PMA Monthly approvals from 6/1/2022 to 6/30/2022

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200044	06/28/2022	PMAO - PMA Origi	LUNGFIT PH	BEYOND AIR, INC.	Approval for The LungFit® PH. The device is indicated to deliver nitric oxide (NO), a vasodilator, generated by the device into the inspiratory limb of the patient breathing circuit of a ventilator in a way that provides a constant concentration of NO, as set by the user, to the patient throughout the inspired breath. The LungFit® PH provides continuous integrated monitoring of inspired oxygen (O2), nitrogen dioxide (NO2) and NO, and a comprehensive alarm system. The LungFit® PH includes an integrated backup NO delivery system that is a completely independent backup NO generating system; it has its own NO generator and gas flow delivery system. The backup flow is delivered at 1 L/min at 220ppm NO to either a ventilator circuit or to a bagging system, depending upon the user selected setting. The NO generated by the LungFit® PH System is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S040	06/24/2022	S - Special CBE	GELFOAM	PFIZER, INC.	Approval for updating the Gelfoam Instructions for Use to include language on visualization of the target bleeding site before application and to update the Adverse Reactions section to include duct stenosis (such as bile duct stenosis).
P830055/S289	06/29/2022	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval to replace the unsealed tanks for storing Porocoat® spray binder in a non-electrostatic spray booth and a electrostatic spray booth in the CoCrMo Porocoat® area, with a single sealed, pressurized storage tank with agitation.
P850007/S046	06/14/2022	R - Real-Time Proc	PHYSIO-STIM(TM) I & II MODEL 6000 & 7000	ORTHOFIX, INC.	Approval for updates to Orthofixs currently marketed STIM onTrack mobile medical application.
P870024/S059	06/08/2022	R - Real-Time Proc	FLUOROPERM RGP CONTACT LENSES	COOPERVISIO N, INC.	Approval for the promotion of 3% hydrogen peroxide cleaning and disinfection solution for the disinfection of Paragon CRT family of rigid gas permeable contact lenses (Paragon CRT®, Paragon CRT®100, Paragon CRT Dual Axis®, Paragon RG-4 Rigid Gas Permeable Contact Lenses in Clear and Tints).
P870024/S060	06/16/2022	O - Normal 180 Da	FLUOROPERM RGP CONTACT LENSES	COOPERVISIO N, INC.	Approval for a new manufacturing site, Paragon Vision Sciences. Inc. located at 2120 W. Guadalupe Rd. Gilbert, Arizona 85233. This facility is responsible for manufacturing of the contact lens materials and finished lenses, shipping, R&D, and administration.
P880047/S046	06/15/2022	N - Normal 180 Day	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Approval for updates to the device instructions for use and other product labeling related to MRI safety, Carcinogenic, Mutagenic, Toxic to Reproduction (CMR) and Endocrine Disruption (ED) safety, and administrative/clerical changes.

Data as of 07/19/2022 04:58 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890055/S081	06/22/2022	S - Special CBE	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Approval for changes to Instructions for Use.
P960009/S424	06/15/2022	R - Real-Time Proc	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for changes to the Medtronic Model A610 DBS Clinician Programmer Application version 3.0. The changes consist of a fix to a software defect subject to field corrective action, as well as fixes to other minor defects in the A610 application.
P970003/S236	06/06/2022	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for a change to the reed switch (i.e., change from Durel to Rhodium reed switch) that is used in the Model 1000 and M1000-D Generators.
P980016/S816	06/29/2022	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a specification change to a component of the battery to ensure hermeticity and improve manufacturability.
P990081/S045	06/10/2022	Y - 135 Review Tra	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P010031/S783	06/29/2022	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a specification change to a component of the battery to ensure hermeticity and improve manufacturability.
P020055/S025	06/10/2022	Y - 135 Review Tra	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P030034/S017	06/14/2022	R - Real-Time Proc	CERVICAL-STIM MODEL 505L CERVICAL FUSION SYSTEM	ORTHOFIX, INC.	Approval for updates to Orthofixs currently marketed STIM onTrack mobile medical application.
P030050/S037	06/27/2022	Y - 135 Review Tra	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for replacement of an old autoclave with a new autoclave containing a new automated unloading system
P060040/S086	06/23/2022	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	ABBOTT MEDICAL	Approval for an alternate drop-in replacement battery cell within the Battery Stack sub-assembly.
P080011/S139	06/09/2022	O - Normal 180 Da	BIOFINITY (COMFILCON A)	COOPERVISIO N, INC.	Aapproval for the addition of the CooperVision, Inc. facility located at 711 North Road, Scottsville, New York 14546 as a manufacturing site for Biofinity Torie Multi focal.
P100006/S013	06/13/2022	O - Normal 180 Da	AUGMENT BONE GRAFT	BIOMIMETIC THERAPEUTI CS,LLC	Approval for a modified package insert incorporating updated clinical data based on completion of the postapproval clinical study.
P100027/S035	06/10/2022	Y - 135 Review Tra	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.

