PMA Monthly approvals from 5/1/2022 to 5/31/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P210022	05/05/2022	PMAO - PMA Origi	ALINITY M CMV	ABBOTT MOLECULAR, INC.	Approval for Alinity m CMV. Alinity m CMV AMP Kit The Alinity m CMV assay is an in vitro polymerase chain reaction (PCR) assay for use with the automated Alinity m System to quantitate cytomegalovirus (CMV) DNA in human EDTA plasma. The Alinity m CMV assay is intended for use as an aid in the management of Hematopoietic Stem Cell Transplant and Solid Organ Transplant patients who are undergoing anti-cytomegalovirus therapy. The Alinity m CMV assay can be used to assess virological response to anti-cytomegalovirus therapy. The results from the Alinity m CMV test must be interpreted within the context of all relevant clinical and laboratory findings. The Alinity m CMV test is not intended as a screening test for the presence of CMV DNA in blood or blood products. Alinity m CTRL Kit The Alinity m CMV controls are for validity determination of the quantitative Alinity m CMV assay on the automated Alinity m System. These controls are intended to be used with the Alinity m CMV assay; refer to the assay package insert for additional information. Alinity m CAL Kit The Alinity m CMV calibrators are for calibration for the Alinity m CMV assay on the automated Alinity m System when used for the quantitative determination of CMV DNA. The calibrators are intended to be used with the Alinity m CMV assay; refer to the assay package insert for additional information.
P210029	05/09/2022	PMAO - PMA Origir	APTIMA CMV QUANT ASSAY	HOLOGIC, INC.	Approval of The Aptima CMV Quant Assay - This device is approved for: The Aptima CMV Quant Assay is an in vitro nucleic acid amplification test for the quantitation of human cytomegalovirus (CMV) DNA in human EDTA plasma on the fully automated Panther system. The Aptima CMV Quant Assay is intended for use to aid in the management of solid-organ transplant patients and hematopoietic stem cell transplant patients. In patients receiving anti-CMV therapy, serial DNA measurements can be used to assess viral response to treatment. The results from Aptima CMV Quant Assay must be interpreted within the context of all relevant clinical and laboratory findings. Aptima CMV Quant Assay is not intended for use as a screening assay for the presence of CMV in blood or blood products.
P210032	05/13/2022	PMAO - PMA Origi	GORE TAG THORACIC BRANCH ENDOPROSTHESIS (TBE DEVICE)	W. L. GORE & ASSOCIATES, INC.	Approval for the GORE® TAG® Thoracic Branch Endoprosthesis. The device is intended for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures.
P210035	05/03/2022	PMAO - PMA Origir	ACCELSTIMTM BONE GROWTH STIMULATOR	ORTHOFIX US LLC	Approval for the AccelStim Ultrasound Bone Growth Stimulator, a non-invasive Low-Intensity Pulsed Ultrasound (LIPUS) device intended to aid fracture healing. The device is Rx only, and intended for single patient use in adult patients only.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S089	05/18/2022	Y - 135 Review Tra	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for software changes to the Auto Cutter machine (HEMOAC01) for SURGICEL® FIBRILLAR and SURGICEL® SNoW Absorbable Hemostats at ETHICON LLC.
P830055/S287	05/13/2022	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for two inspections to the CNC machining process step for the internal thread minor diameter and inside hole diameter for the PFC Sigma Knee System Femoral Stems approved under the LCS® Total Knee System.
P840001/S499	05/13/2022	N - Normal 180 Day	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for the Model EMBSNV20 BSNV-8 1x8 Adaptor Extension and a minor configuration change to previously approved software devices: Model A710 Intellis Clinician Programmer Application and Model A71200 Vanta/Sequentia LT Clinician Programmer Application.
P880086/S323	05/17/2022	R - Real-Time Proc	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ABBOTT MEDICAL	Approval for Merlin Patient Care System (PCS) 3650 Model 3330 v25.8.1 software and Merlin 2 PCS Model MER3400 vl.8.1 software to improve the accuracy of the remaining battery longevity estimate by the programmer.
