PMA Monthly approvals from 6/1/2019 to 6/30/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160029	06/06/2019	PMAO - PMA Origi	HEARTSTART ONSITE DEFIBRILLATOR (MODEL M5066A) AND HEARTSTART HOME DEFIBRILLATOR (MODEL M5068A)	PHILIPS MEDICAL SYSTEMS, INC.	Approval for the HeartStart OnSite Defibrillator (Model M5066A) and HeartStart Home Defibrillator (Model M5068A). The HeartStart OnSite Defibrillator (M5066A) is indicated for use on potential victims of sudden cardiac arrest with the following symptoms: 1) Unconsciousness; and 2) Absence of normal breathing. The HeartStart OnSite (Model M5066A) is indicated for adults over 55 pounds (25 kg). It is also indicated for infants and children under 55 lbs (25 kg) or 8 years old when used with the optional infant/child SMART pads. If Infant/Child SMART pads are not available, or you are uncertain of the childs age or weight, proceed with treatment using adult SMART pads. The HeartStart Home Defibrillator (M5068A) is indicated for use on potential victims of cardiac arrest with the following symptoms: 1) Unconsciousness; and 2) Absence of normal breathing. The HeartStart Home (M5068A) is indicated for adults over 55 pounds (25 kg). They are also indicated for infants and children under 55 lbs (25 kg) or 8 years old when used with the optional infant/child SMART pads. If Infant/Child SMART pads are not available, or you are uncertain of the childs age or weight, proceed with treatment using adult SMART pads.
P160036	06/04/2019	PMAO - PMA Origi	HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM	DT MEDTECH LLC	Approval for the Hintermann Series H3 Total Ankle Replacement System. The device is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis or arthritis secondary to inflammatory disease (e.g. rheumatoid arthritis, hemochromatosis, etc.). The device system is for prescription use.

Total: 2

Data as of 07/05/2019 02:49 AM

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S238	06/10/2019	R - Real-Time Proc	PACEMAKER DEVICES: ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT, (INSIGNIA AND ALTRUA II SUPPORTED BY LATITUDE CONSULT ONLY)	BOSTON SCIENTIFIC CORP.	Approval for hardware changes to the Latitude NXT Patient Management System Communicators.
P810006/S083	06/14/2019	Y - 135 Review Tra	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION	Approval for the implementation of a new instrument to calculate the percent solids of Alkali Dispersions.
P830055/S232	06/13/2019	S - Special CBE	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for an additional inspection verification step for the 2D barcode that is laser etched onto the ATTUNE Revision Femoral and Tibial Augment components.
P840001/S405	06/14/2019	Y - 135 Review Tra	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEM AND PISCES, SPECIFY AND VECTRIS SPRINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for a change in the external supplier lithium source and an addition of a lithium purification process step.
P840001/S425	06/12/2019	R - Real-Time Proc	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for modifying the Restore Clinician Programmer and changing the name to Restore Clinician Programmer, Model A71100.
P840062/S069	06/14/2019	Y - 135 Review Tra	COLLACOTE AND COLLATAPE ABSORBABLE COLLAGEN WOND DRESSING FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Approval for the implementation of a new instrument to calculate the percent solids of Alkali Dispersions.
P850007/S041	06/18/2019	R - Real-Time Proc	PHYSIOSTIM AND SPINALSTIM	ORTHOFIX, INC.	Approval for software and firmware updates to the SpinalStim. CervicalStim, and PhysioStim devices. The updates made are identical to each device, and include modifications to the mobile medical phone application.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850010/S083	06/14/2019	Y - 135 Review Tra	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT	INTEGRA LIFESCIENCES CORPORATION	Approval for the implementation of a new instrument to calculate the percent solids of Alkali Dispersions.
P850064/S039	06/14/2019	Y - 135 Review Tra	LIFEPULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Approval for the manufacturer of the injection molded parts including the Patient Circuit Cartridge halves, Cartridge Back and Cartridge Front, and the LifePort Adapters Patient End and Machine End, all sizes.
P860004/S316	06/14/2019	Y - 135 Review Tra	SYNCHROMED INFUSION SYSTEM, ASCENDS INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for a change in the external supplier lithium source and an addition of a lithium purification process step.
P880081/S043	06/27/2019	S - Special CBE	TECNIS CL FOLDABLE SILICONE INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval to revise the TECNIS® CL, Model Z9002, Directions for Use (DFU) to inform the user of the interaction of silicone material with inherent risk factors as follows: Addition of the following to Warning #10: It has been reported that silicone oil droplets, which remain adherent to the intraocular lens, may reduce the optical quality of the lens and obscure the view of the fundus.
P890003/S406	06/04/2019	R - Real-Time Proc	CARELINK SMARTSYNC AZURE ASTRA APPLICATION	MEDTRONIC, INC.	Approval for updates to the Medtronic CareLink SmartSync Azure Astra Application and updates to the CareLink SmartSync Device Manager.
P890003/S407	06/11/2019	R - Real-Time Proc	CARELINK SMARTSYNC HOST, PLATFORM, COMMON APPLICATION	MEDTRONIC, INC.	Approval for the CareLink SmartSync Percepta Serena Solara Application as well as a flashware update to the Percepta Serena Solara devices.
P890003/S408	06/11/2019	R - Real-Time Proc	MYCARELINK FIRMWARE	MEDTRONIC, INC.	Approval for updates to firmware version 7.4 to provide 4G cellular capability and network optimization.
P910065/S009	06/18/2019	S - Special CBE	AIA-PACK PSA	TOSOH BIOSCIENCE, INC.	Approval for labeling changes to the Tosoh AIA-PACK PSA Test to reflect newly acquired information that enhances the safety of the device as allowed by 21 CFR 814.39(d).
P910077/S171	06/10/2019	R - Real-Time Proc	LATITUDE WAVE COMMUNICATOR	BOSTON SCIENTIFIC	Approval for hardware changes to the Latitude NXT Patient Management System Communicators.
P920047/S116	06/17/2019	R - Real-Time Proc	BLAZER II XP, BLAZER PRIME HTD, BLAZER PRIME XP CARDIAC ABLATION PERCUTANEOUS CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a minor design change to the tensioning mechanism for its temperature and open-irrigated cardiac ablation catheters.
P930021/S023	06/21/2019	Y - 135 Review Tra	STRAUMANN EMDOGAIN	THE STRAUMANN COMPANY	Approval to implement an additional nitrogen gas wash at the end of the ethylene oxide sterilization cycle of the Emdogain product.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P940016/S027	06/07/2019	Y - 135 Review Tra	H.E.L.P. FUTURA APHERESIS SYSTEM	B. BRAUN AVITUM AG	Approval for a change in the cutting process in the manufacturing of the H.E.L.P. Ultrafilter HI PS 20 included in the H.E.L.P. Futura Set.
