PMA Monthly approvals from 1/1/2019 to 1/31/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170037	01/30/2019	PMAO - PMA Origi	SANGIA TOTAL PSA TEST	OPKO DIAGNOSTICS , LLC.	Approval for the Sangia Total PSA Test. The Sangia Total PSA Test is an immunoassay indicated to quantitatively measure total PSA in capillary whole blood from a fingerstick collected by a healthcare professional and is used in conjunction with a digital rectal exam (DRE) as an aid in the detection of prostate cancer in men aged 50 years and older. The Sangia Total PSA Test is performed using the Claros 1 Analyzer in point-of-care settings. A prostate biopsy is required for the diagnosis of prostate cancer.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S151	01/15/2019	R - Real-Time Proc	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Approval for labeling and minor packaging modifications.
P830055/S213	01/08/2019	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a change in packaging configuration at new site.
P830055/S217	01/31/2019	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval of the Imorphics Cartilage Generation Software to be incorporated within the TRUMATCH 3.0 System.
P860004/S319	01/18/2019	R - Real-Time Proc	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling updates to the Model A820 myPTM app Patient User Guide used with the SynchroMed II Personal Therapy Manager (PTM). The labeling updates include the addition of pairing instructions for the patient to pair replacement parts of the PTM with the implanted pump and other minor clarifications

