MA Monthly approvals from 11/1/2017 to 11/30/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160055	11/22/2017	PMAO - PMA Origi	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for The Light Adjustable Lens and Light Delivery Device system is indicated for the reduction residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag, in adult patients: 1) With pre-existing corneal astigmatism of => 0.75 diopters; and 2) Without pre-existing macular disease. The system also reduces the likelihood of clinically significant residual spherical refractive errors.
P160057	11/13/2017	PMAO - PMA Origi	TRIVISC	ORTHOGENRX,INC	Approval for TriVisc. The device is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).
P170008	11/28/2017	PMAO - PMA Origi	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for the EluNIR Ridaforolimus Eluting Coronary Stent System. This device is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo lesions <=30mm in length in native coronary arteries with reference diameter of 2.50mm to 4.25mm.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170019	11/30/2017	PMAO - PMA Origi	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for the FoundationOne CDx (F1CDx). This device is a next generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The test is intended 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, F1CDx 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. The F1CDx assay is a single-site assay performed at Foundation Medicine, Inc. Table 1: Companion diagnostic indications Indication: Non-small cell lung cancer (NSCLC). - Biomarker: EGFR exon 19 deletions and EGFR exon 21 L858R alterations. Therapy: Gilotrif® (afatinib), Iressa® (gefitinib), or Tarceva® (erlotinib). - Biomarker: EGFR exon 20 T790M alterations. Therapy: Tagrisso® (osimertinib). - Biomarker: ALK rearrangements. Therapy: Alecensa® (alectinib), Xalkori® (crizotinib), or Zykadia® (ceritinib). - Biomarker: BRAF V600E. Therapy: Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib). Indication: Melanoma. - Biomarker: BRAF V600E. Therapy: Tafinlar® (dabrafenib) or Zelboraf® (vemurafenib) - Biomarker: BRAF V600E and V600K. Therapy: Mekinist® (trametinib) or Cotellic® (cobimetinib) in combination with Zelboraf® (vemurafenib). Indication: Breast cancer. Biomarker: ERBB2 (HER2) amplification. Therapy: Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab). Indication: Colorectal cancer. - Biomarker: KRAS wild-type (absence of mutations in codons 12 and 13). Therapy: Erbitux® (cetuximab) - Biomarker: KRAS wild-type (absence of mutations in exons 2, 3, and 4) and NRAS wild type (absence of mutations in exons 2, 3, and 4). Therapy: Vectibix® (panitumumab) Indication: Ovarian cancer. Biomarker: BRCA1/2 alterations. Therapy: Rubraca®

