PMA Monthly approvals from 8/1/2020 to 8/31/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180045	08/29/2020	PMAO - PMA Origi	LIAISON® XL MUREX HBC IGM, LIAISON® MUREX CONTROL HBC IGM	DIASORIN INC.	Approval for the LIAISON® XL MUREX HBc IgM, LIAISON® MUREX Control HBc IgM. The LIAISON® XL MUREX HBc IgM assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of IgM antibodies to hepatitis B virus core antigen (HBc IgM) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and K2 EDTA), including separator tubes, on the LIAISON® XL Analyzer. Assay results, in conjunction with other hepatitis B virus (HBV) serological markers and clinical information may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The presence of anti-HBc IgM is indicative of acute or recent HBV infection. This assay is not approved for use in screening blood, plasma or tissue donors. The LIAISON® XL MUREX Control HBc IgM (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX HBc IgM assay. The performance characteristics of LIAISON® XL MUREX Control HBc IgM have not been established for any other assays or instrument platforms.
P180048	08/29/2020	PMAO - PMA Origi	LIAISON® XL MUREX HBEAG, LIAISON® XL MUREX CONTROL HBEAG	DIASORIN INC.	Approval for the LIAISON® XL MUREX HBeAg, LIAISON® XL MUREX Control HBeAg. The LIAISON® XL MUREX HBeAg assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of hepatitis B virus (HBV) e antigen (HBeAg) in human adult and pediatric (2-21 years) serum and plasma (lithium and sodium heparin, sodium citrate and K2 EDTA), including separator tubes, on the LIAISON® XL Analyzer. Assay results in conjunction with other laboratory results and clinical information may be used as an aid in the diagnosis of hepatitis B virus (HBV) infection in patients with symptoms of hepatitis or who may be at risk for hepatitis B (HBV) infection. The assay is not intended for use in screening blood, plasma, or tissue donors. The LIAISON® XL MUREX Control HBeAg (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX HBeAg assay. The performance characteristics of LIAISON® XL MUREX Control HBeAg have not been established for any other assays or instrument platforms.

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P180049	08/29/2020	PMAO - PMA Origi	LIAISON® XL MUREX ANTI-HBE, LIAISON® XL MUREX CONTROL ANTI-HBE	DIASORIN INC.	Approval for the LIAISON® XL MUREX anti-HBe, LIAISON® XL MUREX Control anti-HBe. The LIAISON® XL MUREX Anti-HBe assay is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative detection of total antibodies to hepatitis B e antigen (anti-HBe) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and K2 EDTA), including separator tubes, on the LIAISON® XL Analyzer. Assay results in conjunction with other laboratory results and clinical information may be used as an aid in the diagnosis of hepatitis B virus (HBV) infection in patients with symptoms of hepatitis or who may be at risk for hepatitis B (HBV) infection. This assay is not approved for use in screening blood, plasma or tissue donors. The LIAISON® XL MUREX Control Anti-HBe (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX Anti-HBe assay. The performance characteristics of LIAISON® XL MUREX Control Anti-HBe have not been established for any other assays or instrument platforms different from LIAISON® XL Analyzer.
P190007	08/07/2020	PMAO - PMA Origi	CARDINAL HEALTH MULTIFUNCTIONAL DEFIBRILLATION ELECTRODE	CARDINAL HEALTH	Approval for the Cardinal Health Multifunctional Defibrillation Electrodes. These devices are indicated for: The Multifunctional Defibrillation Electrodes are intended to transfer energy from a cardiac defibrillator or pacer to the body of a patient for the purpose of defibrillation, synchronized cardioversion, pacing, or for ECG monitoring. The Kendall and Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control LIFEPAK (LP) defibrillators are compatible with Physio-Control / Stryker LP 15, LP 20, LP 20E, LP 1000, LP CR Plus, and LP Express defibrillators with the exception of the Kendall 1010P Adult Multi-Function Defibrillation Electrode, which is compatible with Physio-Control LP 20 and LP 20e defibrillators and the Physio-Control FAST-PATCH® cable. The Medi-Trace Cadence Pediatric Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control / Stryker defibrillators are compatible with Physio-Control LP 15, LP 20, and LP 20e defibrillators. The Kendall and Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with Zoll defibrillators are compatible with Zoll R Series BLS, R Series Plus, R Series ALS, X Series, and Propaq MD defibrillators. The Physio-Control/Stryker QUIK-COMBO Adult pacing/defibrillation/ECG electrodes and QUIK-COMBO Pediatric pacing/defibrillation/ECG electrodes are compatible with LP 15, LP 20, and LP 20e defibrillators. The Physio-Control/Stryker QUIK-COMBO pacing/ defibrillation/ECG electrode with REDI-PAK Preconnect system is compatible with LP 15, LP 20, LP 20e, LP 1000, LP CR Plus, and LP EXPRESS defibrillators.

