PMA Monthly approvals from 9/1/2019 to 9/30/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190006	09/06/2019	PMAO - PMA Origir	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGI ES, INC.	Approval for the Axonics Sacral Neuromodulation System. This device is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S241	09/18/2019	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for hardware modifications to the IS-1 lead bore cavity and spring coil in the IS-1 pulse generator header for all pacemakers and cardiac resynchronization therapy pacemakers within the Accolade family and a subset of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators within the NG3 and NG4 families.
P830063/S012	09/18/2019	R - Real-Time Proc	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATION AL, INC.	Approval for the use of the Prismaflex TPE2000 Set with the PrisMax Control Unit (Version 2) and modifications to the Instructions for Use.
P860004/S325	09/06/2019	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for spot welding additions to the motor assembly of the SynchroMed II (SMII) Implantable Drug Infusion Pump (Model 8637).
P910056/S037	09/06/2019	S - Special CBE	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval for an off-axis cosmetic inspection for lathe lines and environmental control for the room temperature in the polishing room.

Data as of 10/04/2019 03:16 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930016/S057	09/09/2019	P - Panel Track	VISX EXCIMER LASER SYSTEM MODELS "B" AND "C"	AMO MANUFACTURING USA, LLC	Approval for the STAR S4 IR® Excimer Laser System and iDESIGN® Refractive Studio. This device is indicated for wavefront-guided photorefractive keratectomy (PRK) in patients: 1) with myopia, with or without astigmatism, as measured by iDESIGN® Refractive Studio System with spherical equivalent up to -8.00 D, and cylinder up to -3.00 D. 2) with agreement between manifest refraction (adjusted for optical infinity) and iDESIGN® Refractive Studio System refraction as follows: a) Spherical Equivalent: Magnitude of the difference is less than 0.625 D. b) Cylinder: Magnitude of the difference is less than or equal to 0.5 D. 3) in patients 18 years of age or older. 4) with refractive stability (a change of </= 1.0 D in manifest refraction spherical equivalent for a minimum of 12 months prior to surgery), and 5) with wavefront capture diameter of at least 4 mm.
P950009/S022	09/05/2019	N - Normal 180 Day	AUTOPAP(R) 300 QC AUTOMATIC PAP SCREENER/QC SYSTEM	BD DIAGNOSTICS	Approval for hardware and associated software modifications necessary to achieve compliance to the European Union RoHS Directive.
P950039/S038	09/03/2019	R - Real-Time Proc	THINPREP(R) PROCESSOR, MODEL TP 2000	HOLOGIC, INC.	Approval for software upgrade to the ThinPrep 5000 processor
P960009/S357	09/04/2019	S - Special CBE		MEDTRONIC INC.	Approval of the Changes Being Effected (CBE) for the Deep Brain Stimulation Therapy System for Parkinson's Disease. The changes being effected include changes to Medtronic DBS Therapy physician and patient labeling, to enhance and harmonize the information regarding the risks of depression, suicide ideation, and suicide across the device type.
P960040/S440	09/18/2019	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for hardware modifications to the IS-1 lead bore cavity and spring coil in the IS-1 pulse generator (PG) header for all pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) within the Accolade family and a subset of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-D) within the NG3 and NG4 families.
P970003/S226	09/05/2019	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for Symmetry Model 8103 Generator for Depression, updates to MRI Labeling so that the Model 103 and Model 8103 Generator reflect the same expanded MRI conditions specified for the Model 105, Model 106 and Model 1000 Generator; and Model 3000 v1.5 Programmer Updates.
P970004/S294	09/11/2019	R - Real-Time Proc	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for changes to the labeling to provide information regarding the impact of certain cycling settings on battery longevity.
P980023/S093	09/04/2019	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for the Ilivia Neo family of ICD and CRT-D devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980025/S004	09/05/2019	O - Normal 180 Day		CARESTREAM DENTAL LLC	Approval for a manufacturing site in Atlanta, GA, USA for Logicon Caries Detection Software.
P980040/S095	09/13/2019	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for an additional packaging configuration for SENSAR®, TECNIS® and TECNIS® OptiBlue one-piece IOLs into the new SmartLOAD Delivery Technology
P990040/S029	09/18/2019	N - Normal 180 Day	TRUFILL N-BUTYL CYANOACRYLATE LIQUID EMBOLIC SYSTEM	CODMAN & SHURTLEFF, INC.	Approval for a change to the BHA concentration specified for n-BCA during manufacture, prior to the dry heat sterilization process.