P960009/S322	06/14/2019	Y - 135 Review Tra	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for a change in the external supplier lithium source and an addition of a lithium purification process step.
P960009/S347	06/24/2019	R - Real-Time Proc	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for a minor design change to the lead holder accessory included in Medtronic Deep Brain Stimulation (DBS) lead kits.
P960040/S436	06/10/2019	R - Real-Time Proc	ICD DEVICES TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILANT, PERCIVA	BOSTON SCIENTIFIC	Approval for hardware changes to the Latitude NXT Patient Management System Communicators.
P970051/S182	06/05/2019	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for new accessories and modifications to the firmware and software of the Nucleus 7 system, as well as a research tool named the Cochlear Research Platform.
P970051/S183	06/14/2019	N - Normal 180 Day	COCHLEAR NUCLEUS CI600 SERIES COCHLEAR IMPLANTS	COCHLEAR AMERICAS	Approval for a new series of Nucleus Cochlear Implants, the CI600 Series Cochlear Implants, comprising the CI612, CI622 and CI632, and two accessories (Nucleus Non-Magnetic Cassette and Nucleus Replacement Magnet Cassette).
P970054/S015	06/13/2019	O - Normal 180 Day	PARVOVIRUS B19 IGG ENZYME IMMUNOASSAY (V519IGUS)	DIASORIN	Approval for relocating the manufacturing site to DiaSorin S.p.A., at Via Crescentino Snc, Saluggia, Italy.
P970055/S017	06/13/2019	O - Normal 180 Day	PARVOVIRUS B19 IGM ENZYME IMMUNOASSAY (V619IMUS)	DIASORIN	Approval for relocating the manufacturing site to DiaSorin S.p.A., at Via Crescentino Snc, Saluggia, Italy.
P980016/S702	06/11/2019	R - Real-Time Proc	EVERA MRI, EVERA, MARQUIS, SECURA MAXIMO II, INTRINSIC, PROTECTA, PROTECTA XT, VIRTUOSO II, VISIA AF	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updates to firmware version 7.4 for Model 24950 MyCareLink monitors.
P980035/S581	06/06/2019	R - Real-Time Proc	ADAPTA,VERSA, SENSIA IPG, ADVISA DR IPG, DR MRI IPG, SR MRI IPG, RELIA IPG, SPHERA DR MRI IPG	MEDTRONIC INC.	Approval for minor design (material) changes and related manufacturing process changes to the tantalum capacitors used in select product families of ICDs and IPGs.
P980035/S583	06/04/2019	R - Real-Time Proc	CARELINK SMARTSYNC DEVICE MANAGER	MEDTRONIC INC.	Approval for updates to the Medtronic CareLink SmartSync Azure Astra Application and updates to the CareLink SmartSync Device Manager.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S584	06/11/2019	R - Real-Time Proc	ADAPTA, VERSA, SENSIA, ADVISA, ADVISA MRI, ENPULSE, KAPPA	MEDTRONIC INC.	Approval for updates to firmware version 7.4 for Model 24950 MyCareLink monitors.
P980037/S073	06/03/2019	R - Real-Time Proc	ANGIOJET ULTRA THROMBECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a dimensional change and modified incoming inspection process for a device component.
P980040/S099	06/26/2019	N - Normal 180 Day	TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for the extension of the cylinder power range of the TECNIS Symfony Toric IOL line to include the cylinder powers 4.50D, 5.25D, and 6.00D.
P000013/S014	06/21/2019	R - Real-Time Proc	OSTEONICS ABC/TRIDENT SYSTEMS	HOWMEDICA OSTEONICS CORP.	Approval for the addition of new sterilization trays.
P000015/S034	06/05/2019	N - Normal 180 Day	NUCLEUS ABI541 AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Approval order should be issued for new accessories and modifications to the firmware and software of the Nucleus 7 system, as well as a research tool named the Cochlear Research Platform.
P000025/S100	06/07/2019	N - Normal 180 Day	MED-EL COCHLEAR IMPLANT	MED-EL CORP.	Approval for the remote programming of MED-EL Cochlear Implants.
P000025/S110	06/04/2019	R - Real-Time Proc	MI1250 SYNCHRONY 2 (PIN) COCHLEAR IMPLANT	MED-EL CORP.	Approval for the Mi1200 SYNCHRONY 2 (PIN) implant which incorporates a design change to a central lead exit of the approved Mi1200 SYNCHRONY (PIN) implant.
P010012/S501	06/10/2019	R - Real-Time Proc	CRT-D RESYNCHRONIZATION DEVICES COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILIANT	BOSTON SCIENTIFIC CORP.	Approval for hardware changes to the Latitude NXT Patient Management System Communicators.
P010015/S397	06/06/2019	R - Real-Time Proc	CONSULTA CRT-P; SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for minor design (material) changes and related manufacturing process changes to the tantalum capacitors used in select product families of ICDs and IPGs.
P010015/S399	06/11/2019	R - Real-Time Proc	CARELINK SMARTSYNC PERCEPTA SERENA SOLARA APPLICATION; PERCEPTA, SERENA, SOLARA QUARD CRT-P MRI SURESCAN.	MEDTRONIC INC.	Approval for the CareLink SmartSync Percepta Serena Solara Application as well as a flashware update to the Percepta Serena Solara devices.
P010015/S400	06/11/2019	R - Real-Time Proc	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for updates to firmware version 7.4 for Model 24950 MyCareLink monitors.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S662	06/11/2019	R - Real-Time Proc	VIVA, BRAVA, PROTECTA, XT, CONCERTO, CONCERTO II, MAXIMO II, INSYNC II PROTECT, AMPLIA, COMPIA, CLARIA	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for updates to firmware version 7.4 for Model 24950 MyCareLink monitors.
P020012/S020	06/26/2019	Y - 135 Review Tra	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for implementation of an alternate oven to be used for drying PMMA microspheres.
P020012/S027	06/10/2019	R - Real-Time Proc	BELLAFILL DERMA FILLER	SUNEVA MEDICAL, INC.	Approval for a change in shipping container, shipping duration, and shipping temperature conditions of Bellafill Derma Filler.
P020025/S120	06/17/2019	R - Real-Time Proc	BLAZER II, BLAZER II HTD, BLAZER II XP, BLAZER PRIME HTD, BLAZER PRIME XP, INTELLATIP MIFI XP, INTELLANAV MIFI XP, INTELLANAV XP, AND INTELLANAV ST CARDIAC ABLATION PERCUTANEOUS CATHETER	BOSTON SCIENTIFIC	Approval for a minor design change to the tensioning mechanism for its temperature and open-irrigated cardiac ablation catheters.
