PMA Monthly approvals from 8/1/2018 to 8/31/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170034	08/10/2018	PMAO - PMA Origi	HYDRUS MICROSTENT	IVANTIS, INC.	Approval for the Hydrus® Microstent. This device is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S203	08/31/2018	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a line extension for Sizes 1, 2, 9, and 10 of the ATTUNE Revision Constrained Revision System (CRS) RP Tibial Inserts
P840062/S067	08/30/2018	O - Normal 180 Day	COLLACOTE, COLLATAPE, COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Approval for additional trade names: creos xenocote, creos xenotape, and creos xenoplug Absorbable Collagen Wound Dressings for Dental Surgery.
P850007/S039	08/22/2018	R - Real-Time Proc	PHYSIOSTIM, SPINALSTIM	ORTHOFIX, INC.	Approval for the addition of two alternative external power supply units.
P860004/S311	08/22/2018	R - Real-Time Proc	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for a change to the XT038 TAZ series tantalum capacitor along with the required manufacturing and inspection procedure adjustments to accommodate the change.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890023/S034	08/01/2018	R - Real-Time Proc	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES, BIOMEDICS 55 SPHERE, BIOMEDICS TORIC	THE COOPER COMPANIES	Approval for a modification to the packaging formulation and process used in the packaging of ocufilcon D Soft (hydrophilic) extended wear contact lenses.
P930021/S019	08/14/2018	Y - 135 Review Tra	STRAUMANN EMDOGAIN	THE STRAUMANN COMPANY	Approval for the change made to an original ¿visual inspection¿ room E166. The room was remodeled by means of taking down dividing walls and extended to incorporate existing E143 ¿labeling¿ space to form one large ¿labeling¿ room. Both rooms are considered to be ¿clean rooms¿.
P950021/S015	08/03/2018	N - Normal 180 Day	ATELLICA IM PROSTATE-SPECIFIC ANTIGEN (PSA)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval of the migration of the ADVIA Centaur PSA Assay to the Atellica IM Analyzer.
P950037/S190	08/15/2018	R - Real-Time Proc	PSW 1801.U	BIOTRONIK, INC.	Approval for PSW 1801.U programmer software update.
P950037/S194	08/27/2018	N - Normal 180 Day	SIELLO T 53; SIELLO T 60; SIELLO JT 45; SIELLO JT 53; SOLIA T 53; SOLIA T 60; SOLIA JT 45; SOLIA JT 53	BIOTRONIK, INC.	Approval for Solia T/JT passive fixation bipolar endocardial pacing leads.
P960040/S426	08/21/2018	O - Normal 180 Day	MANAGE HF STUDY	BOSTON SCIENTIFIC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P960058/S129	08/28/2018	N - Normal 180 Day	HIRES ULTRA 3D COCHLEAR IMPLANT	ADVANCED BIONICS	Approval for the HiRes Ultra 3D Cochlear Implant and associated accessories,.
P980016/S677	08/10/2018	R - Real-Time Proc	PROTECTA ICD, PROTECTA VR/XT ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an alternate Defibrillation Controller Integrated Circuit used in Protecta families of ICDs and CRT-Ds
P980016/S680	08/10/2018	R - Real-Time Proc	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICD, PRIMO MRI VR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a minor design change to the glass feed through used in select CRT-D and ICD devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980044/S047	08/16/2018	R - Real-Time Proc	SUPARTZ FX AND VISCO-3	SEIKAGAKU CORP.	Approval for a change to the shape of the finger grip component of the syringe container closure system for SUPARTZ FX and VISCO-3 and for modifications to assembly and blister packaging equipment.
P990055/S016	08/03/2018	N - Normal 180 Day	ATELLICA IM CPSA ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur cPSA assay to the Atellica IM system
P000009/S076	08/15/2018	R - Real-Time Proc	PSW 1801.U	BIOTRONIK, INC.	Approval for PSW 1801.U programmer software update.
P010012/S486	08/21/2018	O - Normal 180 Day	MANAGE HF STUDY	BOSTON SCIENTIFIC CORP.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P010012/S487	08/20/2018	O - Normal 180 Day	LONGITUDINAL SURVEILLANCE REGISTRY OF THE ACUITY SPIRAL LEAD	BOSTON SCIENTIFIC CORP.	Approval for labeling updates for the Longitudinal Surveillance Registry of the ACUITY Spiral Lead.
P010030/S091	08/03/2018	N - Normal 180 Day	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for display of S3, S4, and EMAT heart sounds parameters.
P010030/S108	08/23/2018	S - Special CBE	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for a minor labeling update.
P010031/S637	08/10/2018	R - Real-Time Proc	PROTECTA CRT-D, PROTECTA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an alternate Defibrillation Controller Integrated Circuit used in Protecta families of ICDs and CRT-Ds.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S639	08/10/2018	R - Real-Time Proc	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a minor design change to the glass feedthrough used in select CRT-D and ICD devices.
P010033/S037	08/24/2018	Y - 135 Review Tra	QUANTIFERON TB GOLD AND QUANTIFERON TB GOLD PLUS	QIAGEN	Approval for a change to the testing process and specification for reagent components.
P020012/S014	08/28/2018	N - Normal 180 Day	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for changes to the 1mL syringe barrel material and changes to the syringe cap design and material supplier.
P020012/S021	08/27/2018	Y - 135 Review Tra	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for a new microplate reader for endotoxin testing.
P020050/S030	08/09/2018	R - Real-Time Proc	WAVELIGHT EX500 LASER SYSTEM WITH PATIENT BED SWIVEL 1125	ALCON LABORATORIES, INC.	Approval for change to the firmware of Patient Bed 1125.
P030008/S026	08/09/2018	R - Real-Time Proc	WAVELIGHT EX500 LASER SYSTEM WITH PATIENT BED SWIVEL 1125	ALCON LABORATORIES, INC.	Approval for change to the firmware of Patient Bed 1125.
P030028/S004	08/20/2018	O - Normal 180 Day	ARTISAN/VERISYSE MYOPIA PHAKIC INTRAOCULAR LENS (IOL)	OPHTEC BV	Approval for modifying the physician and patient labeling to include the results from the new enrollment post-approval study.
P030028/S005	08/20/2018	O - Normal 180 Day	ARTISAN/VERISYSE MYOPIA PHAKIC INTRAOCULAR LENS	OPHTEC BV	Approval for modifying the physician and patient labeling to include the results from the extended follow-up post-approval study.