P000006/S051	09/05/2019	R - Real-Time Proc	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Approval to update the device labeling to incorporate instructions regarding the use of a manual modeling technique when the device is implanted in the presence of Peyronie¿s Disease.
P000009/S080	09/04/2019	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for the Ilivia Neo family of ICD and CRT-D devices.
P000018/S050	09/19/2019	R - Real-Time Proc		BEST VASCULAR, INC	Approval for the design and manufacturing changes to your Indicator of Source Train.
P000025/S111	09/27/2019	N - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for MAESTRO 8.0 fitting software.
P010003/S035	09/05/2019	Y - 135 Review Tra	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Approval for a modification to the extraction method of the mixing and spreader tips for the Limulus Amebocyte Lysate (LAL) endotoxin testing, as well as modifications to the test method for LAL endotoxin testing.
P010012/S506	09/18/2019	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for hardware modifications to the IS-1 lead bore cavity and spring coil in the IS-1 pulse generator (PG) header for all pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) within the Accolade family and a subset of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-D) within the NG3 and NG4 families.
P010030/S121	09/19/2019	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for a new material used in the LifeVest garment.
P010030/S122	09/19/2019	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for the redesign of the electrode belt trunk cable connector overmold on the LifeVest Wearable Defibrillator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010032/S149	09/17/2019	N - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for updating the Clinician Programmer Application and Patient Controller Application to support an expanded allowable impedance range for MR Conditional devices entering MRI Mode, and to amend your labeling and software to change the term Program Mode to Dosage and Cycle to Intermittent.
P010032/S151	09/09/2019	R - Real-Time Proc	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for rebranding the Proclaim Elite device to the Proclaim XR and for changing the company name from SJM to Abbott and approval for revising the labeling to include additional cycling parameters within previously approved cycling range on the 36600, 3661, 3662, and 3663 Proclaim Implanted Pulse Generator models.
P010032/S154	09/26/2019	R - Real-Time Proc	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval for minor packaging design changes to the Torque Wrench and 8-Channel Adapters Kits
P030005/S186	09/18/2019	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for hardware modifications to the IS-1 lead bore cavity and spring coil in the IS-1 pulse generator (PG) header for all pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) within the Accolade family and a subset of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-D) within the NG3 and NG4 families.
P030011/S072	09/19/2019	R - Real-Time Proc	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for a change in the velour material on the cannula of the SynCardia temporary Total Artificial Heart (TAH-t).
P030017/S327	09/13/2019	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of the 50 cm Infinion CX Lead (SC-2317-50) and the 50 cm Artisan MRI lead (SC-8416-50) to the head-only MR conditional labeling for the Precision Spectra and Spectra WaveWriter spinal cord stimulator (SCS) systems.
P040024/S115	09/30/2019	R - Real-Time Proc	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for the removal of testing of heavy metals in raw materials as per USP<231> and replacing it by a risk analysis on the final product based on ICH Q3D guideline for Elemental Impurities for Restylane Injectable Gels
P050006/S077	09/17/2019	O - Normal 180 Day	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for minor changes to the PAS Protocol.
P050023/S132	09/24/2019	O - Normal 180 Day	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval of the revised protocols (Versions May 6, 2019 and September 6, 2019) for the post-approval study (PAS) protocol.
P050023/S133	09/04/2019	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for the Ilivia Neo family of ICD and CRT-D devices.
P070008/S104	09/24/2019	O - Normal 180 Day	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval of the revised protocols (Versions May 6, 2019 and September 6, 2019) for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080011/S085	09/18/2019	Y - 135 Review Tra	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for a Modified Automated Inspection System (AIS) Distortion Tolerance for use in the manufacture of Biofinity toric (comfilcon A) and Biofinity XR toric (comfilcon A) soft contact lenses.
P080012/S060	09/23/2019	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for introducing Software Version 2.01.5 for the Prometra Clinician Programmer, Cat. Nos. 12828 and 13828, used with Prometra and Prometra II Programmable Pumps and minor labeling changes to explain reduced functionality accompanying this revision.
P080025/S189	09/11/2019	R - Real-Time Proc	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for changes to the labeling to provide information regarding the impact of certain cycling settings on battery longevity.
P100006/S009	09/11/2019	N - Normal 180 Day	AUGMENT BONE GRAFT	BIOMIMETICS THERAPEUTICS,LLC	Approval for use of lot UV0023 of the drug substance rhPDGF-BB manufactured by Novartis to be used in the manufacture of the drug product used in AUGMENT Bone Graft and AUGMENT Injectable.