Data as of 09/09/2019 02:09 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P880047/S028	01/10/2019	S - Special CBE	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Approval for endotoxin testing and limit requirements for GYNECARE INTERCEED® Absorbable Adhesion Barrier manufactured at the San Lorenzo, Puerto Rico and Neuchatel Switzerland sites.
P890003/S401	01/07/2019	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for updates to the Baseline Operating System Software in the Medtronic CareLink 2090 Programmer Model 9986 software and CareLink Encore Programmer Model SW028 software.
P900056/S174	01/10/2019	R - Real-Time Proc	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for a dimensional change to a device component.
P910077/S167	01/09/2019	O - Normal 180 Day	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval of a manufacturing site duplication for the Model 3300 Programmer, Model 6395 Telemetry Wand, and accessories packaging/labeling.
P920047/S110	01/28/2019	N - Normal 180 Day	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval to update the firmware/software of the Maestro 4000 Controller from version 5.14 to version 5.23 and the MetriQ Pump version 0.0.64 to version 1.1.
P920047/S112	01/09/2019	Y - 135 Review Tra	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval of manufacturing changes, specifically, the addition of BSC Heredia as an alternate supplier for the Steering Control Wire Subassembly.
P930016/S055	01/29/2019	O - Normal 180 Day	VISX EXCIMER LASER SYSTEM MODELS "B" AND "C"	AMO MANUFACTURING USA, LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P960013/S099	01/03/2019	N - Normal 180 Day	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Approval for new models of cardiac resynchronization therapy pacemakers (CRT-P) devices, Quadra Allure PM3542 and Quadra Allure MP PM3562
P960016/S076	01/10/2019	S - Special CBE	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Approval for updates to the warnings section of the Instructions for Use for Ampere Generator and its accessories.
P980003/S087	01/28/2019	N - Normal 180 Day	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval to update the firmware/software of the Maestro 4000 Controller from version 5.14 to version 5.23 and the MetriQ Pump version 0.0.64 to version 1.1.
P980016/S692	01/09/2019	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a minor design change, corresponding manufacturing documentation updates, and the addition of an in-process 100% visual inspection for the advanced valve metal capacitor component.
P000025/S103	01/22/2019	N - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for the Mi1210 SYNCHRONY ST Cochlear Implant +Standard, +Medium, +Compressed, +FLEXSOFT, +FLEX24, +FLEX28 (for non-EAS patients), the Mi1210 SYNCHRONY ST Cochlear Implant +FLEX20, +FLEX24 (for EAS patients), the Mi1210 Implant Template, and associated surgical accessories.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000054/S052	01/15/2019	N - Normal 180 Day	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for an additional 6000 L bioreactor to be located in Building B, Suite C/D at the Andover site.
P000058/S071	01/15/2019	N - Normal 180 Day	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for an additional 6000 L bioreactor to be located in Building B, Suite C/D at the Andover site.
P010013/S072	01/09/2019	Y - 135 Review Tra	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Approval for the addition of a second supplier for the gold-plated yarn material used in the Bipolar Electrode Mesh Array of the NovaSure Impedance Controlled Endometrial Ablation System.
P010030/S110	01/07/2019	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for a new software version to increase the significance and frequency of a service message.
P010031/S650	01/09/2019	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a minor design change, corresponding manufacturing documentation updates, and the addition of an in-process 100% visual inspection for the advanced valve metal capacitor component.
P010031/S657	01/10/2019	O - Normal 180 Day	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval of the revised protocol for the REVERSE Product Surveillance Registry.
P020024/S052	01/11/2019	N - Normal 180 Day	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for the AMPLATZER Piccolo Occluder.
P020025/S113	01/28/2019	N - Normal 180 Day	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval to update the firmware/software of the Maestro 4000 Controller from version 5.14 to version 5.23 and the MetriQ Pump version 0.0.64 to version 1.1.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020025/S115	01/09/2019	Y - 135 Review Tra	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval of manufacturing changes, specifically, the addition of BSC Heredia as an alternate supplier for the Steering Control Wire Subassembly.
P030035/S171	01/03/2019	N - Normal 180 Day	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Approval for new models of cardiac resynchronization therapy pacemakers (CRT-P) devices, Quadra Allure PM3542 and Quadra Allure MP PM3562.
P030054/S356	01/03/2019	N - Normal 180 Day	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Approval for new models of cardiac resynchronization therapy pacemakers (CRT-P) devices, Quadra Allure PM3542 and Quadra Allure MP PM3562.
P040014/S035	01/10/2019	S - Special CBE	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Approval for updates to the warnings section of the Instructions for Use for Ampere Generator and its accessories.
P040021/S037	01/17/2019	R - Real-Time Proc	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ST. JUDE MEDICAL, INC.	Approval for the replacement of nylon suture with polyester suture for certain areas of construction of the Biocor and Epic heart valves.
P040037/S105	01/03/2019	Y - 135 Review Tra	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for the use of two new heparin coaters.
P040042/S041	01/10/2019	S - Special CBE	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Approval for updates to the warnings section of the Instructions for Use for Ampere Generator and its accessories.
P050038/S032	01/24/2019	Y - 135 Review Tra	ARISTA AH ABSORBABLE HEMOSTAT	C.R. BARD, INC.	Approval for a new supplier of the subcomponent raw material HST (hydrolyzed starch technology) which is used in the manufacturing of the DSM-A (non-sterile powder) component of the Arista¿ AH device. Additionally, the supplement includes an improvement in the test method for hydrolyzed starch characterization.
P050053/S043	01/15/2019	N - Normal 180 Day	INFUSE BONE GRAFT	MEDTRONIC INC.	Approval for an additional 6000 L bioreactor to be located in Building B, Suite CD at the Andover site.
P060019/S044	01/10/2019	S - Special CBE	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Approval for updates to the warnings section of the Instructions for Use for Ampere Generator and its accessories.
P080012/S040	01/28/2019	N - Normal 180 Day	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for updates to the hardware (Clinician Programmer Model #13828), software and labeling of the Clinician Programmer and modifications to the software and labeling of the Patient Therapy Controller (PTC) for the Prometra Programmable Infusion Pump System.
P080012/S050	01/31/2019	N - Normal 180 Day	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for the addition of baclofen (baclofen injection, intrathecal, 500-2000 microgram/mL) to the Prometra Programmable Infusion Pump System indications for use and corresponding labeling changes to the device system.
P090015/S006	01/23/2019	R - Real-Time Proc	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Approval for replacement of BOND-MAX Slide Staining Assembly (SSA) Printed Wiring Assembly (PWA) and BOND software update from version 5.1 to 6.0.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100044/S036	01/10/2019	R - Real-Time Proc	PROPEL	INTERSECT ENT	Approval for extending the storage shelf life of the component fibers used in the manufacture of the Propel Family of Sinus Implants (Propel, Propel Mini, Propel Contour) to 20 months.
P100045/S007	01/04/2019	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for increasing the shelf life of the system.
P100045/S034	01/17/2019	R - Real-Time Proc	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Approval for minor changes to the CardioMEMS HF Patient Electronic System handheld LCD screen.
P110016/S058	01/10/2019	S - Special CBE	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for updates to the warnings section of the Instructions for Use for Ampere Generator and its accessories.
P130006/S044	01/03/2019	Y - 135 Review Tra	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Approval for the use of two new heparin coaters.
P130008/S031	01/28/2019	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for a new Model 4340 Respiratory Sensing Lead.
P130008/S037	01/24/2019	R - Real-Time Proc	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for a new potting epoxy within the Model 3028 IPG.
P130019/S017	01/25/2019	R - Real-Time Proc	MAESTRO RECHARGEABLE SYSTEM	RESHAPE LIFESCIENCES, INC.	Approval for updates to the application firmware (v5.0A) used in the Model 2402 mobile charger.
P130019/S018	01/25/2019	R - Real-Time Proc	MAESTRO RECHARGEABLE SYSTEM	RESHAPE LIFESCIENCES, INC.	Approval for updates to the MOSFET components in the circuit assembly of the Model 2402 mobile charger.
P130026/S037	01/10/2019	S - Special CBE	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for updates to the warnings section of the Instructions for Use for Ampere Generator and its accessories.
P140003/S028	01/09/2019	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for a change in the cannula production process.

