PMA Monthly approvals from 4/1/2022 to 4/30/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190020	04/14/2022	PMAO - PMA Origi	BIOFREEDOM DRUG COATED CORONARY STENT SYSTEM	BIOSENSORS INTERNATIONAL USA, INC.	Approval for the BioFreedom Drug Coated Stent System. This device is indicated for improving coronary luminal diameter in patients at high risk for bleeding with symptomatic ischemic heart disease due to de novo lesions of length <= 32 mm in native coronary arteries with a reference diameter ranging between 2.25 mm and 4.0 mm.
P210006	04/19/2022	PMAO - PMA Origi	THORAFLEX¿ HYBRID	VASCUTEK LTD.	Approval for the Thoraflex Hybrid. The device is intended for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta with or without involvement of the ascending aorta in cases of aneurysm and/or dissection.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16895/S104	04/20/2022	R - Real-Time Proc	SOFLENS CONTACT LENSES (POLYMACON)	BAUSCH & LOMB, INC.	Approval for removal of the Sagittal Depth measurement acceptance criteria from the finished product specifications and for minor editorial changes to finished product specification for Soflens® 38 (polymacon) Visibility Tinted Contact Lenses
N17600/S034	04/01/2022	Y - 135 Review Tra	AVITENE (MICROFIBRILLAR COLLAGEN HOMOSTAT)	DAVOL, INC., SUB. C.R. BARD, INC.	Approval for the replacement of current qualitative in process heavy metals testing with a quantitative test and removal of in process testing of total ash content
P800002/S027	04/01/2022	Y - 135 Review Tra	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT NON-WOVEN WEB	C.R. BARD, INC.	Approval for the replacement of current qualitative in process heavy metals testing with a quantitative test and removal of in process testing of total ash content
P950037/S234	04/11/2022	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for updated programmer software versions PSW 2201.U/1 and NEO 2201.U/1.
P960009/S419	04/06/2022	R - Real-Time Proc	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for an update to the primary Information for Prescribers (IFP) clinician labeling, and update to the primary Patient Therapy Guide (PTG) to mitigate the potential for implantable neurostimulator (INS) malfunction during a cardioversion procedure.
P970051/S208	04/29/2022	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for modification to Cochlear Research Platform Software resulting in version 2.0 of the software. This software update makes minor performance changes to existing electrocochleography functionality and implements a new software design to allow for introduction of future functionality.
P980023/S111	04/11/2022	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for updated programmer software versions PSW 2201.U/1 and NEO 2201.U/1.

Data as of 05/12/2022 03:01 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000009/S097	04/11/2022	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for updated programmer software versions PSW 2201.U/1 and NEO 2201.U/1.
P000013/S020	04/01/2022	S - Special CBE	TRIDENT SYSTEM	HOWMEDICA OSTEONICS CORP.	Approval for updating the instructions for use (IFU) for the Trident Acetabular System: Trident Alumina Inserts because of European Union (EU) requirements.
P010031/S775	04/11/2022	O - Normal 180 Day	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for labeling updates to the clinical study summary for the post approval study.
P030002/S039	04/08/2022	O - Normal 180 Day	CRYSTALENS MODEL AT-45 ACCOMMODATING POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	BAUSCH & LOMB, INC.	Approval for revised device labeling to describe results of the New Enrollment Study Post Approval Study (PAS) protocol.
P050023/S166	04/11/2022	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for updated programmer software versions PSW 2201.U/1 and NEO 2201.U/1.
P050051/S043	04/14/2022	N - Normal 180 Day	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORI ES INC	Approval for conversion of the microparticle coating process from an automated microparticle processing system to a magnetic separation coating process.
P070008/S136	04/11/2022	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 updated programmer software versions PSW 2201.U/1 and NEO 2201.U/1.
P080012/S072	04/28/2022	S - Special CBE	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for labeling updates to the refill kit and MRI scan instructions for use.
P100021/S102	04/07/2022	S - Special CBE	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for implementation of changes to the taper tip manufacturing and inspection processes at the supplier and updates to the inspection plan for the taper tip assembly at Medtronics receiving inspection.
P100031/S027	04/04/2022	N - Normal 180 Day	ELECSYS ANTI-HBC IMMUNOASSAY & ELECSYS PRECICONTROL ANTI-HBC	ROCHE DIAGNOSTICS CORP.	Approval for modification of the assay reagents to improve the tolerance to biotin interference, updating the sample stability claims, and revisions to the device labeling.
