PMA Monthly approvals from 4/1/2019 to 4/30/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170027	04/02/2019	PMAO - PMA Origi	THEROX DOWNSTREAM SYSTEM	THEROX, INC.	Approval for the TherOx Downstream System. This device is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO2 Therapy) to targeted ischemic regions perfused by the patients left anterior descending coronary artery immediately following revascularization by means of percutaneous coronary intervention (PCI) with stenting that has been completed within 6 hours after the onset of anterior acute myocardial infarction (AMI) symptoms caused by a left anterior descending artery infarct lesion.
P180014	04/26/2019	PMAO - PMA Origi	XPS WITH STEEN SOLUTION PERFUSATE	XVIVO PERFUSION, INC.	Approval for the XPS™ with STEEN Solution Perfusate.. The device is indicated for use in flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the ex vivo function of the lungs can be reassessed for transplantation.
P180024	04/16/2019	PMAO - PMA Origi	TRANSPYLORIC SHUTTLE/ TRANSPYLORIC SHUTTLE DELIVERY DEVICE	BARONOVA, INC	Approval for the TransPyloric Shuttle/TransPyloric Shuttle Delivery Device. The TransPyloric Shuttle/TransPyloric Shuttle Delivery Device is indicated for weight reduction in adult patients with obesity with a Body Mass Index (BMI) of 35.0-40.0 kg/m2 or a BMI of 30.0 to 34.9 kg/m2 with one or more obesity-related comorbid conditions and is intended to be used in conjunction with a diet and behavior modification program.
P180029	04/23/2019	PMAO - PMA Origi	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Approval for the LOTUS Edge Valve System. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of <= 1.0 cm2 or index of <= 0.6 cm2/m2) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality >= 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).
P180034	04/11/2019	PMAO - PMA Origi	TACK ENDOVASCULAR SYSTEM (6F)	INTACT VASCULAR, INC.	Approval for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5mm to 6.0mm for the repair of post percutaneous transluminal balloon angioplasty dissection(s).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180043	04/12/2019	PMAO - PMA Origi	THERASCREEN FGFR RGQ RT-PCR KIT	QIAGEN GMBH	Approval for the THERASCREEN® FGFR RGQ PCR KIT. The Therascreen FGFR RGQ RT-PCR Kit is a real-time, reverse transcription PCR test for the qualitative detection of two point mutations in exon 7 [p.R248C (c.742C>T), p.S249C (c.746C>G)], two point mutations in exon 10 [p.G370C (c.1108G>T) and p.Y373C (c.1118A>G)] and two fusions (FGFR3-TACC3v1 and FGFR3-TACC3v3) in the fibroblast growth factor receptor 3 (FGFR3) gene in RNA samples derived from formalin-fixed paraffin-embedded (FFPE) urothelial tumor tissue. The test is indicated for use as an aid in identifying urothelial cancer (UC) patients who harbor these alterations and are therefore eligible for treatment with BALVERSA (erdafitinib). Specimens are processed using the RNeasy DSP FFPE Kit for manual sample preparation followed by reverse transcription and then automated amplification and detection on the Rotor-Gene Q MDx (US) instrument.

Total: 6

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S150	04/01/2019	R - Real-Time Proc	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Approval for the labeling and packaging changes for AMS 700 Inflatable Penile Prosthesis with and without InhibiZone (AMS 700).
P810031/S065	04/29/2019	N - Normal 180 Day	SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES (OVD)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for Healon GV® PRO, a modification of the Healon5 PRO OVD with the sodium hyaluronate concentration changed from 23 mg/mL to 18 mg/mL. The device, as modified, will be marketed under the trade name Sodium Hyaluronate Ophthalmic Viscoelastc Device (OVD), Healon GV® PRO and is indicated for use in anterior segment ophthalmic surgical procedures of the human eye. The Healon GV® PRO OVD is designed to create and maintain a deep anterior chamber which facilitates manipulation inside the eye with reduced trauma to the corneal endothelium and other ocular tissues. The Healon GV® PRO OVD can also be used to efficiently separate and control ocular issues. The Healon GV® PRO OVD is not designed to have any pharmacological effect.