P900033/S098	05/17/2022	Y - 135 Review Tra	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Approval for the qualification of a new Scanning Electron Microscope (SEM) for imaging Integra Dermal Regeneration Template (IDRT) product samples for pore size analysis.
P910001/S115	05/05/2022	R - Real-Time Proc	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for a new design specification and inspection requirement to be implemented during manufacturing of the Philips Laser System.
P910023/S443	05/17/2022	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Approval for Merlin Patient Care System (PCS) 3650 Model 3330 v25.8.1 software and Merlin 2 PCS Model MER3400 vl.8.1 software to improve the accuracy of the remaining battery longevity estimate by the programmer.
P970004/S356	05/12/2022	R - Real-Time Proc	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for a change in the supplier of the C12 capacitor in the recharge circuit of the model 97810 InterStim Micro implantable neurostimulator (INS).
P970013/S090	05/17/2022	R - Real-Time Proc	MICRONY PACEMAKERS	ABBOTT MEDICAL	Approval for Merlin Patient Care System (PCS) 3650 Model 3330 v25.8.1 software and Merlin 2 PCS Model MER3400 vl.8.1 software to improve the accuracy of the remaining battery longevity estimate by the programmer.
P000025/S123	05/18/2022	R - Real-Time Proc	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for the Mi1050 CONCERTO 2 (PIN) implant which incorporates a design change to a central lead exit of the approved Mi1000 CONCERT (PIN) implant.
P000025/S124	05/17/2022	R - Real-Time Proc	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for changes to the MAESTRO System Software 9.
P000040/S042	05/26/2022	O - Normal 180 Day	HYDRO THERMABLATOR ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL, INC.	Approval for manufacturing sites located at Life Science Outsourcing, Inc, 830 Challenger Street, Brea, CA 92821 and sterilization services at STERIS Applied Sterilization Technologies, 43425 Business Park Drive, Temecula, CA 92590.
P030016/S042	05/20/2022	O - Normal 180 Da	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	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
P030016/S043	05/04/2022	O - Normal 180 Day	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Approval of the protocol for the post-approval study (PAS) protocol.
P030035/S189	05/17/2022	R - Real-Time Proc	ANTHEM AND FRONTIER II CRT-P'S	ABBOTT MEDICAL	Approval for Merlin Patient Care System (PCS) 3650 Model 3330 v25.8.1 software and Merlin 2 PCS Model MER3400 vl.8.1 software to improve the accuracy of the remaining battery longevity estimate by the programmer.
P030054/S398	05/17/2022	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ABBOTT MEDICAL	Approval for Merlin Patient Care System (PCS) 3650 Model 3330 v25.8.1 software and Merlin 2 PCS Model MER3400 vl.8.1 software to improve the accuracy of the remaining battery longevity estimate by the programmer.
P040037/S152	05/26/2022	O - Normal 180 Da	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for the labeling update to include the final results of the RELINE MAX New Enrollment Study (ISR 04-04)
P050050/S021	05/06/2022	O - Normal 180 Day	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	DJO GLOBAL	Approval of the post approval study protocol referenced in the Actual Condition of Use Study (STAR 2).
P060001/S033	05/23/2022	R - Real-Time Proc	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Approval for increasing the tolerance of the delivery system component.
P070026/S097	05/05/2022	S - Special CBE	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for an additional inspection at the machining and in-process (IPC) process steps for the Pinnacle Cup components of the CERAMAX® Ceramic Total Hip System.
P080025/S251	05/12/2022	R - Real-Time Proc	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a change in the supplier of the C12 capacitor in the recharge circuit of the model 97810 InterStim Micro implantable neurostimulator (INS).
P100022/S039	05/13/2022	Y - 135 Review Tra	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK IRELAND, LTD.	Approval for a site change of an Active Pharmaceutical Ingredient (API) supplier.