P100032/S021	04/04/2022	N - Normal 180 Day	ELECSYS ANTI-HBC IMMUNOASSAY, ELECSYS PRECICONTROL ANTI-HBC FOR USE ON THE ELECSYS 2010 IMMUNOASSAY ANALYZER	ROCHE DIAGNOSTICS CORP.	Approval for modification of the assay reagents to improve the tolerance to biotin interference, updating the sample stability claims, and revisions to the device labeling.
P100045/S059	04/12/2022	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for updates to the software contained in the CardioMEMS Hospital System (CM3100).

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P110010/S194	04/29/2022	Y - 135 Review Tra	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for removing a wash step during stent cleaning and preparation.
P110014/S012	04/06/2022	O - Normal 180 Day	DUNE MEDICAL DEVICES MARGINPROBE SYSTEM	DILON MEDICAL TECHNOLOGIES, LTD.	Approval for labeling changes including post-approval study clinical data
P130005/S034	04/06/2022	R - Real-Time Proc	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for software updates which provide additional cybersecurity protection.
P130008/S074	04/29/2022	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the Model 4063 Silicone Stimulation Lead and the Model 4340 Silicone Sensing Lead lengths 25cm and 45cm.
P130016/S046	04/29/2022	R - Real-Time Proc	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for modification to Cochlear Research Platform Software resulting in version 2.0 of the software. This software update makes minor performance changes to existing electrocochleography functionality and implements a new software design to allow for introduction of future functionality.
P130017/S051	04/13/2022	R - Real-Time Proc	COLOGUARD	EXACT SCIENCES CORPORATION	Approval for a minor change in the wording of the Indications for Use. Cologuard Stool DNA-Based Colorectal Cancer Screening Test is indicated for Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. Cologuard is for use with the Cologuard® collection kit and the following instruments: BioTek ELx808 Absorbance Microplate Reader; Applied Biosystems 7500 Fast Dx Real-Time PCR; Hamilton Microlab STARlet; and the Exact Sciences System Software with Cologuard Test Definition. Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average-risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.
P130021/S109	04/29/2022	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Approval for 1) modifications to the Medtronic Evolut FX Instructions for Use to include the clinical data; and 2) reformatting the clinical study summaries and revising the legal manufacturer address in the IFUs for the Evolut R, Evolut PRO, Evolut PRO+, and Evolut FX Systems.
P130026/S078	04/27/2022	R - Real-Time Proc	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for the TactiSys Quartz Equipment SW v1.7.2 software maintenance release to disable the charging of a non-rechargeable Real Time Clock (RTC) battery.
P140003/S088	04/19/2022	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for revising the Instructions for Use to allow the use of sodium bicarbonate (25 or 50 mEq/L) as an alternative to heparin (25 or 50 U/mL) in the purge fluid during clinical use of the Impella catheters in patients intolerant to heparin or in whom heparin is contraindicated.
P140003/S092	04/05/2022	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for modifications to the labeling to specify the use of the Aortic Placement Signal pressure reading as a diagnostic aortic pressure reading once the catheter is correctly placed with respect to the aortic valve.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140003/S093	04/08/2022	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for software changes (v11.0).
P140010/S062	04/07/2022	N - Normal 180 Day	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for an 0.018 inch guidewire compatible device configuration.
P140016/S005	04/14/2022	S - Special CBE	ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT	COOK MEDICAL INCORPORATED	Approval for an additional seal on one side of the Zenith Alpha Thoracic Endovascular Graft primary packaging and new specifications for the position of an already applied seal on the opposite side.
P140026/S016	04/28/2022	P - Panel Track	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for the expansion of the Indications for Use to include treatment of patients at standard risk for adverse events from carotid endartectomy.
P150026/S013	04/02/2022	N - Normal 180 Day	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for a manufacturing site located at Sterigenics, Inc., 84 Park Road, Queensbury, NY 12804 as an alternate sterilization site for the HeartLight X3 Catheter with Excalibur Balloon.
P150031/S048	04/04/2022	R - Real-Time Proc	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the Vercise Neural Navigator 4 programming software (version 4.0.2).
P160042/S017	04/20/2022	Y - 135 Review Tra	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for a change to the sample preparation in the Lidocaine HCl assay
P170005/S004	04/11/2022	S - Special CBE	ABBOTT REALTIME IDH2	ABBOTT MOLECULAR INC.	Approval for addition of specifications to quality control testing.