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P190017	08/29/2020	PMAO - PMA Origi	LIAISON® XL MUREX HBSAG QUAL, LIAISON® MUREX CONTROL HBSAG, AND LIAISON® XL MUREX HBSAG CONFIRMATORY TEST	DIASORIN INC	Approval for the LIAISON® XL MUREX HBsAg Qual, LIAISON® MUREX Control HBsAg, and LIAISON® XL MUREX HBsAg Confirmatory Test. The LIAISON® XL MUREX HBsAg Qual assay is an in vitro chemiluminescent immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 to 21 years) serum and plasma (lithium and sodium heparin, sodium citrate and potassium EDTA) including separator tubes, on the LIAISON® XL Analyzer. Assay results in conjunction with other hepatitis B virus (HBV) serological and clinical information, may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The assay may also be used to screen for HBV infection in pregnant women to identify neonates who are at risk for acquiring hepatitis B during the perinatal period. The LIAISON® XL MUREX Control HBsAg Qual (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL MUREX HBsAg Qual assay. The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON® XL. For details, refer to the Analyzer Operator's Manual. The LIAISON® XL MUREX HBsAg Confirmatory is an in vitro neutralization assay for confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma samples found repeatedly reactive for HBsAg by the LIAISON® XL MUREX HBsAg Qual ([REF] 318250).

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P190032	08/26/2020	PMAO - PMA Origi	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE INC.	Approval for the FoundationOne® Liquid CDx. The device 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 and copy number losses only in BRCA1 and BRCA2. 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. Additionally, FoundationOne® Liquid CDx is intended to provide tumor mutation profiling for substitutions and indels to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Table 1: Companion diagnostic indications Tumor Type Biomarker(s) Detected Therapy Non-small cell lung cancer (NSCLC) EGFR exon 19 deletions and EGFR exon 21 L858R alteration IRESSA® (gefitinib) TAGRISSO® (osimertinib) TARCEVA® (erlotinib) Prostate cancer BRCA1, BRCA2 alterations RUBRACA® (rucaparib) 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 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.

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P200010	08/07/2020	PMAO - PMA Origi	GUARDANT360 CDX	GUARDANT HEALTH, INC.	Approval order for Guardant360® CDx. Guardant360® CDx is a qualitative next generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 55 genes, copy number amplifications (CNAs) in two (2) genes, and fusions in four (4) genes. Guardant360 CDx utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs). The test is intended to be used as a companion diagnostic to identify non-small cell lung cancer (NSCLC) patients who may benefit from treatment with the targeted therapy listed in Table 1 in accordance with the approved therapeutic product labeling. Table 1. Companion Diagnostic Indications Indication: Non-small cell lung cancer (NSCLC); Biomarker: EGFR exon 19 deletions, L858R, and T790M*; Therapy: TAGRISSO® (osimertinib) A negative result from a plasma specimen does not assure that the patients tumor is negative for genomic findings. NSCLC patients who are negative for the biomarkers listed in Table 1 should be reflexed to tissue biopsy testing for Table 1 biomarkers using an FDA-approved tumor tissue test, if feasible. *The efficacy of TAGRISSO® (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained. Additionally, the test is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms. The test is for use with patients previously diagnosed with cancer and in conjunction with other laboratory and clinical findings. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product. Guardant360 CDx is a single-site assay performed at Guardant Health, Inc.
P200013	08/29/2020	PMAO - PMA Origi	ALINITY M HBV	ABBOTT MOLECULAR, INC.	Approval for the Alinity m HBV. The Alinity m HBV assay is an in vitro polymerase chain reaction (PCR) with fluorescent labeled probes assay for use with the automated Alinity m System to quantitate Hepatitis B Virus (HBV) DNA in human plasma and serum. The Alinity m HBV assay is intended for use as an aid in the management of patients with chronic HBV infection undergoing anti-viral therapy. The assay can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment. The results from the Alinity m HBV assay must be interpreted within the context of all relevant clinical and laboratory findings. This assay is not intended to be used in screening blood, blood products, or cell, tissue, and cellular and tissue-based products (HCT/Ps), or as a diagnostic test to confirm the presence of HBV infection.
P200015	08/31/2020	PMAO - PMA Origi	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE SYSTEM WITH EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC	Approval for the Edwards SAPIEN 3 Transcatheter Heart Valve (THV) System with Commander Delivery System is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic valve in the pulmonic position with greater than or equal to moderate regurgitation and/or a mean RVOT gradient of greater than or equal to 35 mmHg.

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Total: 9

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S463	08/17/2020	R - Real-Time Proc	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Approval for a minor packaging change to SCS Accessories; Models 3550-14, 3550-28, and 3550-43, to remove redundant, outer packaging.
P860004/S338	08/21/2020	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval to change the molding process for the SynchroMed Infusion System and Ascenda Intrathecal Catheters components(Fill Port Septum and the Catheter Access Port Septum).
P890003/S431	08/25/2020	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for Model 25000 MyCareLink Smart Patient Reader firmware version 4.5.0 and Model 30100 and 30101 Apps software version 5.1.0.
P910007/S051	08/07/2020	N - Normal 180 Day	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Approval for the migration of the Abbott ARCHITECT Total PSA assay to the Alinity i Analyzer.
P950039/S039	08/12/2020	Y - 135 Review Tra	THINPREP(R) PROCESSOR, MODEL TP 2000	HOLOGIC, INC.	Approval of an alternate supplier for the membrane material for the ThinPrep Pap Test Filter used in the ThinPrep processors.
P960009/S378	08/12/2020	S - Special CBE	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval of Changes being Effected (CBE) for the enhancement and harmonization of the physician and patient labeling to include precaution statements regarding risks of loss of coordination during activities requiring coordination (e.g. swimming) and bathing in the labeling across the device type.
P970051/S197	08/31/2020	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a change in electronic assembly design for the Nucleus Cochlear Implant System (CI600 series implants), and for adding Cochlear Brisbane Operations as a supplier of the new electronic assemblies.
P980040/S113	08/27/2020	O - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for a manufacturing site located at AMO Puerto Rico Manufacturing Inc., Road 402 North, KM 4.2, Añasco, PR 00610; and, approval for a contract sterilization site located at Edwards Life Sciences Technology SARL, Hwy # 402 North, KM 1.4, Añasco, PR 00610.
P990004/S042	08/27/2020	S - Special CBE	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEIDCAL DEVICES A/S	Approval for implementation of a water sample monitoring program for the washing machines used to wash items used for the manufacturing of SURGIFOAM Absorbable Gelatin Sponge, SURGIFOAM Absorbable Gelatin Powder and SURGIFLO Hemostatic Matrix.
P990009/S058	08/07/2020	N - Normal 180 Day	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Approval for the removal of the lower limit for the syringe extrusion force as a lot-release specification for the 5mL and 10mL configurations of the Floseal Hemostatic Matrix (Floseal).
P000025/S116	08/25/2020	R - Real-Time Proc	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for the RONDO 3 Audio Processor, MAESTRO System Software 9.0, and WaterWear for RONDO 3.

