PMA Monthly approvals from 11/1/2020 to 11/30/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P016	11/06/202T0	PMAO - PMA Origi	FOUNDATIONONE LIQUID CDX	FOUNDATION MEDICINE, INC.	Approval for the FoundationOne® Liquid CDx is a qualitative next generation sequencing based in vitro diagnostic test that uses targeted high throughput hybridization-based capture technology to detect and report substitutions, insertions and deletions (indels) in 311 genes, including rearrangements in four (4) genes, and copy number alterations in three (3) genes. FoundationOne® Liquid CDx utilizes circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of cancer patients collected in FoundationOne® Liquid CDx cfDNA blood collection tubes included in the FoundationOne® Liquid CDx Blood Sample Collection Kit. The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. Table 1: Companion diagnostic indications Tumor Type Biomarker(s) Detected Therapy Non-small cell lung cancer (NSCLC) ALK Rearrangements ALECENSA® (alectinib) EGFR Exon 19 deletions and EGFR Exon 21 L858R alteration IRESSA® (gefitinib) TAGRISSO® (osimertinib) TARCEVA® (erlotinib) Prostate cancer BRCA1, BRCA2, and ATM alterations LYNPARZA® (olaparib) BRCA1, BRCA2 alterations RUBRACA® (rucaparib) Ovarian Cancer BRCA1, BRCA2 alterations RUBRACA® (rucaparib) Breast Cancer PIK3CA mutations C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y PIQRAY® (alpelisib) Additionally, FoundationOne® Liquid CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. A negative result from a plasma specimen does not mean that the patients tumor is negative for genomic findings. Patients who are negative for the mutations listed in Table 1 should be reflexed to routine biopsy and their tumor mutation status confirmed using an FDA-approved tumor tissue test, if feasible. Genomic findings other than those listed in Table 1 of the intended use statement are not prescriptive or conclusive for labeled use of any specific therapeutic product. FoundationOne® Liquid CDx is a single-site assay performed at Foundation Medicine, Inc. in Cambridge, MA.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810031/S066	11/25/2020	N - Normal 180 Day	HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for changes in labeling to include a new Warning, modifications to the Device Description and Precautions, and the addition of two surgical techniques for removal of the Healon GV® PRO OVD from the eye.
P830055/S254	11/03/2020	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for packaging and product shelf life extension from 5 years to 8 years for ATTUNE AOX Rotating Platform (RP) Tibial Inserts for both CR (Cruciate Retaining) and PS (Posterior Stabilized) Configurations, as well as for the associated update to shelf life printed on the package labels.
P840001/S468	11/03/2020	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Approval to add the use of tin-lead plating for the terminations of both ends of the T8 tantalum capacitors and for the Model 97810 InterStim Micro INS only, change the solder paste stencil tooling for the 1411 capacitor size to increase the amount of solder paste to match the mount used on other capacitor case sizes.
P860004/S352	11/10/2020	Y - 135 Review Tra	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for change of a new sterile packaging (sterile pack) sealing equipment. This change applies to the Refill Kits, Catheter Access Port (CAP) Kit and Catheter Patency Kit in use with the SynchroMed Infusion System Ascenda Intrathecal catheter and Implantable System for remodulin.
P860004/S363	11/18/2020	R - Real-Time Proc	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for a minor design change to the Sutureless Catheter Seal Connector for catheter model number 8731SC and its revision kits model numbers 8578 and 8596SC for the SynchroMed Intrathecal Catheter; as well as the intravascular catheter model number 8201 for the Implantable System for Remodulin.
P890003/S434	11/02/2020	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for an alternate cellular modem and firmware update to M13.0.
P900056/S191	11/23/2020	O - Normal 180 Day	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at 4100 Hamline Avenue North, St. Paul, Minnesota, 55112 for the manufacture, repair, distribution and warehousing activities for the Rotablator and ROTAPRO Consoles.
P920048/S015	11/06/2020	Y - 135 Review Tra	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Approval for the addition of a sorting procedure for batching a cassette raw material into sub-lots during the manufacturing of Rapid fFN Cassettes for the TLiIQ System.