P100022/S034	09/13/2019	S - Special CBE		COOK MEDICAL INCORPORATED	Approval for updates to the device labeling.
P100026/S063	09/19/2019	Y - 135 Review Tra	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for the current NeuroPace supplier of the Tunneling Tool Straw (Straw), Teleflex Medical OEM (located at 50 Plantation Drive, Jaffrey NH 03452), to source raw polytetrafluoroethylene (PTFE) resin used in the Straw manufacture from an alternate supplier.
P110014/S009	09/20/2019	O - Normal 180 Day		DUNE MEDICAL DEVICES INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P110020/S033	09/25/2019	R - Real-Time Proc	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for a formulation change to the cobas® DNA Sample Preparation Kit used with the cobas® 4800 BRAF V600 Mutation Test (P110020).
P120011/S015	09/19/2019	Y - 135 Review Tra	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for a change to the manufacturing tooling and heighten quality control for patch component #7 inside diameter.
P120016/S027	09/18/2019	N - Normal 180 Day	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Approval for modifying the braid design and related device components.
P120019/S029	09/25/2019	R - Real-Time Proc	COBAS EGFR MUTATION TEST	ROCHE	Approval for a formulation change to the cobas® DNA Sample Preparation Kit used with the cobas® EGFR Mutation Test for plasma and tissues specimens.
P120022/S020	09/26/2019	S - Special CBE		QIAGEN MANCHESTER LTD	Approval for updates to the limitations section of the instructions for use to include additional cross-reactivity information for the therascreen® EGFR RGQ PCR Kit.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130005/S021	09/19/2019	N - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for inclusion and use of the ViperWire Advance Coronary Guide Wire with Flex Tip with the Diamondback 360 Coronary Orbital Atherectomy System.
P130009/S100	09/17/2019	S - Special CBE		EDWARDS LIFESCIENCES, LLC.	Approval for the introduction of 100% visual inspection of the Sapien XT introducer sheath.
P130017/S029	09/20/2019	N - Normal 180 Day	COLOGUARD	EXACT SCIENCES CORPORATION	Approval to expand the indicated age range for Cologuard Stool DNA-Based Colorectal Cancer Screening Test from 50 years or older to 45 years or older.
P130021/S059	09/19/2019	N - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for various modifications to the CoreValve Evolut PRO System. The device, as modified, will be marketed under the trade name Evolut PRO+ System.
P130024/S029	09/13/2019	S - Special CBE		LUTONIX	Approval for updates to the device labeling.
P140003/S050	09/24/2019	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for various modifications to the Impella 5.0 System. The modified system is trademarked as ¿Impella 5.5 with SmartAssist System.¿
P140003/S056	09/24/2019	S - Special CBE		ABIOMED, INC.	Approval for the addition of information on heparin anticoagulation management to the Impella systems instructions for use (IFUs).
P140004/S014	09/10/2019	O - Normal 180 Day	SUPERION INTERSPINOUS SPACER	BOSTON SCIENTIFIC NEUROMODULATION	Approval for the revised post-approval study protocol.
P140009/S046	09/17/2019	N - Normal 180 Day	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for updating the Clinician Programmer Application and Patient Controller Application to support an expanded allowable impedance range for MR Conditional devices entering MRI Mode, and to amend the labeling and software to change the term Program Mode to Dosage and Cycle to Intermittent.
P140009/S049	09/26/2019	R - Real-Time Proc	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for minor packaging design changes to the Torque Wrench and 8-Channel Adapters Kits
P140009/S050	09/05/2019	S - Special CBE		ABBOTT MEDICAL	Approval of the Changes Being Effected (CBE) for the Infinity Deep Brain Stimulation System. The changes being effected include: 1) Changes to DBS System physician and patient labeling, to enhance and harmonize the information regarding the risks of depression, suicide ideation, and suicide across the device type; and 2) A minor change to the Program Storage Capacity Section of the Infinity IPG Clinicians Manual to updated from 15 programs with 1 stim set per lead to 15 programs to reflect the addition of the MultiStim feature.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140010/S047	09/13/2019	S - Special CBE		MEDTRONIC INC.	updates to your device labeling
P140029/S019	09/30/2019	R - Real-Time Proc	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for the removal of testing of heavy metals in raw materials as per USP<231> and replacing it by a risk analysis on the final product based on ICH Q3D guideline for Elemental Impurities for Restylane Refyne and Restylane Defyne.
P140031/S094	09/17/2019	S - Special CBE		EDWARDS LIFESCIENCES, LLC.	Approval for the introduction of 100% visual inspection of the Sapien 3 introducer sheath.