P030005/S183	06/10/2019	R - Real-Time Proc	CRT-P RESYNCHRONIZATION DEVICES INVIVE, INTUA, VISIONIST, VALITUDE	GUIDANT CORP.	Approval for hardware changes to the Latitude NXT Patient Management System Communicators.
P030017/S324	06/03/2019	R - Real-Time Proc	IMPLANTABLE PULSE GENERATOR (IPG) PRECISION SPECTRA, SPECTRA WAVEWRITER, PRECISION NOVI, PRECISION MONTAGE AND PRECISION MONTAGE MRI SPINAL CORD STIMULATOR (SCS) SYATEMS	BOSTON SCIENTIFIC CORP.	Approval for a material and a design change to the IPG Port Plug.
P030034/S014	06/18/2019	R - Real-Time Proc	CERVICALSTIM	ORTHOFIX, INC.	Approval for software and firmware updates to the SpinalStim. CervicalStim, and PhysioStim devices. The updates made are identical to each device, and include modifications to the mobile medical phone application.
P040024/S104	06/28/2019	Y - 135 Review Tra	RESTYLANE AND PERLANE	Q-MED AB	Approval for the replacement of a compressor for compressed air used in the manufacture of Restylane and Perlane.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040024/S106	06/06/2019	N - Normal 180 Day	RESTYLANE-L	Q-MED AB	Approval for revisions to the clinician and patient labeling of Restylane-L to include updated safety information based on post marketing surveillance data.
P040047/S052	06/26/2019	O - Normal 180 Day	COAPTITE	MERZ NORTH AMERICA, INC	Approval for a Post-Approval Study Labeling update.
P050011/S006	06/03/2019	O - Normal 180 Day	ADEPT ADHESION REDUCTION SOLUTION	BAXTER HEALTHCARE CORP.	Approval for a transfer of the design-owning organization from Baxter AG Vienna, Austria to Baxter Alliance Park Braine-L'Alleud, Belgium and final release testing and product release functions from Baxter AG Vienna, Austria to Baxter Castlebar, Ireland for the ADEPT Adhesion Reduction Solution.
P050042/S034	06/18/2019	N - Normal 180 Day	ALINITY I ANTI-HCV REAGENT KIT, ALINITY I ANTI-HCV CALIBRATOR, ALINITY I ANTI-HCV CONTROLS	ABBOTT LABORATORIES INC	Approval for migration of the ARCHITECT Anti-HCV Reagent kit, ARCHITECT Anti-HCV Calibrator and ARCHITECT Anti-HCV Controls onto the Alinity i Analyzer. The manufacture of the Alinity i analyzer would be done at a new contract manufacturer, Sanmina, Singapore.
P050047/S071	06/26/2019	S - Special CBE	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Approval for the inclusion of an additional inspection step to the current manual inspection method during the manufacturing process for the Juvederm Injectable Gel Implants.
P060030/S077	06/13/2019	R - Real-Time Proc	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Approval for a change to the PCR curve call parameter Delta B Min (Bmin) in the Test Definition File (TDF) to address an issue with reported false positive samples.
P060035/S026	06/20/2019	N - Normal 180 Day	ALINITY I ANTI-HBC IGM REAGENT KIT, ALINITY I ANTI-HBC IGM CALIBRATORS, ALINITY I ANTI-HBC IGM CONTROLS	ABBOTT LABORATORIES	Approval for migration of the ARCHITECT CORE-M Reagent Kit, ARCHITECT CORE-M Calibrators, ARCHITECT CORE-M Controls onto the Alinity i Analyzer. The manufacture of the Alinity i analyzer would be done at a new contract manufacturer, Sanmina, Singapore.
P080012/S049	06/18/2019	N - Normal 180 Day	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for the addition of REF16827, a 40mL drug capacity pump with Access Port Spacer component to be used at the Clinician's discretion; software modifications to revision 2.01.3 of the system's Clinician Programmer REF13828 and REF12828 and revision 2.01.1 of the systems Patient Therapy Controller (PTC) REF12860; and labeling updates made to reflect the above changes and differentiate the 40mL pump from the 20mL pump.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100006/S007	06/28/2019	O - Normal 180 Day	AUGMENT BONE GRAFT AND AUGMENT INJECTABLE	BIOMIMETIC THERAPEUTICS,LLC	Approval for the following manufacturing sites: Pyramid Laboratories, Inc. 3598 Cadillac Avenue Costa Mesa, California 92626 alternate site for the rhPDGF-BB vial tray packaging Parter Sterilization Services 17115 Kingsview Avenue Carson, California 90746 alternate Ethylene Oxide (EtO) contract sterilizer of finished vial trays
P100006/S008	06/11/2019	O - Normal 180 Day	AUGMENT INJECTABLE	BIOMIMETIC THERAPEUTICS,LLC	Approval of the protocol for the post-approval study (PAS) protocol.
P100009/S030	06/03/2019	S - Special CBE	MITRACLIP SYSTEM (NTR AND XTR)	ABBOTT VASCULAR INC.	Approval for an update to the Instructions for Use to clarify correct device use.
P100010/S093	06/27/2019	R - Real-Time Proc	ARTIC FRONT ADVANCE PRO CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Approval for a catheter check valve material change.
P100010/S094	06/04/2019	O - Normal 180 Day	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Approval for a manufacturing site located at: Medtronic, Inc. Medtronic Puerto Rico Operations Co. Rd. 149, Km 56.3, Call Box 6001 Villalba, Puerto Rico 007766 USA
P100026/S066	06/19/2019	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for an alternate Wand with minor design changes.
P100046/S010	06/26/2019	O - Normal 180 Day	ATRICURE SYNERGY ABLATION SYSTEM	ATRICURE INC.	Approval of labeling updates to include the results of the ABLATE Post Approval Study (PAS) for the AtriCure Synergy Ablation System.
P100047/S129	06/06/2019	Y - 135 Review Tra	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the addition of an alternate semi-automated process for preparing epoxy mixture during the HVAD pump housing assembly.
P110033/S046	06/26/2019	S - Special CBE	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Approval for inclusion of an additional inspection step to the current manual inspection method during the manufacturing process for the Juvederm Injectable Gel Implants.
P110042/S125	06/10/2019	R - Real-Time Proc	SUBCUTANEOUS ICD DEVICES: EMBLEM	BOSTON SCIENTIFIC CORPORATION	Approval for hardware changes to the Latitude NXT Patient Management System Communicators.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120008/S011	06/25/2019	N - Normal 180 Day	ALINITY I AFP ASSAY	ABBOTT LABORATORIES	Approval for the migration of the Abbott ARCHITECT AFP Assay to the Alinity i Analyzer.