P950037/S214	11/05/2020	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval to introduce a physician notification system component under the current Home Monitoring System, Version 3.49.
P960009/S382	11/03/2020	R - Real-Time Proc	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval to add the use of tin-lead plating for the terminations of both ends of the TM8 capacitors and to change the solder paste stencil tooling for the 1411 capacitor size for the Model 97810 InterStim Micro INS to increase the amount of solder paste to match the mount used on other capacitor case sizes.
P960016/S084	11/02/2020	N - Normal 180 Day	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Approval for software and cybersecurity updates to the Ampere Ablation Generator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960040/S457	11/12/2020	O - Normal 180 Day	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval to suspend enrollment in the MANAGE-HF Phase II Post-Approval Study for six (6) months due to COVID-19.
P970004/S315	11/03/2020	R - Real-Time Proc	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval to add the use of tin-lead plating for the terminations of both ends of the T8 tantalum capacitors and for the Model 97810 InterStim Micro INS only, change the solder paste stencil tooling for the 1411 capacitor size to increase the amount of solder paste to match the mount used on other capacitor case sizes.
P980016/S752	11/02/2020	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an alternate cellular modem and firmware update to M13.0.
P980023/S102	11/05/2020	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval to introduce a physician notification system component under the current Home Monitoring System, Version 3.49.
P980035/S638	11/02/2020	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for an alternate cellular modem and firmware update to M13.0.
P980040/S118	11/04/2020	O - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for the alternate manufacturing and sterilization site is located at AMO Groningen B.V., 5 Van Swietenlaan, Groningen, The Netherlands 9728NX.
P990064/S082	11/03/2020	Y - 135 Review Tra	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Approval for removal of the Leaflet Touching Bias inspection.
P990081/S043	11/13/2020	R - Real-Time Proc	PATHWAY ANTI-HCR-2/ NCU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P000009/S087	11/05/2020	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval to introduce a physician notification system component under the current Home Monitoring System, Version 3.49.
P010012/S526	11/12/2020	O - Normal 180 Day	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval to suspend enrollment in the MANAGE-HF Phase II Post-Approval Study for six (6) months due to COVID-19.
P010015/S447	11/02/2020	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for an alternate cellular modem and firmware update to M13.0.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S143	11/18/2020	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for updated fully recyclable cardboard clamshell packaging for the LifeVest Wearable Defibrillator.
P010031/S713	11/02/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an alternate cellular modem and firmware update to M13.0.
P010032/S165	11/15/2020	N - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for a change to the labeling which reflects an alternate lead implantation procedure for the Protege/Prodigy/Proclaim XR family of SCS systems.
P020055/S023	11/13/2020	R - Real-Time Proc	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P040014/S040	11/02/2020	N - Normal 180 Day	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Approval for software and cybersecurity updates to the Ampere Ablation Generator.
P040042/S046	11/02/2020	N - Normal 180 Day	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Approval for software and cybersecurity updates to the Ampere Ablation Generator.
P050023/S150	11/05/2020	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval to introduce a physician notification system component under the current Home Monitoring System, Version 3.49.
P050047/S079	11/25/2020	S - Special CBE	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for revisions to the patient labeling of Juvéderm® Ultra, Juvéderm® Ultra Plus, Juvéderm® Ultra XC Wrinkles and Folds, Juvéderm® Ultra XC Lips, and Juvéderm® Ultra Plus XC to include updated safety information based on post marketing surveillance data.
P060019/S048	11/02/2020	N - Normal 180 Day	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Approval for software and cybersecurity updates to the Ampere Ablation Generator.
P070008/S117	11/05/2020	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 to introduce a physician notification system component under the current Home Monitoring System, Version 3.49.