P150004/S029	09/17/2019	N - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for updating the Clinician Programmer Application and Patient Controller Application to support an expanded allowable impedance range for MR Conditional devices entering MRI Mode, and to amend the labeling and software to change the term Program Mode to Dosage and Cycle to Intermittent.
P150012/S080	09/18/2019	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for hardware modifications to the IS-1 lead bore cavity and spring coil in the IS-1 pulse generator (PG) header for all pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) within the Accolade family and a subset of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-D) within the NG3 and NG4 families.
P150031/S022	09/04/2019	S - Special CBE		BOSTON SCIENTIFIC CORP.	Approval of the Changes Being Effected (CBE) for the Vercise Deep Brain Stimulation (DBS) Systems. The changes being effected include changes to Vercise Deep Brain Stimulation (DBS) Systems physician and patient labeling, to enhance and harmonize the information regarding the risks of depression, suicide ideation, and suicide across the device type.
P160024/S007	09/09/2019	O - Normal 180 Day	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Approval for updates to the LifeStream Balloon Expandable Vascular Covered Stent labeling to incorporate the 3-year results of the BOLSTER Clinical Study.
P160035/S007	09/18/2019	N - Normal 180 Day	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for a change in the material of the de-airing port.
P160049/S007	09/13/2019	S - Special CBE		THE SPECTRANETICS CORP.	Approval for updates to the device labeling.
P170011/S014	09/24/2019	S - Special CBE		ABIOMED, INC.	Approval for the addition of information on heparin anticoagulation management to the Impella systems instructions for use (IFUs).
P170039/S001	09/23/2019	O - Normal 180 Day	CUSTOMFLEX ARTIFICIAL IRIS	CLINICAL RESEARCH CONSULTANTS, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180011/S011	09/13/2019	S - Special CBE		BOSTON SCIENTIFIC CORP.	Approval for updates to the device labeling.

Total: 69

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S243	09/24/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Change the degreaser solvent used in the vapor degreaser process.
N970012/S167	09/20/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Change to the number of nitrogen gas washes performed as part of ethylene oxide (EO) sterilization Cycle 101 from three to six.
P780007/S062	09/10/2019	X - 30-Day Notice		COOPERVISION, INC.	Introduction of a new flow cytometry analyzer to be used in replacement of the current cytometry analyzer at the CooperVision Caribbean Corporation facility in Juana Diaz, Puerto Rico.
P830061/S175	09/27/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P840001/S442	09/17/2019	X - 30-Day Notice		MEDTRONIC NEUROMODULATION	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).
P840001/S443	09/27/2019	X - 30-Day Notice		MEDTRONIC NEUROMODULATION	Update the titanium dioxide paste specification as well as the receiving inspection procedure, allowing a new test method to be implemented and detect both aluminum oxide and titanium dioxide.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850079/S084	09/05/2019	X - 30-Day Notice		COOPERVISION, INC.	Relocation of six packaging/labeling lines to the new packaging and labeling facility in Mountpark, Southampton, United Kingdom.
P850089/S144	09/27/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P860004/S339	09/04/2019	X - 30-Day Notice		MEDTRONIC INC.	Implement re-test activities for the Bulkhead and Top Shield weld joint Helium Leak Test manufacturing steps.
P860004/S341	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Updates to the titanium dioxide paste specification as well as the receiving inspection procedure, allowing a new test method to be implemented and detect both aluminum oxide and titanium dioxide.
P860057/S191	09/24/2019	X - 30-Day Notice		EDWARDS LIFESCIENCES, LLC.	Expansion of the Heart Valve Center Chemical Mixing Suite and increased manning of the Chemical Mixing Suite at the Irvine facility.
P890003/S419	09/27/2019	X - 30-Day Notice		MEDTRONIC, INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P890023/S038	09/10/2019	X - 30-Day Notice		THE COOPER COMPANIES	Introduction of a new flow cytometry analyzer to be used in replacement of the current cytometry analyzer at the CooperVision Caribbean Corporation facility in Juana Diaz, Puerto Rico.
P900033/S086	09/06/2019	X - 30-Day Notice		INTEGRA LIFESCIENCES CORP.	Change to the sampling plan for the seal integrity QC inspection procedure.
P900061/S155	09/27/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P910023/S418	09/04/2019	X - 30-Day Notice		ST. JUDE MEDICAL	Replace bond tabs and epoxy with aluminum wire ultrasonically bonded directly to the substrate on high voltage hybrid assemblies.