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P010015/S439	08/12/2020	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for an update to the tantalum capacitor technology.
P010030/S138	08/04/2020	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for a mechanical design change to the LifeVest 4000 and HWD 1000 Monitor to improve the ruggedness of the Electrode Belt connector.
P010032/S167	08/18/2020	R - Real-Time Proc	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for a minor design change to remove a microelectromechanical systems (MEMS) sensor, which is an accelerometer component on the IPGs printed circuit board. This MEMS sensor was intended to detect and collect data on patient activity levels for research and development purposes only; it is not related to productperformance.
P020050/S035	08/21/2020	N - Normal 180 Day	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for software changes on the WaveLight® EX500 and the associated WaveNet Planning Software (WPS) to include enhanced WaveFront Optimized (eWFO) treatment with finer adjustment steps for targeted refraction and targeted optical zone.
P030008/S031	08/21/2020	N - Normal 180 Day	WAVELIGHT ALLEGRETTO WAVE EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for software changes on the WaveLight® EX500 and the associated WaveNet Planning Software (WPS) to include enhanced WaveFront Optimized (eWFO) treatment with finer adjustment steps for targeted refraction and targeted optical zone.
P030039/S024	08/14/2020	N - Normal 180 Day	COSEAL SURGICAL SEALANT	BAXTER BIO SCIENCE	Approval for a design change to the applicator and changes to the manufacturing site and labeling to reflect the updated applicator.
P030053/S053	08/28/2020	O - Normal 180 Day	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Approval of the completion of the Mentor MemoryGel Large Post-Approval Study Re-Op Phase close out plan.
P040020/S095	08/28/2020	O - Normal 180 Day	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P040029/S014	08/24/2020	O - Normal 180 Day	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	Approval for model name additions to the Euclid Systems Orthokeratology (oprifocon A) or (tisilfocon A) Contact Lenses for Overnight Wear lenses.
P040034/S031	08/17/2020	R - Real-Time Proc	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for the addition of a silver colorant to the syringe plunger shaft.
P050006/S084	08/06/2020	R - Real-Time Proc	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for implementing a change to the colorant in the coating of the impacted components.
P050011/S008	08/21/2020	R - Real-Time Proc	ADEPT (4% ICODEXTRIN) ADHESION REDUCTION SOLUTION	BAXTER HEALTHCARE CORP.	Approval for bag fill volume changes to the polyvinylchloride storage bag for the ADEPT® Adhesion Reduction Solution.
P050027/S022	08/17/2020	R - Real-Time Proc	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for increase in the tolerance of the countersink angle of the outer shell of the Grasping Mechanism of the Tricam camera heads from 82 +/-I degree to 82 +7/-3 degrees.

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P050027/S023	08/17/2020	R - Real-Time Proc	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for modified cooling fin of the D-Light C High Power Light Unit for PDD.
P050027/S024	08/17/2020	R - Real-Time Proc	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for updating the tolerances on the 6100042200 plate (#212770) and changing the raw material on the Z09170 (shaft adapter) from 304 SS to 303 SS (#213303).
P060001/S029	08/04/2020	R - Real-Time Proc	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Approval for changing a delivery system tensile strength specification.
P070006/S014	08/11/2020	N - Normal 180 Day	T SPOT-TB TEST	OXFORD IMMUNOTEC,LTD.	Approval for change to the age limitation in the current T-SPOT.TB test labeling to allow use of the test in individuals 2 years of age and older.
P080013/S019	08/17/2020	R - Real-Time Proc	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for the addition of a silver colorant to the syringe plunger shaft.
P100010/S107	08/13/2020	R - Real-Time Proc	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Approval for a design change to the buckling force requirement for Arctic Front Advance (AFA) (Models 2AF234 and 2AF284).
P100026/S082	08/04/2020	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for a minor update to the RNS Tablet (programmer) software and related update to the Patient Data Management System (PDMS) software, and a minor product configuration change to remove the infrequently used dial-up accessories from the Remote Monitor Kit and supply them in a separate new kit (model 5104).
P100045/S043	08/04/2020	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for updates to the software and connectivity hardware of the patient electronics system.
P100047/S151	08/06/2020	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the implementation of the C6 Monitor for the HeartWare HVAD System.
P110008/S012	08/05/2020	S - Special CBE	COFLEX® INTERLAMINAR TECHNOLOGY	RTI SURGICAL, INC	Approval for additional warnings in the labeling.
P110023/S029	08/04/2020	R - Real-Time Proc	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Approval for changing a delivery system tensile strength specification.
P120024/S009	08/12/2020	O - Normal 180 Day	ACTIVL ARTIFICIAL DISC	AESCULAP IMPLANT SYSTEMS, LLC	Approval for modifications to the labeling resulting from Post Approval Study (PAS) follow-up protocol.