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S139	11/29/2017	R - Real-Time Proc	AMS 700 INFLATABLE PENILE PROSTHESIS WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Approval for expanding the available tubing lengths of the preconnected penoscrotal CX and LGX devices.
P810002/S105	11/16/2017	R - Real-Time Proc	SJM MASTERS SERIES MECHANICAL HEART VALVE, SJM REGENT VALVE, SJM MASTERS SERIES AORTIC VALVED GRAFT WITH HEMASHIELD TECHNOLOGY, SJM MASTERS HP VALVED GRAFT WITH GELWEAVE VALSALVA TECHNOLOGY.	ST. JUDE MEDICAL, INC.	Approval for a change to the graphite density specification used for the valve orifice component.
P830055/S188	11/06/2017	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for change to the inner blister tray packaging for a select list of tibial articular surfaces within the LCS Total Knee System.
P840001/S374	11/17/2017	Y - 135 Review Tra	RESTORE, ITREL AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for implementing new test equipment and test methods to Medtronics current heavy metals testing of enhanced tear resistant silicone rubber.
P840024/S090	11/17/2017	N - Normal 180 Day	NUCLEUS N22 COCHLEAR IMPLANT SYSTEMS	COCHLEAR AMERICAS	Approval for the remote programing of Nucleus Cochlear Implant System using telehealth technology.
P860004/S289	11/17/2017	Y - 135 Review Tra	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for implementing new test equipment and test methods to Medtronics current heavy metals testing of enhanced tear resistant silicone rubber.
P880086/S290	11/09/2017	R - Real-Time Proc	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for a software update to the Merlin PCS Programmer software version 24.0.1 Rev. 1 and pacemaker firmware update.
P890003/S380	11/20/2017	R - Real-Time Proc	MYCARELINK PATIENT MONITOR TELEMETRY HEAD PRINTED CIRCUIT BOARD	MEDTRONIC, INC.	Approval for a minor design change to the MyCareLink Patient Monitor.
P890027/S059	11/17/2017	N - Normal 180 Day	NUCLEUS N22 COCHLEAR IMPLANT SYSTEMS	COCHLEAR AMERICAS	Approval order for the remote programing of Nucleus N22 Cochlear Implant System using telehealth technology should be issued.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900056/S165	11/02/2017	R - Real-Time Proc	ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a change in the UV Bond Adhesive used in the RotaLink Advancer.
P910023/S396	11/09/2017	R - Real-Time Proc	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY, ASSURA, EPIC/ EPIC+, ATLAS/II/+ FAMILYOF ICD'S	ST. JUDE MEDICAL	Approval for a software update to the Merlin PCS Programmer software version 24.0.1 Rev. 1 and a pacemaker firmware update.
P950037/S181	11/08/2017	R - Real-Time Proc	SIELLO S AND SOLIA S, EFH-6F-W AND DH IS-1/DF4	BIOTRONIK, INC.	Approval for an alternative fixation tool DH IS-1/DF4 and an alternative white lead fixation sleeve EFH-6F-W.
P960009/S292	11/17/2017	Y - 135 Review Tra	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for implementing new test equipment and test methods to Medtronics current heavy metals testing of enhanced tear resistant silicone rubber.
P960040/S405	11/17/2017	O - Normal 180 Day	SMART-MSP	BOSTON SCIENTIFIC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P960058/S121	11/14/2017	N - Normal 180 Day	HIFOCUS SLIMJ ELECTRODE	ADVANCED BIONICS	Approval for the Hires Ultra Implant with HiFocus SlimJ electrode and associated tools.
P960058/S122	11/14/2017	N - Normal 180 Day	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Approval order for the Naida CI Q90 Acoustic Earhook (Acoustic Earhook) that is intended for use with the approved Naida CI Q90 Sound Processor.
P970004/S254	11/17/2017	Y - 135 Review Tra	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODU LATION	Approval for implementing new test equipment and test methods to Medtronics current heavy metals testing of enhanced tear resistant silicone rubber.
P970013/S075	11/09/2017	R - Real-Time Proc	MICRONY FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for a software update to the Merlin PCS Programmer software version 24.0.1 Rev. 1 and pacemaker firmware update.
P970051/S164	11/17/2017	N - Normal 180 Day	NUCLEUS® COCHLEAR ¿ IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval order for the remote programing of Nucleus Cochlear Implant System using telehealth technology should be issued.
P980035/S518	11/29/2017	N - Normal 180 Day	ADVISA DR IPG, ADVISA DR MRI IPG	MEDTRONIC INC.	Approval of a new supplier for an alternate set screw block design.
P990009/S048	11/08/2017	R - Real-Time Proc	FLOSEAL HEMOSTATIC MATRIX	BAXTER HEALTHCARE CORP.	Approval for design changes to the FLOSEAL Hemostatic Matrix syringe connector supplied by Medplast.
P990009/S049	11/09/2017	R - Real-Time Proc	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Approval to add an alternate sterilization facility for the Thrombin Pouches to increase capacity.
P000053/S081	11/03/2017	R - Real-Time Proc	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Approval for design and process changes to the fluid resistor component and the addition of a second supplier site for the fluid resistor component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S464	11/17/2017	O - Normal 180 Day	SMART-MSP	BOSTON SCIENTIFIC CORP.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P030017/S280	11/14/2017	O - Normal 180 Day	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Clonmel Limited, Cashel Road, Clonmel , Co. Tipperary, Ireland as an additional manufacturing site for the Implantable Pulse Generators (IPG) of Precision SCS Systems.
P030017/S295	11/22/2017	O - Normal 180 Day	PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of an alternate Ethylene Oxide sterilization site at the Boston Scientific Clonmel manufacturing site at Cashel Road, Clonmel, Co. Tipperary, Ireland and new sterilization cycle parameters for that facility.
P030017/S296	11/22/2017	O - Normal 180 Day	PRECISION SPINAL CORD/ SPECTRA/NOVI SPINAL CORD STIMULATIOR (SCS) SYSTEM, PRECISION MONTAGE MRI AND PRECISION MONTAGE SPINAL CORD STIMULATOR (SCS) SYSTEM, SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of an alternate Ethylene Oxide sterilization site at the Boston Scientific Dorado manufacturing site at No. 12, Road 698, Dorado, Puerto Rico and new sterilization cycle parameters for that facility.
P030035/S162	11/09/2017	R - Real-Time Proc	ANTHEM, ALLURE/ RF,ALLURA QUADRA/RF FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for a software update to the Merlin PCS Programmer software version 24.0.1 Rev. 1 and pacemaker firmware update.
P030054/S340	11/09/2017	R - Real-Time Proc	PROMOTE/+/RF/Q. PROMOTE ACCEL, PROMOTE QUADRA, UNITY, UNITY ASSURA, UNITY QUADRA, QUADRA ASSURA , EPIC+/HF/HF+/ II HF, ATLAS+HF/II HH/II+HF FAMILY OF CRT-D'S	ST. JUDE MEDICAL	Approval for a software update to the Merlin PCS Programmer software version 24.0.1 Rev. 1 and pacemaker firmware update.
P050027/S009	11/30/2017	Y - 135 Review Tra	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for changes in cable assembly and solder used in printed circuit board for Photodynamic D-Light Camera Heads and Camera Control Unit.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050027/S010	11/30/2017	Y - 135 Review Tra	KARL STORZ PHOTODYNAMIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for a change in measurement method used for spectral analysis of the light output of the D-Light C Light Source.