P920015/S236	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P930014/S127	09/24/2019	X - 30-Day Notice		ALCON RESEARCH, LTD.	implementation of an automated assembly system for the Ultrasert Preloaded Delivery System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930021/S025	09/03/2019	X - 30-Day Notice		THE STRAUMANN COMPANY	Updating the environmental monitoring program; relocating the doors to a refrigerator and freezer (moved from one wall to another); and introducing a cutting tool and changed tolerance for seal strength test strips
P930039/S204	09/13/2019	X - 30-Day Notice		MEDTRONIC, INC.	Qualify Greatbatch Medical as a second source supplier for a transvenous lead electrode component.
P950024/S088	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P960009/S358	09/17/2019	X - 30-Day Notice		MEDTRONIC INC.	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).
P960040/S442	09/24/2019	X - 30-Day Notice		BOSTON SCIENTIFIC	Change the degreaser solvent used in the vapor degreaser process.
P970004/S297	09/17/2019	X - 30-Day Notice		MEDTRONIC NEUROMODULATION	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).
P970004/S298	09/27/2019	X - 30-Day Notice		MEDTRONIC NEUROMODULATION	Change to the fastener bracket component manufacturing process at first-tier supplier Greatbatch Medical Mexico (GMM).
P980016/S718	09/13/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a second source supplier for the L4 11-Pin Array Ferrule.
P980016/S720	09/27/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P980035/S605	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P980037/S076	09/30/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Change in material supplier location.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980040/S106	09/11/2019	X - 30-Day Notice		JOHNSON & JOHNSON SURGICAL VISION, INC.	Addition of an alternate supplier for the nut component used for the TECNIS® 1-Piece Intraocular Lens (IOL) with the TECNIS® iTEC Preloaded Delivery System, Model PCB00 and TECNIS® Multifocal 1-Piece IOL with the TECNIS® iTEC Preloaded Delivery System, Model PMB00.
P990038/S030	09/27/2019	X - 30-Day Notice		DIASORIN, INC.	Chromatography column cleaning procedure modifications.
P990041/S029	09/27/2019	X - 30-Day Notice		DIASORIN, INC.	Chromatography column cleaning procedure modifications.
P990042/S026	09/27/2019	X - 30-Day Notice		DIASORIN, INC.	Chromatography column cleaning procedure modifications.
P990043/S030	09/27/2019	X - 30-Day Notice		DIASORIN, INC.	Chromatography column cleaning procedure modifications.
P990044/S027	09/27/2019	X - 30-Day Notice		DIASORIN, INC.	Chromatography column cleaning procedure modifications.
P990045/S027	09/27/2019	X - 30-Day Notice		DIASORIN, INC.	Chromatography column cleaning procedure modifications.
P000040/S037	09/13/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Update the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P000053/S107	09/20/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Change to the number of nitrogen gas washes performed as part of ethylene oxide (EO) sterilization Cycle 101 from three to six.
P010012/S509	09/24/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Change the degreaser solvent used in the vapor degreaser process.
P010013/S077	09/26/2019	X - 30-Day Notice		HOLOGIC, INC.	Change in the amount of antioxidant in the pellethane liner and a change of supplier of black ink used in the pellethane liner.
P010014/S091	09/11/2019	X - 30-Day Notice		BIOMET MANUFACTURING CORP.	Addition of an upgrade to the firms CR97-1 cleanroom.
P010014/S092	09/12/2019	X - 30-Day Notice		BIOMET MANUFACTURING CORP.	Add an in-process ultrasonic clean system and upgrade to the sensitivity level of the penetrant dye to increase penetrant inspection sensitivity for the casting process at the Fair Lawn facility.
P010014/S093	09/27/2019	X - 30-Day Notice		BIOMET MANUFACTURING CORP.	Process parameter changes to the nitric acid bioburden reduction process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S419	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P010030/S125	09/03/2019	X - 30-Day Notice		ZOLL MANUFACTURING CORPORATION	Replace the cleaning solvent used during the manufacture of the therapy electrodes and addition of distilled water to the cleaning process.
P010031/S679	09/13/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add a second source supplier for the L4 11-Pin Array Ferrule.
P010031/S681	09/27/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P020004/S168	09/26/2019	X - 30-Day Notice		W.L. GORE & ASSOCIATES,INC	Updates to the manufacturing process for the leading tip of the Excluder device delivery systems.
P030005/S189	09/24/2019	X - 30-Day Notice		GUIDANT CORP.	Change the degreaser solvent used in the vapor degreaser process.