P170011/S035	04/19/2022	N - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for revising the Instructions for Use to allow the use of sodium bicarbonate (25 or 50 mEq/L) as an alternative to heparin (25 or 50 U/mL) in the purge fluid during clinical use of the Impella catheters in patients intolerant to heparin or in whom heparin is contraindicated.
P170012/S028	04/22/2022	Y - 135 Review Tra	HEMOBLAST¿ BELLOWS	BIOM'UP FRANCE SAS	Approval for the modification of the blending method for the three constituent components that compose the finished HEMOBLAST Bellows Hemostatic Powder in the manufacturing process.
P170019/S034	04/13/2022	O - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval of the clinical protocol entitled Statistical Analysis Plan for MK-3475 MSI-H FMI F1CDx Post Approval Analysis.
P180001/S004	04/14/2022	S - Special CBE	ZENITH DISSECTION ENDOVASCULAR SYSTEM	WILLIAM COOK EUROPE APS	Approval for an additional seal on one side of the Zenith Dissection Endovascular Graft primary packaging and new specifications for the position of an already applied seal on the opposite side.
P180027/S005	04/26/2022	O - Normal 180 Day	FLOW RE-DIRECTION ENDOLUMINAL DEVICE (FRED®) SYSTEM	MICROVENTION, INC.	Approval of the revised protocol for the post-approval study (PAS).
P180050/S002	04/14/2022	N - Normal 180 Day	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval to add Model 9020 Barostim Programmer as an alternate programmer and additional branding updates.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180050/S004	04/12/2022	O - Normal 180 Day	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval for the revised Statistical Analysis Plan for Extended Phase BeAT-HF PAS.
P180051/S001	04/27/2022	P - Panel Track	ORGAN CARE SYSTEM (OCS) HEART SYSTEM	TRANSMEDICS, INC.	Approval for the Organ Care System (OCS) Heart System for expanding the indication to include donation-after-circulatory-death (DCD) donor hearts. The device is indicated for the preservation of donation-after-brain-death (DBD) hearts initially deemed unsuitable for procurement and transplantation at initial evaluation due to limitations of prolonged cold static cardioplegic preservation (e.g., > 4 hours of cross-clamp time). The OCS Heart System is also indicated for the ex vivo reanimation, functional monitoring, and beating-heart preservation of DCD hearts.
P190002/S002	04/06/2022	S - Special CBE	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Approval for updated labeling to limit use of the lead extension to the trial procedure, rather than at permanent implantation
P200035/S001	04/12/2022	O - Normal 180 Day	ORGANOX METRA SYSTEM	ORGANOX LIMITED	Approval of the revised protocol for the post-approval study (PAS) protocol.
P200046/S008	04/08/2022	O - Normal 180 Day	HARMONY¿ TPV SYSTEM	MEDTRONIC, INC.	Approval of the revised protocols for the post-approval studies.
P210014/S001	04/08/2022	O - Normal 180 Day	SLENDER SIROLIMUS-ELUTING CORONARY STENT INTEGRATED DELIVERY SYSTEM AND DIRECT SIROLIMUS-ELUTING CORONARY STENT RAPID EXCHANGE DELIVERY SYSTEM	SVELTE MEDICAL SYSTEMS, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 49

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S190	04/01/2022	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Process change to the water bath monitoring requirements for assembly of the AMS 700 IPP and AMS 800.
N970012/S191	04/20/2022	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Incorporation of alternate step in the minocycline hydrochloride manufacturing process.
P810006/S098	04/28/2022	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Installation of a new Air Handling Unit at the Integra Collagen Manufacturing Center Building 105 in Plainsboro, NJ.
P830055/S288	04/27/2022	X - 30-Day Notice	LCS(R) TOTAL KNEE	DEPUY, INC.	Addition of an alternate site (DePuy Ireland) for the heat treatment manufacturing process

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S206	04/21/2022	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P830063/S023	04/07/2022	X - 30-Day Notice	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Transfer of the manufacturing process of the twin tube component of the Prismaflex TPE2000 set to an in-house supplier.
P840062/S084	04/28/2022	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Installation of a new Air Handling Unit at the Integra Collagen Manufacturing Center Building 105 in Plainsboro, NJ.