P100034/S029	05/10/2022	N - Normal 180 Day	NOVOCURE LTD'S NOVOTTF-100A TREATMENT KIT	NOVOCURE GMBH	Approval for changes to the specifications of the ceramic discs used in the INE Transducer Arrays to make them lead-free, and the addition of a new supplier for these lead-free ceramic discs, Vishay Electronics GmbH, located at Dr.-Felix-Zandman-Platz 1, Selb 95100, Germany.
P100047/S184	05/18/2022	Y - 135 Review Tra	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for updates to the Pioneer II Controller Assembly Procedure.
P110019/S120	05/06/2022	O - Normal 180 Da	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval of the protocol for the post-approval study.
P110042/S169	05/18/2022	O - Normal 180 Day	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for updated labeling to include a clinical summary for the S-ICD Post Approval Study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130006/S091	05/26/2022	O - Normal 180 Da	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Approval for the post-approval labeling update to include the final results of the RELINE MAX New Enrollment Study (ISR 04-04)
P130022/S046	05/13/2022	S - Special CBE	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for labeling changes to rebrand the charger (CHGR2500) and patient remote (PTR2500) to the HFX Masterbrand.
P140029/S033	05/27/2022	N - Normal 180 Day	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for (1) a new syringe and new plunger, new plunger rod, new finger grip, and new secondary packaging for products approved under PMA P140029; (2) implementation of these changes on a new manufacturing line (L3) for automated assembly and packaging; and (3) modification of the secondary packaging and labelling to fit the new syringe and packaging line.
P140033/S072	05/17/2022	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ABBOTT MEDICAL	Approval for Merlin Patient Care System (PCS) 3650 Model 3330 v25.8.1 software and Merlin 2 PCS Model MER3400 vl.8.1 software to improve the accuracy of the remaining battery longevity estimate by the programmer.
P150009/S007	05/19/2022	O - Normal 180 Da	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Approval of the revised protocol for the AngelMed Guardian post-approval study.
P160008/S019	05/31/2022	R - Real-Time Proc	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Approval for the manufacturing of the SAM 350P, SAM 360P and SAM 450P defibrillators and accessory Pad-Paks using certain lead-free components.
P160013/S009	05/06/2022	R - Real-Time Proc	ORGAN CARE SYSTEM (OCS¿) LUNG SYSTEM	TRANSMEDICS, INC	Approval for the addition of the Lung Small Trachea Cannula Set to the currently available trachea cannulas for the OCS Lung System.
P160029/S014	05/09/2022	R - Real-Time Proc	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Approval for a change in formula for the hydrogel used on the M5071A and M5072A Adult and Infant/Child SMART Pads.
P160043/S055	05/12/2022	N - Normal 180 Day	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for changes to the delivery system and marketing under the Onyx Frontier Zotarolimus-Eluting Coronary Stent System trade name.
P160048/S018	05/04/2022	O - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval of the revised protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160048/S019	05/24/2022	O - Normal 180 Da	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170019/S032	05/06/2022	O - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval of the clinical protocol entitled F1CDx Validation Protocol and Statistical Analysis Plan: NTRK Clinical Efficacy Post Approval Study for larotrectinib
P180014/S008	05/09/2022	R - Real-Time Proc	XPS¿ WITH STEEN SOLUTION¿ PERFUSATE	XVIVO PERFUSION, INC.	Approval for a software upgrade in the XPS (software v5.3.0) to address minor bug fixes and to remove the software control of XPS¿ auxiliary pumps.
P180014/S009	05/09/2022	R - Real-Time Proc	XPS¿ WITH STEEN SOLUTION¿ PERFUSATE	XVIVO PERFUSION, INC.	Approval for a XPS hardware update to replace obsoleted pump components with the manufacturers recommended new model components.
P180032/S010	05/31/2022	S - Special CBE	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Approval for the modification to the manufacturing process for the subject device. This change is the addition of an inspection step made to the manufacturing process to verify that the control software has been successfully loaded onto the device.
P180034/S007	05/24/2022	N - Normal 180 Day	TACK ENDOVASCULAR SYSTEM (6F)	PHILIPS IMAGE GUIDED THERAPY CORPORATION	Approval for a change of quality management system and design ownership from Intact Vascular, Inc. to Philips Image Guided Therapy Corporation.