P060002/S038	11/28/2017	Y - 135 Review Tra	FLAIR ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR	Approval for an update to the inspection procedure for the bond peel strength test for the FLAIR® and FLUENCY® plus endovascular stent graft systems.
P060019/S041	11/02/2017	R - Real-Time Proc	COOL POINT TUBING SET	IRVINE BIOMEDICAL, INC.	Approval for a change in the size of the unit carton (outer box) for the Cool Point Tubing Set.
P070004/S011	11/30/2017	S - Special CBE	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for changes to the labeling including modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P070014/S053	11/14/2017	N - Normal 180 Day	LIFESTENT VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval for marketing the LifeStent 5F Vascular Stent System.
P070026/S046	11/08/2017	R - Real-Time Proc	CERAMAX® CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for the addition of a Ceramic Liner Inserter Instrument and corresponding labeling changes to the surgical technique.
P080006/S114	11/09/2017	O - Normal 180 Day	MEDTRONIC ATTAIN ABILITY MODEL 4196	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post approval study.
P080025/S149	11/17/2017	Y - 135 Review Tra	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for implementing new test equipment and test methods to Medtronic¿s current heavy metals testing of enhanced tear resistant silicone rubber.
P100030/S009	11/20/2017	Y - 135 Review Tra	WATER FOR INJECTION STERILE, USP	MALLINCKRODT PHARMA IP TRADING DAC	Approval for an alternate supplier for the Sterile Water for Injection.
P110004/S023	11/01/2017	O - Normal 180 Day	NIRTRAKS CLINICAL STUDY	MEDINOL LTD.	Approval for revised protocol for the post-approval study (PAS) protocol.
P110013/S065	11/30/2017	Y - 135 Review Tra	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Approval for the addition of a vendor (Medtronic Ireland) for the Parylene coating process on the Resolute Integrity Stent.
P110035/S042	11/09/2017	R - Real-Time Proc	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a modification to the delivery system floating bumper component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120005/S060	11/03/2017	Y - 135 Review Tra	DEXCOM G4 PLATINUM CONTINUOUS GLUCOSE MONITORING SYSTEM; DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for extending the environmental temperature upper limit for sensors and applicators while being stored at their sterilization site prior to undergoing sterilization, as well as for establishing a limit on the amount of time sensors and applicators may be stored at their sterilization site prior to undergoing sterilization.
P120011/S010	11/17/2017	S - Special CBE	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for changes to the labeling including modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P130005/S020	11/17/2017	R - Real-Time Proc	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM (OAS) MICRO CROWN ORBITAL ATHERECTOMY DEVICE (OAD)	CARDIOVASCULAR SYSTEMS, INC.	Approval to extend the product shelf life to 24 months.
P130016/S028	11/17/2017	N - Normal 180 Day	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval order for the remote programing of Nucleus Hybrid L24 Implant System using telehealth technology should be issued.
P130017/S017	11/06/2017	N - Normal 180 Day	COLOGUARD	EXACT SCIENCES CORPORATION	Approval for changes to the Cologuard Hemoglobin Assay Process and Reagents. The device, as modified, will be marketed under the trade name Cologuard and is indicated for use as follows: Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. Cologuard is for use with the Cologuard collection kit and the following instruments: BioTek® Epoch 2 Absorbance Microplate Reader; Applied Biosystems® 7500 Fast Dx Real-Time PCR; Hamilton Microlab® STARlet; and the Exact Sciences System Software with Cologuard Test Definition. This assay is to be performed at Exact Sciences Laboratory, located at 145 E. Badger Rd, Suite 100, Madison, Wisconsin. Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.
P130024/S020	11/28/2017	O - Normal 180 Day	LUTONIX DRUG COATED BALLOON	LUTONIX	Approval of the revised protocol for the post-approval study (PAS) protocol.
P130027/S003	11/15/2017	N - Normal 180 Day	ARTUS CMV RGQ AND QS-RGQ MDX KIT	QIAGEN, INC.	Approval for a change to the enzyme in a component of the device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130029/S006	11/28/2017	Y - 135 Review Tra	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Approval for an update to the inspection procedure for the bond peel strength test for the FLAIR and FLUENCY plus endovascular stent graft systems.
P140003/S020	11/01/2017	Y - 135 Review Tra	IMPELLA VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC.	Approval for a new environmentally controlled area at the current manufacturing facility
P140003/S025	11/27/2017	R - Real-Time Proc	AUTOMATED IMPELLA CONTROLLER	ABIOMED, INC.	Approval for a design change to the USB cable in the Automated Impella Controller (AIC).
P140021/S010	11/03/2017	N - Normal 180 Day	ELECSYS ANTI-HCV II, PRECICONTROL ANTI-HCV	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for the migration of claims from the FDA approved Elecsys Anti-HCV II Immunoassay and PreciControl Anti-HCV on the cobas e 601 immunoassay analyzer to the cobas e 801 immunoassay analyzer.
P140025/S006	11/06/2017	N - Normal 180 Day	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the VENTANA ALK (D5F3) CDx Assay. The device is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung carcinoma (NSCLC) tissue stained with a BenchMark XT or BenchMark ULTRA automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib) or ZYKADIA® (ceritinib) or ALECENSA® (alectinib).
P140031/S047	11/20/2017	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval of the protocol for the post-approval study (PAS) protocol.
P140031/S048	11/20/2017	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval of the protocol for the post-approval study (PAS) protocol.
P140033/S017	11/09/2017	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI FAMILY OF PACEMAKERS,	ST. JUDE MEDICAL, INC.	Approval for a software update to the Merlin PCS Programmer software version 24.0.1 Rev. 1 and pacemaker firmware update.
P150013/S007	11/20/2017	O - Normal 180 Day	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approved for labeling changes to include results from additional non-clinical studies.
P150021/S008	11/16/2017	Y - 135 Review Tra	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for changes to the manufacturing process to facilitate an increase in the Sensor Kit manufacturing capacity by implementing new high volume (HV) assembly lines for the Printed Circuit Board Assembly (PCBA), Sensor Applicator, and Sensor Container processes.
P150030/S003	11/30/2017	O - Normal 180 Day	R3 DELTA CERAMIC ACETABULAR SYSTEM	SMITH & NEPHEW, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160019/S001	11/01/2017	N - Normal 180 Day	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for migration of the Elecsys HBsAg II, Elecsys HBsAg Confirmatory Test, and PreciControl HBsAg II to the cobas e 602 immunoassay analyzer.
P160043/S001	11/16/2017	P - Panel Track	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for the Resolute Onyx Zotarolimus-Eluting Coronary Stent System. This device is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus, with symptomatic ischemic heart disease due to de novo lesions of length <= 35 mm in native coronary arteries with reference vessel diameters of 2.0 mm to 5.0 mm.

