PMA Monthly approvals from 9/1/2018 to 9/30/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180011	09/18/2018	PMAO - PMA Origi	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the ELUVIA Drug-Eluting Vascular Stent System. The device is indicated for improving luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters (RVD) ranging from 4.0 - 6.0 mm and total lesion lengths up to 190 mm.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S206	09/20/2018	S - Special CBE	ATTUNE REVISION FEMORAL SLEEVES	DEPUY, INC.	Approval for an increase in the inspection frequency of the overall height dimension performed at the vendor site(Tecomet), and for the addition of the overall height dimension check at the receiving inspection at the finished goods manufacturing site (DePuy Warsaw).
P890023/S033	09/07/2018	R - Real-Time Proc	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Approval to request a minor modification to the lens edge form.
P900056/S170	09/07/2018	Y - 135 Review Tra	ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for updating the sterilization process at the BSC Coventry, Rhode Island facility.
P920015/S217	09/19/2018	R - Real-Time Proc	6726 "Y" ADAPTOR/ EXTENDER KIT	MEDTRONIC INC.	Approval for a cable coating material change from PTFE to ETFE for the Model 6726 Y-Adaptor/Extender.

Data as of 10/04/2018 03:42 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920047/S108	09/07/2018	Y - 135 Review Tra	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Approval for updating the optimized BSC2000-2 cycle conducted in Chamber 7 at the BSC Coventry, Rhode Island facility with new Programmable Logic Controller (PLC) software.
P930021/S018	09/28/2018	Y - 135 Review Tra	STRAUMANN EMDOGAIN	THE STRAUMANN COMPANY	Approval for: 1) Revision of ventilation and implementation of cooling in clean rooms; 2) Emdogain bulk tank will be covered by a sterile autoclave bag during storage time between compounding and filling; 3) Implementation of heat-sealed autoclave pouch for sterilization and storage of stopper hopper; 4) The sterile phase of the P2R2 autoclave program, validated for sterilization of filters and other equipment used for aseptic production, was increased from 20 to 25 min; 5) Sampling and weighing method of the PGA has been changed to be conducted in plastic Nalgene bottles; 6) The rules for analysis and reference sampling for each sub batch of Emdogain were updated to reduce the overall number of samples taken per day; 7) Specifications for nitrogen gas and compressed air were updated; and 8) An alternative IPC method (IR spectroscopy) for protein content determination in
P950022/S107	09/24/2018	N - Normal 180 Day	HV STEROID ELUTING CARDIAC LEADS	ST. JUDE MEDICAL, INC.	Approval for the removal of steroid dip coating.
P980003/S085	09/07/2018	Y - 135 Review Tra	CHILLI II COOLED ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Approval for updating the optimized BSC2000-2 cycle conducted in Chamber 7 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software.
P980040/S089	09/26/2018	Y - 135 Review Tra	SENSAR/TECNIS 1-PIECE IOL, TECNIS TORIC IOL, TECNIS SYMFONY EXTENDED RANGE OF VISION IOL, TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOLS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for modifications to the cryotumbling process.
P990071/S037	09/04/2018	N - Normal 180 Day	NGEN PUMP	BIOSENSE WEBSTER, INC.	Approval for the new peristaltic irrigation pump, the nGEN Pump.
P990081/S038	09/13/2018	R - Real-Time Proc	PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for implementing a BenchMark Scanners software supplement for Ventana Systems Software (VSS) 12.3 on the BenchMark ULTRA Instrument.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S104	09/21/2018	R - Real-Time Proc	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for minor mechanical design change to the LifeVest Model 4000 Electrode Belt involving addition of epoxy to secure unused wires.
P010047/S051	09/12/2018	O - Normal 180 Day	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Approval for alternate sterilization sites located at Bard Regional Sterilization, 1211 Mary Magnum Boulevard, Madison, Georgia and Bard Regional Sterilization, 8195 Industrial Boulevard, Covington, Georgia.
P020012/S018	09/25/2018	Y - 135 Review Tra	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for adding an alternate supplier as an approved source to perform sterility testing for product release
P020025/S111	09/07/2018	Y - 135 Review Tra	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Approval for updating the optimized BSC2000-2 cycle conducted in Chamber 7 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software.
P020049/S006	09/28/2018	O - Normal 180 Day	PROCOL VASCULAR BIOPROSTHESIS	LEMAITRE VASCULAR INC	Approval for a manufacturing site located at Isomedix Operations, Inc., 435 Whitney Street, Northborough, Massachusetts, for sterilization of the ProCol Vascular Bioprothesis.