P030034/S012	08/22/2018	R - Real-Time Proc	CERVICALSTIM	ORTHOFIX, INC.	Approval for two proposed alternate external power supply units for Orthofix¿s currently marketed CervicalStim (Model 5505), SpinalStim (Model 5212) and PhysioStim (Models 5302, 5303, 5313, 5314L, 5314R, 5315) non-invasive Bone Growth Stimulator devices.
P030040/S014	08/24/2018	O - Normal 180 Day	ATELLICA IM HEPATITIS B CORE IGM (AHBCM) ASSAY; ATELLICA IM HEPATITIS B CORE LGM QUALITY CONTROL (AHBCM QC)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for change of the proprietary names of Atellica IM Hepatitis B core Antigen (aHBcM) and Atellica IM Hepatitis B Core Antigen Quality Control (aHBcM QC) to Atellica IM Hepatitis B core IgM (aHBcM) assay and Atellica IM Hepatitis B core IgM Quality Control (aHBcM QC).

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P040002/S061	08/09/2018	S - Special CBE	AFX ENDOVASCULAR AAA SYSTEM	ENDOLOGIX, INC.	Approval for modifications to the AFX System Instructions for Use, specifically the inclusion of a sizing algorithm and clarification on device sizing guidelines.
P040003/S021	08/16/2018	R - Real-Time Proc	EXABLATE 2100/2100V1 SYSTEM	INSIGHTEC, LTD	Approval for modification to the connector port between the MRI scanner and the ExAblate 2100/2100VI System.
P050023/S119	08/15/2018	R - Real-Time Proc	PSW 1801.U	BIOTRONIK, INC.	Approval for PSW 1801.U programmer software update.
P050023/S123	08/27/2018	N - Normal 180 Day	SIELLO T 53; SIELLO T 60; SIELLO JT 45; SIELLO JT 53; SOLIA T 53; SOLIA T 60; SOLIA JT 45; SOLIA JT 53	BIOTRONIK, INC.	Approval for Solia T/JT passive fixation bipolar endocardial pacing leads.
P050037/S089	08/12/2018	Y - 135 Review Tra	RADIESSE 0.8CC AND 1.5CC	MERZ NORTH AMERICA, INC	Approval for the optimization and scale-up of the Calcium Hydroxylapatite particle manufacturing process.
P050052/S105	08/12/2018	Y - 135 Review Tra	RADIESSE (+) LIDOCAINE 0.8CC AND 1.5CC	MERZ NORTH AMERICA, INC	Approval for the optimization and scale-up of the Calcium Hydroxylapatite particle manufacturing process.
P070008/S092	08/15/2018	R - Real-Time Proc	PSW 1801.U	BIOTRONIK, INC.	Approval for PSW 1801.U programmer software update.
P070008/S096	08/27/2018	N - Normal 180 Day	SIELLO T 53; SIELLO T 60; SIELLO JT 45; SIELLO JT 53; SOLIA T 53; SOLIA T 60; SOLIA JT 45; SOLIA JT 53	BIOTRONIK, INC.	
P070014/S055	08/01/2018	R - Real-Time Proc	BARD LIFESTENT 5F VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval for a labeling change to add 0.014¿ guidewires for use with the LifeStent 5F Vascular Stent System.
P070014/S058	08/27/2018	S - Special CBE	LIFESTENT 5F VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval for the addition of a dimensional inspection for a delivery system component.
P080004/S017	08/06/2018	Y - 135 Review Tra	PRESET TIPS	HOYA SURGICAL OPTICS, INC.	Approval for modifications to the injector tip acceptance criteria.
P080012/S051	08/17/2018	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for changes made to the dimensions of the Access Port Spacer part in the PROMETRA Programmable Infusion Pump System.
P100009/S026	08/13/2018	O - Normal 180 Day	MITRACLIP SYSTEM (NT)	ABBOTT VASCULAR INC.	Approval for labeling changes based off the MitraClip Analysis Cohort (MAC) Post Approval Study (PAS).

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P100020/S032	08/08/2018	R - Real-Time Proc	COBAS X 480, COBAS HPV TEST, 240/960 TESTS	ROCHE MOLECULAR SYSTEMS, INC.	Approval for changes in the manufacturer, design, and specifications of the heater/shaker unit of the cobas 480 x Instrument, a component of the cobas 4800 System.
P100047/S122	08/13/2018	R - Real-Time Proc	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for changing the HVAD Battery configuration mode from "removable" to "non-removable".
P100047/S124	08/06/2018	O - Normal 180 Day	HEARTWARE HVAD SYSTEM	MEDTRONIC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P110006/S010	08/24/2018	O - Normal 180 Day	INVENIA ABUS (AUTOMATED BREAST ULTRASOUND SYSTEM) 2.0	U-SYSTEMS, INC.	Approval for a manufacturing site in Wuxi, China for U-Systems Invenia ABUS (Automated Breast Ultrasound System) 2.0, which includes a Scan Station (with automated transducer).
P110010/S151	08/30/2018	N - Normal 180 Day	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMINUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a new bonding process and material for the midshaft catheter bond.
P110019/S099	08/23/2018	O - Normal 180 Day	XIENCE XPEDITION, XIENCE XPEDITION SV, XIENCE XPEDITION LL EVEROLIMUS ELUTING CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Approval for labeling updates to the IFU to included clinical data from the EXPERT CTO trial.
P110039/S010	08/16/2018	R - Real-Time Proc	EXABLATE 2100/2100V1 SYSTEM	INSIGHTEC	Approval for modification to the connector port between the MRI scanner and the ExAblate 2100/2100VI System.