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P130017/S042	08/26/2020	O - Normal 180 Day	COLOGUARD	EXACT SCIENCES CORPORATION	Approval of the clinical protocol titled A Real-World Study of Patients Under the Age of 50 Screened for Colorectal Cancer (CRC) Using Cologuard® in the U.S.Tidal, for the post-approval study (PAS) protocol.
P130021/S076	08/17/2020	N - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for modifying a precaution in the labeling regarding patients with a congenital bicuspid aortic valve.
P140003/S072	08/04/2020	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for: 1) a new design for the Impella 2.5, Impella CP, and Impella CP with SmartAssist pigtail subcomponent; 2) the addition of a second supplier for the new pigtail design; and 3) a change in material and supplier of the encapsulant on the optical sensor used on the Impella CP with SmartAssist and the Impella 5.5 with SmartAssist catheters.
P140004/S018	08/05/2020	R - Real-Time Proc	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Approval for a design and manufacturing change for an instrument component.
P140009/S061	08/12/2020	S - Special CBE	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval of Changes being Effected (CBE) for the enhancement and harmonization of the physician and patient labeling to include precaution statements regarding risks of loss of coordination during activities requiring coordination (e.g. swimming) and bathing in the labeling across the device type.
P140009/S063	08/18/2020	R - Real-Time Proc	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for a minor design change to remove a microelectromechanical systems (MEMS) sensor, which is an accelerometer component on the IPGs printed circuit board. This MEMS sensor was intended to detect and collect data on patient activity levels for research and development purposes only; it is not related to productperformance.
P140011/S007	08/21/2020	N - Normal 180 Day	MAMMOMAT INSPIRATION WITH TOMOSYNTHESIS OPTION	SIEMENS MEDICAL SOLUTIONS USA, INC.	Approval for 1) a new processing scheme for synthetic mammograms (new Insight 2D/3D), and 2) an updated Indications for Use to include Digital Breast Tomosynthesis (DBT) in combination with synthesized image sets, Insight 2D, or Insight 2D and Insight 3D, as a screening mode, for MAMMOMAT Revelation with Tomosynthesis Option.
P150003/S058	08/10/2020	P - Panel Track	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for the SYNERGY and SYNERGY XD Everolimus-Eluting Platinum Chromium Coronary Stent Systems. The SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System is indicated for improving luminal diameter in patients, including those at high risk for bleeding, with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation MI or documented silent ischemia due to atherosclerotic lesions in native coronary arteries >=2.25 mm to <= 5.00 mm in diameter in lesions <= 34 mm in length. The SYNERGY XD Everolimus-Eluting Platinum Chromium Coronary Stent System is indicated for improving luminal diameter in patients, including those at with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation MI or documented silent ischemia due to atherosclerotic lesions in native coronary arteries >= 2.25 mm to <= 5.00 mm in diameter in lesions <= 44 mm in length and for high risk bleeding patients with coronary arteries >= 2.25 mm to <= 5.00 mm in diameter in lesions <= 34 mm in length.

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P150004/S042	08/18/2020	R - Real-Time Proc	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for a minor design change to remove a microelectromechanical systems (MEMS) sensor, which is an accelerometer component on the IPGs printed circuit board. This MEMS sensor was intended to detect and collect data on patient activity levels for research and development purposes only; it is not related to productperformance.
P150012/S096	08/26/2020	O - Normal 180 Day	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for labeling updates for the ImageReady MR Conditional Pacing System and INGEVITY Pace/Sense Lead based on the SAMURAI and INGEVITY clinical studies.
P150030/S008	08/21/2020	O - Normal 180 Day	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Approval of a revised protocol for the post-approval study protocol.
P150031/S036	08/12/2020	S - Special CBE	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval of Changes being Effected (CBE) for the enhancement and harmonization of the physician and patient labeling to include precaution statements regarding risks of loss of coordination during activities requiring coordination (e.g. swimming) and bathing in the labeling across the device type.
P160017/S076	08/31/2020	P - Panel Track	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval of the MiniMed 770G System to expand the indications for use to use users down to 2 years old and to update the pump communication protocol to Bluetooth Low Energy (BLE).
P160022/S013	08/25/2020	N - Normal 180 Day	X SERIES®, R SERIES®, AED PRO®, AED 3 BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER BATTERY PACK, SUREPOWER II BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 BATTERY PACK, SUREPOWER CHARGER, AND SUREPOWER SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Approval for a software update to Version 02.34 (including implementation of Real Bag-Valve Mask Help Ventilation Feedback (Real BVM Help), a traumatic brain injury dashboard (TBI Dashboard), and the ability to retry to 12-Lead electrocardiograph report transmission up to five times), the addition of the AccuVent Sensor System accessory, and the rebranding of the device from X Series to X Series Advanced.
P160055/S010	08/07/2020	N - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for the expansion of the refractive cylinder treatment parameter ranges of the Light Delivery Device (LDD) to include 0.50 diopter.
P170011/S025	08/04/2020	O - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a labeling change related to the Impella RP best practice selection algorithm.
P170018/S007	08/27/2020	R - Real-Time Proc	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Approval for a change in printed circuit board laminate material and material supplier.
P170038/S005	08/28/2020	O - Normal 180 Day	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180003/S003	08/13/2020	O - Normal 180 Day	BIOMIMICS 3D VASCULAR STENT SYSTEM	VERYAN MEDICAL LTD.	Approval for updates to the labeling with final clinical data from the MIMICS-2 study.