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P100044/S049	06/24/2022	R - Real-Time Proc	PROPEL	INTERSECT ENT	Approval for the change of e-beam sterilization dose for the Propel Contour Sinus Implant.
P110023/S034	06/07/2022	S - Special CBE	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Approval for updates to the IFU to include a troubleshooting technique during partial deployment events
P110027/S014	06/17/2022	S - Special CBE	THERASCREEN KRAS RGQ PCR KIT	QIAGEN GMBH	Approval for changes to the instructions for use (IFU) to strengthen information in relation to interpretation of results for NSCLC patients to enhance the safety of the QIAGEN therascreen KRAS RGQ PCR Kit.
P130016/S049	06/16/2022	O - Normal 180 Da	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval of the revised protocol for the post-approval study (PAS) protocol.
P140025/S016	06/10/2022	Y - 135 Review Tra	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P150038/S021	06/07/2022	R - Real-Time Proc	EXABLATE	INSIGHTEC	Approval for the replacement of the Control Personal Computer (PC) and Workstation PC to address end-of-life and software-related defects.
P160002/S016	06/10/2022	Y - 135 Review Tra	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P160008/S017	06/23/2022	O - Normal 180 Da	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Approval for change to the Indications for Use (IFU) from prescription to Over-the-Counter (OTC) use with associated labeling changes.
P160046/S011	06/10/2022	Y - 135 Review Tra	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P160049/S018	06/22/2022	O - Normal 180 Da	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval for a manufacturing site located at Philips Image Guided Therapy Corporation, 5905 Nathan Lane North, Plymouth, MN 55442 for catheter assembly of the Stellarex 035 Drug Coated Balloon.
P170002/S021	06/14/2022	R - Real-Time Proc	RHA 2, RHA 3, RHA 4	TEOXANE S.A.	Approval for design changes of the plunger and finger grip of the syringe.
P170013/S009	06/28/2022	O - Normal 180 Da	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval to place the post-approval study titled LVIS X PAS on hold, because the sponsor does not intend to market the LVIS X and LVIS Jr. X devices in the United States at this time.
P170019/S014	06/07/2022	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order to expand the intended use of FoundationOne®CDx (F1CDx) to include a companion diagnostic indication for NTRK1, NTRK2, and NTRK3 fusions in patients with solid tumors and for ROS1 fusions in patients with non-small cell lung cancer who may benefit from treatment with ROZLYTREK® (entrectinib).