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P140010/S042	01/04/2019	O - Normal 180 Day	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for labeling changes to include 5-year data from your continued-follow up post-approval study.
P140028/S036	01/10/2019	S - Special CBE	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Approval for modifications to the MR Conditional labeling.
P140033/S034	01/03/2019	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for new models of cardiac resynchronization therapy pacemakers (CRT-P) devices, Quadra Allure PM3542 and Quadra Allure MP PM3562.
P150005/S039	01/28/2019	N - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval to update the firmware/software of the Maestro 4000 Controller from version 5.14 to version 5.23 and the MetriQ Pump version 0.0.64 to version 1.1.
P150005/S041	01/09/2019	Y - 135 Review Tra	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval of manufacturing changes, specifically, the addition of BSC Heredia as an alternate supplier for the Steering Control Wire Subassembly.
P150011/S014	01/08/2019	S - Special CBE	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for labeling changes implemented to provide safety information regarding future valve in valve implantations.
P150024/S010	01/15/2019	O - Normal 180 Day	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval of the revised protocol with modifications including use of local labs for blood work, changes to the minimum and maximum number of patients enrolled per site, and a revised study timeline for the post-approval study (PAS) protocol.
P150031/S001	01/10/2019	N - Normal 180 Day	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the Vercise PC Deep Brain Stimulation (DBS) System and Vercise Gevia Deep Brain Stimulation (DBS) System.
P150031/S002	01/18/2019	N - Normal 180 Day	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the Cartesia Deep Brain Stimulation directional lead.
P150046/S002	01/14/2019	N - Normal 180 Day	NEVISENSE	SCIBASE AB	Approval for hardware and software modifications including replacement of discontinued PC board and associated HW and SW changes; addition of radio module; LVDS ferrite bead replacement; new cells for rechargeable battery and reprogrammed battery safety circuit; replacement of speaker; software updates to adapt to new platform; NeviFile software; Quick Measurement function; reference measurement feedback dialogs.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160001/S021	01/25/2019	O - Normal 180 Day	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval of the revised protocol that includes inflation can branding, a new timeline, product performance observations, a deviation log, an additional clinical site to be enrolled, and editorial modifications to avoid redundancy and add clarification as needed for the PAS protocol.
P160001/S027	01/11/2019	R - Real-Time Proc	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for software changes relating to battery voltage thresholds and Touch Dispenser screens.
P160014/S005	01/17/2019	R - Real-Time Proc	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for a change to the device packaging.
P160039/S004	01/30/2019	N - Normal 180 Day	REMEDE® SYSTEM	RESPICARDIA	Approval for a change in packaging and sterilization process to the remed? System IPG.
P160043/S013	01/17/2019	N - Normal 180 Day	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval to introduce changes to the drug-polymer coating process.
P160048/S007	01/15/2019	O - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for modification to the approved post-approval study protocol to include nurse practitioners and physicians assistants, in addition to physicians, as practitioners who will perform sensor insertions and removals.
P160048/S008	01/28/2019	R - Real-Time Proc	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval to label the Eversense Sensor as Magnetic Resonance (MR) Conditional.
P160054/S015	01/18/2019	O - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval of the protocols for the post-approval studies protocol.
P160054/S016	01/08/2019	R - Real-Time Proc	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for an additional Controller configuration with a lower Low Flow Hazard alarm threshold.
P170012/S007	01/18/2019	N - Normal 180 Day	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Approval for the Hemoblast Bellows Laparoscopic Applicator to deliver the Hemoblast Bellows device to bleeding surgical sites through a 5mm diameter trocar.
P180002/S004	01/28/2019	O - Normal 180 Day	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval for a waiver of the 6-month Post Approval Study (PAS) reporting requirement for the LIBERATE extension study.