P030017/S329	09/13/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Use of alternate cleaning equipment for the initial cleaning process for the Printed Circuit Board Assemblies (PCBAs) of the Implantable Pulse Generators (IPGs) for the Precision Spectra, Precision Novi, Precision Montage, Precision Montage MRI, and Spectra WaveWriter Spinal Cord Stimulator (SCS) Systems.
P030017/S330	09/24/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Statistical Process Monitoring and Control (SPC)-based sampling plan to be used for in-process monitoring of validated processes at the Boston Scientific Neuromodulation (BSN) manufacturing sites.
P030036/S113	09/20/2019	X - 30-Day Notice		MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to assay and content uniformity acceptance criteria.
P030054/S370	09/04/2019	X - 30-Day Notice		ST. JUDE MEDICAL	Replace bond tabs and epoxy with aluminum wire ultrasonically bonded directly to the substrate on high voltage hybrid assemblies.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040045/S110	09/26/2019	X - 30-Day Notice		VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modifications of process conditions for steps in the manufacturing process of VISTAKON® (senofilcon A) ¿ ACUVUE OASYS® for Astigmatism Brand Contact Lenses.
P050023/S135	09/16/2019	X - 30-Day Notice		BIOTRONIK, INC.	Alternative models and suppliers for batteries, power supplies and flash memory for the CardioMessenger Smart 3G.
P050028/S078	09/12/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for critical components.
P060030/S079	09/12/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for critical components.
P060039/S096	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P060040/S075	09/12/2019	X - 30-Day Notice		THORATEC CORP.	Add an alternate supplier for the Mobile Power Unit (MPU) Patient Cable.
P080006/S140	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P080011/S096	09/05/2019	X - 30-Day Notice		COOPERVISION, INC.	Relocation of six packaging/labeling lines to the new packaging and labeling facility in Mountpark, Southampton, United Kingdom.
P080011/S097	09/10/2019	X - 30-Day Notice		COOPERVISION, INC.	Introduction of a new flow cytometry analyzer to be used in replacement of the current cytometry analyzer at the CooperVision Caribbean Corporation facility in Juana Diaz, Puerto Rico.
P080025/S192	09/17/2019	X - 30-Day Notice		MEDTRONIC NEUROMODULATION	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).
P080025/S193	09/27/2019	X - 30-Day Notice		MEDTRONIC NEUROMODULATION	Change to the fastener bracket component manufacturing process at first-tier supplier Greatbatch Medical Mexico (GMM).
P080027/S035	09/11/2019	X - 30-Day Notice		ORASURE TECHNOLOGIES INC.	Modification of an existing automated assembly system for manufacturing.
P090015/S008	09/12/2019	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Adding a second supplier for a reagent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090018/S038	09/26/2019	X - 30-Day Notice		ENVOY MEDICAL CORPORATION	Change in a component supplier for the Model 7010 Sensor and Model 7510 Driver transducers.
P100009/S035	09/11/2019	X - 30-Day Notice		ABBOTT VASCULAR INC.	Several modifications to component suppliers, test methods, and inspections.
P100009/S036	09/30/2019	X - 30-Day Notice		ABBOTT VASCULAR INC.	Several manufacturing changes to the MitraClip gripper line.
P100010/S096	09/19/2019	X - 30-Day Notice		MEDTRONIC CRYOCATH LP	Addition of manufacturing line for the Arctic Front Advance Cryoablation catheter.
P100018/S023	09/20/2019	X - 30-Day Notice		MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR	Changes to the packaging operations of the Pipeline Flex Embolization Device, including the addition of a new pouch heat sealer and replacing quality control visual inspections with equivalent in-line inspections.
P100020/S048	09/03/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Scale-up production of a reagent component and add an intermediate process hold time.
P100042/S026	09/16/2019	X - 30-Day Notice		GEN-PROBE INCORPORATED	Increase the manufacturing scale for critical assay components.
P100047/S145	09/06/2019	X - 30-Day Notice		MEDTRONIC	Clarify the process and inspection instructions by including step-by-step instructions for the procedure and dedicated inspection of soldering.
P110013/S100	09/16/2019	X - 30-Day Notice		MEDTRONIC VASCULAR	Implement a new cleanroom space at the Galway manufacturing site.
P110019/S107	09/10/2019	X - 30-Day Notice		ABBOTT VASCULAR	Modification to the annual stability study for XIENCE Xpedition and XIENCE Alpine family of everolimus eluting coronary stent systems.