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P180029/S020	08/17/2020	Y - 135 Review Tra	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Approval for implementation of a Visual Standard to aid operators in distinguishing between acceptable and rejectable surface defects on the Multi-Lumen Extrusion (MLE) of the Lotus Edge Valve System.
P180038/S002	08/06/2020	R - Real-Time Proc	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Approval for software version change to the LIAISON XL analyzer software.
P180039/S001	08/06/2020	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 software version change to the LIAISON XL analyzer software.
P180043/S001	08/18/2020	N - Normal 180 Day	THERASCREEN FGFR RGQ RT-PCR KIT	QIAGEN GMBH	Approval for the therascreen FGFR RGQ RT-PCR Kit is a reverse transcription, real-time PCR test for the qualitative detection of two point mutations in exon 7 [p.R248C (c. 742C>T), p.S249C (c.746C>G)], two point mutations in exon 10 [p.G370C (c.1108G>T) and p.Y373C (c.1118A>G)] and two fusions (FGFR3-TACC3v1 and FGFR3-TACC3v3) in the fibroblast growth factor receptor 3 (FGFR3) gene in RNA samples derived from formalin-fixed paraffin-embedded (FFPE) urothelial tumor tissue. The test is indicated for use as an aid in identifying urothelial cancer (UC) patients who harbor these alterations and are therefore eligible for treatment with BALVERSA (erdafitinib). Specimens are processed using the RNeasy DSP FFPE Kit for manual sample preparation followed by reverse transcription and then automated amplification and detection on the Rotor-Gene Q MDx (US) instrument.
P180046/S015	08/31/2020	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGI ES, INC.	Approval for a curved belt accessory.
P180047/S004	08/06/2020	R - Real-Time Proc	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for software version change to the LIAISON XL analyzer software.
P190006/S015	08/31/2020	N - Normal 180 Day	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGI ES, INC.	Approval for curved belt accessory.
P190011/S002	08/06/2020	R - Real-Time Proc	LIAISON XL MUREX HCV AB; LIAISON XL MUREX CONTROL HCV AB	DIASORIN INC.	Approval for software version change to the LIAISON XL analyzer software.
P190015/S002	08/20/2020	S - Special CBE	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Approval for implementation of an in-process inspection step in the manufacturing of the TREO Abdominal Stent-Graft System.
P190024/S001	08/14/2020	N - Normal 180 Day	CINTEC PLUS CYTOLOGY	VENTANA MEDICAL SYSTEMS, INC.	Approval for expanding the indications for use to add the cobas® 6800/8800 Systems (cobas® HPV) test to identify HPV positive patients.

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N12159/S074	08/14/2020	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Change to the Roller Compaction machines Programmable Logic Controller software.
N970003/S252	08/03/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Automate parts of the final pack manufacturing process.
P830061/S184	08/06/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer and expand inspection activities at the MPROC Juncos Facility.
P830063/S017	08/27/2020	X - 30-Day Notice	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Change in the extrusion process for the pump segment tubing of the PRISMAFLEX TPE 2000 Set.
P850089/S149	08/06/2020	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer and expand inspection activities at the MPROC Juncos Facility.
P870024/S054	08/13/2020	X - 30-Day Notice	FLUOROPERM RGP CONTACT LENSES	PARAGON VISION SCIENCES	Addition of a new computer numeric control (CNC) lathe process used for contact lens manufacturing.
P870024/S055	08/18/2020	X - 30-Day Notice	FLUOROPERM RGP CONTACT LENSES	PARAGON VISION SCIENCES	Qualification of a second supplier of a raw material monomer used in the manufacture of Paragon HDS® (paflufocon B), FluoroPerm® 151 (paflufocon D), and Paragon HDS® 100 (paflufocon D) Rigid Gas Permeable (RGP) Contact Lenses.
P870024/S056	08/31/2020	X - 30-Day Notice	FLUOROPERM RGP CONTACT LENSES	PARAGON VISION SCIENCES	Addition of a new DAC brand of lathe machines.
P870024/S057	08/31/2020	X - 30-Day Notice	FLUOROPERM RGP CONTACT LENSES	PARAGON VISION SCIENCES	Addition of a new laser machine to engrave the lenses.
P890003/S433	08/06/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.

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P900061/S160	08/06/2020	X - 30-Day Notice	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer and expand inspection activities at the MPROC Juncos Facility.
P910023/S431	08/06/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Add an alternate supplier for the metal case and lid used to manufacture HV Capacitor.
P920015/S245	08/06/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P920048/S017	08/12/2020	X - 30-Day Notice	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Relocation of a suppliers manufacturing site of a raw material used in the Rapid fFN Cassette. The Rapid fFN Cassette is part of the TLiIQ System.
P930027/S023	08/18/2020	X - 30-Day Notice	IMMULITE SYSTEMS PSA & THIRD GENERATION PSA REAGENTS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Removal of redundant annual stability testing.
P930036/S015	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR AFP REAGENTS AND CALIBRATORS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Procedure for testing raw materials, in-process and final products.
P930039/S214	08/06/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P950021/S022	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Procedure for testing raw materials, in-process and final products.
P950024/S094	08/06/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P950029/S126	08/10/2020	X - 30-Day Notice	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Introduction of automated equipment during the manufacturing of select pacemakers and defibrillators.
P960009/S377	08/21/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Review of an update to the hybrid printed-circuit board test software and the associated specification documents.
P960040/S452	08/03/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Automate parts of the final pack manufacturing process.