P130016/S036	06/05/2019	N - Normal 180 Day	NUCLEUS HYBRID COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval order should be issued for new accessories and modifications to the firmware and software of the Nucleus 7 system, as well as a research tool named the Cochlear Research Platform.
P130026/S046	06/13/2019	R - Real-Time Proc	TACTISYS QUARTZ SYSTEM	ST. JUDE MEDICAL	Approval for software update to the TactiSys Quartz System.
P140008/S017	06/03/2019	S - Special CBE	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGERY INC	Approval for revised labeling to include current post-market surveillance information, clarifications intended to enhance safety, and additional labeling pieces intended to enhance safety.
P140031/S088	06/04/2019	R - Real-Time Proc	SAPIEN 3 ULTRA TRANSCATHETER HEART VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval for updates to the labeling of the SAPIEN 3 Ultra Transcatheter Heart Valve and Accessories regarding the option to use the eSheath as an accessory for the SAPIEN 3 Ultra procedure.
P140032/S018	06/14/2019	Y - 135 Review Tra	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for a change in the external supplier lithium source and an addition of a lithium purification process step.
P150005/S045	06/17/2019	R - Real-Time Proc	BLAZER OI, INTELLANAV OI, INTELLATIP MIFI OI, AND INTELLANAV MIFI OI CARDIAC ABLATION PERCUTANEOUS CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a minor design change to the tensioning mechanism for its temperature and open-irrigated cardiac ablation catheters.
P150012/S075	06/10/2019	R - Real-Time Proc	PACEMAKER DEVICES: INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI	BOSTONSCIENTIFIC	Approval for hardware changes to the Latitude NXT Patient Management System Communicators.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150013/S014	06/10/2019	P - Panel Track	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for the PD-L1 IHC 22C3 pharmDx. This 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) and gastric or gastroesophageal junction (GEJ) adenocarcinoma, cervical cancer, urothelial carcinoma and head and neck squamous cell carcinoma (HNSCC) tissues using EnVision FLEX visualization system on Autostainer Link 48. 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. PD-L1 protein expression in gastric or GEJ adenocarcinoma, cervical cancer, urothelial carcinoma and HNSCC is determined by using Combined Positive Score (CPS), which is the number of PDL1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. Companion Diagnostic Indications Tumor Indication* PD-L1 Expression Level Intended Use NSCLC TPS >= 1%, PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). * Gastric or GEJ adenocarcinoma 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 CPS >= 1 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying cervical cancer patients for treatment with KEYTRUDA® (pembrolizumab). Urothelial Carcinoma CPS >= 10 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying urothelial carcinoma patients for treatment with KEYTRUDA® (pembrolizumab). * HNSCC CPS >= 1 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying head and neck squamous cell carcinoma patients for treatment with KEYTRUDA® (pembrolizumab). * **See the KEYTRUDA® product label for specific clinical circumstances guiding PD-L1 testing.
P150026/S006	06/24/2019	S - Special CBE	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for a labeling change to add a contraindication.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150031/S016	06/03/2019	R - Real-Time Proc	IMPLANTABLE PLUSE GENERATOR (IPG): VERCISE PC AND VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Approval for a material and a design change to the IPG Port Plug.
P150033/S051	06/03/2019	R - Real-Time Proc	MICRA TRANSCATHETER PACING SYSTEM (TPS)	MEDTRONIC INC.	Approval for labeling updates for the Micra Transcatheter Pacing System.
P150033/S052	06/11/2019	R - Real-Time Proc	MICRA	MEDTRONIC INC.	Approval for updates to firmware version 7.4 for Model 24950 MyCareLink monitors.
P150038/S009	06/28/2019	N - Normal 180 Day	EXABLATE MODEL 4000 SYSTEM	INSIGHTEC	Approval for the Exablate 4000 Type 1.1 System SW Version 7.3 to support the operation of the Type 1.1 System SW version 7.2 and to include compatibility with the GE Premier Magnetic Resonance (MR) System.
P160038/S011	06/19/2019	O - Normal 180 Day	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Approval for a manufacturing site located at Illumina, Inc., 5200 Illumina Way, San Diego, CA 92122.
P160047/S004	06/14/2019	O - Normal 180 Day	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Approval for labeling update.
P160048/S006	06/06/2019	P - Panel Track	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for the Eversense CGM System. The device is indicated for continually measuring glucose levels in adults (age 18 and older) with diabetes for up to 90 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. The system is intended to: 1) Provide real-time glucose readings; 2) Provide glucose trend information; and 3) Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns seen over time. The system is intended for single patient use.
P160054/S017	06/04/2019	N - Normal 180 Day	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for a labeling update to include instructions on implantation procedure using surgical techniques other than full median sternotomy.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170003/S008	06/24/2019	O - Normal 180 Day	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval of the changes to the Informed Consent Form for the New Enrollment PAS Registry.

Total: 85

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N17600/S032	06/21/2019	X - 30-Day Notice	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH) FLOUR, SYRINGEAVITENE AND ULTRAFOAM	DAVOL, INC., SUB. C.R. BARD, INC.	Change to in-process manufacturing test methods and in process bioburden monitoring specifications of the Avitene bulk flour component prior to sterilization.
N18033/S105	06/07/2019	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Validation of an existing production line currently producing extended wear VISTAKON (etafilcon A) Brand Contact Lenses with changeover capability between an existing 510(k) VISTAKON etafilcon A contact lens design.
N970003/S240	06/21/2019	X - 30-Day Notice	ACCOLADE PACEMAKERS	BOSTON SCIENTIFIC CORP.	Update the inspection for leaked overmolding epoxy material.
P800002/S025	06/21/2019	X - 30-Day Notice	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH) NON-WOVEN WEB AND ENDOAVITENE	C.R. BARD, INC.	Change to in-process manufacturing test methods and in process bioburden monitoring specifications of the Avitene bulk flour component prior to sterilization.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810006/S089	06/27/2019	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC-MICROFIBRILLAR FORM (INSTAT)	INTEGRA LIFESCIENCES CORPORATION	Equipment modifications and introduction of a one-piece flow within the Cutting, Inspection and Packaging room within the Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, New Jersey.
P830061/S169	06/04/2019	X - 30-Day Notice	CAPSURE SENSE LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Replace all Calrod Heating Coils and implement single piece thermal shaping tray configuration.
P830061/S170	06/26/2019	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYworks software to Release 9.6.
P830061/S171	06/19/2019	X - 30-Day Notice	CAPSURE SENSE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Removal of the use of clean benches for several lead operations at Medtronic Singapore Operations.
P830061/S172	06/24/2019	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.