P030016/S001	09/13/2018	P - Panel Track	VISIAN TORIC ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Approval for the Visian® Toric ICL (Implantable Collamer Lens). The device is indicated for use in patients 21-45 years of age: 1) for the correction of myopic astigmatism with spherical equivalent ranging from -3.0D to less than or equal to -15.0D (in the spectacle plane) with cylinder (spectacle plane) of 1.0D to 4.0D; 2) for the reduction of myopic astigmatism with spherical equivalent ranging from greater than -15.0D to -20.0D (in the spectacle plane) with cylinder (spectacle plane) 1.0D to 4.0D; 3. with an anterior chamber depth (ACD) of 3.00 mm or greater, when measured from the corneal endothelium to the anterior surface of the crystalline lens and a stable refractive history (within 0.5D for both spherical equivalent and cylinder for 1 year prior to implantation); and 4) The Visian® TICL is intended for placement in the posterior chamber (ciliary sulcus) of the phakic eye.
P030040/S013	09/11/2018	R - Real-Time Proc	ATELLICA IM HEPATITIS B CORE IGM (AHBCM)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the placement of these assays on the Atellica Solution.
P030056/S013	09/11/2018	R - Real-Time Proc	ATELLICA IM ANALYZER HEPATITIS C (AHCV)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the placement of these assays on the Atellica Solution.
P040004/S014	09/11/2018	R - Real-Time Proc	ATELLICA IM ANTI-HBC TOTAL (HBCT)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the placement of these assays on the Atellica Solution.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040044/S079	09/10/2018	N - Normal 180 Day	MYNX CONTROL VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Approval for modifications to the delivery system handle and changes to the delivery system component materials.
P060006/S091	09/07/2018	Y - 135 Review Tra	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEMT	BOSTON SCIENTIFIC CORP.	Approval for updating the optimized BSC2000-2 cycle conducted in Chamber 7 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software.
P090024/S005	09/11/2018	R - Real-Time Proc	ATELLICA IM HEPATITIS B E ANTIGEN (HBEAG)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the placement of these assays on the Atellica Solution.
P090029/S010	09/27/2018	S - Special CBE	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for modifications to the Prestige LP Streamlined Instrument labeling (surgical technique document) to reference new drill bits to be used with the system to enhance the safe use of the device.
P100006/S006	09/26/2018	R - Real-Time Proc	AUGMENT BONE GRAFT AND AUGMENT INJECTABLE	BIOMIMETIC THERAPEUTICS,LLC	Approval for an alternate secondary packaging configuration for AUGMENT Injectable and corresponding changes in the AUGMENT Injectable package insert and surgical technique guide reflecting this alternate packaging configuration; re-design of the AUGMENT Injectable kit carton to accommodate a pouch in pouch configuration; and modifications to the payload area and the number of frozen gel packs utilized in the approved shipping unit for both AUGMENT Injectable and AUGMENT Bone Graft.
P100022/S027	09/10/2018	N - Normal 180 Day	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Approval for the 5 mm diameter stent.
P100027/S029	09/13/2018	R - Real-Time Proc	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for implementing a BenchMark Scanners software supplement for Ventana Systems Software (VSS) 12.3 on the BenchMark ULTRA Instrument.
P100029/S035	09/10/2018	S - Special CBE	TRIFECTA VALVE / TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Approval for labeling changes implemented to provide safety information regarding future valve in valve implantations.
P100039/S006	09/11/2018	R - Real-Time Proc	ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2)	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the placement of these assays on the Atellica Solution.
P110010/S154	09/19/2018	N - Normal 180 Day	PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a design change and manufacturing change to the delivery system, and various labeling changes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110010/S155	09/07/2018	Y - 135 Review Tra	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING STENT SYSTEM/PROMUS PREMIER EEVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for updating the sterilization process at the BSC Coventry, Rhode Island facility.
P110041/S006	09/11/2018	R - Real-Time Proc	ATELLICA IM HBSAGII (HBSII)/ATELLICA IM HBSAG CONFIRMATORY	SIEMENS CORP.	Approval for the placement of these assays on the Atellica Solution.
P120022/S018	09/27/2018	N - Normal 180 Day	THERASCREEN EGFR RGQ PCR KIT	QIAGEN MANCHESTER LTD	Approval for to extend the intended use of the therascreen® EGFR RGQ PCR Kit to include the selection of patients with NSCLC for whom dacomitinib is indicated.