P120011/S012	08/06/2018	R - Real-Time Proc	IDEAL IMPLANT STRUCTURED BREAST IMPLANT	IDEALIMPLANT	Approval for an extension of the shelf life for the fill tube assembly (FTA) from 3 years to 5 years

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P120019/S019	08/22/2018	N - Normal 180 Day	COBAS EGFR MUTATION TEST V2, COBAS DNA AND CFDNA SAMPLE PREPARATION KIT	ROCHE	Approval for the cobas® EGFR Mutation Test v2. The device is a real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) or circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood. The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment with the targeted therapies listed in Table 1 below in accordance with the approved therapeutic product labeling: Table 1 Drug FFPET Plasma TARCEVA® (erlotinib) Exon 19 deletions and L858R Exon 19 deletions and L858R TAGRISSO® (osimertinib) Exon 19 deletions, L858R and T790M Exon 19 deletions, L858R and T790M* IRESSA® (gefitinib) Exon 19 deletions and L858R Exon 19 deletions and L858R Patients with positive cobas® EGFR Mutation Test v2 test results using plasma specimens for the presence of the EGFR mutations listed above are eligible for treatment with the corresponding drug as indicated in Table 1 (see Note* for T790M). Patients who are negative for these mutations by this test using plasma specimens should be reflexed to routine biopsy and testing for EGFR mutations with the FFPET sample type. Note: *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. Drug safety and efficacy have not been established for the following EGFR mutations also detected by the cobas® EGFR Mutation Test v2: Table 2 Drug FFPET Plasma TARCEVA® (erlotinib) G719X, Exon 20 insertions, T790M, S768I and L861Q G719X, Exon 20 insertions, T790M, S768I and L861Q TAGRISSO® (osimertinib) G719X, Exon 20 insertions, S768I, and L861Q G719X, Exon 20 insertions, S768I, and L861Q IRESSA® (gefitinib) G719X, Exon 20 insertions, T790M, S768I and L861Q G719X, Exon 20 insertions, T790M, S768I and L861Q For manual sample preparation, FFPET specimens are processed using the cobas® DNA Sample Preparation Kit and plasma specimens are processed using the cobas® cfDNA Sample Preparation Kit. The cobas z 480 analyzer is used for automated amplification and detection.
P120024/S007	08/10/2018	Y - 135 Review Tra	ACTIVL ARTIFICIAL DISC	AESCULAP IMPLANT SYSTEMS, LLC	Approval for a manufacturing process flow change to the milling process for the PE inlay of the device.

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P130021/S051	08/24/2018	N - Normal 180 Day	COREVALVE EVOLUT R SYSTEM AND COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Approval for modifying the labeling to remove the precaution regarding patients with a congenital bicuspid aortic valve.
P130024/S022	08/29/2018	N - Normal 180 Day	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER (LUTONIX DCB)	LUTONIX	Approval for an extension of the product matrix to include balloon lengths up to 220 mm for all diameters of the Lutonix 035 Drug Coated Balloon.
P140002/S011	08/01/2018	Y - 135 Review Tra	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Approval for a change to the supplier of the device pouch.
P140004/S015	08/24/2018	N - Normal 180 Day	SUPERION® INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORATED	Approval of three (3) manufacturing sites for Structure Medical, LLC, located at: 111 Cayuga Drive, Mooresville, North Carolina, 28117 to manufacture components in versions 1 and 2 (v1.0 and v2.0) of the Superion® implant; 9935 Business Circle, Naples, Florida, 34112 to manufacture components in v1.0 and v2.0 of the Superion® implant, assemby and final inspections of the implants; and, 3511 Plover Avenue, Naples, Florida 34117 for passivation activities of components in v1.0 and v2.0 of the Superion® implant.
P140008/S013	08/17/2018	O - Normal 180 Day	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Approval for the ORBERA Intragastric Balloon System. The device is indicated for use as an adjunct to weight reduction for adults with obesity with Body Mass Index (BMI) of >= 30 and <= 40 kg/m2 and is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of significant long-term weight loss and maintenance of that weight loss. ORBERA is indicated for adult patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs. The maximum placement period for ORBERA is 6 months.
P140009/S036	08/10/2018	Y - 135 Review Tra	DBS SYSTEM 4CH LEAD / DBS SYSTEM 8CH DIRECTIONAL LEAD	ST. JUDE MEDICAL NEUROMODULATION	Approval for updating the primer application step of the parylene coating of the stim tips and term tips from vapor deposition to dipping application.
P140026/S010	08/16/2018	N - Normal 180 Day	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for label printing and final packaging at a manufacturing site located at 1213 Innsbruck Drive, Sunnyvale, California.
P140032/S013	08/22/2018	R - Real-Time Proc	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for a change to the XT038 TAZ series tantalum capacitor along with the required manufacturing and inspection procedure adjustments to accommodate the change.
P140032/S017	08/24/2018	S - Special CBE	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for labeling changes to the Implantable System for Remodulin Technical Manual.
P150003/S036	08/30/2018	N - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMINUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a new bonding process and material for the midshaft catheter bond.

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P150005/S035	08/01/2018	N - Normal 180 Day	BLAZER OPEN-IRRIGATED AND INTELLANAV OPEN-IRRGATED ABLATION CATHETERS	BOSTON SCIENTIFIC CORP.	Approval for expanded indications for use to include the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation. The devices, as modified, will be marketed under the trade name IntellaTip MiFi Open-Irrigated Ablation Catheter and IntellaNav MiFi Open-Irrigated Ablation Catheter when used with a compatible Radiofrequency Controller and Irrigation Pump, are indicated for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, radiofrequency ablation of sustain or recurrent Type 1 Atrial Flutter in patients age 18 or older, and treatment of drug refractory, recurrent, symptomatic, paroxysmal atrial fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system.
P150009/S001	08/14/2018	O - Normal 180 Day	ANGELMED GUARDIAN SYSTEM	ANGEL MEDICAL SYSTEMS INC.	Approval for the AngelMed Guardian System. This device is an implantable cardiac monitor with patient alerting capability and an additional external alarm device. The device is indicated for use in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events. The Guardian System is indicated as an adjunct to patient recognized symptoms. The Guardian System detects potential ongoing ACS events, characterized by sustained ST segment changes, and alerts the patient to seek medical attention for those potential ACS events. A Guardian System alert is a more accurate predictor of ACS events when compared to patient recognized symptoms alone and demonstrates a reduced rate over time of patient presentations without ACS events (false positives) when compared to patient recognized symptoms alone. In the absence of symptoms, the Guardian System may identify asymptomatic ACS events and prompt the patient to seek medical attention.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150013/S011	08/16/2018	P - Panel Track	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for the PD-L1 IHC 22C3 pharmDx. The device is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction (GEJ) adenocarcinoma, cervical cancer and urothelial carcinoma tissues using EnVision FLEX visualization system on Autostainer Link 48. Non-Small Cell Lung Cancer (NSCLC) PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. The specimen should be considered to have PD-L1 expression if TPS >= 1% and high PD-L1 expression if TPS >= 50%. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). See the KEYTRUDA® product label for expression cutoff values guiding therapy in specific clinical circumstances. Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma PD-L1 protein expression in gastric or GEJ adenocarcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS >= 1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab). Cervical Cancer PD-L1 protein expression in cervical cancer is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS >= 1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying cervical cancer patients for treatment with KEYTRUDA® (pembrolizumab). Urothelial Carcinoma PD-L1 protein expression in urothelial carcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS >= 10. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying urothelial carcinoma patients for treatment with KEYTRUDA® (pembrolizumab). See the KEYTRUDA® product label for specific clinical circumstances guiding PD-L1 testing.