P850010/S100	04/20/2022	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Relocation of the supplier site for Tyvek envelope processing.
P850010/S101	04/28/2022	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Installation of a new Air Handling Unit at the Integra Collagen Manufacturing Center Building 105 in Plainsboro, NJ.
P850089/S161	04/21/2022	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P890003/S452	04/21/2022	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P890003/S453	04/28/2022	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	New automated equipment for mixing, coating, and rolling processes for lithium-ion batteries.
P900056/S199	04/28/2022	X - 30-Day Notice	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Changes in the sterile barrier manufacturing process for the ROTAWIRE Drive.
P900061/S168	04/21/2022	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910018/S033	04/29/2022	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.	Qualification of new equipment for the EVOH coating process and the Hollow Fiber (HF) drying process to increase hollow fiber production capacity.
P920015/S267	04/21/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P920048/S022	04/13/2022	X - 30-Day Notice	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Change in incoming release criteria for the nitrocellulose component of the Rapid fFN for the TLiIQ System.
P930039/S241	04/21/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P950024/S103	04/21/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P960040/S477	04/13/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Modify the process for the seal plug cavity of the Tachy DF4 header core.
P970004/S359	04/15/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Replacement of degreasing equipment and use of new degreasing solvent.
P970004/S360	04/26/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Implement a minimum shade requirement for laser mark intensity on affected leads and to qualify a visual standard tool for inspection of the laser mark intensity.
P980016/S810	04/01/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add the Cobalt and Chrome products in the Medtronic Polaris family to the repack process at the Americas Repack Center at the Distribution Center in Memphis, TN.
P980016/S811	04/15/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new transfer mold process and equipment used in manufacturing at Medtronic Tempe Campus.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S812	04/21/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P980016/S814	04/26/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement minor updates in the manufacturing of hybrids at Medtronic Tempe Campus.
P980035/S712	04/21/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P980035/S713	04/26/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement minor updates in the manufacturing of hybrids at Medtronic Tempe Campus.
P980050/S137	04/21/2022	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P990004/S054	04/06/2022	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Implementation of new automatic washing machines and new modified trolleys for cleaning plating trays.
P990065/S012	04/12/2022	X - 30-Day Notice	SIR-SPHERES	SIRTEX MEDICAL PTY LTD	Addition of an alternate qualified supplier (Niowave, Inc.) for a critical raw material, Y-90 chloride solution.
P000006/S061	04/15/2022	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Process change to the Tyvek lid labeling for the Coloplast Titan IPP.
P000053/S124	04/01/2022	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Process change to the water bath monitoring requirements for assembly of the AMS 700 and AMS 800.
P000053/S125	04/20/2022	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Incorporation of alternate step in the minocycline hydrochloride manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S553	04/13/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Modify the process for the seal plug cavity of the Tachy DF4 header core.
P010014/S101	04/04/2022	X - 30-Day Notice	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	The following PET/AlOx/LLDPE packaging pouch related changes: 1) new 2nd tier supplier for the layer lamination process; 2) alternate adhesive material used in lamination process; 3) relocation of PET/AlOx production; and 4) alternate supplier of LLDPE sealant layer material.
P010015/S495	04/21/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P010015/S496	04/26/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement minor updates in the manufacturing of hybrids at Medtronic Tempe Campus.
P010031/S777	04/01/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add the Cobalt and Chrome products in the Medtronic Polaris family to the repack process at the Americas Repack Center at the Distribution Center in Memphis, TN.
P010031/S779	04/15/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement a new transfer mold process and equipment used in manufacturing at Medtronic Tempe Campus.
P010031/S780	04/21/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P010031/S781	04/26/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement minor updates in the manufacturing of hybrids at Medtronic Tempe Campus.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030009/S107	04/19/2022	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Transfer of component extrusion manufacturing operations.
P030036/S137	04/21/2022	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P030047/S044	04/27/2022	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS US CORPORATION	Automation of a welding process for the delivery system.
P040021/S049	04/14/2022	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ABBOTT MEDICAL	Addition of three new tissue suppliers/abbatoirs.
P040021/S050	04/26/2022	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ABBOTT MEDICAL	Modifications to the Steady Flow Hydrodynamic Tester.
P040044/S091	04/25/2022	X - 30-Day Notice	MATRIX VASCULAR CLOSURE SYSTEM (VSG)	CORDIS US CORPORATION	Addition of an alternate supplier for components of the MYNX® Vascular Closure Device (VCD).