P180038/S010	05/05/2022	R - Real-Time Proc	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval to allow the LIAISON XL Analyzer to be connected to the Beckman DxA 5000, an FDA-cleared third party Laboratory Automation System (LAS).
P180039/S009	05/05/2022	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Approval to allow the LIAISON XL Analyzer to be connected to the Beckman DxA 5000, an FDA-cleared third party Laboratory Automation System (LAS).
P180045/S007	05/05/2022	R - Real-Time Proc	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Approval to allow the LIAISON XL Analyzer to be connected to the Beckman DxA 5000, an FDA-cleared third party Laboratory Automation System (LAS).
P180047/S014	05/05/2022	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval to allow the LIAISON XL Analyzer to be connected to the Beckman DxA 5000, an FDA-cleared third party Laboratory Automation System (LAS).
P180048/S007	05/05/2022	R - Real-Time Proc	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Approval to allow the LIAISON XL Analyzer to be connected to the Beckman DxA 5000, an FDA-cleared third party Laboratory Automation System (LAS).
P180049/S007	05/05/2022	R - Real-Time Proc	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Approval to allow the LIAISON XL Analyzer to be connected to the Beckman DxA 5000, an FDA-cleared third party Laboratory Automation System (LAS).
P180050/S003	05/05/2022	N - Normal 180 Day	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval for MR Conditional labeling for the Barostim System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190017/S004	05/05/2022	R - Real-Time Proc	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approval to allow the LIAISON XL Analyzer to be connected to the Beckman DxA 5000, an FDA-cleared third party Laboratory Automation System (LAS).
P190027/S004	05/24/2022	N - Normal 180 Day	TACK ENDOVASCULAR SYSTEM (4F, 1.5-4.5MM)	PHILIPS IMAGE GUIDED THERAPY CORPORATIO N (FORMERLY INTACT)	Approval for a change of quality management system and design ownership from Intact Vascular, Inc. to Philips Image Guided Therapy Corporation.
P190032/S003	05/25/2022	N - Normal 180 Day	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval for updating of Dual Index Barcode (DIB) primer from DIBv1 to DIBv2 for F1L CDx Device.
P200010/S004	05/18/2022	R - Real-Time Proc	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval to qualify serial number-controlled instrument changes.
P200021/S012	05/27/2022	O - Normal 180 Day	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Approval of the changes (e.g., additional minor changes to the protocol to align with US sites routine practice reported to Oticon Medical in the course of study site recruitment) of the protocol for the post-approval study (PAS) protocol.
P200028/S009	05/02/2022	R - Real-Time Proc	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Approval for updates to the DiamondTemp Irrigation Pump user manual, including a new flow rate verification procedure.
P200035/S002	05/27/2022	O - Normal 180 Day	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval for the OrganOx metra® New Enrollment PAS. The OrganOx metra® New Enrollment PAS is a multi-center, single-arm, unblinded post-approval study designed to compare recipients of PAS NMP livers versus IDE SCS livers with respect to adverse biliary-related events. Recruitment will take place at a minimum of 10 sites which are UNOS member liver transplant centers.
P210001/S005	05/20/2022	O - Normal 180 Da	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Approval of the clinical protocol entitled Statistical Analysis Plan for MK-3475 dMMR VENTANA MMR RxDx Panel Post Approval Analysis.
P210020/S004	05/17/2022	R - Real-Time Proc	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Approval for validation of a new Low EO sterilization cycle utilizing a lower ethylene oxide (EO) concentration and lower EO dwell time.

Total: 58

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S092	05/25/2022	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Validation of a new Reactor for the oxidation of the ORC used in the manufacturing of SURGICEL NU-KNIT.
P810006/S099	05/20/2022	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Replacement of the current two (2) modules of the water purification (RODEI) system with four (4) like-in-kind modules from the same manufacturer to increase purified water capacity at the Integra NeuroSciences manufacturing facility located at Road 402 North, Km 1.2 Añasco, PR 00610.