P130024/S024	09/10/2018	R - Real-Time Proc	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER (LUTONIX DCB)	LUTONIX	Approval for a change to the balloon wall thickness for the 6 x 220 mm and 7 x 80 - 220 mm balloon sizes as well as a reduction in the labeled introducer sheath compatibility of these device sizes.
P130028/S022	09/20/2018	R - Real-Time Proc	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Approval for modifying the design of the Algovita Model 4200 Programmer Charger cable, and the Model 4230 Charging Paddle cable to improve the mechanical reliability (flex reliability) of the cables.
P130030/S050	09/07/2018	Y - 135 Review Tra	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for updating the sterilization process at the BSC Coventry, Rhode Island facility.
P140002/S013	09/20/2018	Y - 135 Review Tra	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Approval for modifications to the manufacturing and inspections of the delivery catheter.
P140003/S040	09/25/2018	R - Real-Time Proc	IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0, AND IMPELLA LD SYSTEMS	ABIOMED, INC.	Approval for a design change to the optical version of the Automated Impella Controller, adding a cover over the pump plug receptacle.
P140008/S008	09/04/2018	Y - 135 Review Tra	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGERY INC	Approval for increases to the routine bioburden monitoring alert and action limits.
P140025/S009	09/13/2018	R - Real-Time Proc	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for implementing a BenchMark Scanners software supplement for Ventana Systems Software (VSS) 12.3 on the BenchMark ULTRA Instrument.
P140032/S005	09/06/2018	O - Normal 180 Day	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval of the ISR Initial Market Release Training Human Factors Validation plan for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150004/S024	09/14/2018	R - Real-Time Proc	DRG SMALL/BIG CURVE DELIVERY SHEATH KIT, 22CM; DRG LEAD ACCESSORIES KIT; SLIMTIP DRG TRIAL LEAD KIT, 50CM AND 90CM; SLIMTIP DRG IMPLANT LEAD KIT, 50CM AND 90CM	ST. JUDE MEDICAL	Approval for alternative ink for the pad printed marker bands on the DRG delivery sheaths.
P150005/S036	09/07/2018	Y - 135 Review Tra	BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for updating the optimized BSC2000-2 cycle conducted in Chamber 7 at the BSC Coventry, Rhode Island facility with new Programmable Logic Controller (PLC) software.
P150016/S010	09/12/2018	O - Normal 180 Day	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Approval for alternate sterilization sites located at Bard Regional Sterilization, 1211 Mary Magnum Boulevard, Madison, Georgia and Bard Regional Sterilization, 8195 Industrial Boulevard, Covington, Georgia.
P150038/S005	09/20/2018	N - Normal 180 Day	EXABLATE MODEL 4000 SYSTEM	INSIGHTEC	Approval for the Exablate 4000 Type 1.1 System, an expansion of the Exablate 4000 Type 1.0 System to add compatibility with Siemens 3T Skyra, Prisma and PrismaFIT MR systems, including hardware changes to the devices Helmet System, changes to the electronics of the devices Front End Cabinet, and changes to the device sub-systems required for connectivity with these Siemens MRI systems.
P160001/S007	09/25/2018	N - Normal 180 Day	OBALON TOUCH INFLATION SYSTEM	OBALON THERAPEUTICS, INC.	Approval for the Obalon Touch Inflation System (as an alternative to the EzFill Inflation System) to be used with the Obalon Balloon System.
P160002/S007	09/13/2018	R - Real-Time Proc	VENTANA PD-L1(SP142) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for implementing a BenchMark Scanners software supplement for Ventana Systems Software (VSS) 12.3 on the BenchMark ULTRA Instrument.
P160022/S006	09/03/2018	R - Real-Time Proc	ZOLL R SERIES DEVICE	ZOLL MEDICAL CORPORATION	Approval for a change to the CPR algorithm and modified case upload capabilities.
P160030/S025	09/25/2018	O - Normal 180 Day	FREESTYLE LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160039/S003	09/12/2018	N - Normal 180 Day	REMEDE® SYSTEM	RESPICARDIA	Approval for a change in the material of the remede IPG from Hysol to EPO-TEK 301 as the Epoxy Resin Encapsulation material.
P160045/S005	09/06/2018	O - Normal 180 Day	ONCOMINE DX TARGET	LIFE TECHNOLOGIES CORPORATION	Approval for final updated labeling for the software change from Torrent Suite Dx version 5.6.4 to version 5.8.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160046/S005	09/13/2018	R - Real-Time Proc	VENTANA PD-L1 (SP263) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for implementing a BenchMark Scanners software supplement for Ventana Systems Software (VSS) 12.3 on the BenchMark ULTRA Instrument.
