/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Replace a manual clean-line with a semi-automatic clean line, at Tegra Medical.
P840001/S526	09/07/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Repositing of equipment (and cleanroom) within the existing manufacturing facility of a critical supplier to Medtronic that manufactured fabricated metal components.
P840001/S528	09/13/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Replacement of inspection equipment at external supplier Innovize, Inc., for the inspection of components used at the Medtronic Energy and Component Center (MECC) site.
P840064/S077	09/13/2022	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Change in the maximum Ethylene Oxide (EO) sterilization process parameter specifications (without change to the EO sterilization process set points or final product release specifications).
P840064/S078	09/15/2022	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Change to the blister seal integrity test method for the testing of the OVD blister.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860003/S108	09/23/2022	X - 30-Day Notice	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Change in the manufacturing process of the American RENOLIT PVC film used in the Cellex procedural kit and Treatment and Return Bags.
P860004/S396	09/08/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Clarification added to an inspection procedure and work instructions added for material handling in a related process for the SynchroMed Infusion system.
P860004/S398	09/22/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Upgrade to the inspection procedure used by the supplier of critical electronic components.
P860004/S399	09/28/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Alternate supplier for components used in the SynchroMed II pump.
P860057/S208	09/12/2022	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Outsource polyester band manufacturing steps currently performed in-house to an existing supplier.
P860057/S209	09/23/2022	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Implementation of an enhanced temperature indicator packaging component to monitor surgical and transcatheter heart valves during transit and storage.
P890023/S049	09/23/2022	X - 30-Day Notice	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	Addition of Biomedics 55 Asphere lens capability onto existing manufacturing lines at CooperVision Manufacturing Puerto Rico, LLC.
P890047/S058	09/13/2022	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Change in the maximum Ethylene Oxide (EO) sterilization process parameter specifications (without change to the EO sterilization process set points or final product release specifications).
P890047/S059	09/15/2022	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Change to the blister seal integrity test method for the testing of the OVD blister.
P890055/S083	09/29/2022	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Supplier change for a component used in the Intera 3000 Hepatic Artery Infusion Pump.
P910023/S448	09/09/2022	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Implement an automated weighing system at the battery supplier.
P920015/S271	09/15/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Minor updates for manufacturing and inspection processes for the Monolithic Controlled Release Devices.
P920047/S128	09/21/2022	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Modified adhesive curing process and parameters.
P930036/S020	09/30/2022	X - 30-Day Notice	ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Manufacturing process change to the affinity purification method used to purify the anti-AFP polyclonal antibodies (Lite Reagent).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930039/S245	09/15/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Minor updates for manufacturing and inspection processes for the Monolithic Controlled Release Devices.
P950005/S085	09/30/2022	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Add an additional chamber for the sterilization of catheters and cables at the Isomedix Operation, Inc. (Steris Grand Prairie) facility in Grand Prairie, Texas.
P950020/S125	09/15/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Additional blade bonding equipment.
P950020/S126	09/30/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Relocate manufacturing equipment.
P950037/S238	09/15/2022	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Implement an additional electrical test to the IPG header Inspection process.
P960009/S437	09/07/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Repositioning of equipment (and cleanroom) within the existing manufacturing facility of a critical supplier to Medtronic that manufactured fabricated metal components.
P960040/S481	09/27/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Implement an automatic handling system for the helium leak test process.
P960058/S156	09/09/2022	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Facility move at a supplier for manufacture of implant parts used in the assembly of the HiRes Ultra and HiRes Ultra 3D cochlear implants.
P970004/S373	09/13/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Replacement of inspection equipment at external supplier Innovize, Inc., for the inspection of components used at the Medtronic Energy and Component Center (MECC) site.
P970020/S086	09/07/2022	X - 30-Day Notice	MULTI-LINK ULTRA/ ZETA CORONARY STENT SYSTEMS	ABBOTT VASCULAR INC.	Addition of secondary sterilization equipment.
P980006/S035	09/29/2022	X - 30-Day Notice	PURE VISION VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR	BAUSCH & LOMB, INC.	Alternate diluent used in the manufacture of the PureVision® (balafilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses.
P980016/S835	09/19/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Removal of the pressed cathode process limit guard band.