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P960043/S108	08/12/2020	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Use of alternative sheath coating equipment for the Perclose ProGlide Suture-Mediated Closure System.
P970051/S199	08/13/2020	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Relocation of the subassembly process for the Radial Welded Magnet Assembly, and the addition of new laser welding equipment.
P970054/S019	08/13/2020	X - 30-Day Notice	BIOTRIN PARVOVIRUS B19 IGG	DIASORIN	Manufacturing process changes.
P970055/S021	08/13/2020	X - 30-Day Notice	BIOTRIN PARVOVIRUS IGM EIA (V619IMUS)	DIASORIN	Manufacturing process changes.
P980016/S749	08/04/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement automated equipment for containing and transferring between chemical baths for etching wafers at an external supplier.
P980016/S750	08/03/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to selected electrolyte incoming inspection documentation.
P980016/S751	08/24/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Tighten the material controls of fluorinated carbon material received from an external supplier.
P980035/S633	08/05/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Use of both ADEC and InCal burn-in systems at Medtronic Tempe Campus.
P980035/S634	08/04/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement automated equipment for containing and transferring between chemical baths for etching wafers at an external supplier.
P980035/S635	08/03/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to selected electrolyte incoming inspection documentation.
P980035/S636	08/24/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Tighten the material controls of fluorinated carbon material received from an external supplier.

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P980037/S081	08/10/2020	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Removal of an in process inspection.
P980040/S119	08/03/2020	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Align the flat time test procedure using mainly one (1) representative procedure (QI356) to perform flat time test as opposed to using various procedures for different packaging configurations/delivery systems.
P980049/S138	08/10/2020	X - 30-Day Notice	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Introduction of automated equipment during the manufacturing of select pacemakers and defibrillators.
P980050/S128	08/06/2020	X - 30-Day Notice	MEDTRONIC(R) JEWEL(R) AF 7250 DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, MODEL 9961 PROGRAMMER APPLICATION SOF	MEDTRONIC INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P990009/S063	08/28/2020	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Addition of a previously approved packaging configuration for the 5mL and 10mL Floseal Hemostatic Matrix (FLOSEAL) device to be used with FLOSEAL Fast Prep.
P990038/S031	08/13/2020	X - 30-Day Notice	DIASORIN ETI MAK-2 PLUS ASSAY	DIASORIN, INC.	Manufacturing process changes.
P990041/S030	08/13/2020	X - 30-Day Notice	DIASORIN ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Manufacturing process changes.
P990042/S027	08/13/2020	X - 30-Day Notice	DIASORIN ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Manufacturing process changes.
P990043/S031	08/13/2020	X - 30-Day Notice	DIASORIN ETI-EBK PLUS ASSAY	DIASORIN, INC.	Manufacturing process changes.
P990044/S028	08/13/2020	X - 30-Day Notice	DIASORIN ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Manufacturing process changes.
P990045/S028	08/13/2020	X - 30-Day Notice	DIASORIN ETI-AB-COREK PLUS ASSAY	DIASORIN, INC.	Manufacturing process changes.
P990055/S022	08/25/2020	X - 30-Day Notice	BAYER IMMUNO 1 COMPLEXED PSA ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Procedure for testing raw materials, in-process and final products.
P000015/S043	08/13/2020	X - 30-Day Notice	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Relocation of the subassembly process for the Radial Welded Magnet Assembly, and the addition of new laser welding equipment.
P000053/S115	08/26/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an updated KRT extruder.

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P000054/S063	08/27/2020	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Introduction of vaccine drug substance protein manufacturing at the dibotermin alfa manufacturing site in Pfizers Andover, MA facility.
P000058/S082	08/27/2020	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Introduction of vaccine drug substance protein manufacturing at the dibotermin alfa manufacturing site in Pfizers Andover, MA facility.
P010007/S012	08/18/2020	X - 30-Day Notice	IMMULITE/IMMULITE 1000 AFP AND IMMULITE 2000/ IMMULITE 2500 AFP	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Removal of redundant annual stability testing.
P010012/S521	08/03/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Automate parts of the final pack manufacturing process.
P010015/S443	08/04/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implement automated equipment for containing and transferring between chemical baths for etching wafers at an external supplier.
P010015/S444	08/06/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P010015/S445	08/03/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Updates to selected electrolyte incoming inspection documentation.
P010015/S446	08/24/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Tighten the material controls of fluorinated carbon material received from an external supplier.
P010021/S033	08/07/2020	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS , INC.	Amendment of the assay specific release for sale limits used in the release testing of Immunodiagnostic Products, VITROS Anti-HCV reagent pack and calibrators.
P010031/S709	08/04/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implement automated equipment for containing and transferring between chemical baths for etching wafers at an external supplier.

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P010031/S710	08/03/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Updates to selected electrolyte incoming inspection documentation.
P010031/S712	08/24/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Tighten the material controls of fluorinated carbon material received from an external supplier.
P030005/S198	08/03/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Automate parts of the final pack manufacturing process.
P030017/S340	08/11/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Implementation of additional production line to manufacture the printed circuit board assembly (PCBA) of the charger device.
P030036/S122	08/06/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer and expand inspection activities at the MPROC Juncos Facility.
P030040/S018	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR HBC IGM READYPACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Procedure for testing raw materials, in-process and final products.
P030049/S015	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR HBSAG READY PACK REAGENTS/ CONFIRMATORY READY PACK REAGENTS/QUALITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS	Procedure for testing raw materials, in-process and final products.
P030054/S383	08/06/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Add an alternate supplier for the metal case and lid used to manufacture HV Capacitor.
P030056/S018	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR HCV READY PACK REAGENTS, ADVIA CENTAUR HCV QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Procedure for testing raw materials, in-process and final products.
P040002/S066	08/05/2020	X - 30-Day Notice	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, INC.	Manufacturing process changes related to the AFX2 implant loading procedure into the delivery system.