P840001/S436	06/03/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update of the thermoformed packaging trays drawings, the implementation of an inspection test method, and the documentation/procedures updates associated with the transfer of a supplier to a quality program.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840062/S076	06/27/2019	X - 30-Day Notice	COLLACOTE, COLLATAPE, COLLATAPE, COLLAPLUG, ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Equipment modifications and introduction of a one-piece flow methodology within the Cutting, Inspection and Packaging room within the Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, New Jersey.
P850010/S089	06/27/2019	X - 30-Day Notice	HELISTAT, HELITENE ABSORBABLE COLLAGEN HEMAOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Equipment modifications and introduction of a one-piece flow within the Cutting, Inspection and Packaging room within the Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, New Jersey.
P850079/S083	06/10/2019	X - 30-Day Notice	METHAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Introduction of manufacturing equipment at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P850089/S141	06/26/2019	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYworks software to Release 9.6.
P850089/S142	06/24/2019	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.
P860004/S332	06/03/2019	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM AND ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Update of the thermoformed packaging trays drawings, the implementation of an inspection test method, and the documentation/procedures updates associated with the transfer of a supplier to a quality program.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S190	06/11/2019	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, RSR PERICARDIAL AORTIC BIOPROSTHESIS, THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA PERICARDIAL AORTIC BIOPROSTHESIS, MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, PLUS PERICARDIAL MITRAL BIOPROSTHESIS, THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, AND MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Removal of two redundant visual inspections for valve leaflets.
P890003/S413	06/26/2019	X - 30-Day Notice	CAPSURE VDD-2 LEADAND VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Update the FACTORYworks software to Release 9.6.
P890003/S414	06/24/2019	X - 30-Day Notice	CAPSURE VDD-2 LEAD AND VITATRON BRILLIANT S+VDD LEAD	MEDTRONIC, INC.	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900061/S154	06/26/2019	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYworks software to Release 9.6.
P910073/S156	06/19/2019	X - 30-Day Notice	RELIANCE 4-FRONT STEROID ELUTING LEADS	BOSTON SCIENTIFIC	Updates to potency and elution acceptance criteria for finished leads.
P920015/S230	06/19/2019	X - 30-Day Notice	SPRINT QUATTRO LEAD	MEDTRONIC INC.	Update the proximal sleeve head component, to update the helix shaft assembly fixture and to add visual inspection criteria for the proximal sleeve head of Sprint Quattro leads.
P920015/S231	06/27/2019	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT AND SPRINT QUATTRO LEAD	MEDTRONIC INC.	Update the receiving inspection criteria of 20% glass-filled polyurethane.
P920015/S232	06/26/2019	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT, IS-1 CONNECTOR PORT PIN PLUG KIT, TRANSVENE CS/SVC LEAD AND SPRINT QUATTRO LEAD	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P920015/S233	06/24/2019	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT AND SPRINT QUATTRO LEAD	MEDTRONIC INC.	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.
P930038/S096	06/11/2019	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATION	Transfer the anchor component manufacturing to a new manufacturing facility.
P930039/S198	06/04/2019	X - 30-Day Notice	CAPSUREFIX NOVUS LEADS	MEDTRONIC, INC.	Replace all Calrod Heating Coils and implement single piece thermal shaping tray configuration.
P930039/S199	06/26/2019	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD AND VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Update the FACTORYworks software to Release 9.6.
P930039/S200	06/19/2019	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD	MEDTRONIC, INC.	Removal of the use of clean benches for several lead operations at Medtronic Singapore Operations.
P930039/S201	06/24/2019	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD AND VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950024/S085	06/26/2019	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P960009/S350	06/03/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update of the thermoformed packaging trays drawings, the implementation of an inspection test method, and the documentation/procedures updates associated with the transfer of a supplier to a quality program.
P960040/S439	06/21/2019	X - 30-Day Notice	NG3 AND NG4 IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS)	BOSTON SCIENTIFIC	Update the inspection for leaked overmolding epoxy material.
P960042/S066	06/28/2019	X - 30-Day Notice	SPECTRANETICS LASER SHEATH (SLS) II AND GLIDELIGHT LASER SHEATH	SPECTRANETICS CORP.	Add an alternate supplier for the bifurcate subcomponent and update the respective inspection equipment.
P970004/S290	06/03/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Update of the thermoformed packaging trays drawings, the implementation of an inspection test method, and the documentation/procedures updates associated with the transfer of a supplier to a quality program.
P980016/S708	06/05/2019	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR/VR ICD, EVERA XT DR/ VR ICD, MIRRO/PRIMO MRI DR/VR ICD, PROTECTA ICD, PROTECTA VR/XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the material and deposition process on diodes used in hybrids.
P980016/S709	06/21/2019	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the test method and instrumentation for assessing electrolyte material.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S710	06/26/2019	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR/VR ICD, EVERA XT DR/ VR ICD, MIRRO MRI DR/VR ICD, PRIMO MRI VR/DR ICD, PROTECTA ICD, PROTECTA VR/XT ICD, SECURA DR ICD, VISIA AF MRI DF1 ICD, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the FACTORYworks software to Release 9.6.
P980035/S596	06/21/2019	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the test method and instrumentation for assessing electrolyte material.
P980035/S597	06/26/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR/SR MRI IPG, ASTRA S DR/SR MRI IPG, ASTRA XT DR/SR MRI IPG, ATTESTA DR/SR MRI IPG, AZURE S DR/SR MRI IPG, AZURE XT DR/SR MRI IPG, RELIA IPG AND SPHERA DR/SR MRI IPG	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P980050/S122	06/26/2019	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P000014/S035	06/19/2019	X - 30-Day Notice	VITROS ANTI-HBS	ORTHO-CLINICAL DIAGNOSTICS , INC.	Establishment of a new Environmental Controlled Area Room at an existing facility.
P000021/S040	06/20/2019	X - 30-Day Notice	DIMENSION TPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Addition of an alternate supplier for the source lamp that is used in the manufacture of the Dimension family of instruments for use with the Dimension® TPSA Flex® reagent cartridge and Dimension® FPSA Flex® reagent cartridge
P000021/S041	06/26/2019	X - 30-Day Notice	DIMENSION VISTA TPSA FLEX REAGENT CARTRIDGE (K6451)	SIEMENS HEALTHCARE DIAGNOSTICS	Add an alternate supplier to manufacture resin used in the production of Dimension Vista® Chemibead and Sensibead reagents.
P000044/S040	06/19/2019	X - 30-Day Notice	VITROS HBSAG	ORTHO-CLINICAL DIAGNOSTICS , INC.	Establishment of a new Environmental Controlled Area Room at an existing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S505	06/21/2019	X - 30-Day Notice	NG3 AND NG4 CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS)	BOSTON SCIENTIFIC CORP.	Update the inspection for leaked overmolding epoxy material.