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P150016/S009	08/10/2018	Y - 135 Review Tra	TRIDYNE VASCULAR SEALANT; TRIDYNE VS STANDARD SPRAY TIPS; TRIDYNE VS 6" EXTENDED SPRAY TIP	NEOMEND, INC.	Approval to implement changes to the human serum albumin (HSA) filling and polyethylene glycol (PEG) filling processes.
P150017/S007	08/28/2018	O - Normal 180 Day	CARTIVA SCI REUSABLE INSTRUMENTATION	CARTIVA, INC	Approval for a manufacturing site located at Arcamed LLC, 5101 Decatur Blvd Ste A, Indianapolis, Indiana to manufacture the instruments for Cartiva Synthetic Cartilage.
P150031/S005	08/23/2018	N - Normal 180 Day	VERCISE DBS SYSTEM / VERCISE PC DBS SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Arcamed LLC, 5101 Decatur Blvd Ste A, Indianapolis, Indiana to manufacture the instruments for Cartiva Synthetic Cartilage Implant.
P150048/S012	08/09/2018	P - Panel Track	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards Pericardial Mitral Bioprosthesis, Model 11000M. This device is indicated for the replacement of native or prosthetic mitral heart valves.
P150048/S012	08/09/2018	P - Panel Track	EDWARDS PERICARDIAL MITRAL BIOPROSTHESIS, MODEL 11000M	EDWARDS LIFESCIENCES, LLC.	Approval for the Edwards Pericardial Mitral Bioprosthesis, Model 11000M. This device is indicated for the replacement of native or prosthetic mitral heart valves.
P150048/S025	08/15/2018	S - Special CBE	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS / EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Approval to implement a in-process inspection for damage to glass chemical containers.
P150048/S025	08/15/2018	S - Special CBE	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Approval to implement a in-process inspection for damage to glass chemical containers.
P160001/S018	08/01/2018	O - Normal 180 Day	OBALON BALLOON KIT	OBALON THERAPEUTICS, INC.	Approval for the Obalon Balloon System. The device is a swallowable intragastric balloon system indicated for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40 kg/m2) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed 6 months after the first balloon is placed.
P160007/S004	08/16/2018	R - Real-Time Proc	GUARDIAN SENSOR (3)	MEDTRONIC MINIMED	Approval for a minor design change to the introducer needle component of the Guardian Sensor (3) for the Guardian Connect System along with the addition of an alternate needle supplier.
P160017/S050	08/31/2018	O - Normal 180 Day	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval of the Outcomes Study for MiniMed 670G System for the post-approval study (PAS).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160022/S005	08/03/2018	R - Real-Time Proc	ZOLL X SERIES DEVICE	ZOLL MEDICAL CORPORATIO N	Approval for introducing the following three new software features to the ZOLL X Series device: readiness test, AutoPulse recognition, and ResQPUMP recognition.
P160025/S005	08/22/2018	O - Normal 180 Day	ASTRON PULSAR AND PULSAR-18 STENT SYSTEMS	BIOTRONIK, INC.	Approval for updated labeling to include clinical data from the BIOFLEX-I Study.
P160026/S001	08/06/2018	R - Real-Time Proc	LIFEPAK 15 MONITOR/ DEFIBRILLATOR	PHYSIO-CONTROL. INC.	Approval for modifications to the non-invasive blood pressure (NIBP) module, MiniMedi CO2 module and CO2 Filterline Recognition Safe Guard assembly (FRS) components of the LIFEPAK 15 Monitor/Defibrillator.
P160042/S003	08/02/2018	N - Normal 180 Day	REVANESSE VERSA +	PROLLENIUM MEDICAL TECHNOLOGI ES INC.	Approval for the addition of lidocaine to the formulation of Revanesse Versa.
P160054/S004	08/06/2018	Y - 135 Review Tra	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM PUMP ROTOR SUB-ASSEMBLY	THORATEC CORPORATIO N	Approval for adding an alternative supplier for the pump rotor subassembly.
P160054/S005	08/24/2018	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORPORATIO N	Approval for the addition of the Surgical Enhancement Tools, including the Mini Apical Cuff, the Coring Tool, and the Apical Cuff Holder.
P170008/S008	08/23/2018	Y - 135 Review Tra	ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Approval for changes to the sampling plan for mechanical testing and to packaging inspection.
P170042/S001	08/27/2018	S - Special CBE	COVERA¿ VASCULAR COVERED STENT	C.R. BARD, INC	Approval for the addition of a dimensional inspection for a delivery system component.

Total: 83

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N16895/S102	08/03/2018	X - 30-Day Notice	SOFLENS 38 (POLYMACON) VISIBILITY TINTED CONTACT LENS	BAUSCH & LOMB, INC.	Add an alternate supplier of USP grade sodium chloride which is a component of the packaging solution of the Soflens 38 (polymacon) Visibility Tinted Contact lens.
N17600/S030	08/01/2018	X - 30-Day Notice	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH)	DAVOL, INC., SUB. C.R. BARD, INC.	Alternate in-process test method and test equipment (digital meter) used for % Ethanol determination during AviteneTM Microfibrillar Collagen Hemostat bulk flour production.
P800002/S023	08/01/2018	X - 30-Day Notice	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH)	C.R. BARD, INC.	Alternate in-process test method and test equipment (digital meter) used for % Ethanol determination during AviteneTM Microfibrillar Collagen Hemostat bulk flour production.
P820076/S028	08/09/2018	X - 30-Day Notice	EFH-16; S60-K; S 60-J; S 60-S	BIOTRONIK, INC.	Changes to the sterilization process used for leads and accessories.
P830055/S205	08/24/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Change of manufacturing location for knee and hip instruments from one approved site to another approved site.
P840001/S403	08/14/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLISTM SPINAL CORD STIMULATION SYSTEMS AND PISCESTM SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Alternate manufacturing site to perform the parts passivation / nitric acid cleaning for piece parts (components).
P840001/S404	08/30/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Reduction of environmental monitoring frequency of surfaces in MPROC-Villalba CEA rooms N-1 and N-2.