P840001/S515	05/10/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	New automated environmental monitoring system.
P840001/S516	05/12/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Changes to the final acceptance procedures for hybrid modules and assemblies and the hybrid final pack and bag RFID process specifications procedures to correct identified gaps in standard work as determined during a CAPA investigation.
P840001/S517	05/24/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Change the testing of the M960543A Stim Integrated Circuit and the M960545A Multi-Function Integrated Circuit wafer products from the LTX to the SPEA Compact Automated Test Equipment at the Medtronic Tempe Campus.
P840001/S518	05/25/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Implement a validated thermal bonding rework process for the Spinal Cord Stimulation and Deep Brain Stimulation extensions manufactured at the Medtronic Villalba site.
P840062/S085	05/20/2022	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Replacement of the current two (2) modules of the water purification (RODEI) system with four (4) like-in-kind modules from the same manufacturer to increase purified water capacity at the Integra NeuroSciences manufacturing facility located at Road 402 North, Km 1.2 Añasco, PR 00610.
P850010/S102	05/20/2022	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Replacement of the current two (2) modules of the water purification (RODEI) system with four (4) like-in-kind modules from the same manufacturer to increase purified water capacity at the Integra NeuroSciences manufacturing facility located at Road 402 North, Km 1.2 Añasco, PR 00610.
P860003/S107	05/25/2022	X - 30-Day Notice	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Qualification of a mold tool with a material change for the core insert. The change is being made for improving production readiness.
P860004/S389	05/05/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Changes to bacterial endotoxin test procedure and addition of new incubator shaker.
P860004/S390	05/10/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	New automated environmental monitoring system.
P860004/S391	05/12/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Changes to the final acceptance procedures for hybrid modules and assemblies and the hybrid final pack and bag RFID process specifications procedures to correct identified gaps in standard work as determined during a CAPA investigation.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P870024/S062	05/10/2022	X - 30-Day Notice	FLUOROPERM RGP CONTACT LENSES	COOPERVISION, INC.	Addition of a new power reader in the manufacturing process, the establishment of a fourth manufacturing line and a change in the blocking process for lens lathing.
P890023/S048	05/24/2022	X - 30-Day Notice	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	Addition of Biomedics 55 Asphere lens capability to the Low Volume Automation (LVA1) manufacturing line at the CooperVision, Inc. facility in Scottsville, New York.
P890055/S080	05/20/2022	X - 30-Day Notice	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Change to Suture Loop supplier
P900033/S099	05/05/2022	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Removal of two points of use from the WFI system.
P900033/S100	05/20/2022	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Replacement of the current two (2) modules of the water purification (RODEI) system with four (4) like-in-kind modules from the same manufacturer to increase purified water capacity at the Integra NeuroSciences manufacturing facility located at Road 402 North, Km 1.2 Añasco, PR 00610.
P910023/S444	05/18/2022	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Addition of an alternate supplier for the 9-pin filtered feedthrough assembly components used in ICD devices.
P920015/S268	05/03/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Change the heat shrinking manufacturing process for the indicator band component.
P920048/S023	05/09/2022	X - 30-Day Notice	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Eliminate an incoming inspection of an assay reagent that is a component of the Rapid fFN for the TLiIQ System; transfer of the manufacturing site for assay standards of the Rapid fFN for the TLiIQ System; and transfer of the manufacturing site for the TLiIQ QCette of the Rapid fFN for the TLiIQ System.
P930014/S143	05/18/2022	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Introduction of an additional sterilization chamber for routine sterilization of the subject devices using a new sterilization cycle at existing, approved sterilization service provider, Steris - AST Tullamore Ireland.
P930039/S242	05/11/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Updates to the top hat surrogate sampling process and IPA wipes for MCRDs at Medtronic Rice Creek.
P950020/S121	05/19/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Additional top assembly line.
P950020/S122	05/03/2022	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Additional blade casting cell to the wolverine manufacturing processes.