P010015/S408	06/21/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the test method and instrumentation for assessing electrolyte material.
P010015/S409	06/26/2019	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, CONSULAT CRT-P, PERCEPA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P010015/S412	06/24/2019	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD AND ATTAIN OTW LV LEAD	MEDTRONIC INC.	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.
P010021/S032	06/19/2019	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Establishment of a new Environmental Controlled Area Room at an existing facility.
P010030/S118	06/24/2019	X - 30-Day Notice	LIFEVST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Addition of a cleaning process for connector pins during rework.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S668	06/05/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAV 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/XT CRT-D AND VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to the material and deposition process on diodes used in hybrids.
P010031/S669	06/21/2019	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the test method and instrumentation for assessing electrolyte material.
P010031/S670	06/26/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUARD CRT-P, 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 AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the FACTORYworks software to Release 9.6.
P020011/S014	06/21/2019	X - 30-Day Notice	APTIMA HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Transfer in-process, QC testing services for raw materials used in specific components to a separate contractor facility.
P020027/S035	06/20/2019	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Addition of an alternate supplier for the source lamp that is used in the manufacture of the Dimension family of instruments for use with the Dimension® TPSA Flex® reagent cartridge and Dimension® FPSA Flex® reagent cartridge
P020027/S036	06/26/2019	X - 30-Day Notice	DIMENSION VISTA TPSA FLEX REAGENT CARTRIDGE (K6452)	SIEMENS HEALTHCARE DIAGNOSTICS	Add an alternate supplier to manufacture resin used in the production of Dimension Vista® Chemibead and Sensibead reagents.

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P020036/S041	06/21/2019	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Transfer of Final Release activities from the Cordis Miami Lakes site to the Cordis de Mexico site.
P020056/S049	06/27/2019	X - 30-Day Notice	NATRELLE SILICONE FILLED BREAST IMPLANTS	ALLERGAN	Implementing changes to the gel filling process, specifically, changing from manual filling to an automated process.
P030004/S018	06/06/2019	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Remove mycoplasma testing from the incoming inspection acceptance criteria for non-sterile DMSO.
P030004/S019	06/17/2019	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Supplier manufacturing site change for the molded tray components of the Onyx Liquid Embolic System.
P030005/S185	06/21/2019	X - 30-Day Notice	ACCOLADE CRT ¿ PACEMAKERS (CRT-PS)	GUIDANT CORP.	Update the inspection for leaked overmolding epoxy material.
P030011/S069	06/26/2019	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Change of location for a component supplier for the Freedom Driver.
P030024/S029	06/19/2019	X - 30-Day Notice	VITROS ANTI-HBC	ORTHO-CLINICAL DIAGNOSTICS	Establishment of a new Environmental Controlled Area Room at an existing facility.
P030026/S036	06/19/2019	X - 30-Day Notice	VITROS ANTI-HBC IGM	ORTHO-CLINICAL DIAGNOSTICS, INC.	Establishment of a new Environmental Controlled Area Room at an existing facility.
P030036/S110	06/26/2019	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the FACTORYworks software to Release 9.6.
P030047/S039	06/21/2019	X - 30-Day Notice	PRECISE PRO RX NITINOL STENT SYSTEM	CORDIS CORP.	Transfer of Final Release activities from the Cordis Miami Lakes site to the Cordis de Mexico site.
P040024/S111	06/19/2019	X - 30-Day Notice	RESTYLANE INJECTABLE GELS	Q-MED AB	Change in the sterilizer provider for the plungers used for Restylane, Restylane-L, Perlane, Restylane Lyft with Lidocaine and Restylane Silk.
P040024/S113	06/20/2019	X - 30-Day Notice	RESTYLANE NASHA	Q-MED AB	Outsourcing the method of analysis for D-value determination of biological indicators produced by Galderma Uppsala, Sweden.
P040044/S084	06/21/2019	X - 30-Day Notice	MYNX CONTROL VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Utilize an alternative sterilization site already approved under this PMA for sterilization of the Mynx CONTROL vascular closure device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040045/S109	06/12/2019	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification to the post-hydration process for VISTAKON® (senofilcon A) Brand Contact Lenses.
P040046/S030	06/27/2019	X - 30-Day Notice	NATRELLE 410 HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE FILLED BREAST IMPLANTS	ALLERGAN	Implementing changes to the gel filling process, specifically, changing from manual filling to an automated process.
P040047/S053	06/07/2019	X - 30-Day Notice	COAPTITE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Update the LLOYD test instrument firmware and instrument control software.
P040047/S054	06/07/2019	X - 30-Day Notice	COAPTITE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	New moisture analyzer, Mettler Toledo model HE73, to replace a discontinued model moisture analyzer Mettler Toledo HR83.
P050037/S095	06/06/2019	X - 30-Day Notice	RADIESSE 1.5CC AND 0.8CC	MERZ NORTH AMERICA, INC	Upgrades to the instrument control and data acquisition software of the accelerated surface area and porosimetry system.
P050037/S096	06/07/2019	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Update the LLOYD test instrument firmware and instrument control software.
P050037/S097	06/07/2019	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	New moisture analyzer, Mettler Toledo model HE73, to replace a discontinued model moisture analyzer Mettler Toledo HR83.
P050052/S112	06/06/2019	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMAL FILLER (1.5CC AND 0.8CC)	MERZ NORTH AMERICA, INC	Upgrades to the instrument control and data acquisition software of the accelerated surface area and porosimetry system.
P050052/S113	06/07/2019	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Update the LLOYD test instrument firmware and instrument control software.
P050052/S114	06/07/2019	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANY AND RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	New moisture analyzer, Mettler Toledo model HE73, to replace a discontinued model moisture analyzer Mettler Toledo HR83.
P060001/S028	06/17/2019	X - 30-Day Notice	PROTÉGÉ GPS AND PROTÉGÉ RX CAROTID STENT SYSTEMS, AND PROTÉGÉ GPS PERIPHERAL STENT SYSTEMS	MEDTRONIC VASCULAR INC	Alternate manufacturing facility for an existing supplier.
P060006/S096	06/18/2019	X - 30-Day Notice	EXPRESS SD PREMOUNTED STENT SYSTEM (ESD)	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for stent finishing chemicals.
P060039/S094	06/26/2019	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060039/S095	06/24/2019	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.
P080006/S134	06/27/2019	X - 30-Day Notice	ATTAIN PERFORMA LEAD AND ATTAIN STABILITY QUAD MRI LEAD	MEDTRONIC INC.	Update the receiving inspection criteria of 20% glass-filled polyurethane.