Total: 69

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S417	01/08/2019	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Use of new battery case laser marking equipment to replace the current aging laser marking equipment.
P840001/S418	01/08/2019	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Manufacturing transfer of the M926634A001 Crimp Sleeve, from the current supplier Lake Region Medical to RMS.
P860003/S100	01/10/2019	X - 30-Day Notice	UVAR PHOTOPHERESIS SYSTEM	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Change in the manufacturing process for the CELLEX Procedural Kits' drive tube assemblies so that the same manufacturing steps used at the approved Mack Molding manufacturing site can also be used at the approved Harmac Medical, Buffalo, New York site.
P860004/S322	01/08/2019	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Use of new battery case laser marking equipment to replace the current aging laser marking equipment.
P860004/S323	01/16/2019	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	New fixture added to the manufacturing process for the Ascenda Intrathecal Catheter.
P910073/S152	01/10/2019	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Change the authorized laboratory for testing USP grade polyethylene glycol (PEG) 3350 and mannitol material to other service providers.
P930038/S090	01/17/2019	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICE	TERUMO MEDICAL CORPORATION	Transfer of bacterial endotoxin testing from the Abbott facility (Plymoth, MN) to the Terumo Puerto Rico facility (Caguas, PR) for ANGIO-SEAL devices manufactured at the Terumo Puerto Rico facility.
P940015/S043	01/10/2019	X - 30-Day Notice	SYNVISC ONE	SANOFI GENZYME CORP.	Change to the frequency of routine sampling and testing of the water for injection and purified water systems.
P940015/S044	01/16/2019	X - 30-Day Notice	SYNVISC ONE	SANOFI GENZYME CORP.	Modified sterilization cycles and loads for the sterilization of equipment parts used in the manufacturing of Synvisc and Synvisc-One.
P960004/S087	01/10/2019	X - 30-Day Notice	THINLINE ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Change the authorized laboratory for testing USP grade polyethylene glycol (PEG) 3350 and mannitol material to other service providers.
P960009/S334	01/08/2019	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Use of new battery case laser marking equipment to replace the current aging laser marking equipment.
P960009/S335	01/08/2019	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Manufacturing transfer of the M926634A001 Crimp Sleeve, from the current supplier Lake Region Medical to RMS.

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P960040/S432	01/23/2019	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Addition of a second supplier for the Hydrogen Getter Sheet Material and a process change to increase the lot size.
P960058/S134	01/09/2019	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Alternative packaging option for the external components of the HiResolution Bionic Ear System.
P960058/S135	01/11/2019	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	New electronic distribution as an additional delivery method for software for the HiResolution Bionic Ear System.
P970004/S281	01/08/2019	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Use of new battery case laser marking equipment to replace the current aging laser marking equipment.
P980035/S574	01/07/2019	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	New battery case laser marking equipment to replace the current aging laser marking equipment.
P980037/S072	01/10/2019	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Changes to the process parameters for a device component.
P980040/S096	01/15/2019	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Removing a redundant purification process for a UV absorber.
P980040/S097	01/15/2019	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Changing an in-process sampling procedure for buttons used to manufacture 1-piece and 3-piece IOLs.
P980044/S051	01/18/2019	X - 30-Day Notice	SUPARTZ FX	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture SUPARTZ FX and VISCO-3 for the purpose of the manufacturing of an investigational product.
P990080/S047	01/15/2019	X - 30-Day Notice	CEEON EDGE FOLDABLE ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS, MODEL 911A	JOHNSON & JOHNSON SURGICAL VISION, INC.	Removing a redundant purification process for a UV absorber.