P080004/S035	11/03/2020	R - Real-Time Proc	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Approval for the PreVue Preloaded IOL System Model PreVue Y and to rename the Clarisert Preloaded IOL System Model CLSRT to the PreVue Preloaded IOL System Model PreVue C.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080025/S210	11/03/2020	R - Real-Time Proc	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval to add the use of tin-lead plating for the terminations of both ends of the T8 tantalum capacitors and for the Model 97810 InterStim Micro INS only, change the solder paste stencil tooling for the 1411 capacitor size to increase the amount of solder paste to match the mount used on other capacitor case sizes.
P100027/S033	11/13/2020	R - Real-Time Proc	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for a replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P100046/S011	11/20/2020	N - Normal 180 Day	ATRICURE SYNERGY ABLATION SYSTEM	ATRICURE INC.	Approval for the use of an alternate ABS resin material for the OSL2, OLL2 clamp.
P100047/S159	11/23/2020	Y - 135 Review Tra	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for a retrospective approval of the change in the HVAD Outflow Graft soiling inspection criteria at supplier Vascutek/Terumo from subjective to objective.
P100047/S163	11/18/2020	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for changes to the Instructions for Use and Patient Manual as a result of remediation activities.
P110016/S070	11/02/2020	N - Normal 180 Day	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for software and cybersecurity updates to the Ampere Ablation Generator.
P110033/S057	11/25/2020	S - Special CBE	JUVEDERM VOLUMA XC	ALLERGAN	Approval for revisions to the clinician labeling of Juvéderm® Voluma XC, and patient labeling of Juvéderm® Voluma XC Cheek, Juvéderm® Voluma XC Chin, Juvéderm® Vollure XC, and Juvéderm® Volbella XC to include updated safety information based on post marketing surveillance data.
P120011/S017	11/19/2020	Y - 135 Review Tra	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for a change in the procedures used to manage Out-of-Specification (OOS) mechanical testing measurements.
P130008/S055	11/16/2020	O - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval of manufacturing site located at Cirtec Medical, 99 Print Shop Rd, Enfield, CT 06082, USA, (for sterilization process for the finished device, Inspire Model 3028 IPG).
P130008/S057	11/27/2020	Y - 135 Review Tra	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for the implementation of a new welding process for the Model 3028 IPG.
P130026/S062	11/02/2020	N - Normal 180 Day	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for software and cybersecurity updates to the Ampere Ablation Generator.
P140025/S013	11/13/2020	R - Real-Time Proc	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P140032/S049	11/10/2020	Y - 135 Review Tra	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for change of a new sterile packaging (sterile pack) sealing equipment. This change applies to the Refill Kits, Catheter Access Port (CAP) Kit and Catheter Patency Kit in use with the SynchroMed Infusion System Ascenda Intrathecal catheter and Implantable System for remodulin.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140032/S061	11/18/2020	R - Real-Time Proc	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for the minor design change to the Sutureless Catheter Seal Connector for catheter model number 8731SC and its revision kits model numbers 8578 and 8596SC for the SynchroMed Intrathecal Catheter; as well as the intravascular catheter model number 8201 for the Implantable System for Remodulin.
P140033/S062	11/20/2020	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for a shelf-life extension from 18 months to 36 months.
P150013/S019	11/06/2020	O - Normal 180 Day	PD-L1 IHC 22C3 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval for a manufacturing site located at Dako Denmark ApS, Produktionsvej 42, DK-2600 Glostrup, Denmark for device manufacturing.
P150013/S020	11/13/2020	P - Panel Track	PD-L1 IHC 22C3 PHARMDX	AGILENT TECHNOLOGIES, INC.	Approval for the PD-L1 IHC 22C3 pharmDX for expanding the indications to include detection of PD-L1 protein in patients with triple-negative breast cancer (TNBC) for treatment with KEYTRUDA.
P150014/S037	11/02/2020	R - Real-Time Proc	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for changes to the cobas HBV Assay Specific Analytical Package (ASAP) software for use with the cobas HBV test and cobas HCV ASAP software for use with the cobas HCV test for use with the cobas 6800/8800.
P150015/S039	11/02/2020	R - Real-Time Proc	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	changes to the cobas HBV Assay Specific Analytical Package (ASAP) software for use with the cobas HBV test (P150014) and cobas HCV ASAP software for use with the cobas HCV test (P150015) for use with the cobas 6800/8800
P150033/S085	11/02/2020	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for an alternate cellular modem and firmware update to M13.0.