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P980016/S836	09/19/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer the dicing process from one supplier to another, and to automate the pick and place process.
P980035/S728	09/16/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Use of a variant test system and update the test program for integrated circuit wafers.
P980035/S729	09/21/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Replace the water wash manufacturing process with a plasma surface treatment.
P980035/S730	09/15/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement a replacement microscope camera for the measurement of weld penetration.
P990023/S017	09/15/2022	X - 30-Day Notice	CELLUGEL(R) OPHTHALMIC VISCOSURGICAL DEVICE	ALCON LABORATORI ES	Change to the pouch seal integrity test method for the testing of the CELLUGEL OVD pouch.
P990023/S018	09/22/2022	X - 30-Day Notice	CELLUGEL(R) OPHTHALMIC VISCOSURGICAL DEVICE	ALCON LABORATORI ES	Additional release testing site for the primary and secondary packaging components used in the production of CELLUGEL OVD.
P990025/S070	09/30/2022	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Add an additional chamber for the sterilization of catheters and cables at the Isomedix Operation, Inc. (Steris Grand Prairie) facility in Grand Prairie, Texas.
P990071/S056	09/30/2022	X - 30-Day Notice	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Add an additional chamber for the sterilization of catheters and cables at the Isomedix Operation, Inc. (Steris Grand Prairie) facility in Grand Prairie, Texas.
P000053/S127	09/01/2022	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Process change to the Global Labeling System version 3.0 software and infrastructure from the current Minnetonka Labeling System.
P010012/S557	09/27/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Implement an automatic handling system for the helium leak test process.
P010015/S506	09/21/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Replace the water wash manufacturing process with a plasma surface treatment.

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P010031/S801	09/19/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Removal of the pressed cathode process limit guard band.
P010031/S802	09/19/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer the dicing process from one supplier to another, and to automate the pick and place process.
P010032/S190	09/09/2022	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Add second tier suppliers of the electrolyte and binder used to build the rechargeable batteries for the implantable pulse generators.
P010047/S067	09/06/2022	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Relocation of the Glass Cartridge Syringe Manufacturing site.
P010068/S070	09/30/2022	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Add an additional chamber for the sterilization of catheters and cables at the Isomedix Operation, Inc. (Steris Grand Prairie) facility in Grand Prairie, Texas.
P020003/S011	09/16/2022	X - 30-Day Notice	COLOPLAST SALINE-FILLED TESTICULAR PROSTHESIS	COLOPLAST CORP.	Implementation of a size inspection step for the Torosa Saline Filled Testicular Prosthesis (SFTP) during manufacturing.
P020004/S191	09/13/2022	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Implementation of updates to the Radio Frequency (RF) bonding process used in the manufacturing of the delivery system for the GORE EXCLUDER AAA Endoprosthesis (AAA) and GORE EXCLUDER Iliac Branch Endoprosthesis (IBE).
P020025/S136	09/21/2022	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Modified adhesive curing process and parameters.
P020047/S075	09/07/2022	X - 30-Day Notice	MULTI-LINK VISION/MINI/8 CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Addition of secondary sterilization equipment.
P030005/S221	09/27/2022	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Implement an automatic handling system for the helium leak test process.
P030011/S082	09/22/2022	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Add new sub-supplier for Freedom Onboard Battery PCBA and to add new sub-components to Freedom Onboard Battery PCBA.

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P030031/S128	09/30/2022	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Add an additional chamber for the sterilization of catheters and cables at the Isomedix Operation, Inc. (Steris Grand Prairie) facility in Grand Prairie, Texas.
P030054/S402	09/09/2022	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Implement an automated weighing system at the battery supplier.
P040024/S134	09/30/2022	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Add a permanent transverse wall between cleanrooms 9:175 and 9:176 in manufacturing L3 for Restylane®, Restylane®-L, Restylane® Lyft with Lidocaine, Perlane® and Restylane® Silk production.
P040036/S090	09/30/2022	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Add an additional chamber for the sterilization of catheters and cables at the Isomedix Operation, Inc. (Steris Grand Prairie) facility in Grand Prairie, Texas.
P040037/S154	09/01/2022	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Update to the acceptance criteria for radiopaque (RO) marker placement.
P040045/S128	09/01/2022	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate supplier for a raw material used in the manufacturing process of VISTAKON® (senofilcon A) Brand Contact Lenses.
P050006/S102	09/23/2022	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Adoption of an Occluder Stringing Station for the manufacturing of the GORE® CARDIOFORM Septal Occluder.
P050050/S025	09/29/2022	X - 30-Day Notice	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	DJO GLOBAL	Replacing a milling machine with three newer machines. The milling machine is used in the manufacturing of the STAR Ankle polyethylene bearing components.
P050051/S046	09/30/2022	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Change in test method used in the manufacture of an assay component.
P060022/S030	09/20/2022	X - 30-Day Notice	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS,MODEL ADAPT	BAUSCH & LOMB, INC.	Add the Bubble Leak Test to incoming inspection as an alternate test method.
P070008/S139	09/15/2022	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 an additional electrical test to the IPG header Inspection process.
P080025/S268	09/13/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Replacement of inspection equipment at external supplier Innovize, Inc., for the inspection of components used at the Medtronic Energy and Component Center (MECC) site.
P090013/S324	09/15/2022	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Minor updates for manufacturing and inspection processes for the Monolithic Controlled Release Devices.