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P990080/S048	01/15/2019	X - 30-Day Notice	CEEON EDGE FOLDABLE ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS, MODEL 911A	JOHNSON & JOHNSON SURGICAL VISION, INC.	Changing an in-process sampling procedure for buttons used to manufacture 1-piece and 3-piece IOLs.
P000008/S046	01/18/2019	X - 30-Day Notice	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	RESHAPE LIFESCIENCES, INC.	Change in manufacturing site for the contract manufacturer of a critical device component ¿s accessory.
P000039/S063	01/08/2019	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Change to the stock and adhesive for package labels.
P010003/S032	01/04/2019	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Use an electronic system to monitor environmental conditions and equipment in the BioGlue manufacturing, quality control and raw material warehouse areas.
P010012/S493	01/10/2019	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Change the authorized laboratory for testing USP grade polyethylene glycol (PEG) 3350 and mannitol material to other service providers.
P010012/S495	01/23/2019	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Addition of a second supplier for the Hydrogen Getter Sheet Material and a process change to increase the lot size.
P010015/S388	01/07/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	New battery case laser marking equipment to replace the current aging laser marking equipment.
P010015/S389	01/22/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Transfer the manufacturing location of the electrode component due to material availability.
P010030/S112	01/16/2019	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Updates to the soldering process for the LifeVest Model 4000 and HWD 1000 monitors.

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P010032/S146	01/16/2019	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Addition of alternate biological indicator testing sites at Plymouth, Minnesota and Plano, Texas; and a change in release time of ambient aeration.
P010033/S042	01/04/2019	X - 30-Day Notice	QUANTTFERON-TB GOLD AND TB GOLD-IN-THE-TUBE	QIAGEN	Replace a raw material and scale-up the production of an associated bulk solution.
P020004/S162	01/02/2019	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate machine for use in nitinol wire manufacturing for the following devices: GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE TIGRIS Vascular Stent and GORE CARDIOFORM Septal Occluder.
P020024/S053	01/08/2019	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Change to the stock and adhesive for package labels.
P030011/S066	01/09/2019	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Change of location for a component supplier of the Companion 2 Driver System.
P030044/S006	01/17/2019	X - 30-Day Notice	DAKOCYTOMATION EGFR PHARMDX	DAKO NORTH AMERICA, INC.	Implementation of an in-process QC specification.
P040027/S069	01/02/2019	X - 30-Day Notice	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate machine for use in nitinol wire manufacturing for the following devices: GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE TIGRIS Vascular Stent and GORE CARDIOFORM Septal Occluder.
P040037/S125	01/02/2019	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate machine for use in nitinol wire manufacturing for the following devices: GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE TIGRIS Vascular Stent and GORE CARDIOFORM Septal Occluder.
P040040/S034	01/08/2019	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Change to the stock and adhesive for package labels.
P040043/S108	01/02/2019	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate machine for use in nitinol wire manufacturing for the following devices: GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE TIGRIS Vascular Stent and GORE CARDIOFORM Septal Occluder.