P160048/S001	09/18/2018	O - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval of the protocol for the post-approval study (PAS) protocol.
P160054/S011	09/12/2018	R - Real-Time Proc	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM (HM3 LVAS)	THORATEC CORPORATION	Approval for an update to the HeartMate 3 System Controller Main Application software.
P160054/S012	09/12/2018	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORPORATION	Approval for the addition of an Intensive Care Unit (ICU) Cover accessory.
P170011/S008	09/25/2018	R - Real-Time Proc	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a design change to the optical version of the Automated Impella Controller, adding a cover over the pump plug receptacle.
P180002/S002	09/25/2018	O - Normal 180 Day	PULMONX ZEPHYR ENDOBRONCHIAL VALVE (EBV)	PULMONX CORPORATION	Approval for The Pulmonx Zephyr® Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation.

Total: 57

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S148	09/19/2018	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/ INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Relocation of and changes to the milling and molding process of the silicone front tip component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830055/S207	09/11/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Increase in the batch size of ATTUNE Revision RP Polyethylene End Plugs that can be processed at any one time through the final clean line and centrifugal dryer in the polyethylene value stream.
P830055/S208	09/27/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Change the inspection fixture and in-process inspection method of the ATTUNE Revision Tibial Augment components as part of the LCS Total Knee System.
P900033/S073	09/12/2018	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE AND INTEGRA MESHED DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Revision to the allowable presterile shipping temperature range.
P900056/S173	09/19/2018	X - 30-Day Notice	ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.
P910001/S106	09/25/2018	X - 30-Day Notice	CVX-300 AND CVX-300-P EXCIMER LASER SYSTEMS	SPECTRANETICS CORP.	Use of a new receiving inspection tool, FARO Articulating Arm Coordinated Measurement Machine, to measure flatness during component production.
P910054/S006	09/13/2018	X - 30-Day Notice	TORAY INOUE BALLOON CATHETER	TORAY INDUSTRIES (AMERICA), INC.	Addition of new packaging heat sealing equipment.
P920047/S111	09/19/2018	X - 30-Day Notice	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.
P930029/S061	09/17/2018	X - 30-Day Notice	RF CONTACTR, RF ENHANCR II, RF MARINR, RF CONDUCTR, CARDIAC ABLATION PERCUTANEOUS CATHETERS	MEDTRONIC INC.	Automated polytetrafluoroethylene (PTFE) application process as a replacement for the current manual process for deflection wire coating.
P950020/S090	09/14/2018	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON MICROSURGICAL DILATION DEVICE (MR)	BOSTON SCIENTIFIC CORP.	Alternate port bonding process in catheter manufacturing.
P960009/S323	09/21/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Three (3) manufacturing changes that will further align the manufacturing of Medtronic¿s newly approved Model 37441 Intercept Patient Programmer with existing manufacturing of other market approved Medtronic products: 1) FACTORYworks MES Upgrade to Version 9.3; 2) Patient Programmer Real-Time Clock Capacitor Change; and 3) Patient Programmer Heating.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960040/S428	09/04/2018	X - 30-Day Notice	DYNAGEN MINI ICD, INOGEN MINI/EL ICD, ORIGEN MINI/EL ICD, DYNAGEN EL ICD, AUTOGEN EL ICD, VIGILANT EL ICD, PERCIVA ICD, RESONATE EL/HF ICD, PERCIVA HF ICD, MOMENTUM EL ICD, PUNCTUA ICD, ENERGEN ICD, ICEPTA ICD	BOSTON SCIENTIFIC	Addition of an alternate supplier for the molybdenum feedthru pin.
P970037/S011	09/06/2018	X - 30-Day Notice	AUTODELFIA HAFP TEST KIT	PERKINELMER, INC.	Update of the plate washer manifold, a component of the AutoDELFIA instrument.
P970051/S181	09/10/2018	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	New internal electrode supplier for the rechargeable battery assemblies.
P980003/S088	09/19/2018	X - 30-Day Notice	CHILLI II COOLED ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.