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P040004/S018	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR HBC TOTAL READYPACK REAGENTS/ADVIA CENTAUR HBC TOTAL QUALITY CONTROL MATERIALS	SIEMENS HEALTHCARE DIAGNOSTICS	Procedure for testing raw materials, in-process and final products.
P040043/S117	08/05/2020	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate manufacturing process for the primary tubular sleeve component of the GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System.
P050028/S083	08/26/2020	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P050031/S006	08/31/2020	X - 30-Day Notice	PARAGON Z CRT (TISILFOCON A) RIGID GAS PERMEABLE CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY	PARAGON VISION SCIENCES	Addition of a new DAC brand of lathe machines.
P050031/S007	08/31/2020	X - 30-Day Notice	PARAGON Z CRT (TISILFOCON A) RIGID GAS PERMEABLE CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY	PARAGON VISION SCIENCES	Addition of a new laser machine to engrave the lenses.
P050042/S044	08/28/2020	X - 30-Day Notice	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Modifications to the sourcing and testing of materials used in the manufacture of an internal reference panel, which is used for quality control evaluation during in-process reagent manufacturing.
P050050/S014	08/20/2020	X - 30-Day Notice	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	STRYKER CORPORATION	Modification to the gamma sterilization load configuration.
P050053/S054	08/27/2020	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Introduction of vaccine drug substance protein manufacturing at the dibotermin alfa manufacturing site in Pfizers Andover, MA facility.
P060001/S030	08/18/2020	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	MEDTRONIC VASCULAR INC	Addition of an equivalent CNC machine at a supplier for a catheter component.
P060005/S011	08/18/2020	X - 30-Day Notice	IMMULITE / IMMULITE 1000 AND IMMULITE 2000 FREE PSA ASSAYS	SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS LIMITED	Removal of redundant annual stability testing.
P060006/S101	08/17/2020	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to the stent crimper software and equipment.

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P060027/S103	08/10/2020	X - 30-Day Notice	OVATIO CRT SYSTEM	MICROPORT CRM USA INC.	Introduction of automated equipment during the manufacturing of select pacemakers and defibrillators.
P060030/S084	08/26/2020	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P060037/S066	08/03/2020	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change of a Biological Indicator (BI) for hydrogen peroxide gas plasma sterilization.
P060039/S101	08/06/2020	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P080006/S150	08/06/2020	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P080011/S109	08/11/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Manufacture of Biofinity XR Toric lenses on Biofinity Line 20 at the CooperVision Manufacturing Ltd. facility in Hamble, United Kingdom.
P080011/S111	08/11/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Manufacture of Biofinity Toric lenses on Biofinity Line 17 at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080011/S113	08/27/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Introduction of a new order management and dispatch software system for the Biofinity lathing products at the CooperVision Manufacturing Ltd. facility in Hamble, UK.
P090013/S308	08/06/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Transfer and expand inspection activities at the MPROC Juncos Facility.
P090024/S009	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR HBEAG ASSAY AND QUALITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS	Procedure for testing raw materials, in-process and final products.
P100020/S053	08/26/2020	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P100039/S010	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR ANTI-HBS2 (AHBS2) ASSAY AND QAULITY CONTROL MATERIAL	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Procedure for testing raw materials, in-process and final products.
P100045/S045	08/14/2020	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Manufacturing process changes to the wafer bonding of the PA Pressure Sensor.
P100046/S012	08/14/2020	X - 30-Day Notice	ATRICURE SYNERGY ABLATION SYSTEM	ATRICURE INC.	Expand the existing manufacturing controlled room used for device packaging.
P110010/S181	08/20/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of an initial soaking step as pat of the electropolishing process.

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P110014/S011	08/14/2020	X - 30-Day Notice	DUNE MEDICAL DEVICES MARGINPROBE SYSTEM	DILON MEDICAL TECHNOLOGIES, LTD.	Changes to device and instructions for use labeling reflecting change in ownership and removal of CE mark.
P110020/S035	08/26/2020	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P110023/S030	08/18/2020	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Addition of an equivalent CNC machine at a supplier for a catheter component.
P110028/S021	08/28/2020	X - 30-Day Notice	ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYSTEM	ABBOTT VASCULAR INC.	Adding automated tab welding equipment and modifying tab weld geometry.
P110035/S062	08/28/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reduction of the in-process inspection frequency for the marker swaging process.
P110037/S054	08/26/2020	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P110041/S010	08/25/2020	X - 30-Day Notice	ADVIA CENTAUR HBSAGII	SIEMENS CORP.	Procedure for testing raw materials, in-process and final products.
P110042/S140	08/06/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change suppliers, update manufacturing procedures, and update test protocols for the flash memory component used in EMBLEM S-ICD Pulse Generators.
P110042/S141	08/03/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Automate parts of the final pack manufacturing process.
P120017/S023	08/06/2020	X - 30-Day Notice	MODEL 5071 LEAD	MEDTRONIC INC.	Transfer and expand inspection activities at the MPROC Juncos Facility.
P120019/S032	08/26/2020	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Manufacturing process change to use an alternate filter.
P130014/S008	08/14/2020	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Addition of an automated check valve inserter process.
P130026/S064	08/25/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Modification of proximal cable leakage current in-process controls for the TactiCath Contact Force Ablation Catheter, Sensor Enabled (TactiCath SE).