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P040045/S103	01/15/2019	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Qualification of an existing production line to produce VISTAKON® (senofilcon A) ACUVUE OASYS® Brand Contact Lenses.
P040045/S104	01/16/2019	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of an alternate test method for finished product release for VISTAKON® (senofilcon A) Brand Contact Lenses.
P050006/S072	01/02/2019	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate machine for use in nitinol wire manufacturing for the following devices: GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE TIGRIS Vascular Stent and GORE CARDIOFORM Septal Occluder.
P050028/S073	01/02/2019	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement a new cleaning process for bulk formulation tanks.
P050042/S038	01/24/2019	X - 30-Day Notice	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Change of a supplier test method used to qualify critical raw materials.
P050047/S067	01/31/2019	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Changes to an existing syringe assembly and packaging line for the Juvederm injectable gel implants.
P060030/S072	01/02/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement a new cleaning process for bulk formulation tanks.
P080010/S016	01/15/2019	X - 30-Day Notice	TECNIS MULTIFOCAL FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Removing a redundant purification process for a UV absorber.
P080010/S017	01/15/2019	X - 30-Day Notice	TECNIS MULTIFOCAL FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Changing an in-process sampling procedure for buttons used to manufacture 1-piece and 3-piece IOLs.

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P080011/S086	01/11/2019	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION MANUFACTURING, LTD.	Addition of the option to perform the lathe cut as a 2-step process in the manufacture of the Biofinity XR Toric (comfilcon A) Soft (hydrophilic) Extended Wear Contact Lenses.
P080011/S088	01/28/2019	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION MANUFACTURING, LTD.	Introduction and validation of a new secondary packaging line at the CooperVision Manufacturing, Inc., labeling and packaging facility at West Henrietta, New York.
P080025/S176	01/08/2019	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Use of new battery case laser marking equipment to replace the current aging laser marking equipment.
P090026/S023	01/09/2019	X - 30-Day Notice	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Change to the process for the Access p2PSA calibrator verification testing.
P100010/S087	01/03/2019	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Implementation of three automated manufacturing processes, as well as changes to the guide wire lumen manufacturing support and inspection process.
P100020/S042	01/02/2019	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement a new cleaning process for bulk formulation tanks.
P110010/S161	01/17/2019	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the electropolishing process.
P110033/S041	01/31/2019	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Changes to an existing syringe assembly and packaging line for the Juvederm injectable gel implants.
P110037/S044	01/02/2019	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Implement a new cleaning process for bulk formulation tanks.
P110042/S121	01/23/2019	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of a second supplier for the Hydrogen Getter Sheet Material and a process change to increase the lot size.
P120021/S009	01/08/2019	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Change to the stock and adhesive for package labels.

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P130006/S064	01/02/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate machine for use in nitinol wire manufacturing for the following devices: GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE TIGRIS Vascular Stent and GORE CARDIOFORM Septal Occluder.
P130008/S038	01/09/2019	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Manufacturing equipment upgrades at a vendor that produces a hybrid electronic circuit component for the Model 3028 Implantable Pulse Generator.
P130030/S058	01/17/2019	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Change to the electropolishing process.
P140003/S045	01/07/2019	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Addition of an alternative manufacturing method for the printing of an Impella drive catheter component.
P140009/S044	01/16/2019	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Addition of alternate biological indicator testing sites at Plymouth, Minnesota and Plano, Texas; and a change in release time of ambient aeration.
P140032/S023	01/08/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Use of new battery case laser marking equipment to replace the current aging laser marking equipment.
P150012/S069	01/10/2019	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Change the authorized laboratory for testing USP grade polyethylene glycol (PEG) 3350 and mannitol material to other service providers.
P150013/S013	01/17/2019	X - 30-Day Notice	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Implementation of an in-process QC specification.
P150014/S023	01/02/2019	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement a new cleaning process for bulk formulation tanks.
P150015/S023	01/02/2019	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement a new cleaning process for bulk formulation tanks.
P150025/S010	01/17/2019	X - 30-Day Notice	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Implementation of an in-process QC specification.

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P160004/S024	01/02/2019	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate machine for use in nitinol wire manufacturing for the following devices: GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface, GORE TIGRIS Vascular Stent and GORE CARDIOFORM Septal Occluder.
P160026/S005	01/22/2019	X - 30-Day Notice	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Manufacturing site change for the Shield Inverter component.
P160038/S007	01/08/2019	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Automation of an encoding process.
P160041/S016	01/02/2019	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Implement a new cleaning process for bulk formulation tanks.
P170012/S013	01/11/2019	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Changes to equipment maintenance for the ice machines used in Collagen extraction and purification.

Total: 77