P980016/S683	09/05/2018	X - 30-Day Notice	EVERA MRI: DF-1 ICD, ICD; EVERA S: DR ICD, VR ICD; EVERA XT, DR ICD, VR ICD; MIRRO MRI: DR ICD, VR ICD; PRIMO MRI: DR ICD, VR ICD; PROTECTA: ICD, VR ICD, XT ICD; SECURA: DR ICD, ICD; VISIA AF MRI: DF1 ICD, VR ICD VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transition from battery grade raw material lithium to technical grade raw material lithium.
P980016/S684	09/05/2018	X - 30-Day Notice	PROTECTA ICD, PROTECTA VR ICD, AND PROTECTA XT ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Titan Device Level Final Functional Tester for the Protecta family devices.
P980016/S687	09/28/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the distribution control sorter tool (DCST) system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S560	09/05/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ASTRA XT DR MRI IPG; ASTRA S DR MRI IPG; ASTRA S SR MRI IPG; ASTRA XT SR MRI IPG; ATTESTA DR MRI IPG; ATTESTA SR MRI IPG; AZURE S DR MRI IPG; AZURE S SR MRI IPG; AZURE XT DR MRI IPG; AZURE XT SR MRI IPG; RELIA IPG	MEDTRONIC INC.	Transition from battery grade raw material lithium to technical grade raw material lithium.
P980035/S562	09/25/2018	X - 30-Day Notice	ASTRA S DR MRI, ASTRA S SR MRI, ASTRA XT DR MRI, ASTRA XT SR MRI, AZURE S DR MRI, AZURE S SR MRI, AZURE XT DR MRI AND AZURE XT SR MRI IPG	MEDTRONIC INC.	Minor updates to the integrated circuit Electrical Test Requirements Specification and Automated Test Equipment software.
P980035/S563	09/28/2018	X - 30-Day Notice	ADAPTA VERSA SENSIA IPG / ATTESTA IPG / SPHERA IPG	MEDTRONIC INC.	Replace the current Boiling Heptane Cleaning process with Plasma Cleaning.
P980041/S040	09/12/2018	X - 30-Day Notice	ACCESS AFP REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Manufacturing change (cell culture) to the AFP reagent antibody production process for increased productivity (batch size) and improved capacity.
P000015/S033	09/10/2018	X - 30-Day Notice	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	New internal electrode supplier for the rechargeable battery assemblies.
P000025/S105	09/19/2018	X - 30-Day Notice	MED-EL COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Change in the manufacturing of the cochlear implants SONATA, Mi1000 MED-EL CONCERT, and Mi1200 SYNCHRONY.
P000029/S084	09/14/2018	X - 30-Day Notice	DEFLUX INJECTABLE GEL	VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	Replacement of a compressor for compressed air used in the manufacture of the Deflux and Solesta Injectable Gel.
P000053/S092	09/20/2018	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Relocation of and changes to the milling and molding process of the silicone balloon adapter component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S489	09/04/2018	X - 30-Day Notice	DYNAGEN CRT-D, DYNAGEN X4 CRT-D, INOGEN CRT-D, INOGEN X4 CRT-D, ORIGEN CRT-D, ORIGEN X4 CRT-D, AUTOGEN CRT-D, AUTOGEN X4 CRT-D, MOMENTUM CRT-D, MOMENTUM X4 CRT-D, VIGILANT X4 CRT-D, VIGILANT CRT-D, RESONATE CRT-D, RESONATE X4/HF CRT-D, PUNCTUA CRT-D, ENERGEN CRT-D, INCEPTA CRT-D	BOSTON SCIENTIFIC CORP.	Addition of an alternate supplier for the molybdenum feedthru pin.
P010015/S377	09/05/2018	X - 30-Day Notice	CONSULTA CRT-P; SYNCRA CRT-P; VIVA CRT-P	MEDTRONIC INC.	Transition from battery grade raw material lithium to technical grade raw material lithium.
P010015/S379	09/25/2018	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, AND SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Minor updates to the integrated circuit Electrical Test Requirements Specification and Automated Test Equipment software.
P010031/S642	09/05/2018	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; CONSULTA CRT-D; PROTECTA CRT-D; PROTECTA XT CRT-D; VIVA QUAD S CRT-D; VIVA QUAD XT CRT-D; VIVA S CRT-D; VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transition from battery grade raw material lithium to technical grade raw material lithium.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S643	09/05/2018	X - 30-Day Notice	PROTECTA CRT-D AND PROTECTEA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Titan Device Level Final Functional Tester for the Protecta family devices.
P010047/S060	09/13/2018	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Modify the manufacturing process for the siliconized cartridges.