Total: 62

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N17679/S038	11/16/2017	X - 30-Day Notice	PREFERENCE (TETRAFILCON A) SOFT (HYDROPHILLIC) CONTACT LENSES	COOPERVISIO N, INC.	Conversion of manufacturing equipment for Preference Sphere (tetrafilcon A) lenses produced at the CooperVision Incorporated manufacturing facility in Scottsville, New York.
N18033/S096	11/15/2017	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Change for modification of a raw material process involved in the production of VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lenses.
P780007/S058	11/22/2017	X - 30-Day Notice	POLYMACON SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISIO N, INC.	Minor modification in the sterilization cycle parameters for ocufilcon D and polymacon extended wear lenses.
P830055/S193	11/27/2017	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Change in manufacturing process for the polishing of the LCS Total Knee System.

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P830061/S151	11/09/2017	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of new auto-winder equipment.
P830063/S010	11/21/2017	X - 30-Day Notice	PRISMAFLEX TPE 2000 SET	BAXTER INTERNATIONAL, INC.	Addition of a new extrusion tubing machine, transfer of the tubing extrusion process, and transfer of the tubing subassembly process to another Baxter facility.
P840001/S380	11/03/2017	X - 30-Day Notice	RESTORE, AND ITREL SPINAL CORD STIMULATION SYSTEMS	MEDTRONIC NEUROMODULATION	Changes to the acceptance parameter specification limits for the T84 wafers and a change to allow use of the original passivation EKC recipe.
P840001/S381	11/16/2017	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES. SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Equipment changes and expansion of the manufacturing line for the medium rate batteries.
P840064/S067	11/01/2017	X - 30-Day Notice	DUOVISC, VISCOAT, DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Use of an alternative method for the raw material release testing.
P850079/S076	11/22/2017	X - 30-Day Notice	FREQUENCY XCEL TORIC (METHAFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES. / FREQUENCY XCEL TORIC XR (METHAFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES.	COOPERVISION, INC.	Introduction of a new Rapid Readout Biological Indicators (RRBIs) incubator and the reduction in the number of RRBIs.
P850089/S128	11/09/2017	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE Z NOVUS LEAD, VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of new auto-winder equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S170	11/27/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS; THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THE THERMAFIX TISSUE PROCESS; RSR PERICARDIAL AORTIC BIOPROSTHESIS; THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PLUS PERICARDIAL MITRAL BIOPROSTHESIS; THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS;	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom adjacent to an existing cleanroom.
P880086/S289	11/08/2017	X - 30-Day Notice	ACCENT, ASSURITY, ENDURITY, VERITY ADX, ZEPHYR, IDENTITY ADX, VICTORY	ST. JUDE MEDICAL, INC.	Updates to manufacturing operator procedures and operator retraining.
P890003/S382	11/09/2017	X - 30-Day Notice	CAPSURE VDD 2 LEAD, VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Implementation of new auto-winder equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890023/S029	11/22/2017	X - 30-Day Notice	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Minor modification in the sterilization cycle parameters for ocufilcon D and polymacon extended wear lenses.
P890047/S052	11/01/2017	X - 30-Day Notice	PROVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON RESEARCH, LTD.	Use of an alternative method for the raw material release testing.
P900033/S066	11/28/2017	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE ANDINTEGRA OMNIGRAFT DERMAL REGENERATION MAXTRIX	INTEGRA LIFESCIENCES CORP.	Qualification of a second Electron Beam for the sterilization of Collagen Glycosaminoglycan (GAG) Matrix products at Steris Applied Sterilization Technologies' Saxonburg, Pennsylvania facility.
P900056/S167	11/01/2017	X - 30-Day Notice	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM GUIDEWIRE	BOSTON SCIENTIFIC CORP.	Update the software control system and the vacuum pump used in Sterilization Chamber 1 at the BSC Coventry Rhode Island facility.
P910023/S395	11/08/2017	X - 30-Day Notice	FORTIFY, FORTIFY ASSURA, QUADRA ASSURA, ELLIPSE	ST. JUDE MEDICAL	Updates to manufacturing operator procedures and operator retraining.
P910056/S026	11/01/2017	X - 30-Day Notice	ENVISTA HYDROPHOBIC ACRYLIC INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Change to the method of manufacturing the enVista Hydrophobic Acrylic IOL Model MX60.
P920047/S105	11/01/2017	X - 30-Day Notice	BLAZER II CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Update the software control system and the vacuum pump used in Sterilization Chamber 1 at the BSC Coventry Rhode Island facility.
P930014/S106	11/30/2017	X - 30-Day Notice	ACRYSOF SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of a new test method for determining the % Purity of an AcrySof Intraocular Lens raw material.
P930039/S177	11/09/2017	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Implementation of new auto-winder equipment.
P940016/S024	11/07/2017	X - 30-Day Notice	HEPARIN-INDUCED EXTRACORPOREAL LDL PRECIPITATION (H.E.L.P.) FUTURA APHERESIS SYSTEM	B. BRAUN AVITUM AG	Automate manufacturing processes related to the Ultrafilter, a component of the H.E.L.P. Futura Set.