P040045/S124	04/27/2022	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Adding an alternate supplier for a raw material used in VISTAKON® (senofilcon A) Brand Contact Lenses.
P050017/S019	04/04/2022	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK IRELAND, LTD.	Supplier change for the delivery system tip component.
P050047/S085	04/28/2022	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Implementation of additional duplicate manufacturing equipment for the Juvderm injectable gel products.
P060039/S110	04/21/2022	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P060040/S085	04/11/2022	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Additional supplier for PCBA boards used in the universal battery charger.
P070026/S096	04/14/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Introduction of a new alternative asset (i.e., a Dry Bag Press) which will be used in the manufacturing process for the Biolox Delta Ball Head components of the CERAMAX Ceramic Total Hip System.
P080006/S170	04/21/2022	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P080011/S140	04/14/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Updates to the software used in the Wet Automated Inspection System for the Biofinity Automated Wet Lines at the CooperVision Manufacturing facility in Hamble UK.

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P080011/S143	04/27/2022	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Extension of Lens Transfer II process to include non-toric Biofinity cast-moulded products at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080025/S254	04/15/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Replacement of degreasing equipment and use of new degreasing solvent.
P080025/S255	04/26/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Implement a minimum shade requirement for laser mark intensity on affected leads and to qualify a visual standard tool for inspection of the laser mark intensity.
P090013/S320	04/21/2022	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P100016/S013	04/20/2022	X - 30-Day Notice	EC-3 INTRAOCULAR LENS (IOL) AND EC-3 PRECISION ASPHERIC LENS (PAL) IOL	CARL ZEISS MEDITEC PRODUCTION LLC	Use of a newly qualified refractometer in the production of CT LUCIA Intraocular Lens (IOL).
P100021/S103	04/19/2022	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion manufacturing operations.
P100029/S046	04/14/2022	X - 30-Day Notice	ST JUDE MEDICAL TRIFECTA VALVE	ABBOTT MEDICAL	Addition of three new tissue suppliers/abbatoirs.
P100040/S051	04/19/2022	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion manufacturing operations.
P100045/S062	04/11/2022	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Implement an additional sterilization chamber for the CardioMEMS PA Sensor and Delivery System (CM2000) at the Abbott Sylmar, CA facility.
P110013/S116	04/19/2022	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion manufacturing operations.
P110033/S066	04/28/2022	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Implementation of additional duplicate manufacturing equipment for the Juvderm injectable gel products.
P120010/S141	04/29/2022	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of an alternate bioburden and sterility contract testing laboratory for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P120017/S030	04/21/2022	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P130008/S082	04/01/2022	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Notification of implementing automated final functional testing for the Model 2580 Patient Remote.
P130008/S083	04/07/2022	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Additional lathe equipment to be used to manufacture the terminal pin used in the connector assembly of the Inspire leads, Model 4340 and Model 4063, to increase production capacity.

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P130021/S113	04/19/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Transfer of component extrusion manufacturing operations.
P140003/S097	04/12/2022	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Modification to the process used to manufacture the Pressure Storage Set
P150001/S096	04/28/2022	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Manufacturing changes for the next generation pump (NGP) case assembly. The NGP case assembly is a component of the Medtronic MiniMed 630G, 670G, and 770G insulin pump systems.
P150001/S097	04/28/2022	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Addition of an alternate supplier of a raw material used in the manufacture of the CONTOUR NEXT test strips. The test strip is a component of the MiniMed 630G and MiniMed 670G systems.
P150001/S098	04/29/2022	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Addition of an alternate bioburden and sterility contract testing laboratory for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P150019/S065	04/29/2022	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of an alternate bioburden and sterility contract testing laboratory for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P150021/S057	04/28/2022	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Update an analytical method used to evaluate a raw ingredient of the glucose sensor component and to introduce the evaluation process to an additional manufacturing site. The glucose sensor is a component of the FreeStyle Libre 14-Day and FreeStyle Libre Pro Glucose Monitoring Systems.
P150029/S038	04/29/2022	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Addition of an alternate bioburden and sterility contract testing laboratory for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P150030/S019	04/01/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Change to the gamma sterilization load configuration.
P150033/S136	04/21/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the equipment used for monitoring temperature and humidity in Controlled Environment Area number 2 at Medtronic Rice Creek.