P960009/S425	05/10/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	New automated environmental monitoring system.
P960009/S426	05/12/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Changes to the final acceptance procedures for hybrid modules and assemblies and the hybrid final pack and bag RFID process specifications procedures to correct identified gaps in standard work as determined during a CAPA investigation.

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P960009/S427	05/24/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Medtronics external supplier, Medicoil, to qualify additional new equipment for the coil winding and laser processes of Minicoils components.
P960009/S428	05/24/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change the testing of the M960543A Stim Integrated Circuit and the M960545A Multi-Function Integrated Circuit wafer products from the LTX to the SPEA Compact Automated Test Equipment at the Medtronic Tempe Campus.
P960009/S429	05/25/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Implement a validated thermal bonding rework process for the Spinal Cord Stimulation and Deep Brain Stimulation extensions manufactured at the Medtronic Villalba site.
P970004/S361	05/10/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	New automated environmental monitoring system.
P970004/S362	05/12/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Changes to the final acceptance procedures for hybrid modules and assemblies and the hybrid final pack and bag RFID process specifications procedures to correct identified gaps in standard work as determined during a CAPA investigation.
P980016/S815	05/03/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement the replacement of Trichloroethylene Vapor Solvent Degreaser with SolVantage Vapor Solvent Degreaser.
P980016/S818	05/16/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Manufacturing process changes to the surface mount tantalum capacitor manufactured by AVX Tantalum Corporation.
P980016/S819	05/17/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement an equipment controller for the plasma cleaner equipment at Medtronic Swiss Operations.
P980016/S820	05/26/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of a capacitor manufacturing line.
P980016/S821	05/25/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a second manufacturing line for shield assemblies at an existing supplier.

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P980016/S822	05/20/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add an anode seal inspection during the Polaris battery manufacturing process.
P980035/S714	05/03/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement the replacement of Trichloroethylene Vapor Solvent Degreaser with SolVantage Vapor Solvent Degreaser.
P980035/S715	05/10/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Additional inspection for the insulator type for feedthroughs at internal supplier - Medtronic Energy and Component Center.
P980035/S717	05/17/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement an equipment controller for the plasma cleaner equipment at Medtronic Swiss Operations.
P980037/S088	05/06/2022	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Process devices using the reduced EtO S756 sterilization cycle at the BSC Coventry Rhode Island, BSC Galway Ireland, and Steris Tullamore Ireland facilities.
P980040/S147	05/18/2022	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Perform the flat time test prior to sterilization as opposed to post sterilization.
P990009/S069	05/20/2022	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Replacement of the reverse osmosis (RO) pretreatment skid for the USP Purified Water System.
P010003/S040	05/25/2022	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Alternative irradiation box and configuration for shipping product, and a new supplier for the strong ammonium solution.
P010015/S497	05/03/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement the replacement of Trichloroethylene Vapor Solvent Degreaser with SolVantage Vapor Solvent Degreaser.
P010015/S499	05/17/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement an equipment controller for the plasma cleaner equipment at Medtronic Swiss Operations.
P010031/S782	05/03/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement the replacement of Trichloroethylene Vapor Solvent Degreaser with SolVantage Vapor Solvent Degreaser.

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P010031/S785	05/16/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Manufacturing process changes to the surface mount tantalum capacitor manufactured by AVX Tantalum Corporation.
P010031/S786	05/17/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement an equipment controller for the plasma cleaner equipment at Medtronic Swiss Operations.
P010031/S787	05/26/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Addition of a capacitor manufacturing line.
P010031/S788	05/25/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add a second manufacturing line for shield assemblies at an existing supplier.
P010031/S789	05/20/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Add an anode seal inspection during the Polaris battery manufacturing process.
P040020/S103	05/18/2022	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Introduction of an additional sterilization chamber for routine sterilization of the subject devices using a new sterilization cycle at existing, approved sterilization service provider, Steris - AST Tullamore Ireland.