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P170041/S004	06/02/2022	O - Normal 180 Da	ABBOTT REALTIME IDH1	ABBOTT MOLECULAR, INC.	Approval for the labeling changes that integrate the data obtained from the non-clinical Condition of Appoval (CoA) study of eluate reproducibility.
P180001/S005	06/02/2022	S - Special CBE	ZENITH DISSECTION ENDOVASCULAR SYSTEM	WILLIAM COOK EUROPE APS	Approval for updating the Instructions for Use to report the theoretical (i.e., calculated) maximum length for the Zenith Dissection Endovascular Stent.
P180038/S012	06/23/2022	R - Real-Time Proc	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval for the addition of the alternate supplier, Balda Medical GmbH (Bad Oeynhausen, Germany), to produce vial and frame plastics components of the Reagent Integral.
P180039/S011	06/23/2022	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 for the addition of the alternate supplier, Balda Medical GmbH (Bad Oeynhausen, Germany), to produce vial and frame plastics components of the Reagent Integral.
P180045/S009	06/23/2022	R - Real-Time Proc	LIAISON® XL MUREX HBC IGM, LIAISON® XL MUREX CONTROL HBC IGM	DIASORIN INC.	Approval for the addition of the alternate supplier, Balda Medical GmbH (Bad Oeynhausen, Germany), to produce vial and frame plastics components of the Reagent Integral.
P180047/S016	06/23/2022	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for the addition of the alternate supplier, Balda Medical GmbH (Bad Oeynhausen, Germany), to produce vial and frame plastics components of the Reagent Integral.
P180048/S009	06/23/2022	R - Real-Time Proc	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Approval for the addition of the alternate supplier, Balda Medical GmbH (Bad Oeynhausen, Germany), to produce vial and frame plastics components of the Reagent Integral.
P180050/S006	06/14/2022	O - Normal 180 Da	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval for the revised statistical analysis plan.
P180050/S007	06/27/2022	O - Normal 180 Da	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P190017/S006	06/23/2022	R - Real-Time Proc	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approval for the addition of the alternate supplier, Balda Medical GmbH (Bad Oeynhausen, Germany), to produce vial and frame plastics components of the Reagent Integral.
P190024/S005	06/10/2022	Y - 135 Review Tra	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P190030/S001	06/17/2022	R - Real-Time Proc	ACTASTIM-S SPINE FUSION STIMULATOR	THERAGEN, INC.	Approval for modifications to the device battery charger.

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P190031/S003	06/10/2022	Y - 135 Review Tra	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P200003/S001	06/17/2022	N - Normal 180 Day	IMAGIO BREAST IMAGING SYSTEM	SENO MEDICAL INSTRUMENTS, INC.	Approval for the Imagio® Breast Imaging System. This device is indicated for use by a trained and qualified healthcare provider for evaluation of palpable and non-palpable breast abnormalities in adult patients who are referred for a diagnostic imaging breast work-up, following clinical presentation or either screening or diagnostic mammography or other imaging examinations. The ultrasound mode should be initially used in a targeted fashion, to assess any focal area(s) of clinical or imaging concerns. In ultrasound mode, the device can be used to assign a BI-RADS category to either breast tissue or a mass that is causing clinical or imaging concerns. Masses that are classified as BI-RADS categories 3 through 5 can then be assessed using the Opto-Acoustic (OA) mode. In the OA mode, the Imagio® Breast Imaging System provides information about the central nidus, boundary and peripheral zones, based on vascularity and blood oxygen saturation of the imaged tissues, to assist in the diagnosis of the benign or malignant mass(es) of interest. For ultrasound BI-RADS 3-5 masses, using the OA features of the mass allows for improved classification of the mass of interest as compared to ultrasound alone. The OA mode is not indicated for ultrasound BI- RADS 1 and 2 findings. The Imagio® Breast Imaging System includes an artificial intelligence (AI) based software function to assist the users in assessing BI-RADS classifications. This device is not intended to be used as a replacement for mammographic screening or for definitive pathologic diagnosis.
P200010/S006	06/27/2022	N - Normal 180 Day	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval for upgrading Guardant360 CDx software sub-component Bioinformatics Pipeline (BIP) software from v3.5.3 to v3.5.4.
P200013/S007	06/28/2022	R - Real-Time Proc	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval for an update to the Amp-Detect Motion Profile configurable parameters stored in the Alinity m System Amp-Detect Units (ADU).
P200015/S021	06/23/2022	O - Normal 180 Da	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval of the revised protocol for the post-approval study 2: Alterra New Enrollment Study.
P200019/S003	06/10/2022	Y - 135 Review Tra	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P210001/S002	06/16/2022	N - Normal 180 Day	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Approval for the VENTANA MMR RxDx Panel as a companion diagnostic for identifying MMR proficient (pMMR) patients with endometrial cancer for treatment with KEYTRUDA in combination with LENVIMA.

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P210001/S003	06/10/2022	Y - 135 Review Tra	VENTANA MMR RXDX PANEL	VENTANA MEDICAL SYSTEMS INC (ROCHE TISSUE DIAGNOSTICS)	Approval for the addition of two new contract manufacturers as approved suppliers for component parts.
P210020/S005	06/10/2022	O - Normal 180 Da	OPTILUME URETHRAL DRUG COATED BALLOON	UROTRONIC, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.