P110035/S052	09/13/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Update the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P110037/S049	09/12/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for critical components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110042/S127	09/13/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORPORATION	Update to the 100% human visual inspection criteria for S-ICD pulse generator high voltage capacitor stacks.
P120007/S024	09/16/2019	X - 30-Day Notice		GEN-PROBE INCORPORATED	Increase the manufacturing scale for critical assay components.
P120017/S019	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P130008/S046	09/11/2019	X - 30-Day Notice		INSPIRE MEDICAL SYSTEMS	Notification of changes being implemented to test specification gain limits associated with the manufacture of the Model 4340 Sensing Lead.
P130009/S099	09/24/2019	X - 30-Day Notice		EDWARDS LIFESCIENCES, LLC.	Expansion of the Heart Valve Center Chemical Mixing Suite and increased manning of the Chemical Mixing Suite at the Irvine facility.
P130014/S006	09/18/2019	X - 30-Day Notice		HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Add an alternate supplier for the bacterial endotoxin test assay.
P130017/S032	09/06/2019	X - 30-Day Notice		EXACT SCIENCES CORPORATION	Alternate supplier of component.
P130021/S063	09/11/2019	X - 30-Day Notice		MEDTRONIC COREVALVE LLC	Introduce a 100% torque test during actuator assembly for the EnVeo R and EnVeo PRO Delivery Catheter System (DCS).
P130026/S050	09/18/2019	X - 30-Day Notice		ST. JUDE MEDICAL	Manufacturing change to alter the adhesive application in the TactiCath Quartz Contact Force Ablation Catheter.
P130028/S029	09/19/2019	X - 30-Day Notice		NUVECTRA CORPORATION	Implementation of an additional bonding step to the manufacturing process of the printed circuit board assembly to provide reinforcement to the interface between the micro USB connector and the circuit board.
P140026/S013	09/04/2019	X - 30-Day Notice		SILK ROAD MEDICAL, INC	Transfer of Final Release activities from the Cordis Miami Lakes site to the Cordis de Mexico site.
P140028/S042	09/13/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORPORATION	Update the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140028/S043	09/06/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORPORATION	Replace the vacuum purge system with a positive pressure purge system.
P140028/S045	09/23/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORPORATION	Replacement of injection molding equipment.
P140029/S020	09/13/2019	X - 30-Day Notice		Q-MED AB	Remove window/wall sections and decommissioned packaging equipment and to install a new door in an ISO Class 8 clean room.
P140031/S092	09/24/2019	X - 30-Day Notice		EDWARDS LIFESCIENCES, LLC.	Expansion of the Heart Valve Center Chemical Mixing Suite and increased manning of the Chemical Mixing Suite at the Irvine facility.
P140031/S095	09/30/2019	X - 30-Day Notice		EDWARDS LIFESCIENCES, LLC.	Change to the visual inspection criteria for the loader tube to hub bond component.
P140032/S040	09/04/2019	X - 30-Day Notice		MEDTRONIC, INC.	Implement re-test activities for the Bulkhead and Top Shield weld joint Helium Leak Test manufacturing steps.
P140032/S041	09/27/2019	X - 30-Day Notice		MEDTRONIC, INC.	Updates to the titanium dioxide paste specification as well as the receiving inspection procedure, allowing a new test method to be implemented and detect both aluminum oxide and titanium dioxide.
P150003/S053	09/13/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORPORATION	Update the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.
P150012/S082	09/24/2019	X - 30-Day Notice		BOSTONSCIENTIFIC	Change the degreaser solvent used in the vapor degreaser process.
P150014/S031	09/04/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Increase the scale of bulk manufacturing of a reagent component.
P150014/S032	09/26/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Increase bulk manufacturing scale and modification of filling processes for critical reagents.
P150015/S033	09/04/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Increase the scale of bulk manufacturing of a reagent component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150015/S034	09/26/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Increase bulk manufacturing scale and modification of filling processes for critical reagents.
P150021/S045	09/12/2019	X - 30-Day Notice		ABBOTT DIABETES CARE INC.	Update to the shipping pallet configuration, removal of the temperature controls from shipping, and extending in-process shelf life of foil-bagged glucose sensor reels. The glucose sensor is a component of the FreeStyle Libre 14-day and FreeStyle Libre Pro Glucose Monitoring System.
P150031/S023	09/12/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Alternate cleaning equipment for the Implantable Pulse Generator (IPG) Printed Circuit Board Assembly (PCBA) of the Vercise PC and Vercise Gevia Deep Brain Stimulation (DBS) Systems.