P040033/S036	05/19/2022	X - 30-Day Notice	BIRMINGHAM HIP RESURFACING (BHR) SYSTEM	SMITH&NEPH EW ORTHOPAEDI CS	Removal of the x-ray equipment used in the post-irradiation receiving process for the Birmingham Hip Resurfacing System.
P050006/S099	05/09/2022	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,I NC	Use of Semi-Automated Eyelet Film Wrappers for the manufacturing of the GORE® CARDIOFORM Septal Occluder.

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P050031/S009	05/10/2022	X - 30-Day Notice	PARAGON Z CRT (TISILFOCON A) RIGID GAS PERMEABLE CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY	COOPERVISION, INC.	Addition of a new power reader in the manufacturing process, the establishment of a fourth manufacturing line and a change in the blocking process for lens lathing.
P050037/S114	05/05/2022	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Change in the number of replicates used during the out of specification of endotoxin testing.
P050052/S135	05/05/2022	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Change in the number of replicates used during the out of specification of endotoxin testing.
P060037/S079	05/20/2022	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change in the gamma sterilization process monitoring, including a substantiation dose change, new master products, and bioburden alert limits.
P080006/S171	05/03/2022	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Change the heat shrinking manufacturing process for the indicator band component.
P080007/S027	05/26/2022	X - 30-Day Notice	BARD E-LUMINEXX VASCULAR STENT	BARD PERIPHERAL VASCULAR, INC.	Alternative supplier for injection molded components on the delivery system.
P080011/S145	05/03/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Introduction of an LED UV curing oven at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080025/S256	05/10/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	New automated environmental monitoring system.
P080025/S257	05/12/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Changes to the final acceptance procedures for hybrid modules and assemblies and the hybrid final pack and bag RFID process specifications procedures to correct identified gaps in standard work as determined during a CAPA investigation.
P090013/S321	05/11/2022	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Updates to the top hat surrogate sampling process and IPA wipes for MCRDs at Medtronic Rice Creek.
P090016/S048	05/05/2022	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Modify the Depyrogenation cycle for the equipment used in the manufacturing of Belotero Balance Dermal Filler and Belotero Balance with Lidocaine Dermal Filler.
P100010/S127	05/06/2022	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATHLP	Addition of a new literature pick and place station and new strapping machines.
P100016/S014	05/13/2022	X - 30-Day Notice	EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Changing the measurement system used for hydrophobic button diameter measurements in CT Lucia 602, CT Lucia 202, and CT Lucia 611P intraocular lens production.
P100021/S104	05/13/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Addition of new laser welding equipment for the spindle hypotube assembly for the Endurant Aortic Delivery System.

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P100047/S197	05/10/2022	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Addition of a holding fixture during assembly of the battery pack, change in the tape used during assembly, and revision of the final inspection procedure.
P110035/S067	05/06/2022	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Process devices using the reduced EtO S756 sterilization cycle at the BSC Coventry Rhode Island, BSC Galway Ireland, and Steris Tullamore Ireland facilities.
P130013/S047	05/06/2022	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Process devices using the reduced EtO S756 sterilization cycle at the BSC Coventry Rhode Island, BSC Galway Ireland, and Steris Tullamore Ireland facilities.
P130013/S048	05/19/2022	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Add an alternate wetline process used the in manufacturing of the WATCHMAN FLX implant.
P130021/S116	05/23/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Reduction in solution volume during tissue fixation.
P140026/S019	05/03/2022	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Automation of a welding process.
P140028/S073	05/06/2022	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Process devices using the reduced EtO S756 sterilization cycle at the BSC Coventry Rhode Island, BSC Galway Ireland, and Steris Tullamore Ireland facilities.
P150003/S085	05/06/2022	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Process devices using the reduced EtO S756 sterilization cycle at the BSC Coventry Rhode Island, BSC Galway Ireland, and Steris Tullamore Ireland facilities.
P150003/S086	05/25/2022	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of Galway as an additional manufacturing site for the Synergy XD and Synergy Megatron Manifold components.