P150038/S010	11/09/2020	O - Normal 180 Day	EXABLATE	INSIGHTEC	Approval of the revised protocol, Protocol Number PD012 ¿ Version 1, amended on April 28, 2020, for the post-approval study (PAS) protocol.
P160002/S013	11/13/2020	R - Real-Time Proc	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P160032/S003	11/18/2020	R - Real-Time Proc	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Approval for minor changes for enhanced EMC compliance and revisions to circuit board layout and related software updates to address a part obsolescence issue in the DDU-2000 Series AEDs.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160046/S008	11/13/2020	R - Real-Time Proc	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P170007/S007	11/29/2020	N - Normal 180 Day	DUROLANE	BIOVENTUS LLC	Approval for the addition of a second supplier of the sodium hyaluronate raw material used in the manufacture of DUROLANE.
P170013/S001	11/17/2020	O - Normal 180 Day	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170027/S001	11/20/2020	O - Normal 180 Day	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Approval for the Therox Downstream System. The device is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO2 Therapy) to targeted ischemic regions perfused by the patient¿s left anterior descending coronary artery immediately following revascularization by means of percutaneous coronary intervention (PCI) with stenting that has been completed within 6 hours after the onset of anterior acute myocardial infarction (AMI) symptoms caused by a left anterior descending artery infarct lesion.
P180032/S002	11/18/2020	S - Special CBE	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS, INC.	Approval of labeling changes to improve safety information related to EMC and electrical safety.
P180047/S006	11/25/2020	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for a software version change to the LIAISON QuantiFERON Software (LQS).
P190024/S002	11/13/2020	R - Real-Time Proc	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P190031/S001	11/13/2020	R - Real-Time Proc	HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for the replacement of dispenser molds used in the injection molding process for six (6) dispenser parts.
P200022/S002	11/05/2020	O - Normal 180 Day	SIMPLIFY® CERVICAL ARTIFICIAL DISC	SIMPLIFY MEDICAL, INC.	Approval of the protocol for the post-approval study (PAS) referenced above. The PAS protocol has been submitted to comply with the conditions of approval outlined in our approval order for P200022.

Total: 65

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S076	11/12/2020	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Addition of SURGICEL Original and NU-KNIT Absorbable Hemostats Extra Small (XS) and NU-KNIT Medium (M) sized foil pouches to the upgraded Final Seal Inspection System on the automated Foiling Line (G11719) at the Ethicon SARL, Switzerland site for the inspection of hermetically sealed foil pouches.
N18033/S108	11/19/2020	X - 30-Day Notice	ACUVUE CONTACT LENS	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Removal of a redundant in-process test used during the manufacture of VISTAKON (senofilcon A) and (etafilcon A) Brand Contact Lenses.
N970003/S258	11/16/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Implement a new manufacturing process for the front desiccant/liner components and remove a supplier of low voltage capacitors.
P810006/S091	11/18/2020	X - 30-Day Notice	COLLASTAT	INTEGRA LIFESCIENCES CORPORATION	Sampling site changes in Routine Environmental Monitoring for Alkaline treatment rooms at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P830055/S258	11/10/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of a supplier for the titanium alloy reinforcing pin component of the ATTUNE Revision CRS (Constrained Revision System) Rotation Platform (RP) Tibial Inserts manufactured at the DePuy Cork facility.
P830055/S259	11/27/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Establish the SAFC St. Louis site as an additional supplier of AOX antioxidant solution to ensure continued availability of the AOX bar stock material, which is used in manufacture of the ATTUNE Revision CRS Rotating Platform Inserts, the ATTUNE CR Rotating Platform Inserts, the ATTUNE PS Rotating Platform Inserts, the Sigma Rotating Platform AO Curved Tibial Inserts, and the Sigma Rotating Platform AO Stabilized Tibial Inserts at the DePuy Cork site; and of the LCS Complete RPS AOX Inserts, the LCS Complete RP AOX Inserts and the Sigma RPF AOX Inserts at the DePuy Raynham site.