P080006/S135	06/26/2019	X - 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEAD AND ATTAIN STABILITY QUAD MRI LEAD	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P080006/S136	06/24/2019	X - 30-Day Notice	ATTAIN ABILITY LEAD AND ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.
P080011/S094	06/10/2019	X - 30-Day Notice	BIOFINITY (COMFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Introduction of manufacturing equipment at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080025/S185	06/03/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Update of the thermoformed packaging trays drawings, the implementation of an inspection test method, and the documentation/procedures updates associated with the transfer of a supplier to a quality program.
P090003/S047	06/18/2019	X - 30-Day Notice	EXPRESS LD PREMOUNTED ILIAC STENT SYSTEM (ELD)	BOSTON SCIENTIFIC CORPORATION	Addition of an alternate vendor for stent finishing chemicals.
P090013/S299	06/26/2019	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Update the FACTORYworks software to Release 9.6.
P090013/S300	06/24/2019	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Facility improvements to achieve ISO 14644-1 Class 8 Cleanroom certification.
P090016/S032	06/18/2019	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Change of the needle supplier for the Belotero Balance Dermal Filler.
P090028/S017	06/19/2019	X - 30-Day Notice	VITROS HBEAG	ORTHO-CLINICAL DIAGNOSTICS, INC.	Establishment of a new Environmental Controlled Area Room at an existing facility.
P100001/S016	06/19/2019	X - 30-Day Notice	VITROS ANTI-HBE	ORTHO-CLINICAL DIAGNOSTICS	Establishment of a new Environmental Controlled Area Room at an existing facility.
P100010/S095	06/17/2019	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Add inspections on the inner balloon.

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P100013/S020	06/21/2019	X - 30-Day Notice	EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS CORPORATION	Transfer of Final Release activities from the Cordis Miami Lakes site to the Cordis de Mexico site.
P100026/S071	06/17/2019	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the magnet non-sterile finished goods packaging to align with the component's supplier packaging.
P100026/S072	06/24/2019	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Change the glass weave used to produce the inner core in the fabrication of the printed circuit board (PCB) of the RNS Neurostimulator (Model RNS-320).
P100044/S042	06/27/2019	X - 30-Day Notice	PROPEL, PROPEL MINI AND PROPEL CONTOUR SINUS IMPLANTS	INTERSECT ENT	Modification of incoming quality assurance inspection criteria and titles for the packaging tray and lid components.
P100047/S140	06/28/2019	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST DEVICE SYSTEM	MEDTRONIC	Update to the leak tester software and firmware.
P110010/S165	06/18/2019	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLAATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE), PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM, AND PROMUS ELITE EVEROLIMUS-ELUTING PLAATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for stent finishing chemicals.
P110010/S166	06/14/2019	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Remove an additional offline inspection after troubleshooting during the balloon forming process.
P110014/S008	06/19/2019	X - 30-Day Notice	MARGINPROBE SYSTEM	DUNE MEDICAL DEVICES INC	New sterilization chamber (No. 8) that has been installed and validated at the Company¿s approved contract sterilizer, Mediplast Isreal, Ltd. (Tel Aviv Israel, FDA Registration Number 3008729892).

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P110023/S027	06/17/2019	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEMS AND EVERFLEX SELF-EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEMS	MEDTRONIC VASCULAR INC	Alternate manufacturing facility for an existing supplier.
P110035/S050	06/18/2019	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for stent finishing chemicals.
P120002/S016	06/21/2019	X - 30-Day Notice	S.M.A.R.T. CONTROL AND S.M.A.R.T. VASCULAR STENT SYSTEM	CORDIS CORP.	Transfer of Final Release activities from the Cordis Miami Lakes site to the Cordis de Mexico site.
P120017/S018	06/26/2019	X - 30-Day Notice	MYOCARDIAL PACKING LEAD	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P120020/S023	06/13/2019	X - 30-Day Notice	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Add an alternate manufacturing site for a supplier of delivery system components.
P130008/S044	06/21/2019	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Manufacturing change to reduce vacuum bake time for the Model 3028 Implantable Pulse Generator prior to case seam welding.
P130013/S029	06/13/2019	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE WITH DELIVEY SYSTEM	BOSTON SCIENTIFIC CORP.	Transfer the nitinol tubing grinding operation to another vendor.
P130013/S030	06/04/2019	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE DEVICE AND DELIVERY SYSTEM AND WATCHMAN ACCESS SYSTEM	BOSTON SCIENTIFIC CORP.	Reduce the frequency of pouch seal strength testing on the WATCHMAN Access System and Delivery System.
P130017/S031	06/13/2019	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Qualified additional storage space.
P130026/S047	06/19/2019	X - 30-Day Notice	TACTICATH QUARTZ CONTACT FORCE ABLATION CATHETER	ST. JUDE MEDICAL	Process change to aid in assembly of the device.

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P130030/S060	06/18/2019	X - 30-Day Notice	REBEL PLANTINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for stent finishing chemicals.
P140003/S052	06/02/2019	X - 30-Day Notice	IMPELLA CP WITH SMARTASSIST	ABIOMED, INC.	Add two alternative suppliers for a pump housing sub-component used in the Impella CP with SmartAssist System.
P140003/S053	06/28/2019	X - 30-Day Notice	IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0 AND IMPELLA LD SYSTEMS	ABIOMED, INC.	Relocation of selected manufacturing processes.
P140003/S054	06/28/2019	X - 30-Day Notice	IMPELLA 5.0/LD	ABIOMED, INC.	Implementation of a second supplier a sub-assembly for Impella 5.0/LD, and Impella RP.
P140010/S046	06/27/2019	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Change to revert a manufacturing process to a previously validated process.
P140018/S015	06/19/2019	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Use of a Laboratory Information Management System (LIMS) as an alternative to the current paper based processes within the analytical testing laboratory.
P140028/S040	06/18/2019	X - 30-Day Notice	INNOVA VASCULAAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Addition of an alternate vendor for stent finishing chemicals.
P140031/S089	06/11/2019	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE AND SAPIEN 3 ULTRA TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCE S, LLC.	Removal of two redundant visual inspections for valve leaflets.
P140032/S034	06/03/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update of the thermoformed packaging trays drawings, the implementation of an inspection test method, and the documentation/procedures updates associated with the transfer of a supplier to a quality program.
P150001/S068	06/14/2019	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Raising the production capacity of the Chemical Vapor Deposition (CVD) chamber 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, and MiniMed 670G systems.

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P150001/S069	06/20/2019	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Addition of a new ISO Class 8 cleanroom for the fabrication of the Guardian Sensor (3). The Guardian Sensor (3) is a component of the Medtronic MiniMed 670G System, MiniMed 630G System, and Guardian Connect System.