P150003/S087	05/19/2022	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to the equipment model used for inspection of the inner pack seal.
P150030/S020	05/03/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Addition of an established packaging site as a second source for performing the packaging processes of the POLARSTEM stems.
P150030/S021	05/17/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Addition of a new forging press and relocation of the trim operation step for the forging process of ANTHOLOGY stems.
P150033/S138	05/03/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement the replacement of Trichloroethylene Vapor Solvent Degreaser with SolVantage Vapor Solvent Degreaser.
P150033/S140	05/17/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement an equipment controller for the plasma cleaner equipment at Medtronic Swiss Operations.
P150035/S001	05/04/2022	X - 30-Day Notice	AVEIR VR LEADLESS SYSTEM	ABBOTT MEDICAL	Updating the docking button cleaning line from manual to an automated cleaning system.

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P160015/S014	05/27/2022	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATIO N	Equivalent resistors used for the AED Plus Printed Circuit Board Assemblies (PCBA).
P160025/S014	05/20/2022	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Increase in laser cutting speed.
P170038/S010	05/11/2022	X - 30-Day Notice	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Add an alternate sub-tier supplier for the PTFE felt material used to manufacture the Apical Sewing Ring for the CentriMag Cannula Drainage Kit.
P180007/S009	05/12/2022	X - 30-Day Notice	SPIRATION® VALVE SYSTEM	GYRUS ACMI, INC.	Minor change to a manufacturing tool used in the assembly of the SVS Deployment Catheter and Loader.
P180011/S049	05/06/2022	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Process devices using the reduced EtO S756 sterilization cycle at the BSC Coventry Rhode Island, BSC Galway Ireland, and Steris Tullamore Ireland facilities.
P180037/S010	05/20/2022	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Delivery system manufacturing process and inspection changes for the 9 French device size.
P180037/S011	05/23/2022	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Delivery system manufacturing process and inspection changes for the 8 French size.
P180038/S011	05/06/2022	X - 30-Day Notice	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Introduce an additional supplier for an assay accessory.
P180039/S010	05/06/2022	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Introduce an additional supplier for an assay accessory.
P180045/S008	05/06/2022	X - 30-Day Notice	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Introduce an additional supplier for an assay accessory.
P180046/S055	05/13/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGI ES, INC.	Additional laser marking equipment.
P180047/S015	05/06/2022	X - 30-Day Notice	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Introduce an additional supplier for an assay accessory.

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P180048/S008	05/06/2022	X - 30-Day Notice	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Introduce an additional supplier for an assay accessory.
P180049/S008	05/06/2022	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Introduce an additional supplier for an assay accessory.
P190002/S006	05/12/2022	X - 30-Day Notice	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Change in the sterilization process at Steris Applied Sterilization Technologies (Steris AST) by increased load density, reduction of injection pressure of EO gas (reduction in EO concentration), and updated chamber temperature specification and tolerances.
P190002/S008	05/26/2022	X - 30-Day Notice	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Add an alternate manufacturer for the anchors used in the Evoke Spinal Cord Stimulation System.
P190006/S055	05/13/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Additional laser marking equipment.
P190017/S005	05/06/2022	X - 30-Day Notice	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Introduce an additional supplier for an assay accessory.
P190018/S019	05/03/2022	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON LABORATORIES, LLC	Transfer of the nozzle coating process during manufacturing of the AutonoMe Automated Pre-loaded Delivery System from Alcon Huntington, West Virginia to Alcon Laboratories, Ireland.

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P190018/S020	05/18/2022	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON LABORATORIES, LLC	Introduction of an additional sterilization chamber for routine sterilization of the subject devices using a new sterilization cycle at existing, approved sterilization service provider, Steris - AST Tullamore Ireland.
P200046/S009	05/23/2022	X - 30-Day Notice	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Reduction in solution volume during tissue fixation.
P210022/S001	05/26/2022	X - 30-Day Notice	ALINITY M CMV	ABBOTT MOLECULAR, INC.	Extended expiration dating for a critical raw material.

Total: 106