P830061/S186	11/18/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P840001/S472	11/12/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Reduction in nonviable air sampling to comply with ISO 14644:2015-1.
P840001/S473	11/19/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Update the manufacturing execution system to FACTORYWorks Release 9.8.
P840001/S474	11/18/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Addition of a second supplier for a coil component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840062/S077	11/18/2020	X - 30-Day Notice	COLLACOTE(TM)	INTEGRA LIFESCIENCES CORP.	Sampling site changes in Routine Environmental Monitoring for Alkaline treatment rooms at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P850010/S091	11/18/2020	X - 30-Day Notice	HELISTAT(TM) ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Sampling site changes in Routine Environmental Monitoring for Alkaline treatment rooms at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P850064/S043	11/25/2020	X - 30-Day Notice	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Change in the manufacturing process to add another Ultrasonic Welder Configuration for use in their Patient Circuit assembly.
P850089/S150	11/18/2020	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P860004/S364	11/19/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYWorks Release 9.8.
P860004/S365	11/30/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Transfer of bioburden testing activities of the pump exterior to a new laboratory
P860057/S200	11/10/2020	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Modifications to the Solutions Mixing Clean Room in the Singapore facility.
P880047/S038	11/04/2020	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Changes related to the SURGICEL and INTERCEED cartoning line at the Ethicon Sari, Neuchatel manufacturing site
P890003/S436	11/18/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P900033/S091	11/18/2020	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Sampling site changes in Routine Environmental Monitoring for Alkaline treatment rooms at the Integra LifeSciences Corporation, Collagen Manufacturing Center in Plainsboro, New Jersey.
P900061/S161	11/18/2020	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P910007/S054	11/05/2020	X - 30-Day Notice	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Adding a process for overhead tank mixing of paramagnetic microparticles using the 650 L microparticle tank in order to improve the manufacturing flexibility of the assays.

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P920015/S247	11/18/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P930039/S217	11/18/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P950020/S110	11/20/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Addition of UV bonding equipment to manufacturing process.
P950024/S095	11/18/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P950037/S216	11/17/2020	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Modify the insulating foil geometry and add adhesive to improve the manufacturing process.
P960009/S386	11/12/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P960009/S387	11/12/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Reduction in nonviable air sampling to comply with ISO 14644:2015-1.
P960009/S388	11/19/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Update the manufacturing execution system to FACTORYWorks Release 9.8.
P960009/S389	11/18/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Addition of a second supplier for a coil component.
P960040/S458	11/05/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Add a lubricant to the battery cathode tab punching process.
P970004/S317	11/04/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODU LATION	Addition of inspection equipment and inspection step.
P970004/S318	11/12/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODU LATION	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P970004/S319	11/12/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODU LATION	Reduction in nonviable air sampling to comply with ISO 14644:2015-1
P970004/S320	11/19/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODU LATION	Update the manufacturing execution system to FACTORYWorks Release 9.8.

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P970004/S321	11/30/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Addition of Meier Tool & Engineering (Meier Tool), Anoka, MN - USA as an alternate supplier for a battery component (second source) for the uncoated battery cathode current collector that is consumed into titanium coated cathode current collectors and eventually into the Delta 26H2 and Delta 26H3 medium rate batteries further used in implantable neurostimulators. And the addition of Incoming Inspection Procedures for Uncoated and Coated Cathode Current Collector Components Originating from Meier Tool.
P980007/S043	11/05/2020	X - 30-Day Notice	AXSYM FREE PSA	ABBOTT LABORATORIES	Adding a process for overhead tank mixing of paramagnetic microparticles using the 650 L microparticle tank in order to improve the manufacturing flexibility of the assays.
P980016/S757	11/11/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the cathode fabrication manufacturing process for the Cobalt XT, Cobalt, and Crome ICD and CRT-D device family.
P980016/S758	11/18/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Alternate supplier of polyurethane resin used to mold a manufacturing aid, the bore plug.