P150002/S003	06/21/2019	X - 30-Day Notice	INCRAFT (R) AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Movement of the manufacturing facility for a critical supplier.
P150002/S004	06/21/2019	X - 30-Day Notice	INCRAFT(R) AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Transfer of Final Release activities from the Cordis Miami Lakes site to the Cordis de Mexico site.
P150003/S047	06/18/2019	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARAY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of an alternate vendor for stent finishing chemicals.
P150003/S048	06/11/2019	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to the incoming specification of the tetrahydrofuran solvent used in the Synergy Everolimus-Eluting Platinum Chromium Coronary Stent manufacturing.
P150003/S049	06/14/2019	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Remove an additional offline inspection after troubleshooting during the balloon forming process.
P150012/S079	06/21/2019	X - 30-Day Notice	ACCOLADE MRI PACEMAKERS	BOSTONSCIENTIFIC	Update the inspection for leaked overmolding epoxy material.
P150014/S028	06/06/2019	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Implementation of a new bulk manufacturing and filling suite.
P150014/S029	06/06/2019	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Scale up for manufacturing of a sub-bulk reagent and subsequent changes to filling operations for a critical component.
P150015/S030	06/06/2019	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Implementation of a new bulk manufacturing and filling suite.
P150015/S031	06/06/2019	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Scale up for manufacturing of a sub-bulk reagent and subsequent changes to filling operations for a critical component.

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P150021/S042	06/20/2019	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Manufacturing change in the order of inspections of parts by a vision system during the sensor pack assembly for the Libre sensor. The Libre sensor is a component of the Freestyle Libre Pro Flash Glucose Monitoring System and the Freestyle Libre 14 day Flash Glucose Monitoring System.
P150030/S007	06/07/2019	X - 30-Day Notice	R3 DELTA CERAMIC ACETABULAR SYSTEM	SMITH & NEPHEW, INC.	Cooling lubricant change for the R3¿ delta Ceramic Acetabular System.
P150031/S020	06/05/2019	X - 30-Day Notice	VERCISE PC AND VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Adding an alternate qualified supplier and a test equipment system software update for the Printed Circuit Board Assembly (PCBA) used in the Programming Wand for the Vercise PC and Vercise Gevia Deep Brain Stimulation Systems.
P150033/S055	06/26/2019	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Update the FACTORYworks software to Release 9.6.
P150036/S040	06/11/2019	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Removal of two redundant visual inspections for valve leaflets.
P150048/S035	06/12/2019	X - 30-Day Notice	EDWARDS PERICRADIAL AORTIC BIOPROSTHESIS AND INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Removal of APFO from the PTFE yarn resin.
P150048/S036	06/11/2019	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, PERICARDIAL MITRAL BIOPROSTHESIS, AND INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Removal of two redundant visual inspections for valve leaflets.
P160003/S008	06/05/2019	X - 30-Day Notice	PRO-KINETIC ENERGY CORONARY STENT SYSTEM, PAPYRUS	BIOTRONIK, INC.	Replace the manual lot verification for PRO-Kinetic Energy Coronary Stent System with an automated lot verification station.
P160007/S021	06/14/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Raising the production capacity of the Chemical Vapor Deposition (CVD) chamber 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, and MiniMed 670G systems.
P160007/S022	06/20/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of a new ISO Class 8 cleanroom for the fabrication of the Guardian Sensor (3). The Guardian Sensor (3) is a component of the Medtronic MiniMed 670G System, MiniMed 630G System, and Guardian Connect System.
P160008/S006	06/19/2019	X - 30-Day Notice	SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS	HEARTSINE TECHNOLOGIES LLC	Relocate some manufacturing operations to a different building within the same establishment.

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P160017/S064	06/14/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Raising the production capacity of the Chemical Vapor Deposition (CVD) chamber 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, and MiniMed 670G systems.
P160017/S065	06/20/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of a new ISO Class 8 cleanroom for the fabrication of the Guardian Sensor (3). The Guardian Sensor (3) is a component of the Medtronic MiniMed 670G System, MiniMed 630G System, and Guardian Connect System.
P160023/S014	06/21/2019	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Transfer in-process, QC testing services for raw materials used in specific components to a separate contractor facility.
P160030/S035	06/20/2019	X - 30-Day Notice	FREESTYLE LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Manufacturing change in the order of inspections of parts by a vision system during the sensor pack assembly for the Libre sensor. The Libre sensor is a component of the Freestyle Libre Pro Flash Glucose Monitoring System and the Freestyle Libre 14 day Flash Glucose Monitoring System.
P160041/S021	06/06/2019	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Implementation of a new bulk manufacturing and filling suite.
P160041/S022	06/06/2019	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Scale up for manufacturing of a sub-bulk reagent and subsequent changes to filling operations for a critical component.
P160042/S009	06/04/2019	X - 30-Day Notice	REVANESSE VERSA AND REVANESSE VERSA+	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Change to the Water For Injection System for Revanesse Versa and Revanesse Versa+.
P160048/S009	06/26/2019	X - 30-Day Notice	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Increased load size for a previously approved sterilization method, as well as approval for a new sealing device for the sterile barrier of the sensor component of the Eversense CGM system.
P160049/S006	06/12/2019	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	New labeling software for printing product labels.
P160055/S006	06/20/2019	X - 30-Day Notice	RXSIGHT LIGHT ADJUSTABLE LENS: LIGH DELIVERY DEVICE	RXSIGHT, INC.	Use alternate manufacturing tools to manufacture the Light Adjustable Lens.
P170006/S014	06/28/2019	X - 30-Day Notice	AVALUS BIOPROSTHESIS	MEDTRONIC INC.	Utilization of alternate bovine pericardial tissue patch sizes during the fixation process.
P170007/S003	06/08/2019	X - 30-Day Notice	DUROLANE, HYALURONIC ACID, STABILIZED SINGLE INJECTION	BIOVENTUS LLC	Alternative source of the sodium chloride solution utilized in the manufacture of DUROLANE.

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P170011/S012	06/28/2019	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Relocation of selected manufacturing processes.
P170011/S013	06/28/2019	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Implementation of a second supplier a sub-assembly for Impella 5.0/LD, and Impella RP.
P170012/S018	06/15/2019	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Change to the bioburden determination method.
P180011/S008	06/18/2019	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate vendor for stent finishing chemicals.
P180029/S001	06/04/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Transfer of component-level tissue fixation and tissue solution manufacturing activities to a different manufacturing facility.
P180029/S004	06/22/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Manufacturing and specification changes to the adaptive seal component of the 27-mm LOTUS Edge Valve.
P180029/S006	06/19/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Automation of a manual dimensional inspection.

Total: 165