P860004/S315	08/14/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Alternate manufacturing site to perform the parts passivation / nitric acid cleaning for piece parts (components).
P880086/S301	08/14/2018	X - 30-Day Notice	VICTORY; ZEPHYR; ACCENT; ASSURITY; ASSURITY+; ENDURITY; IDENTITY XL, IDENTITY ADX XL; VERITY ADXXL	ST. JUDE MEDICAL, INC.	Reduction in frequency of bioburden testing at the Penang, Malaysia manufacturing site.
P900033/S072	08/10/2018	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Modifications to the Clean Compressed Air distribution system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900060/S059	08/07/2018	X - 30-Day Notice	CARBOMEDICS PROSTHETIC HEART VALVE (CPHV)	SORIN GROUP ITALIA S.R.L	Re-introduction of the X-Ray Computed Tomography equipment used for radiographic inspection of the CPHV Orifice component.
P910001/S105	08/14/2018	X - 30-Day Notice	ELCA CORONARY ATHERECTOMY CATHETERS	SPECTRANETICS CORP.	Addition of a vent hood to the main manufacturing clean room wicking stations.
P910023/S411	08/14/2018	X - 30-Day Notice	CURRENT+; FORTIFY; FORTIFY ASSURA; FORTIFY ASSURA (MR CONDITIONAL); ELLIPSE; ELLIPSE (MR CONDITIONAL)	ST. JUDE MEDICAL	Reduction in frequency of bioburden testing at the Penang, Malaysia manufacturing site.
P910056/S031	08/06/2018	X - 30-Day Notice	ENVISTA HYDROPHOBIC ARCYLIC INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Modification of the lens holder internal surface finish for the enVista One Piece Hydrophobic Acrylic Intraocular Lens, Models MX60 and MX60T.
P930038/S089	08/15/2018	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATION	Transfer the carrier tube component manufacturing process to the Puerto Rico facility.
P950037/S193	08/09/2018	X - 30-Day Notice	SELOX ST/JT; SIELLO S; SOLIA S; SETROX S; SAFIO S; S 45-K/53-K; DH; DH IS-1/ DF4; EFH-6F-W; S53-K; S 45-S; S 53-S; S 45-F; S 45-J; S 53-F; S 53-J; S 60-F; S 58-K; S 45-JL; S 53-JL; BS IS-1; BS DF-1	BIOTRONIK, INC.	Changes to the sterilization process used for leads and accessories.
P960009/S320	08/14/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Alternate manufacturing site to perform the parts passivation / nitric acid cleaning for piece parts (components).
P960009/S321	08/30/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Reduction of environmental monitoring frequency of surfaces in MPROC-Villalba CEA rooms N-1 and N-2.
P960016/S075	08/28/2018	X - 30-Day Notice	LIVEWIRE TC ABLATION CATHETER	ST. JUDE MEDICAL	Removal of a wire crimp visual inspection step within the handle assembly.
P960042/S063	08/14/2018	X - 30-Day Notice	SLS LL/GLIDELIGHT CATHETERS	SPECTRANETICS CORP.	Addition of a vent hood to the main manufacturing clean room wicking stations.
P960058/S130	08/13/2018	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Modification of the Environmental Monitoring Plan for the manufacturing facilities in Valencia, California and Sylmar, California.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S276	08/14/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM SNS URINARY	MEDTRONIC NEUROMODULATION	Alternate manufacturing site to perform the parts passivation / nitric acid cleaning for piece parts (components).
P970004/S277	08/30/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY EXTENSIONS AND LEADS)	MEDTRONIC NEUROMODULATION	Reduction of environmental monitoring frequency of surfaces in MPROC-Villalba CEA rooms N-1 and N-2.
P970013/S078	08/14/2018	X - 30-Day Notice	MICRONY	ST. JUDE MEDICAL, INC.	Reduction in frequency of bioburden testing at the Penang, Malaysia manufacturing site.
P980016/S682	08/16/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICD, PRIMO MRI VR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Second source test facility for performing residual gas analysis.
P980022/S205	08/14/2018	X - 30-Day Notice	PARADIGM REAL-TIME INSULIN PUMP, PARADIGM REAL-TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Addition of a new testing station to conduct additional reliability testing for the pump case of the Paradigm Real-Time Insulin Pumps, Paradigm Real-Time Revel Pumps, and MiniMed 530G Insulin Pumps at the manufacturing facility, located at Juncos, Puerto Rico. These pumps are components of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and MiniMed 530G System, respectively.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980023/S086	08/09/2018	X - 30-Day Notice	PROTEGO SD; PROTEGO TD; PROTEGO DF-1 SD; PROTEGO PROMRI SDX; PROTEGO DF-1; PROMRI SD; PLEXA SD; PLEXA PROMRI SD; PLEXA DF-1 SD; PLEXA DF-1 SDX; PLEXA PROMRI DF-1 SD; BK-IS4/DF4; PROTEGO S; PROTEGO T; PROTEGO DF-1 S; PROTEGO DF-1 PROMRI SDX; PROTEGO DF-1 DF-1 PROMRI S ; PLEXA S; PLEXA PROMRI S; PLEXA DF-1 S; PLEXA PROMRI DF-1 S DX; PLEXA PROMRI DF-1 S; DH DF4; DH IS-1/DF4; PLEXA PROMRI DF-1 SD; BK-IS4/ DF4; IS4/DF4-ADAPTER; DH DF4; DH IS-1/DF4; EFH-30 VL; SI-2; TW; EFH-35; EFH-7F-W; EFH-8F-W; S 75-A;S 75-C;S 75-E;S 75-K;S 65-A;S 65-CS 65-E;S 65-K;S 65-C	BIOTRONIK, INC.	Changes to the sterilization process used for leads and accessories.
P980024/S019	08/29/2018	X - 30-Day Notice	PATHVYSION HER-2 DNA PROBE KIT	ABBOTT MOLECULAR, INC.	QC/manufacturing equipment changes and DNA Ladder changes
P980035/S559	08/31/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ATTESTA DR/SR MRI IPG, RELIA IPG, SPHERA DR/SR MRI IPG	MEDTRONIC INC.	Addition of a shield assembly test at the external supplier.
P980044/S048	08/07/2018	X - 30-Day Notice	SUPARTZ FX AND VISCO-3	SEIKAGAKU CORP.	Replace an autoclave.
P990074/S042	08/01/2018	X - 30-Day Notice	NATRELLE SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Replace paper chart recorders and to use an electric heating module rather than water to heat the air in the carousel room.