P020003/S008	09/04/2018	X - 30-Day Notice	TOROSA SALINE FILLED TESTICULAR PROSTHESIS	COLOPLAST CORP.	Use of a new peel-test equipment.
P020025/S114	09/19/2018	X - 30-Day Notice	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.
P020049/S007	09/19/2018	X - 30-Day Notice	PROCOL VASCULAR BIOPROSTHESIS	LEMAITRE VASCULAR INC	Implement a change to bioburden test methods.
P030009/S095	09/27/2018	X - 30-Day Notice	INTEGRITY CORO0NARY STENT SYSTEM.	MEDTRONIC IRELAND	Upgrade to the passivation unit.
P030017/S318	09/15/2018	X - 30-Day Notice	PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Use of the alternate Radio Frequency (RF) tipping and hub molding equipment with new parameter settings to manufacture the Introducer (a surgical accessory used in all of Precision SCS systems).
P030017/S319	09/21/2018	X - 30-Day Notice	PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND PRECISION SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Update to the test equipment system software used for testing the Programming Wand printed circuit board assembly (PCBA) units of your Precision Spectra, Precision Novi, Precision Montage, Precision Montage MRI, and Precision Spectra WaveWriter SCS systems.
P040027/S066	09/26/2018	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Updates to bioburden action/alert limits for the GORE VIABAHN Endoprosthesis and Endoprosthesis with Heparin Bioactive Surface, GORE VIABAHN Endoprosthesis and Endoprosthesis with Heparin Bioactive Surface (AV Access) and GORE VIATORR Tips Endoprosthesis, as well as approval to reassess alert limits periodically according to the given protocol and report updated alert limits in future PMA annual reports

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P040037/S120	09/18/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Update heparin specifications and non-compendial test methods.
P040037/S121	09/26/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Updates to bioburden action/alert limits for the GORE VIABAHN Endoprosthesis and Endoprosthesis with Heparin Bioactive Surface, GORE VIABAHN Endoprosthesis and Endoprosthesis with Heparin Bioactive Surface (AV Access) and GORE VIATORR Tips Endoprosthesis, as well as approval to reassess alert limits periodically according to the given protocol and report updated alert limits in future PMA annual reports.
P040044/S082	09/06/2018	X - 30-Day Notice	MYNXGRIP VASCULAR CLOSURE DEVICE, MYNX ACE VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Implementation of an additional freeze dryer.
P050028/S070	09/19/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0 AND COBAS TAQMAN HBV TEST FOR USE ON THE HIGH PURE SYSTEM	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P050043/S008	09/19/2018	X - 30-Day Notice	FEMORAL INTRODUCER SHEATH AND HEMOSTASIS (FISH) DEVICE	MORRIS INNOVATIVE RESEARCH INC	Replacement of the current laser cutting equipment with a new laser cutting equipment for the SIS patch cutting operation.
P060006/S093	09/19/2018	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.
P060030/S069	09/19/2018	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.	Discontinuation of redundant incoming raw material testing.
P060040/S071	09/20/2018	X - 30-Day Notice	HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORP.	Change of a component on the HeartMate II Controller.
P080014/S022	09/13/2018	X - 30-Day Notice	CERVISTA HPV HR ASSAY	HOLOGIC, INC.	Change in release testing specifications of incoming raw materials.
P080015/S014	09/13/2018	X - 30-Day Notice	CERVISTA HPV 16/18 ASSAY	HOLOGIC, INC.	Change in release testing specifications of incoming raw materials.

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P090022/S035	09/06/2018	X - 30-Day Notice	SOFTEC HD/ HD PS, SOFTEC I, SOFTEC HDO, SOFTEC HDM IOLS	LENSTEC, INC.	Additional lens analyzer be added to the manufacturing process for the Softec HD, Softec HD PS, Softec I, Softec HDO, and Softec HDM IOLs.
P100010/S082	09/25/2018	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Addition of a new manufacturing line for the Arctic Front Advance Cardiac Cryoablation catheter.
P100010/S083	09/24/2018	X - 30-Day Notice	ARCTIC FRONT ADVANCE PRO CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Changes in manufacturing equipment and inspection for the proximal and distal bonds of Arctic Front Advance Pro Catheter and changes in Pebax tubing inspection.
P100010/S085	09/25/2018	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	New inspection of Guide Wire Lumen subassemblies, used in the manufacturing of Arctic Front Advance (Models 2AF234 and 2AF284) catheters.
P100014/S021	09/14/2018	X - 30-Day Notice	SOLESTA INJECTABLE GEL	VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	Replacement of a compressor for compressed air used in the manufacture of the Deflux and Solesta Injectable Gel.