Total: 54

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S207	06/01/2022	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P840001/S519	06/09/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Revision to the manufacturing execution system used in several facilities for the subject devices.
P840001/S520	06/01/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Change to a vapor degreaser rework implementation and process improvements at Medtronics internal supplier, Medtronic Tempe Campus.
P840001/S521	06/02/2022	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Manufacturing process changes to transfer the XTC009 tantalum capacitor manufacturing process to a next generation medical-grade manufacturing process.
P850089/S162	06/01/2022	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P860004/S392	06/09/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Revision to the manufacturing execution system used in several facilities for the subject devices.
P860004/S393	06/01/2022	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Change to a vapor degreaser rework implementation and process improvements at Medtronics internal supplier, Medtronic Tempe Campus.
P890003/S454	06/01/2022	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.

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P900061/S169	06/01/2022	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P910018/S034	06/30/2022	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.	Change in the material supplier of the NK-M3R(UL) which is a component device of the LIPOSORBER LA-15 System and one manufacturing process. The change is being made because the original supplier no longer produces the material.
P910023/S445	06/22/2022	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ABBOTT MEDICAL	Add Abbott Medical as an alternate supplier for header components used in Abbott ICD devices.
P920015/S269	06/01/2022	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P930029/S071	06/01/2022	X - 30-Day Notice	ATAKR(TM) RFCA SYSTEM	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P930031/S069	06/28/2022	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of a delivery system distal tip supplier.
P930039/S243	06/01/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P940019/S060	06/28/2022	X - 30-Day Notice	WALLSTENT(R) ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	Addition of a delivery system distal tip supplier.
P950024/S104	06/01/2022	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P950037/S236	06/21/2022	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Change to the temperature at which final vibration testing is conducted and transfer of final testing from a cleanroom to a grey room.
P960009/S430	06/09/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Revision to the manufacturing execution system used in several facilities for the subject devices.
P960009/S431	06/01/2022	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change to a vapor degreaser rework implementation and process improvements at Medtronics internal supplier, Medtronic Tempe Campus.

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P960040/S478	06/21/2022	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Add an alternate diode supplier for the High Voltage Charge Module used in ICDs and CRT-Ds.
P970004/S363	06/01/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Operational/procedural changes to the final cleaning process at the internal manufacturing supplier.
P970004/S365	06/09/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Revision to the manufacturing execution system used in several facilities for the subject devices.
P970004/S366	06/01/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change to a vapor degreaser rework implementation and process improvements at Medtronics internal supplier, Medtronic Tempe Campus.
P980016/S823	06/01/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P980016/S826	06/28/2022	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional supplier for the capacitor electrical connector component used in ICDs and CRT-Ds.
P980023/S114	06/21/2022	X - 30-Day Notice	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Change to the temperature at which final vibration testing is conducted and transfer of final testing from a cleanroom to a grey room.
P980033/S059	06/28/2022	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATION	Addition of a delivery system distal tip supplier.
P980035/S718	06/01/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P980035/S719	06/01/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Modification to the battery laser marking process and subsequent inspection for selected Medtronic products at MECC.
P980035/S720	06/07/2022	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes to the Preform Assembly Process and implementation of a new Laser Solder Rework Process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980050/S138	06/01/2022	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P990034/S041	06/09/2022	X - 30-Day Notice	MEDTRONIC ISOMED INFUSION SYSTEM	MEDTRONIC INC.	Revision to the manufacturing execution system used in several facilities for the subject devices.
P990071/S054	06/08/2022	X - 30-Day Notice	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Change in the location for inspection of the SmartAblate Irrigation Tubing Set and nGEN Pump from the Irwindale, CA site to the Irvine, CA site.
P000009/S098	06/21/2022	X - 30-Day Notice	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Change to the temperature at which final vibration testing is conducted and transfer of final testing from a cleanroom to a grey room.
P000054/S067	06/09/2022	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Use of sterile connectors in the filtration and filling equipment lines for the rhBMP-2 drug product at the Hospira McPherson, KS facility.
P000058/S086	06/08/2022	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Use of sterile connectors in the filtration and filling equipment lines for the rhBMP-2 drug product at the Hospira McPherson, KS facility.
P010012/S554	06/21/2022	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add an alternate diode supplier for the High Voltage Charge Module used in ICDs and CRT-Ds.
P010015/S500	06/01/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P010015/S501	06/01/2022	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Modification to the battery laser marking process and subsequent inspection for selected Medtronic products at MECC.
P010030/S159	06/01/2022	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Automation of two processes and a solder flux material change used during the manufacture of printed circuit assemblies (PCAs).
P010031/S790	06/01/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.