P000006/S050	08/31/2018	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS (IPP)	COLOPLAST CORP.	New heat sealing and peel-test equipment and processes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000025/S102	08/10/2018	X - 30-Day Notice	MED-EL COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Facility change in the manufacturing of cochlear implants SONATA, Mi1000 MED-EL Concert, Mi1200 Synchrony, and of the single use surgical instruments Insertion Test Device (ITD) and Insertion Electrodes (IE).
P000054/S050	08/29/2018	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Add a pump to aid in manufacture.
P000058/S069	08/29/2018	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAMPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Add a pump to aid in manufacture.
P010019/S067	08/08/2018	X - 30-Day Notice	AIR OPTIX AQUA FOR ASTIGMATISM / AQUA MULTIFOCAL / PLUS HYDRAGLYDE / PLUS HYDRAGLYDE MULTIFOCAL / PLUS HYDRAGLYDE FOR ASTIGMATISM	ALCON LABORATORIES, INC.	Produce spherical AIR OPTIX plus HYDRAGLYDE lotrafilcon B contact lenses on an additional production platform.
P010019/S068	08/28/2018	X - 30-Day Notice	LOTRAFILCON A AND LOTRAFILCON B SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Addition of parametric release as an alternate sterile product batch release option for Alcon Lotrafilcon A and B soft contact lenses.
P010031/S641	08/16/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Second source test facility for performing residual gas analysis.
P020045/S089	08/10/2018	X - 30-Day Notice	CRYOCONSOLE	MEDTRONIC CRYOCATH LP	Update the vacuum pump used in the CryoConsole.
P020056/S048	08/01/2018	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Replace paper chart recorders and to use an electric heating module rather than water to heat the air in the carousel room.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S315	08/01/2018	X - 30-Day Notice	PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AN SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Removal of the weekly Printed Circuit Board Assembly (PCBA) Ionic Contamination (IC) Testing on the Archie, Montana, and Spectra circuit boards which are used in the Implantable Pulse Generators (IPGs) for the Precision Spectra, Precision Novi, Precision Montage, Precision Montage MRI and Spectra WaveWriter Spinal Cord Stimulator (SCS) Systems.
P030017/S316	08/01/2018	X - 30-Day Notice	PRECISION SPECTRA, SPECTRA WAVEWRITER, PRECISION MONTAGE, AND PRECISION MONTAGE MRI SPINAL CORD STIMULATORT (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Addition of an alternate qualified supplier (TIMET) for the raw material (Grade-23 ELI Titanium) that is used by Heraeus Medical when manufacturing the Case Half and Back-up Band for the Precision Spectra, Spectra WaveWriter, Precision Montage, and Precision Montage MRI implantable pulse generators (IPGs).
P030017/S317	08/02/2018	X - 30-Day Notice	PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND PRECISION SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Addition of Guidant Puerto Rico B.V. as an alternate qualified manufacturing site for the laser ablation of multi-lumen tubes used in the assembly of the following leads for the Precision®, Precision Spectra, Precision NoviTM, Precision Montage, Precision MontageTM MRI and Precision Spectra WaveWriter Spinal Cord Stimulator (SCS) Systems: Linear Leads, Linear ST Leads, Linear 3-4 Leads, Linear 3-6 Leads, Lead Extensions, M8 & S8 Adapters, Artisan Surgical Leads, Artisan MRI Surgical Leads, CovcrEdge Surgical Leads, CoverEdge X Surgical Leads, Infinion and Infinion CX 16 Contact Leads.
P030035/S172	08/14/2018	X - 30-Day Notice	ANTHEM; ALLURE, ALLURE QUADRA; QUADRA ALLURE MP	ST. JUDE MEDICAL, INC.	Reduction in frequency of bioburden testing at the Penang, Malaysia manufacturing site.
P030052/S024	08/29/2018	X - 30-Day Notice	UROVYSION BLADDER CANCER KIT	ABBOTT MOLECULAR	QC/manufacturing equipment changes and DNA Ladder changes
P030054/S358	08/14/2018	X - 30-Day Notice	PROMOTE+; UNIFY; UNIFY QUADRA; UNIFY ASSURA; QUADRA ASSURA; QUADRA ASSURA (MR CONDITIONAL); QUADRA ASSURA MP; QUADRA ASSURA MP (MR CONDITIONAL)	ST. JUDE MEDICAL	Reduction in frequency of bioburden testing at the Penang, Malaysia manufacturing site.
P040020/S080	08/16/2018	X - 30-Day Notice	ACRYSOF RESTOR IOLS	ALCON RESEARCH, LTD.	Change to the IOL optic mold material for AcrySof® ReSTOR® Intraocular Lens Models SN6AD1, MN6AD1, SV25T0, SND1T3-T6, SV25T3-T6, SA6AD1, SA25T0, SAD1T3-T6, and SA25T3-T6.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040024/S102	08/02/2018	X - 30-Day Notice	RESTYLANE INJECTABLE GELS	Q-MED AB	Change in supplier for the "puck press" used in manufacturing of Restylane Injectable Gels (Restylane, Restylane-L, Perlane, Restylane Lvft with Lidocaine, and Restylane Silk).
P040037/S119	08/23/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHEIS	W.L. GORE & ASSOCIATES,INC	Update raw material specifications and the non-compendial test methods.
P040046/S029	08/01/2018	X - 30-Day Notice	NATRELLE 410 HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED	ALLERGAN	Replace paper chart recorders and to use an electric heating module rather than water to heat the air in the carousel room.
P050023/S122	08/09/2018	X - 30-Day Notice	S 75-G OTW; S 75-K OTW; S 85-G OTW; S 85-K OTW	BIOTRONIK, INC.	Changes to the sterilization process used for leads and accessories.
P050028/S069	08/17/2018	X - 30-Day Notice	ROCHE COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0 AND COBAS TAQMAN HBV TEST FOR USE ON THE HIGH PURE SYSTEM	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P050053/S041	08/27/2018	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Add a pump to aid in manufacture.
P060022/S024	08/07/2018	X - 30-Day Notice	AKREOS INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Adding a mask to the polishing procedure for manufacturing the Akreos Intraocular Lens, Models AO60 and MI60L.