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P100009/S047	09/09/2022	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT MEDICAL	Increased sterilization capacity for the MitraClip Clip Delivery System through increase in capacity of an existing chamber and addition of a new chamber.
P100010/S130	09/23/2022	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Addition of alternate injection mold equipment.
P110010/S204	09/01/2022	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introducing automated equipment for packaging, sealing, and inspection of the inner pack for PROMUS products in the drug eluting stent production unit.
P110029/S038	09/30/2022	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Change in test method used in the manufacture of an assay component.
P110042/S172	09/27/2022	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Implement an automatic handling system for the helium leak test process.
P110043/S013	09/07/2022	X - 30-Day Notice	OMNILINK ELITE PERIPHERAL BALLOON-EXPANDABLE STENT SYSTEM	ABBOTT VASCULAR-CARDIAC THERAPIES	Addition of secondary sterilization equipment.
P130006/S093	09/01/2022	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Update to the acceptance criteria for radiopaque (RO) marker placement.
P130021/S121	09/09/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Application of the Optimized PCA Sterilization Cycle to Evolut FX.
P130021/S122	09/27/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	New sub-tier supplier for a component of the EnVeo R/PRO/PRO+ delivery catheter systems.
P140003/S105	09/06/2022	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Add a supplier for the partial production of the single pin assembly.
P140010/S067	09/02/2022	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).
P140018/S034	09/13/2022	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Change to the bioburden action and alert limits for the VenaSeal Closure System.

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P140031/S144	09/23/2022	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Implementation of an enhanced temperature indicator packaging component to monitor surgical and transcatheter heart valves during transit and storage.
P150005/S071	09/21/2022	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Modified adhesive curing process and parameters.
P150012/S130	09/27/2022	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Implement an automatic handling system for the helium leak test process.
P150016/S022	09/07/2022	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Relocation of the Glass Cartridge Syringe Manufacturing supplier site.
P150030/S024	09/01/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Addition of alternative milling machines to perform three process steps necessary for machining the POLARSTEM forged blanks at a supplier site.
P150030/S025	09/13/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Introduction of the newest version of the ZEISS microscope used to verify the vacuum plasma spray (VPS) coating process step.
P150030/S026	09/21/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Addition of an additional hydraulic press for the forging process of the SYNERGY stems at the supplier site.
P150030/S027	09/29/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Modification of the tab removal process of the SYNERGY stems at a supplier by replacing the current milling machines with a belt grinding machine.
P150033/S150	09/06/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modifications to the Electronic Module Assembly (EMA) baking time and modifications to the backfill equipment.
P150033/S151	09/15/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Minor updates for manufacturing and inspection processes for the Monolithic Controlled Release Devices.
P150033/S152	09/16/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement modifications to the battery manufacturing process at MECC.
P150036/S063	09/12/2022	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Outsource polyester band manufacturing steps currently performed in-house to an existing supplier.
P150036/S064	09/23/2022	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Implementation of an enhanced temperature indicator packaging component to monitor surgical and transcatheter heart valves during transit and storage.
P150048/S067	09/12/2022	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Outsource polyester band manufacturing steps currently performed in-house to an existing supplier.

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P150048/S068	09/23/2022	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Implementation of an enhanced temperature indicator packaging component to monitor surgical and transcatheter heart valves during transit and storage.
P180035/S010	09/15/2022	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Manufacture of MiSight 1 Day product on Dry Line HE and Wet Line HVE at the CooperVision Warrior Close manufacturing facility in Chandlers Ford, Eastleigh, UK.
P180035/S011	09/22/2022	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Introduction of a secondary packaging line at the CooperVision. Inc. facility in West Henrietta. New York.
P180046/S059	09/08/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Add Deringer-Ney, Inc as an alternate supplier of the Axonics Neurostimulator (Model 4101) antenna assembly.
P180046/S060	09/07/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Add an alternate supplier for the Axonics Stimulation Cable printed circuit board assembly (PCBA).
P190006/S059	09/08/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Add Deringer-Ney, Inc as an alternate supplier of the Axonics Neurostimulator (Model 4101) antenna assembly.
P190006/S060	09/07/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Add an alternate supplier for the Axonics Stimulation Cable printed circuit board assembly (PCBA).
P190016/S005	09/22/2022	X - 30-Day Notice	TULA® SYSTEM	TUSKER MEDICAL, INC.	Modification to the adhesive application process for the earplug.
P200015/S027	09/23/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Implementation of an enhanced temperature indicator packaging component to monitor surgical and transcatheter heart valves during transit and storage.
P210003/S001	09/30/2022	X - 30-Day Notice	ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT, ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT, ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS,	ABBOTT LABORATORIES	Change in test method used in the manufacture of an assay component.

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