P980016/S760	11/18/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P980016/S761	11/18/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify manufacturing and testing processes to detect a new defect and improve troubleshooting of false test failures.
P980035/S653	11/03/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Use a new testing platform for hybrid board pre-burn-in testing during the manufacturing process.
P980035/S655	11/16/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add automated controls to the low-rate battery leak test.
P980035/S658	11/18/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.

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P980035/S660	11/12/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Increase the maximum seam weld cycles and expand the allowable rework loops.
P980035/S661	11/24/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Several modifications to affected manufacturing documentation and statistical software for the laser ribbon bonding process monitoring.
P980035/S662	11/25/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement changes in the hybrid manufacturing and testing process to reduce false test failures.
P980037/S083	11/12/2020	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Changes to incoming inspections.
P980040/S123	11/03/2020	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Alternate manufacturing site located at AMO Puerto Rico Manufacturing Inc., Rd 402 North, Añasco, PR 00610, USA.
P980040/S126	11/12/2020	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding an alternative supplier for the thermal initiator used at the Johnson and Johnson Surgical Vision, Inc. (JJSV) Añasco facility in Puerto Rico for IOL production
P980044/S054	11/12/2020	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Replacement of the filter integrity test system.
P980050/S129	11/18/2020	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P980052/S008	11/24/2020	X - 30-Day Notice	TMJ CONCEPTS PATIENT-FITTED TMJ RECONSTRUCTION PROSTHESIS	TMJ CONCEPTS	Change to implement new sterilization equipment for the same approved sterilization type and cycle.
P990080/S054	11/12/2020	X - 30-Day Notice	CEEON EDGE FOLDABLE ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS, MODEL 911A	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding an alternative supplier for the thermal initiator used at the Johnson and Johnson Surgical Vision, Inc. (JJSV) Añasco facility in Puerto Rico for IOL production
P000029/S090	11/12/2020	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Multiple changes to the Water for Injection (WFI) system and the compressed air system.
P000029/S091	11/18/2020	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Change in the sterilization dose audit schedule.

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P010012/S527	11/05/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Add a lubricant to the battery cathode tab punching process.
P010015/S454	11/18/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Alternate supplier of polyurethane resin used to mold a manufacturing aid, the bore plug.
P010015/S455	11/18/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P010015/S457	11/25/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement changes in the hybrid manufacturing and testing process to reduce false test failures.
P010030/S145	11/17/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Removal of a gas generator reliability test during manufacturing.
P010030/S146	11/05/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Update to the Automated Monitor Detect and Treat test software.
P010031/S718	11/11/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the cathode fabrication manufacturing process for the Cobalt XT, Cobalt, and Crome ICD and CRT-D device family.
P010031/S719	11/18/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Alternate supplier of polyurethane resin used to mold a manufacturing aid, the bore plug.
P010031/S721	11/18/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Manufacturing Execution System to FACTORYworks Release 9.8.

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P010031/S722	11/18/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Modify manufacturing and testing processes to detect a new defect and improve troubleshooting of false test failures.
P030004/S025	11/13/2020	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASC ULAR	Manufacturing location of the supplier of EVOH (ethylene vinyl alcohol) for Onyx Liquid Embolic System from Japan to Belgium to increase the production capacity.
P030005/S204	11/16/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Implement a new manufacturing process for the front desiccant/liner components and remove a supplier of low voltage capacitors.
P030036/S124	11/18/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P030054/S387	11/20/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Process improvements and changes associated with the optimized drug release/elution test method for batch release and annual stability for CRT leads MCRD component manufacturing.
P040024/S121	11/06/2020	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Changes to the distribution systems for Water for Injection (WFI) and changes to producer and distribution system of compressed air in Line 1 (L1) at Q-Med AB Uppsala used for the manufacture of Restylane and Perlane.
P040027/S080	11/25/2020	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Changes to equipment used in the manufacturing of the VIATORR TIPS Endoprosthesis and VIATORR TIPS Endoprosthesis with Controlled Expansion.