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P950020/S086	11/15/2017	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON (MONORAIL; OVER-THEWIRE)	BOSTON SCIENTIFIC CORP.	Modify the inflation pressure used during the cutting balloon leak test.
P950020/S087	11/16/2017	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Use of the optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P950024/S076	11/09/2017	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Implementation of new auto-winder equipment.
P960009/S299	11/03/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Changes to the acceptance parameter specification limits for the T84 wafers and a change to allow use of the original passivation EKC recipe.
P960009/S300	11/16/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Equipment changes and expansion of the manufacturing line for the medium rate batteries.
P960043/S098	11/01/2017	X - 30-Day Notice	PERCLOSE PROGLIDE SUTURE-MEDIATED CLOSURE SYSTEM	ABBOTT VASCULAR INC.	Removal of the sheath threading process from the sheath subassembly.
P960058/S126	11/21/2017	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	New optical measurement system for receiving inspection during manufacturing of the Ultra implant in the HiResolution Bionic Ear system.
P970004/S258	11/03/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Changes to the acceptance parameter specification limits for the T84 wafers and a change to allow use of the original passivation EKC recipe.
P970004/S259	11/09/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Supplier change for an integrated circuit.
P970004/S260	11/16/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Equipment changes and expansion of the manufacturing line for the medium rate batteries.
P970013/S074	11/08/2017	X - 30-Day Notice	MICRONY	ST. JUDE MEDICAL, INC.	Updates to manufacturing operator procedures and operator retraining.
P970031/S061	11/16/2017	X - 30-Day Notice	FREESTYLE BIOPROSTHESIS	MEDTRONIC, INC.	Changes to the alpha amino oleic acid compound manufacturing process.
P980003/S082	11/01/2017	X - 30-Day Notice	CHILLI II COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Update the software control system and the vacuum pump used in Sterilization Chamber 1 at the BSC Coventry Rhode Island facility.

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P980035/S523	11/13/2017	X - 30-Day Notice	ADVISA DR IPG / DR MRI IPG/ SR MRI IPG; ASTRA XT DR MRI IPG / S DR MRI IPG / S SR MRI IPG/ XT SR MRI IPG; AZURA S DR MRI IPG/ S SR MRI IPG/ XT DR MRI IPG/ XT SR MRI IPG	MEDTRONIC INC.	Implementation of additional workstations and updates to the station layout during battery manufacturing.
P980035/S524	11/30/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ATTESTA IPG, SPHERA IPG	MEDTRONIC INC.	Change in the laser ribbon bonding process operating range.
P990009/S050	11/01/2017	X - 30-Day Notice	FLOSEAL HEMOSTATIC MATRIX/ FLOSEAL SPECIAL APPLICATOR TIPS	BAXTER HEALTHCARE CORP.	Change of the Bacterial Endotoxin Test (BET) method to Limulus Amebocyte Lysate (LAL) Kinetic Turbidimetric Method.
P990046/S052	11/18/2017	X - 30-Day Notice	LASER ANGLE MEASUREMENT TOOL FOR OPEN AND CLOSE LEAFLET ANGLES MEASUREMENT	MEDTRONIC ATS MEDICAL, INC.	Implement a new laser measurement tool for the leaflet angle inspection.
P990064/S073	11/16/2017	X - 30-Day Notice	MOSAIC BIOPROSTHESIS	MEDTRONIC, INC.	Changes to the alpha amino oleic acid compound manufacturing process.
P990074/S041	11/03/2017	X - 30-Day Notice	NATRELLE SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Implement an Electronic Data Acquisition (EDA) System to collect cycle parameter, such as temperature and time, for the shell drying after washing and gel curing after shell filling occur in the Blue-M oven. The above change is located 900 Parkway Global Park, La Aurora, Heredia, Costa Rica.
P000021/S034	11/14/2017	X - 30-Day Notice	DIMENSION VISTA TPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Transfer a contract service provider to manufacture subassembly components and service spare parts, which are used in the Dimension Vista® System manufacturing process.
P000044/S036	11/09/2017	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS HBS AG REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Change in the manufacturing process for negative plasma used in production of assay reagent.

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P010015/S345	11/13/2017	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P / PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P / SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P/ SOLAR QUADRIPOLAR CRT-P, SYNCRA CRT-P; VIVA CRT-P	MEDTRONIC INC.	Implementation of additional workstations and updates to the station layout during battery manufacturing.
P010019/S061	11/13/2017	X - 30-Day Notice	AIR OPTIX PLUS HYDRAGLYDE (LOTRAFILCON B) SOFT CONTACT LENSES FOR DAILY AND EXTEDNED WEAR	ALCON LABORATORIES, INC.	Transfer of a raw material pelletization process from in-house to an external supplier and establishing a 3-year shelf life for the raw material based on a stability study completed, thereby removing the periodic material retesting requirement for stability confirmation.
P010030/S101	11/17/2017	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Implementation of new soldering and cleaning equipment.
P010032/S136	11/21/2017	X - 30-Day Notice	GENESIS IPG/EON IPG/ EON C IPG/EON MINI IPG/ PROTEGE IPG/PROTEGE MRI IPG/PRODIGY/ PRODIGY MRI IPG/ PROCLAIM IPG/PORT PLUG ACCESSORY KIT	ST. JUDE MEDICAL	Change to an approved supplier (Plastic Design Corporation (PDC)) manufacturing site location of the polysulfone port plug component of the St. Jude Medical Neurostimulation Systems.
P010032/S138	11/28/2017	X - 30-Day Notice	PROCLAIM FAMILY OF IMPLANTABLE PULSE GENERATORS	ST. JUDE MEDICAL	Supplier site move to a new supplier manufacturing location for ferrules used in the manufacture of battery lids within Implantable Pulse Generators (IPGs), in addition to a new Lid Assembly Machine (LAM) used to weld the ferrules to the battery lid.
P010033/S035	11/21/2017	X - 30-Day Notice	QUANTIFERON - TB GOLD TEST AND TB GOLD PLUS TEST	QIAGEN	Remove in-process QC testing of a raw material used to manufacture a kit subcomponent.
P010047/S050	11/29/2017	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Manufacturing process and location change of DuPont¿s production of Tyvek used in the manufacture of packaging material for the device.
P020011/S010	11/03/2017	X - 30-Day Notice	APTIMA HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Relocate manufacturing equipment within a manufacturing site.