P100016/S006	09/20/2018	X - 30-Day Notice	CT LUCIA 202 AND CT LUCIA 602 INTRAOCULAR LENSES	CARL ZEISS MEDITEC PRODUCTION LLC	Add an alternative machine for lens haptic hole drilling for the CT LUCIA 202 and CT LUCIA 602 intraocular lenses.
P100020/S038	09/19/2018	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P100021/S074	09/27/2018	X - 30-Day Notice	ENDURANT, ENDURANT II, AND ENDURANT IIS STENT GRAFT SYSTEMS	MEDTRONIC VASCULAR	Upgrade to the passivation unit.
P100026/S058	09/05/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Change the sub-supplier of the Wand¿s (Model W-02) USB cable components.
P100026/S059	09/07/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Change the supplier of the Lead Marker Band component of the NeuroPace Depth Leads and NeuroPace Cortical Strip Leads.
P100042/S018	09/13/2018	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Change in release testing specifications of incoming raw materials.
P100042/S019	09/28/2018	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Removal of raw material QC testing not relevant to the product.

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P100044/S034	09/07/2018	X - 30-Day Notice	PROPEL AND PROPEL MINI SINUS IMPLANTS	INTERSECT ENT	Changes to the qualification protocol for the fiber used in the manufacture of the Propel and Propel Mini Sinus Implants.
P100044/S035	09/21/2018	X - 30-Day Notice	PROPEL SINUS IMPLANT, PROPEL MINI SINUS IMPLANT, PROPEL CONTOUR SINUS IMPLANT	INTERSECT ENT	Extending the shelf life of the drug coating solution used in the manufacture of the Propel family of sinus implants, and to scale up the solution storage volume.
P100047/S127	09/18/2018	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Replacement of an existing inspection method for a component on the HVAS.
P100049/S023	09/06/2018	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Integration of updated labeling, shipping, and distribution procedures.
P110010/S159	09/19/2018	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING STENT SYSTEM/ PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.
P110013/S093	09/27/2018	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Upgrade to the passivation unit.
P110020/S029	09/19/2018	X - 30-Day Notice	COBAS BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P110037/S041	09/19/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P110042/S112	09/04/2018	X - 30-Day Notice	EMBLEM S-ICD, EMBLEM MRI S-ICD	BOSTON SCIENTIFIC CORPORATION	Addition of an alternate supplier for the molybdenum feedthru pin.
P110042/S113	09/05/2018	X - 30-Day Notice	EMBLEM S-ICD & EMBLEM MRI S-ICD	BOSTON SCIENTIFIC CORPORATION	Dimensional and widened tolerance range changes to the power inductor's solder termination pads.

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P120007/S016	09/13/2018	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Change in release testing specifications of incoming raw materials.
P120007/S017	09/28/2018	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Removal of raw material QC testing not relevant to the product.
P120019/S024	09/19/2018	X - 30-Day Notice	COBAS EGFR MUTATION TEST AND COBAS EGFR MUTATION TEST V2	ROCHE	Discontinuation of redundant incoming raw material testing.
P120020/S019	09/20/2018	X - 30-Day Notice	SUPERA SELF-EXPANDING STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Change of a manufacturing processing aid for delivery system thermal bonds.
P130006/S059	09/18/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Update heparin specifications and non-compendial test methods.
P130006/S060	09/26/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE (AV ACCESS)	W.L. GORE & ASSOCIATES,INC	Updates to bioburden action/alert limits for the GORE VIABAHN Endoprosthesis and Endoprosthesis with Heparin Bioactive Surface, GORE VIABAHN Endoprosthesis and Endoprosthesis with Heparin Bioactive Surface (AV Access) and GORE VIATORR Tips Endoprosthesis, as well as approval to reassess alert limits periodically according to the given protocol and report updated alert limits in future PMA annual reports.
P130008/S035	09/14/2018	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Alternate supplier of the pressure sensor component used in the Model 4323 Pressure Sensing Lead.
P130009/S093	09/05/2018	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCES, LLC.	Adoption of parametric release in the Irvine and Changi manufacturing facilities.
P130012/S005	09/25/2018	X - 30-Day Notice	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Modification of the manufacturing location of an existing component supplier.
P130016/S035	09/10/2018	X - 30-Day Notice	NUCLEUS HYBRID IMPLANT SYSTEM	COCHLEAR AMERICAS	New internal electrode supplier for the rechargeable battery assemblies.