P060030/S068	08/17/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0 AND COBAS TAQMAN HCV TEST, V2.0 FOR USE ON THE HIGH PURE SYSTEM	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P070008/S095	08/09/2018	X - 30-Day Notice	COROX OTW BP; COROX OTW-L BP; COROX PROMRI OTW BP; SENTUS PROMRI OTW QP S; SENTUS PROMRI OTW QP S-XX/49; COROX OTW-S BP; COROX PROMRI OTW-L BP;COROX PROMRI OTW-S BP; SENTUS PROMRI OTW QP L; SENTUS PROMRI OTW QP L-XX/49	BIOTRONIK, INC.	Changes to the sterilization process used for leads and accessories.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P070014/S057	08/06/2018	X - 30-Day Notice	LIFESTENT 5F VASCULAR STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Removal of an in-process manufacturing inspection for stent pushing force.
P070026/S055	08/24/2018	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change of manufacturing location for knee and hip instruments from one approved site to another approved site.
P080011/S077	08/07/2018	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Introduction of the Biofinity Line 20 Front End Platform for production of Biofinity Sphere (comfilcon A) soft contact lenses.
P080011/S078	08/09/2018	X - 30-Day Notice	BIOFINITY SPHERE AND BIOFINITY XR SPHERE, BIOFINITY ENERGYS; BIOFINITY TORIC AND BIOFINITY XR TORIC; BIOFINITY MULTIFOCAL	COOPERVISION MANUFACTURING, LTD.	Modification in the Quality Control sampling regime for Biofinity lenses.
P080011/S080	08/27/2018	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	New automated cleaning process.
P080014/S021	08/16/2018	X - 30-Day Notice	CERVISTA HPV HR ASSAY	HOLOGIC, INC.	Qualification of a new supplier and purchased raw material and updates to downstream manufacturing processes.
P080015/S013	08/16/2018	X - 30-Day Notice	CERVISTA HPV 16/18 ASSAY	HOLOGIC, INC.	Qualification of a new supplier and purchased raw material and updates to downstream manufacturing processes.
P080020/S030	08/07/2018	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Replace an autoclave.
P080023/S029	08/09/2018	X - 30-Day Notice	ARCHITECT CORE, LN 6L22	ABBOTT LABORATORIES	Extend the expiration date of a critical raw material used to manufacture kit subcomponents.
P080025/S171	08/14/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM SNS BOWEL	MEDTRONIC NEUROMODULATION	Alternate manufacturing site to perform the parts passivation / nitric acid cleaning for piece parts (components).
P080025/S172	08/30/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL EXTENSIONS AND LEADS)	MEDTRONIC NEUROMODULATION	Reduction of environmental monitoring frequency of surfaces in MPROC-Villalba CEA rooms N-1 and N-2.

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P100010/S081	08/07/2018	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	New Automated Preshrink Bonding Equipment and Inspection for the Arctic Front Advance Cardiac CryoAblation Catheter.
P100013/S017	08/09/2018	X - 30-Day Notice	EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS CORPORATIO N	Relocate component manufacturing to a different building within Cordis de Mexico.
P100020/S037	08/17/2018	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P100022/S028	08/29/2018	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT.	COOK MEDICAL INCORPORAT ED	Addition of a delivery system component specification and changes to a suppliers extrusion line.
P100022/S029	08/23/2018	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORAT ED	Modifications to raw material specifications, test methods, and frequency of testing.
P100026/S056	08/01/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the PXI Vader automated test equipment (ATE) power-up software to improve yield of the components used to manufacture the RNS® Neurostimulator (model RNS-320) during the custom packaged integrated circuitry (Cassandra) and printed circuit assembly (PCA) testing. Additionally, the Dog Tag test limits for the integrated circuit are being modified in the PXI Vader ATE, Telemetry Only System (TOS) ATE and the PXI Vader Temperature ATE databases to allow flexibility to also test future integrated circuits for product development purposes.
P100026/S057	08/15/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Implementation of a new minimum loading configuration for the ethylene oxide (EO) sterilization of the NeuroPace RNS® System products.
P100045/S031	08/14/2018	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Change the stripping process on the wire ends of the CardioMEMS HF Sensor coil.
P100047/S126	08/10/2018	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Update to the manufacturing procedure and visual inspection of the packaging for HeartWare Ventricular Assist System.
P110012/S017	08/29/2018	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	QC/manufacturing equipment changes and DNA Ladder changes.
P110019/S101	08/31/2018	X - 30-Day Notice	XIENCE XPEDITION RX/ OTW, APLINE RX/OTW AND SIERRA RX EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	New (replicate) finished good manufacturing line.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110020/S028	08/17/2018	X - 30-Day Notice	COBAS BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P110028/S019	08/01/2018	X - 30-Day Notice	ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYSTEM	ABBOTT VASCULAR INC.	Update to the dimensional requirements for manufacturing of catheter shaft sub-components.
P110037/S040	08/17/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P120010/S119	08/06/2018	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of drying equipment used in the production of the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P120010/S120	08/14/2018	X - 30-Day Notice	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	Addition of a new testing station to conduct additional reliability testing for the pump case of the Paradigm Real-Time Insulin Pumps, Paradigm Real-Time Revel Pumps, and MiniMed 530G Insulin Pumps at the manufacturing facility, located at Juncos, Puerto Rico. These pumps are components of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and MiniMed 530G System, respectively.
P120011/S013	08/22/2018	X - 30-Day Notice	IDEAL IMPLANT STRUCTURED BREAST IMPLANT	IDEALIMPLANT	Replace the current 100% shell inspection for thickness with a zero acceptance number (c=0, AQL=1.0%) shell sampling plan for thickness at the Vesta Intermediate Funding Inc located at 9900 S 57th Street, Franklin, Wisconsin.
P120019/S023	08/15/2018	X - 30-Day Notice	COBAS EGFR MUTATION TEST AND COBAS EGFR MUTATION TEST V2	ROCHE	Manufacturing cleaning process.
P130006/S058	08/23/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Update raw material specifications and the non-compendial test methods.
P130017/S023	08/24/2018	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Introduction of an alternative supplier of a component.

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P130021/S052	08/12/2018	X - 30-Day Notice	COREVALVE EVOLUT R SYSTEM, COREVALVE EVOLUT R XL SYSTEM AND COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Update the in-process sampling requirements for receiving inspection for the Tip Guide Tube and Locking Collar components of the EnVeo Pro Loading System.
P130030/S053	08/22/2018	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the mandrel material used during the stent dimensional inspection.