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P020025/S108	11/01/2017	X - 30-Day Notice	BLAZER II XP CARDIAC RF ABLATION SYSTEM(ALSO BRANDED AS AS BLAZER (II XP, PRIME XP); INTELLATIP MIFI XP; INTELLANAV XP AND INTELLANAV MIFI XP)	BOSTON SCIENTIFIC	Update the software control system and the vacuum pump used in Sterilization Chamber 1 at the BSC Coventry Rhode Island facility.
P020027/S029	11/14/2017	X - 30-Day Notice	DIMENSION VISTA FPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Transfer a contract service provider to manufacture subassembly components and service spare parts, which are used in the Dimension Vista® System manufacturing process.
P020045/S084	11/27/2017	X - 30-Day Notice	FREEZOR CARDIAC CRYOABLATION SYSTEM	MEDTRONIC CRYOCATH LP	Changes to automate serial number label printing and file deletion via USB File Manager.
P020056/S045	11/03/2017	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Implement an Electronic Data Acquisition (EDA) System to collect cycle parameter, such as temperature and time, for the shell drying after washing and gel curing after shell filling occur in the Blue-M oven. The above change is located 900 Parkway Global Park, La Aurora, Heredia, Costa Rica.
P030035/S161	11/08/2017	X - 30-Day Notice	ANTHEM, ALLURE/ALLURE RF, ALLURE QUADRA / ALLURE QUADRA RF, ALLURE QUADRA MP RF	ST. JUDE MEDICAL, INC.	Updates to manufacturing operator procedures and operator retraining.
P030045/S004	11/27/2017	X - 30-Day Notice	INTRASTENT DOUBLESTRUT STENT; VISI-PRO BALLOON-EXPANDABLE PERIPHERAL STENT SYSTEM (ILAC)	MEDTRONIC VASCULAR INC	Implement an alternate 7-pallet sterilizer vessel (#71) at the contract sterilizer, Steris Applied Sterilization Technologies.
P030054/S339	11/08/2017	X - 30-Day Notice	UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, ELLIPSE	ST. JUDE MEDICAL	Updates to manufacturing operator procedures and operator retraining.
P040020/S074	11/30/2017	X - 30-Day Notice	ACRYSOF IQ RESTOR INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of a new test method for determining the % Purity of an AcrySof Intraocular Lens raw material.
P040024/S100	11/17/2017	X - 30-Day Notice	RESTYLANE / PERLANE / RESTYLANE-L / RESTYLANE-LYFT (FORMERLY PERLANE-L) RESTYLANE SILK.	Q-MED AB	Change in the quality specification of Lidocaine Hydrochloride to align it with the updated USP monograph and the introduction of skip testing for some of the in-house tests already performed by the manufacturer of Lidocaine Hydrochloride.
P040037/S106	11/16/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Alternate supplier for a device component.

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P040045/S085	11/06/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Change to automate an existing process used in the formulation of packaging solution used in VISTAKON® (senofilcon A) Brand Contact Lenses.
P040045/S086	11/15/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Change for modification of a raw material process involved in the production of VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lenses.
P040045/S087	11/08/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Removal of a redundant in-process package integrity test.
P040046/S026	11/03/2017	X - 30-Day Notice	NATRELLE 410 HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Implement an Electronic Data Acquisition (EDA) System to collect cycle parameter, such as temperature and time, for the shell drying after washing and gel curing after shell filling occur in the Blue-M oven. The above change is located 900 Parkway Global Park, La Aurora, Heredia, Costa Rica.
P040047/S047	11/30/2017	X - 30-Day Notice	COAPTITE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Remove impressions (disruptions) in the waffle pattern of the seal for foil autoclavable pouches as a critical defect.
P050010/S019	11/15/2017	X - 30-Day Notice	PRODISC-L TOTAL DISC REPLACEMENT	SYNTHES SPINE	Change in the sealing parameters used in the sterile packaging process for the ProDisc-L Total Disc Replacement device.
P050028/S059	11/13/2017	X - 30-Day Notice	ROCHE COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a bulk reagent.
P050037/S083	11/30/2017	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Remove impressions (disruptions) in the waffle pattern of the seal for foil autoclavable pouches as a critical defect.
P050037/S084	11/21/2017	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Change in the calcium hydroxylapatite particle component manufacturing throughput.
P050047/S061	11/16/2017	X - 30-Day Notice	JUVEDERM ULTRA, JUVEDERM ULTRA XC, JUVEDERM ULTRA PLUS, JUVEDERM ULTRA XC, JUVEDERM 30 (JUVEDERM FORMA)	ALLERGAN	Expansion of the drying room.
P050052/S099	11/30/2017	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Remove impressions (disruptions) in the waffle pattern of the seal for foil autoclavable pouches as a critical defect.