P150033/S137	04/26/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement minor updates in the manufacturing of hybrids at Medtronic Tempe Campus.
P150036/S062	04/20/2022	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Add a new supplier to perform the e-beam dose audits for Edwards INTUITY ELITE Delivery System.
P150038/S019	04/06/2022	X - 30-Day Notice	EXABLATE	INSIGHTEC	Change is for a new Extract Trackers Data SW Tool for production in place of the usual manual extract.
P150048/S063	04/08/2022	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Implementation of a LTPD as opposed to a 100% sampling plan for dimensional inspection of the sewing ring of the KONECT RESILIA AVC.

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P150048/S064	04/26/2022	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Modifications to the stent assembly process.
P160007/S044	04/29/2022	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of an alternate bioburden and sterility contract testing laboratory for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P160017/S098	04/28/2022	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Manufacturing changes for the next generation pump (NGP) case assembly. The NGP case assembly is a component of the Medtronic MiniMed 630G, 670G, and 770G insulin pump systems.
P160017/S099	04/28/2022	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of an alternate supplier of a raw material used in the manufacture of the CONTOUR NEXT test strips. The test strip is a component of the MiniMed 630G and MiniMed 670G systems.
P160017/S100	04/29/2022	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of an alternate bioburden and sterility contract testing laboratory for the Enlite sensor and the Guardian Sensor (3). The Enlite sensor is a components of the MiniMed 530G, 630G, Paradigm Real-Time Revel, and iPro2 CGM systems. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect, 670G and 770G systems.
P160030/S051	04/28/2022	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Update an analytical method used to evaluate a raw ingredient of the glucose sensor component and to introduce the evaluation process to an additional manufacturing site. The glucose sensor is a component of the FreeStyle Libre 14-Day and FreeStyle Libre Pro Glucose Monitoring Systems.
P160040/S010	04/11/2022	X - 30-Day Notice	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Change of contractor mycoplasma testing method for Invivoscribe cell lines.
P160043/S059	04/20/2022	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Transfer of component extrusion manufacturing operations.
P160049/S017	04/11/2022	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Introducing an additional sterilization chamber for devices produced in Plymouth MN.
P160054/S047	04/11/2022	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Additional supplier for PCBA boards used in the universal battery charger.
P170008/S039	04/20/2022	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Introduction of alternative aeration room at the sterilization site.
P170008/S040	04/14/2022	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Establish new cleanroom parameters during off hours.

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P170008/S041	04/19/2022	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Introducing a new sterilization loading configuration.
P170011/S038	04/12/2022	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Modification to the process used to manufacture the Pressure Storage Set
P170036/S010	04/05/2022	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Addition of a new Cervical Flexural Resistance (CER-FR) Tester, EQ 0152-03.
P170038/S009	04/01/2022	X - 30-Day Notice	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Add servicing/repair processes for the console and monitor at two existing facilities.
P180003/S006	04/05/2022	X - 30-Day Notice	BIOMIMICS 3D VASCULAR STENT SYSTEM	VERYAN MEDICAL LTD.	Retain stents in production following an in-process quality control test.
P180037/S009	04/22/2022	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Delivery system manufacturing process and inspection changes for the 10 French device size.
P180046/S052	04/20/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Remove high potential testing (hipot) from receiving inspection for the tined lead when redundant with hipot testing done by the tined lead contract manufacturer.
P180050/S005	04/26/2022	X - 30-Day Notice	BAROSTIM NEO® SYSTEM	CVRX, INC.	Reduction in the amount of ethylene oxide and an increase in the load capacity for the sterilization process.
P190002/S004	04/20/2022	X - 30-Day Notice	SALUDA MEDICAL EVOKE SCS SYSTEM	SALUDA MEDICAL PTY LTD	Addition of a new component manufacturer (Heraeus Medical Components LLC) for the Evoke SCS System Stylets (60/90 cm Bent and Straight).
P190006/S052	04/20/2022	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Remove high potential testing (hipot) from receiving inspection for the tined lead when redundant with hipot testing done by the tined lead contract manufacturer.
P190023/S007	04/20/2022	X - 30-Day Notice	PORTICO TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM	ABBOTT MEDICAL	Addition of one new abattoir.
P200015/S019	04/08/2022	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Modification to the inspection method of the Alterra Delivery System inner shaft from use of a Keyence system to a laser micrometer.
Total: 109					