P140003/S037	08/22/2018	X - 30-Day Notice	IMPELLA CP WITH SMARTASSIST; IMPELLA 2.5/5.0 LD; IMPELLA CP; IMPELLA LD	ABIOMED, INC.	Addition of an alternative biological indicator (BI) for the sterilization of all Impella family of catheters and the adoption of Impella CP with SmartAssist into the existing sterilization cycle for other Impella catheters at an alternate site.
P140003/S038	08/28/2018	X - 30-Day Notice	IMPELLA 2.5, IMPELLA CP, IMPELLA 5.0 AND IMPELLA LD	ABIOMED, INC.	Changes to the manufacturing of Impella 2.5, CP, 5.0, and LD.
P140023/S016	08/17/2018	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P140031/S073	08/22/2018	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE (23MM, 26MM, AND 29MM	EDWARDS LIFESCIENCES, LLC.	Addition of an alternate facility for Inner Skirt laser cutting using an updated laser system.
P140032/S016	08/14/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Alternate manufacturing site to perform the parts passivation / nitric acid cleaning for piece parts (components).
P140033/S036	08/14/2018	X - 30-Day Notice	ASSURITY MRI; ENDURITY MRI; TENDRIL MRI	ST. JUDE MEDICAL, INC.	Reduction in frequency of bioburden testing at the Penang, Malaysia manufacturing site.
P150001/S048	08/03/2018	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM WITH GUARDIAN SENSOR (3)/ GUARDIAN SENSOR (3)	MEDTRONIC MINIMED	Addition of an alternative press to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect System, and MiniMed 670G systems.
P150001/S049	08/06/2018	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Addition of drying equipment used in the production of the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150001/S051	08/14/2018	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Adding an alternative injection molding machine to produce the sleeve component used in the MiniMed 630G Pump and the MiniMed 670G Pump. The MiniMed 630G Pump is part of the MiniMed 630G System with SmartGuard and the MiniMed 670G pump is part of the MiniMed 670G System.

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P150003/S041	08/22/2018	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to the mandrel material used during the stent dimensional inspection.
P150014/S019	08/17/2018	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P150015/S018	08/17/2018	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P150019/S045	08/06/2018	X - 30-Day Notice	MINIMED PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of drying equipment used in the production of the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150019/S046	08/14/2018	X - 30-Day Notice	PARADIGM REAL-TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Addition of a new testing station to conduct additional reliability testing for the pump case of the Paradigm Real-Time Insulin Pumps, Paradigm Real-Time Revel Pumps, and MiniMed 530G Insulin Pumps at the manufacturing facility, located at Juncos, Puerto Rico. These pumps are components of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and MiniMed 530G System, respectively.
P150021/S032	08/22/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Changing the assembly process for the FreeStyle Libre Sensor, a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and the Freestyle Libre Flash Glucose Monitoring System.
P150029/S021	08/06/2018	X - 30-Day Notice	MINIMED IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Addition of drying equipment used in the production of the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150031/S008	08/22/2018	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Use of the E84273-100 Tube Ablation System for the ablation process for multi-lumen tubes that are used in the assembly of 8 Contact Extension Lead (55 cm) and Vercise M8 Adapters (15cm and 55cm) at the Boston Scientific Puerto Rico manufacturing facility.
P150037/S011	08/13/2018	X - 30-Day Notice	CYPASS SYSTEM, CYPASS ULTRA SYSTEM, CYPASS MICRO-STENT	ALCON RESEARCH, LTD	Addition of an alternate additional vendor for the laser cutting step in the manufacturing process of the CyPass System Model 241-S and the CyPass Ultra System.
P150041/S004	08/29/2018	X - 30-Day Notice	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC.	QC/manufacturing equipment changes and DNA Ladder changes.

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P160004/S017	08/03/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Alternate raw material resins and modifications to resin processing.
P160004/S018	08/23/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Update raw material specifications and the non-compendial test methods.
P160004/S019	08/21/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Use of an alternate raw material resin for the stent component.
P160007/S008	08/03/2018	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM / GUARDIAN SENSOR (3)	MEDTRONIC MINIMED	Addition of an alternative press to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect System, and MiniMed 670G systems.
P160007/S009	08/06/2018	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of drying equipment used in the production of the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P160017/S046	08/03/2018	X - 30-Day Notice	MEDTRONIC MINIMED 670G SYSTEM / GIARDIAN SENOR (3)	MEDTRONIC MINIMED, INC.	Addition of an alternative press to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G, Guardian Connect System, and MiniMed 670G systems.
P160017/S047	08/06/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of drying equipment used in the production of the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P160017/S049	08/14/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Adding an alternative injection molding machine to produce the sleeve component used in the MiniMed 630G Pump and the MiniMed 670G Pump. The MiniMed 630G Pump is part of the MiniMed 630G System with SmartGuard and the MiniMed 670G pump is part of the MiniMed 670G System.
P160021/S012	08/23/2018	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Update raw material specifications and the non-compendial test methods.
P160023/S005	08/07/2018	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Increase the batch size and modify the manufacturing process of a critical kit subcomponent.
P160024/S005	08/09/2018	X - 30-Day Notice	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Modifications to your testing plan following real time aging.

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P160025/S006	08/09/2018	X - 30-Day Notice	ASTRON PULSAR/ PULSAR-18 STENT SYSTEMS	BIOTRONIK, INC.	Modifications to your laser cutting parameters.
P160030/S024	08/22/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Changing the assembly process for the FreeStyle Libre Sensor, a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and the Freestyle Libre Flash Glucose Monitoring System.
P160041/S012	08/17/2018	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing cleaning process.
P160045/S008	08/14/2018	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Relocate the manufacturing of one component/reagent.
P170006/S006	08/02/2018	X - 30-Day Notice	AVALUS BIOPROSTHESIS	MEDTRONIC INC.	Addition of a new bovine tissue supplier.
P170007/S001	08/17/2018	X - 30-Day Notice	DUROLOANE	BIOVENTUS LLC	Replacement of a raw material supplier for a part used in the manufacture of DUROLANE.
P170011/S006	08/10/2018	X - 30-Day Notice	IMPELLA RP	ABIOMED, INC.	Addition of a second supplier for the hub transition component used in the Impella RP.
P170011/S007	08/22/2018	X - 30-Day Notice	IMPELLA RP	ABIOMED, INC.	Addition of an alternative biological indicator (BI) for the sterilization of all Impella family of catheters and the adoption of Impella CP with SmartAssist into the existing sterilization cycle for other Impella catheters at an alternate site.
P170012/S008	08/08/2018	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Change in the in-process specification for the maximum water content of the collagen powder component.

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