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P010031/S792	06/28/2022	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Additional supplier for the capacitor electrical connector component used in ICDs and CRT-Ds.
P010032/S188	06/28/2022	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Implement the previously approved, feed-thru design at the Abbott PR manufacturing facility with their separate welding process.
P030017/S350	06/23/2022	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to update the Laser Excise process by adding a pre-excise phase, modifying the laser focal point, and shifting the position of the laser closer to the excised edge during the ablation phase during the manufacturing of the Printed Circuit Board assembly (PCBA) of the Implantable Pulse Generator (IPG) at the Boston Scientific Clonmel manufacturing site.
P030022/S047	06/21/2022	X - 30-Day Notice	REFLECTION CERAMIC ACETABULAR SYSTEM	SMITH & NEPHEW, INC.	Removing the benchtop grinding wheel and using a manual process to deburr the R3 Acetabular Shells.
P030036/S138	06/01/2022	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P040044/S092	06/27/2022	X - 30-Day Notice	MATRIX VASCULAR CLOSURE SYSTEM (VSG)	CORDIS US CORPORATIO N	Supplier facility relocation for the manufacture of one component of MynxGrip Vascular Closure Device and one component of Mynx Control Vascular Closure Device.
P040045/S125	06/15/2022	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.
P040045/S126	06/22/2022	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Implementation of a new test method for measurement of leachable components in VISTAKON® (senofilcon A) Brand Contact Lenses.
P050023/S167	06/21/2022	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Change to the temperature at which final vibration testing is conducted and transfer of final testing from a cleanroom to a grey room.
P050053/S058	06/09/2022	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Use of sterile connectors in the filtration and filling equipment lines for the rhBMP-2 drug product at the Hospira McPherson, KS facility.
P060001/S034	06/03/2022	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Addition of a rolling mill machine at a supplier site.
P060039/S111	06/01/2022	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.

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P070008/S137	06/21/2022	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.	Change to the temperature at which final vibration testing is conducted and transfer of final testing from a cleanroom to a grey room.
P070026/S098	06/07/2022	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Manufacturing process change for the forged raw material for the Trilock BPS Femoral Stem as part of the CERAMAX® Ceramic Total Hip system.
P080006/S172	06/01/2022	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P080025/S258	06/01/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Operational/procedural changes to the final cleaning process at the internal manufacturing supplier.
P080025/S260	06/09/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Revision to the manufacturing execution system used in several facilities for the subject devices.
P080025/S261	06/01/2022	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change to a vapor degreaser rework implementation and process improvements at Medtronics internal supplier, Medtronic Tempe Campus.
P090013/S322	06/01/2022	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P100010/S128	06/01/2022	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P100047/S198	06/16/2022	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Changes in the controller battery¿s printed circuit board assembly.
P100047/S199	06/24/2022	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Changes to the sterilization process and documents for the HeartWare Ventricular Assist System.
P100047/S201	06/28/2022	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Add an acceptance test of an internal controller battery.
P100049/S034	06/09/2022	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Qualification of a new components supplier for the LINX Reflux Management System.
P110015/S010	06/01/2022	X - 30-Day Notice	GASTRIC EMPTYING BREATH TEST (GEBT)	ADVANCED BREATH DIAGNOSTICS	Change the quality control testing of the 13C-Spirulina/Egg Mix. The 13C-Spirulina/Egg Mix is a component of the 13C-Spirulina Gastric Emptying Breath Test (GEBT).
P110019/S121	06/22/2022	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Addition of an alternate automated sheath process for the Skypoint LV.