P150031/S024	09/24/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Statistical Process Monitoring and Control (SPC)-based sampling plan to be used for in-process monitoring of validated processes at the Boston Scientific Neuromodulation (BSN) manufacturing sites.
P150033/S056	09/27/2019	X - 30-Day Notice		MEDTRONIC INC.	Transfer of receiving and incoming inspection activities from Medtronic Rice Creek facility to the Medtronic Puerto Rico Operations Company (MPROC) Villalba, MPROC Juncos, and the Federal Express/Third Party Logistics facility in Guaynabo, Puerto Rico.
P150033/S057	09/18/2019	X - 30-Day Notice		MEDTRONIC INC.	Update the Label Printing Software System from Prisym 4.4 to Transform.
P150033/S058	09/19/2019	X - 30-Day Notice		MEDTRONIC INC.	Use of the electronic manufacturing execution system (MES) to replace the current paper-based device history record for Micra TPS.
P150036/S041	09/24/2019	X - 30-Day Notice		EDWARDS LIFESCIENCES, LLC.	Expansion of the Heart Valve Center Chemical Mixing Suite and increased manning of the Chemical Mixing Suite at the Irvine facility.
P150048/S037	09/24/2019	X - 30-Day Notice		EDWARDS LIFESCIENCES, LLC.	Expansion of the Heart Valve Center Chemical Mixing Suite and increased manning of the Chemical Mixing Suite at the Irvine facility.
P160014/S014	09/20/2019	X - 30-Day Notice		CELONOVA BIOSCIENCES, INC.	Changes to the UV cure and balloon folding equipment.
P160016/S004	09/20/2019	X - 30-Day Notice	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)	SIEMENS HEALTHCARE DIAGNOSTICS, INC.	Change plastic resin used in non-critical component vials.
P160030/S038	09/12/2019	X - 30-Day Notice		ABBOTT DIABETES CARE INC.	Update to the shipping pallet configuration, removal of the temperature controls from shipping, and extending in-process shelf life of foil-bagged glucose sensor reels. The glucose sensor is a component of the FreeStyle Libre 14-day and FreeStyle Libre Pro Glucose Monitoring System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160041/S024	09/04/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Increase the scale of bulk manufacturing of a reagent component.
P160041/S025	09/26/2019	X - 30-Day Notice		ROCHE MOLECULAR SYSTEMS, INC.	Increase bulk manufacturing scale and modification of filling processes for critical reagents.
P160043/S028	09/16/2019	X - 30-Day Notice		MEDTRONIC VASCULAR	Implement a new cleanroom space at the Galway manufacturing site.
P160054/S023	09/12/2019	X - 30-Day Notice		THORATEC CORPORATIO N	Add an alternate supplier for the Mobile Power Unit (MPU) Patient Cable.
P160055/S007	09/18/2019	X - 30-Day Notice		RXSIGHT, INC.	Addition of alternate manufacturing inspection equipment.
P170005/S001	09/24/2019	X - 30-Day Notice		ABBOTT MOLECULAR INC.	Additional internal QC testing for the DNA Sample Preparation Kit.
P170007/S004	09/19/2019	X - 30-Day Notice		BIOVENTUS LLC	Extension of the designated shelf life of the HA raw material used in the manufacture of Durolane.
P170008/S021	09/20/2019	X - 30-Day Notice		MEDINOL, LTD.	Change to the stent crimping manufacturing process for the 3.50 x 8 mm EluNIR stent.
P170012/S019	09/12/2019	X - 30-Day Notice		BIOM'UP SA	Change in the controls of the manufacturing environment.
P170035/S006	09/12/2019	X - 30-Day Notice		BAUSCH AND LOMB, INC.	Changing the power measurement method for Toric and Multifocal lenses.
P170036/S003	09/05/2019	X - 30-Day Notice		SPINAL KINETICS LLC	Modify the inspection process for the M6-C Artificial Cervical Disc.
P170041/S001	09/24/2019	X - 30-Day Notice		ABBOTT MOLECULAR, INC.	Additional internal QC testing for the DNA Sample Preparation Kit.
P180011/S010	09/06/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Replace the vacuum purge system with a positive pressure purge system.
P180011/S014	09/13/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Update the software and utilities for sterilization preconditioning and aeration at the BSC Coventry, Rhode Island facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180011/S015	09/23/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Replacement of injection molding equipment.
P180029/S012	09/26/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORPORATION	Replace an existing heat gun with a windows hot jaw in the MLE assembly process.
Total: 130					