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P130030/S070	08/20/2020	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Removal of an initial soaking step as pat of the electropolishing process.
P140004/S019	08/14/2020	X - 30-Day Notice	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Change in welding equipment.
P140023/S023	08/26/2020	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P140028/S064	08/28/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Reduction of the in-process inspection frequency for the marker swaging process.
P140029/S028	08/28/2020	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Change the sterilization validation approach to the overkill method/full cycle approach defined in ISO 17665-1:2006 Annex D4.
P150003/S064	08/20/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Removal of an initial soaking step as pat of the electropolishing process.
P150009/S003	08/28/2020	X - 30-Day Notice	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Material change of the packaging lid for the AngelMed Guardian System.
P150012/S097	08/03/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Automate parts of the final pack manufacturing process.
P150014/S038	08/26/2020	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P150015/S040	08/26/2020	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P150031/S037	08/11/2020	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Implementation of additional production line to manufacture the printed circuit board assembly (PCBA) of the charger device.
P150031/S038	08/14/2020	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add an alternate qualified supplier for the surgical tool components of the SureTek Burr Hole Cover Kit, which are used during the deep brain stimulation (DBS) procedure for the Vercise, Vercise PC, and Vercise Gevia DBS Systems.

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P150033/S079	08/04/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Implement automated equipment for containing and transferring between chemical baths for etching wafers at an external supplier.
P150033/S080	08/03/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Second source capacitor supplier to ensure material availability.
P150033/S081	08/11/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Equipment modification to allow for new tooling to aid in manufacturing of Micra battery cathode fabrication.
P150033/S082	08/03/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Updates to selected electrolyte incoming inspection documentation.
P150033/S083	08/24/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Tighten the material controls of fluorinated carbon material received from an external supplier.
P150033/S084	08/27/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Update Micra battery weld inspection requirements to remove conflicting tether-pin weld rejection criterion.
P160003/S010	08/06/2020	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	New equipment for balloon manufacturing and modifying the sampling plan for final release testing.
P160003/S011	08/20/2020	X - 30-Day Notice	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Addition of identical ultrasonic cleaning machines and updates to the cleaning parameters.
P160016/S006	08/27/2020	X - 30-Day Notice	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)	SIEMENS HEALTHCARE DIAGNOSTICS , INC.	Manufacturing process change to replace with new RNA QC samples.
P160028/S001	08/03/2020	X - 30-Day Notice	PHILIPS HEARTSTART FR3 DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS, INC.	Changes to the inspection procedure for components and sub-assemblies used to build the HeartStart family of defibrillators.
P160029/S005	08/03/2020	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Changes to the inspection procedure for components and sub-assemblies used to build the HeartStart family of defibrillators.
P160029/S006	08/22/2020	X - 30-Day Notice	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Changes to the inspection procedures for components and subassemblies used to build the HeartStart family of defibrillators.

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P160037/S007	08/03/2020	X - 30-Day Notice	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Modification to the qualification sampling plan.
P160041/S030	08/26/2020	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P170006/S017	08/20/2020	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Modification to an existing quality control inspection related to the bovine pericardial leaflet tissue characteristics.
P170008/S028	08/20/2020	X - 30-Day Notice	ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Changes to the sampling plan for the mechanical and packaging release testing.
P170030/S008	08/20/2020	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Addition of identical ultrasonic cleaning machines and updates to the cleaning parameters.
P170042/S006	08/20/2020	X - 30-Day Notice	COVERA VASCULAR COVERED STENT	C.R. BARD, INC	Modifications to the delivery system joint bonding process.
P180011/S037	08/28/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Reduction of the in-process inspection frequency for the marker swaging process.
P180028/S002	08/03/2020	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Changes to the inspection procedure for components and sub-assemblies used to build the HeartStart family of defibrillators.
P180028/S003	08/22/2020	X - 30-Day Notice	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Changes to the inspection procedures for components and subassemblies used to build the HeartStart family of defibrillators.
P180029/S025	08/20/2020	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modification of UV curing parameters for the outer sheath of the Lotus Edge delivery system.
P180031/S003	08/18/2020	X - 30-Day Notice	NEUROFORM ATLAS® STENT SYSTEM	STRYKER NEUROVASCULAR	Process change for the removal of a cleaning step for the Neuroform Atlas Stent System.
P180037/S001	08/20/2020	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Modifications to the delivery system joint bonding process.
P180038/S003	08/13/2020	X - 30-Day Notice	LIAISON XL MUREX ANTI-HBC, LIAISON MUREX CONTROL ANTI-HBC	DIASORIN INC.	Manufacturing process changes.
P180039/S002	08/13/2020	X - 30-Day Notice	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Manufacturing process changes.

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P180047/S005	08/13/2020	X - 30-Day Notice	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Manufacturing process changes.
P190028/S002	08/26/2020	X - 30-Day Notice	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing process change to use an alternate filter
P200014/S001	08/26/2020	X - 30-Day Notice	COBAS® EZH2 MUTATION TEST	ROCHE MOLECULAR SYSTEM, INC.	Manufacturing process change to use an alternate filter

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