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P110023/S035	06/03/2022	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Addition of a rolling mill machine at a supplier site.
P110042/S170	06/21/2022	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add an alternate diode supplier for the uDiode Module used for S-ICDs.
P120017/S031	06/01/2022	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P120024/S012	06/24/2022	X - 30-Day Notice	ACTIVL ARTIFICIAL DISC	AESCULAP IMPLANT SYSTEMS, LLC	Additional raw material supplier (ordered to Specification) of the activL Artificial Disc.
P130008/S084	06/16/2022	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Notification of replacing obsolete Metal- Oxide- Semiconductor Field-Effect Transistor (MOSFET) for the Sensor Assembly and additional lathe equipment to be used to manufacture the terminal pin used in the connector assembly of the leads for the Inspire Models 4340 and 4063 Respiratory Sensing Leads
P130021/S117	06/08/2022	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC, INC.	Implementation of various improvements to the manufacturing process of the Evolut FX Delivery Catheter System (DCS) stability member bond.
P140003/S100	06/16/2022	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Implementation of a centralized inert gas distribution system at a manufacturing facility.
P140009/S078	06/30/2022	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Implement the previously approved feed-thru design at the Abbott PR manufacturing facility with their separate welding process.
P140010/S064	06/21/2022	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Changes to the balloon tube extrusion process for 7.0 mm balloon tubes.
P140026/S021	06/24/2022	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Updating the final goods work instructions to remove redundant inspections and administrative updates.
P150030/S022	06/21/2022	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Removing the benchtop grinding wheel and using a manual process to deburr the R3 Acetabular Shells.
P150031/S050	06/23/2022	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to update the Laser Excise process by adding a pre-excise phase, modifying the laser focal point, and shifting the position of the laser closer to the excised edge during the ablation phase during the manufacturing of the Printed Circuit Board assembly (PCBA) of the Implantable Pulse Generator (IPG) at the Boston Scientific Clonmel manufacturing site.
P150033/S141	06/01/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the FACTORYWorks Manufacturing Execution System to Release 9.10.
P150033/S142	06/22/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modifications to the battery cathode fabrication hardware and software manufacturing and inspection processes.

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P150033/S143	06/30/2022	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to the Micra battery manufacturing instructions.
P150040/S010	06/17/2022	X - 30-Day Notice	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Replace the type of UV light and the supplier of the UV light chamber for the Treatment Pack accessory for the VisuMax Femtosecond Laser.
P160029/S016	06/08/2022	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Use of an alternate Heat Sealer used in the current electrode final assembly.
P160035/S026	06/15/2022	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Manufacturing change to the printed circuit board used in the Berlin Heart EXCOR IKUS Driver.
P160043/S061	06/15/2022	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Use of an electronic Manufacturing Execution System (MES) to replace the current paper-based device history record (DHR).
P160044/S004	06/09/2022	X - 30-Day Notice	ABBOTT REALTIME CMV	ABBOTT MOLECULAR	Manufacturing scale-up of a kit component.
P170011/S041	06/16/2022	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Implementation of a centralized inert gas distribution system at a manufacturing facility.
P170035/S017	06/01/2022	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Implementation of a new power measurement method on the Spin-Blot System for Bausch + Lomb Ultra® (samfilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses for Presbyopia Vision Correction.
P200004/S001	06/16/2022	X - 30-Day Notice	CONMED PADPRO MULTIFUNCTION ELECTRODES, CONMED PADPRO MULTIFUNCTION ELECTRODE ADAPTERS	CONMED CORPORATIO N	Change the test site for sterilization test samples and remove redundant post-sterile finished device testing.
P200013/S008	06/08/2022	X - 30-Day Notice	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Use of an alternate component in a septum cap assembly since the current material is no longer available.
P200021/S014	06/17/2022	X - 30-Day Notice	NEURO COCHLEAR IMPLANT SYSTEM	OTICON MEDICAL	Improved equipment and manufacturing workflow at the electronic assembly supplier; and (2 modification to the tooling used for feedthrough leak testing.
P200028/S011	06/15/2022	X - 30-Day Notice	DIAMONDTEMP ABLATION SYSTEM	MEDTRONIC INC.	Changes to electrical tests for the DiamondTemp Ablation Catheters.
P210006/S002	06/16/2022	X - 30-Day Notice	THORAFLEX¿ HYBRID	VASCUTEK LTD.	Implementation of a new in-process inspection step, new equipment for aeration and new colorant resin for a component of the delivery system of the Thoraflex Hybrid device.

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