P040045/S119	11/23/2020	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Qualification of an existing production line to produce VISTAKON (senofilcon A) ACUVUE OASYS Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR Plus.
P040045/S120	11/19/2020	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Removal of a redundant in-process test used during the manufacture of VISTAKON (senofilcon A) and (etafilcon A) Brand Contact Lenses.
P050051/S040	11/05/2020	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORI ES INC	Adding a process for overhead tank mixing of paramagnetic microparticles using the 650 L microparticle tank in order to improve the manufacturing flexibility of the assays.
P060006/S102	11/18/2020	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to equipment used for the stent laser cutting process.

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P060039/S102	11/18/2020	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P070008/S119	11/17/2020	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.	Modify the insulating foil geometry and add adhesive to improve the manufacturing process.
P070026/S077	11/19/2020	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Relocation of the manufacturing process for the S-ROM® Stem components.
P070026/S078	11/30/2020	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change is a modification of an existing mask at the Porocoat process step and the introduction of a new mask to eliminate rework at the Polish process step for hip components for the CERAMAX® Ceramic Total Hip System.
P080006/S152	11/18/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P080011/S118	11/05/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Component upgrades to a packaging line.
P080011/S119	11/17/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Software update on Biofinity MTO (Made to Order) manufacturing Lines 1 and 2.
P080020/S039	11/12/2020	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Replacement of the filter integrity test system.
P080020/S040	11/17/2020	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Installation of a new pure steam generator used during the manufacture of Gel-One.
P080025/S212	11/04/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Addition of inspection equipment and inspection step.
P080025/S213	11/12/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Changes to the manufacturing process (i.e., copper plating, additional solder mask developing line) for the printed wiring board (PWB) provided from an external supplier.
P080025/S214	11/12/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Reduction in nonviable air sampling to comply with ISO 14644:2015-1.
P080025/S215	11/19/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Update the manufacturing execution system to FACTORYWorks Release 9.8.
P080025/S216	11/30/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Addition of Meier Tool & Engineering (Meier Tool), Anoka, MN - USA as an alternate supplier for a battery component (second source) for the uncoated battery cathode current collector that is consumed into titanium coated cathode current collectors and eventually into the Delta 26H2 and Delta 26H3 medium rate batteries further used in implantable neurostimulators. And the addition of Incoming Inspection Procedures for Uncoated and Coated Cathode Current Collector Components Originating from Meier Tool.

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P090003/S050	11/18/2020	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to equipment used for the stent laser cutting process.
P090013/S310	11/18/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P100010/S109	11/09/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Update the catheter shaft component manufacturing site and add a new laser to the catheter manufacturing process.
P100014/S028	11/12/2020	X - 30-Day Notice	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Multiple changes to the Water for Injection (WFI) system and the compressed air system.
P110010/S183	11/30/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of confirmatory testing for several solvents.
P110010/S184	11/19/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modification to the midshaft adhesive bond length.
P110035/S063	11/30/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changing the tubing used as part of the rack assembly.
P110042/S147	11/16/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Implement a new manufacturing process for the front desiccant/liner components and remove a supplier of low voltage capacitors.
P110042/S149	11/05/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add a lubricant to the battery cathode tab punching process.
P120008/S016	11/05/2020	X - 30-Day Notice	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Adding a process for overhead tank mixing of paramagnetic microparticles using the 650 L microparticle tank in order to improve the manufacturing flexibility of the assays.
P120017/S024	11/18/2020	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P130009/S112	11/10/2020	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modifications to the Solutions Mixing Clean Room in the Singapore facility.
P130017/S045	11/25/2020	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Qualification of a Reagent Manufacturing System
P140003/S077	11/06/2020	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Automate a process during the end qualification test process for the Impella pumps.

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P140010/S054	11/24/2020	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Updated pouch sealer.
P140029/S034	11/06/2020	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Changes to the distribution systems for Water for Injection (WFI) and changes to producer and distribution system of compressed air in Line 1 (L1) at Q-Med AB Uppsala used for the manufacture of Restylane Refyne, Restylane Defyne, and Restylane Kysse.