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P050052/S100	11/21/2017	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Change in the calcium hydroxylapatite particle component manufacturing throughput.
P060001/S026	11/27/2017	X - 30-Day Notice	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEM; PROTEGE GPS SELF-EXPANDING PERIPHERAL STENT SYSTEM (ILIAC)	MEDTRONIC VASCULAR INC	Implement an alternate 7-pallet sterilizer vessel (#71) at the contract sterilizer, Steris Applied Sterilization Technologies.
P060006/S087	11/01/2017	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the software control system and the vacuum pump used in sterilization Chamber 1 at the BSC Coventry Rhode Island facility.
P060037/S053	11/15/2017	X - 30-Day Notice	NEXGEN LPS-FLEX/LPS MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change in manufacturing process by the replacement of a piece of equipment (heat sealer) with a new piece of equipment of a different make and model.
P080011/S062	11/13/2017	X - 30-Day Notice	BIOFINITY TORIC	COOPERVISION MANUFACTURING, LTD.	Validate Biofinity Line 12 to produce Biofinity Toric lenses.
P080011/S063	11/22/2017	X - 30-Day Notice	BIOFINITY XR TORIC (COMFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Introduction of a new Rapid Readout Biological Indicators (RRBIs) incubator and the reduction in the number of RRBIs.
P080025/S153	11/03/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Changes to the acceptance parameter specification limits for the T84 wafers and a change to allow use of the original passivation EKC recipe.
P080025/S154	11/09/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Supplier change for an integrated circuit.
P080025/S155	11/16/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUTION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Equipment changes and expansion of the manufacturing line for the medium rate batteries.
P090013/S264	11/13/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Implementation of additional workstations and updates to the station layout during battery manufacturing.
P100010/S068	11/27/2017	X - 30-Day Notice	ARCTIC FRONT CARDIAC CRYOABLATION SYSTEM	MEDTRONIC CRYOCATH LP	Changes to automate serial number label printing and file deletion via USB File Manager.

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P100020/S027	11/13/2017	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a bulk reagent.
P100029/S027	11/21/2017	X - 30-Day Notice	TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Change to the milling lubricant used in the final milling of the Trifecta GT titanium rings.
P100033/S007	11/03/2017	X - 30-Day Notice	PROGENSA PCA3 ASSAY	GEN-PROBE INCORPORATED	Move filler equipment and upgrade the pump.
P100042/S014	11/03/2017	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Relocate manufacturing equipment within a manufacturing site.
P100047/S113	11/19/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of updated welding software and parameters for a laser welding station.
P100047/S116	11/22/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Addition of a Tier 2 supplier for some electrical components used within the power adaptor.
P110010/S147	11/01/2017	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (REBRAND OF PROMUS ELEMENT PLUS)	BOSTON SCIENTIFIC CORP.	Update the software control system and the vacuum pump used in Sterilization Chamber 1 at the BSC Coventry Rhode Island facility.
P110010/S148	11/17/2017	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the poly-dispersity index material specification for a stent coating component.
P110013/S083	11/07/2017	X - 30-Day Notice	RESOLUTE INTEGRITY CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Remove the quarterly non-viable particulate testing conducted on the isolators.
P110013/S084	11/07/2017	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Create a product group for the purpose of bacterial endotoxin testing using Limulus Amebocyte Lysate.

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P110016/S051	11/29/2017	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER/ FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Implementation of RFID tags to track manufacturing operator performance.
P110020/S023	11/13/2017	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a bulk reagent.
P110023/S024	11/27/2017	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM; EVERFLEX SELF-EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEM; EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (ILIAC)	MEDTRONIC VASCULAR INC	Implement an alternate 7-pallet sterilizer vessel (#71) at the contract sterilizer, Steris Applied Sterilization Technologies.
P110033/S034	11/16/2017	X - 30-Day Notice	JUVEDERM VOLUMA XC, JUVEDERM VOLLURE XC, JUVEDERM VOLBELLA XC	ALLERGAN	Expansion of the drying room.
P110035/S043	11/09/2017	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate tubing supplier.
P110042/S095	11/27/2017	X - 30-Day Notice	EMBLEM SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Implementation of a hybrid battery manufacturing line from existing lines for the S-ICD battery.
P120005/S068	11/14/2017	X - 30-Day Notice	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	New supplier of raw material for the manufacturing of blood glucose sensor probes. The probes are components in Dexom G4 Platinum Continous Glucose Monitoring System and the Dexcom G5 Mobile Continous Glucose Monitoring System.
P120007/S012	11/03/2017	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Relocate manufacturing equipment within a manufacturing site.
P120010/S106	11/28/2017	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of new equipment for the Enlite Sensor substrate manufacturing process. The Enlite Sensor is a component of the following systems: MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System, iPro2 CGM System with Enlite Sensor.
P120019/S017	11/13/2017	X - 30-Day Notice	COBAS EGFR MUTATION TEST AND COBAS EGFR V2 MUTATION TEST	ROCHE	Scale-up production of a bulk reagent.