P130027/S006	09/26/2018	X - 30-Day Notice	ARTUS CMV RGQ MDX KIT AND ARTUS CMV QS-RGO MDX KIT	QIAGEN, INC.	Modify the bulk manufacturing process and QC testing for an assay control reagent.

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P130030/S054	09/13/2018	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MR)	BOSTON SCIENTIFIC CORP.	Alternate port bonding process in catheter manufacturing.
P130030/S055	09/19/2018	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.
P140002/S017	09/20/2018	X - 30-Day Notice	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Installation of a gas chromatography data system.
P140003/S039	09/07/2018	X - 30-Day Notice	IMPELLA CP/IMPELLA CP WITH SMARTASSIST	ABIOMED, INC.	Modify the inspection for the internal motor coil component.
P140018/S012	09/06/2018	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Single sample quantification of adhesive stabilizer concentration at incoming inspection and final VenaSeal adhesive formulation.
P140023/S017	09/19/2018	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P140029/S013	09/20/2018	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Change to introduce equipment to aid in finger grip assembly for Restylane Refyne and Restylane Defyne.
P140031/S072	09/05/2018	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCES, LLC.	Adoption of parametric release in the Irvine and Changi manufacturing facilities.
P140032/S019	09/12/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Changes to the Implantable System for Remodulin (ISR) which include an alternative site for the laser etching process as well as changes to the suture loop length tolerance, environmental monitoring testing, and Device History Record (DHR) review optimization.
P150003/S042	09/19/2018	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORPORATION	Reduction in the number of samples used for batch release and annual stability testing.
P150004/S025	09/19/2018	X - 30-Day Notice	PROCLAIM DRG IPG	ST. JUDE MEDICAL	Updated design of the Manufacturing Test Lead which is used for testing the Proclaim Dorsal Root Ganglion Implantable Pulse Generator during the manufacturing process.
P150005/S040	09/19/2018	X - 30-Day Notice	BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Introduction of an approved sterilization cycle in Chamber 4 of the Costa Rica facility.

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P150014/S020	09/19/2018	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P150015/S020	09/19/2018	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P150016/S016	09/13/2018	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Modify the manufacturing process for the siliconized cartridges.
P150021/S033	09/19/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Higher volume preparations of stock solutions used to prepare FreeStyle Libre sensors, and qualification of a new supplier for reagents used for FreeStyle Libre sensor lot release testing as well as increased shelf life for those reagents. The FreeStyle Libre sensor is a component of the FreeStyle Libre and FreeStyle Libre Pro Continuous Glucose Monitoring Systems.
P150021/S034	09/27/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a new injection molding machine and an alternate higher cavitation mold tool to increase the product capacity for the sheath component of the Freestyle Libre Pro Flash Glucose Monitoring System
P150033/S040	09/05/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Transition from battery grade raw material lithium to technical grade raw material lithium.
P160004/S020	09/18/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Update heparin specifications and non-compendial test methods.
P160014/S004	09/10/2018	X - 30-Day Notice	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES , INC.	New laser bonder for the inner member tip attachment process.
P160021/S013	09/18/2018	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Update heparin specifications and non-compendial test methods.
P160023/S006	09/26/2018	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Implementation of additional in-process testing and associated specifications for lyophilized kit reagents.
P160030/S026	09/19/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Higher volume preparations of stock solutions used to prepare FreeStyle Libre sensors, and qualification of a new supplier for reagents used for FreeStyle Libre sensor lot release testing as well as increased shelf life for those reagents. The FreeStyle Libre sensor is a component of the FreeStyle Libre and FreeStyle Libre Pro Continuous Glucose Monitoring Systems.
P160038/S005	09/04/2018	X - 30-Day Notice	MISEQDX EXTENDED RAS PANEL	ILLUMINA, INC.	Improvement of a QC release testing method.

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P160038/S006	09/20/2018	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Incorporate a new in-process QC test for reagent functionality.
P160041/S013	09/19/2018	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Discontinuation of redundant incoming raw material testing.
P160043/S020	09/27/2018	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Upgrade to the passivation unit.
P160047/S002	09/25/2018	X - 30-Day Notice	AEGEA VAPOR SYSTEM	AEGEA MEDICAL , INC	Change of manufacturing site where the raw materials are purchased, received, inspected, and stored.
P170012/S010	09/26/2018	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Change in the location of the critical component supplier and modified processing steps of the raw material.

Total: 111