P140031/S121	11/10/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modifications to the Solutions Mixing Clean Room in the Singapore facility.
P140031/S122	11/05/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modification of the laser weld visual inspection process.
P140032/S062	11/19/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update the manufacturing execution system to FACTORYWorks Release 9.8.
P140032/S063	11/30/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Transfer of bioburden testing activities of the pump exterior to a new laboratory
P150003/S066	11/30/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Removal of confirmatory testing for several solvents.
P150003/S067	11/19/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modification to the midshaft adhesive bond length.
P150012/S103	11/16/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Implement a new manufacturing process for the front desiccant/liner components and remove a supplier of low voltage capacitors.
P150033/S087	11/18/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update the Manufacturing Execution System to FACTORYworks Release 9.8.
P150036/S053	11/10/2020	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Modifications to the Solutions Mixing Clean Room in the Singapore facility.
P150040/S007	11/23/2020	X - 30-Day Notice	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Additional suppliers for blister packaging which is a part of primary package for the Treatment Pack.

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P150048/S050	11/10/2020	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Modifications to the Solutions Mixing Clean Room in the Singapore facility.
P160008/S015	11/18/2020	X - 30-Day Notice	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Update to the injection molding tooling used to fabricate plastic components and minor associated manufacturing assembly process changes.
P160014/S017	11/19/2020	X - 30-Day Notice	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Modifications to the laser and folding equipment, crimp recipe, and coating solution testing.
P160045/S023	11/11/2020	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Manufacturing relocation of a reagent.
P160047/S016	11/10/2020	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Changes being made to replace a manual calibration process for the Mara Console with an automated calibration process.
P170008/S029	11/24/2020	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Changes to the analytical test methods of the ridaforolimus drug substance.
P170011/S028	11/06/2020	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Automate a process during the end qualification test process for the Impella pumps.
P170024/S005	11/17/2020	X - 30-Day Notice	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Automate the application of the hydrophilic coating on the Surpass Evolve Flow Diverter System.
P170030/S012	11/13/2020	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Revisions to production documents and removal of specific process controls that are subsequently repeated during the manufacturing process.
P170030/S013	11/13/2020	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Introduction of new vials for 40 mm stent and extension of the dwell time.
P170035/S011	11/19/2020	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Alternate supplier of a raw material used in the manufacture of the Bausch + Lomb Ultra® (samfilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180002/S017	11/19/2020	X - 30-Day Notice	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Manufacturing changes affecting inspection of the Zephyr Endobronchial Delivery Catheter and the Endobronchial Valve.
P180011/S038	11/30/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of confirmatory testing for several solvents.
P180029/S028	11/06/2020	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modification to the acceptance criteria for visual inspection of the adaptive seal component of the LOTUS Edge valve.
P180046/S022	11/05/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of manufacturing equipment at a contract manufacturer.
P180046/S023	11/05/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Alternate moisture getter.
P190006/S022	11/05/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Addition of manufacturing equipment at a contract manufacturer.
P190006/S023	11/05/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Alternate moisture getter.
P190008/S008	11/24/2020	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Updated pouch sealer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190018/S007	11/12/2020	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Adding an alternate supplier for the hydrophilic monomer used for the manufacturing of the Clareon Intraocular Lens (IOL) in the Alcon Ireland manufacturing site.
P190018/S008	11/24/2020	X - 30-Day Notice	CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM, CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) WITH THE AUTONOME PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Implementation of new optical metrology equipment, Gen-3 MTF System, to be used as part of the manufacturing process for Clareon PanOptix Intraocular Lenses at the Alcon Ireland manufacturing site.
P190019/S002	11/12/2020	X - 30-Day Notice	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATIO N	Replacement of the current software with new software to collect and process manufacturing test data.
P200015/S001	11/10/2020	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCE S, LLC	Modifications to the Solutions Mixing Clean Room in the Singapore facility.

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P200015/S002	11/05/2020	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCE S, LLC	Modification of the laser weld visual inspection process.

Total: 142