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P130006/S045	11/16/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Alternate supplier for a device component.
P130008/S027	11/08/2017	X - 30-Day Notice	INSPIRE IV IPG	INSPIRE MEDICAL SYSTEMS	Changes to update to software version 1.0.4 of the Serial Number Verification System for the Model 3028 IPG.
P130009/S083	11/27/2017	X - 30-Day Notice	SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom adjacent to an existing cleanroom.
P130021/S045	11/16/2017	X - 30-Day Notice	COREVALVE, EVOLUT-R EVOLUT PRO	MEDTRONIC COREVALVE LLC	Changes to the alpha amino oleic acid compound manufacturing process.
P130021/S046	11/21/2017	X - 30-Day Notice	COREVALVE EVOLUT R SYSTEM AND COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Change to a manufacturing specification related to the leaflet tissue.
P130026/S027	11/27/2017	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Removal of a burn-in step during manufacture of the TactiSys Quartz Equipment.
P130030/S045	11/01/2017	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Update the software control system and the vacuum pump used in Sterilization Chamber 1 at the BSC Coventry Rhode Island facility.
P140009/S031	11/21/2017	X - 30-Day Notice	BRIO IPG/INFINITY IPG	ST. JUDE MEDICAL NEUROMODULATION	Change to an approved supplier (Plastic Design Corporation (PDC)) manufacturing site location of the polysulfone port plug component of the St. Jude Medical Neurostimulation Systems.
P140009/S032	11/28/2017	X - 30-Day Notice	INFINITY FAMILY OF IMPLANTABLE PULSE GENERATORS	ST. JUDE MEDICAL NEUROMODULATION	Supplier site move to a new supplier manufacturing location for ferrules used in the manufacture of battery lids within Implantable Pulse Generators (IPGs), in addition to a new Lid Assembly Machine (LAM) used to weld the ferrules to the battery lid.
P140023/S012	11/13/2017	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a bulk reagent.
P140028/S029	11/09/2017	X - 30-Day Notice	INNOVA SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of an alternate tubing supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140030/S005	11/06/2017	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Changes to your gold coating equipment and processes.
P140031/S055	11/27/2017	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom adjacent to an existing cleanroom.
P140031/S056	11/13/2017	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom for molding the Commander delivery system balloon components.
P140033/S016	11/08/2017	X - 30-Day Notice	ASSURITY MRI, ENDURITY MRI	ST. JUDE MEDICAL, INC.	Updates to manufacturing operator procedures and operator retraining.
P150001/S026	11/07/2017	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	New electroplating machine to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G and MiniMed 670G systems.
P150001/S027	11/28/2017	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of new equipment for the Enlite Sensor substrate manufacturing process. The Enlite Sensor is a component of the following systems: MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System, iPro2 CGM System with Enlite Sensor.
P150004/S018	11/28/2017	X - 30-Day Notice	PROCLAIM DRG IMPLANTABLE PULSE GENERATOR	ST. JUDE MEDICAL	Supplier site move to a new supplier manufacturing location for ferrules used in the manufacture of battery lids within Implantable Pulse Generators (IPGs), in addition to a new Lid Assembly Machine (LAM) used to weld the ferrules to the battery lid.
P150005/S030	11/01/2017	X - 30-Day Notice	BLAZER OPEN IRRIGATED CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Update the software control system and the vacuum pump used in Sterilization Chamber 1 at the BSC Coventry Rhode Island facility.
P150005/S031	11/21/2017	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate supplier for the electrode ring components of IntellaNav OI, IntellaTip MiFi OI, IntellaNav MiFi OI.
P150012/S047	11/28/2017	X - 30-Day Notice	ACTIVE FIXATION INGEVITY LEADS	BOSTONSCIENTIFIC	Duplicate the molding process for active fixation INGEVITY lead neck subassembly by adding an alternate tool.
P150014/S011	11/13/2017	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a bulk reagent.
P150015/S010	11/13/2017	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a bulk reagent.
P150016/S006	11/29/2017	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Manufacturing process and location change of DuPont¿s production of Tyvek used in the manufacture of packaging material for the device.

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P150017/S006	11/09/2017	X - 30-Day Notice	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Expansion of the manufacturing facility for the Cartiva SCI device
P150019/S032	11/28/2017	X - 30-Day Notice	MINIMED 630G SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Addition of new equipment for the Enlite Sensor substrate manufacturing process. The Enlite Sensor is a component of the following systems: MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System, iPro2 CGM System with Enlite Sensor.
P150029/S012	11/28/2017	X - 30-Day Notice	IPRO2 CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Addition of new equipment for the Enlite Sensor substrate manufacturing process. The Enlite Sensor is a component of the following systems: MiniMed 530G System, Paradigm Real-Time Revel System, MiniMed 630G System, iPro2 CGM System with Enlite Sensor.
P150036/S020	11/27/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom adjacent to an existing cleanroom.
P150048/S007	11/27/2017	X - 30-Day Notice	EDWARDS INSPIRIS RESILIA AORTIC VALVE AND EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Addition of a new cleanroom adjacent to an existing cleanroom.
P150048/S008	11/30/2017	X - 30-Day Notice	RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Reduce the frequency of an in-process manufacturing test.
P160017/S024	11/07/2017	X - 30-Day Notice	MINIMED 670G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED, INC.	New electroplating machine to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G and MiniMed 670G systems.
P160025/S003	11/06/2017	X - 30-Day Notice	ASTRON PULSAR/PULSAR - 18 STENT SYSTEM	BIOTRONIK, INC.	Changes to your gold coating equipment and processes.
P160030/S002	11/28/2017	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Change to increase process efficiency by introducing a new sampling machine during sensor manufacture. The sensor is a component of the FreeStyle Libre Flash Glucose Monitoring System.
P160041/S003	11/13/2017	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a bulk reagent.
P160043/S009	11/07/2017	X - 30-Day Notice	RESOLUTE ONYX CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Remove the quarterly non-viable particulate testing conducted on the isolators.
P160043/S010	11/07/2017	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Create a product group for the purpose of bacterial endotoxin testing using Limulus Amebocyte Lysate.

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P170006/S003	11/16/2017	X - 30-Day Notice	AVALUS	MEDTRONIC INC.	Changes to the alpha amino oleic acid compound manufacturing process.
P170006/S004	11/21/2017	X - 30-Day Notice	AVALUS BIOPROSTHESIS	MEDTRONIC INC.	Addition of a new quality control inspection for the valve support frame.

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