P830055/S227	04/24/2019	S - Special CBE	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a change to a component at a raw material supplier site, which is added to a silicone emulsion used as a denest agent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S165	04/10/2019	N - Normal 180 Day	CAPSURE SENSE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Attain Stability¿ Quad MRI SureScan¿ Model 4798 left ventricular (LV) lead.
P840001/S426	04/15/2019	S - Special CBE	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSSTEMS AND PISECES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS AND INTELLIS CLINICIAN PROGRAMMER APPLICATION (CPA)	MEDTRONIC NEUROMODULATION	Approval for changes to the Medtronic Communicator Model 8880T2 Technical Manual and Clinician Programmer Application labeling.
P860004/S328	04/15/2019	S - Special CBE	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL SYNCHROMED II CLINICIAN PROGRAMMER APPLICATION	MEDTRONIC INC.	Approval for changes to the Medtronic Communicator Model 8880T2 Technical Manual and Clinician Programmer Application labeling.
P880081/S042	04/05/2019	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 (such as asteroid hyalosis) as follows: 1) Addition of diabetic retinopathy as an example in Warning #10 to state: The use of silicone lenses in patients with current vitreoretinal disease or those who are at high risk for future vitreoretinal disease (i.e. diabetic retinopathy, etc.) that may require silicone oil as part of therapy should be reconsidered; and. 2) Addition of the following Warning #11: The use of Silicone intraocular lenses in patients with asteroid hyalosis has been associated with opacification of the implanted IOL..
P910062/S008	04/12/2019	R - Real-Time Proc	STAR S4 IR EXCIMER LASER SYSTEM, WAVESCAN WAVEFRONT SYSTEM, AND IDESIGN ADVANCED WAVESCAN STUDIO SYSTEM	AMO MANUFACTURING USA, LLC	Approval for four edits in engineering drawing of "Beam Splitter, Energy Detector" and change of the material in the Beam Splitter component of the Energy Detector from Corning Fused Silica Code 7940 to Corning 7980 HPFS.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S222	04/10/2019	N - Normal 180 Day	SPRINT QUATTRO SECURE S MRI SURESCAN LEAD, SPRINT QUATTRO SECURE MRI SURESCAAN LEAD AND SPRINT QUATTRO MRI SURESCAN LEAD	MEDTRONIC INC.	Approval for the Attain Stability Quad MRI SureScan Model 4798 left ventricular (LV) lead.
P930016/S056	04/12/2019	R - Real-Time Proc	STAR S4 IR EXCIMER LASER SYSTEM, WAVESCAN WAVEFRONT SYSTEM, AND IDESIGN ADVANCED WAVESCAN STUDIO SYSTEM	AMO MANUFACTURING USA, LLC	Approval for four edits in engineering drawing of "Beam Splitter, Energy Detector" and change of the material in the Beam Splitter component of the Energy Detector from Corning Fused Silica Code 7940 to Corning 7980 HPFS.
P930021/S021	04/23/2019	Y - 135 Review Tra	STRAUMANN EMDOGAIN	THE STRAUMANN COMPANY	Approval to change the test method for determining the calcium content of the intermediate bulk product and outsource the calcium content testing to Toxicon AB
P930021/S022	04/26/2019	Y - 135 Review Tra	STRAUMANN EMDOGAIN	THE STRAUMANN COMPANY	Approval to change the test lab for water testing from APL to Mikrolab Stockholm AB
P930039/S194	04/10/2019	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC, INC.	Approval for the Attain Stability Quad MRI SureScan Model 4798 left ventricular (LV) lead.
P950037/S198	04/29/2019	N - Normal 180 Day	SETROX S 53; SAFIO S 53; DEXTRUS 4136;TILDA R53;SOLIA S 45/53/60, JT 45/53; SIELLO S53/60/45/53/60/,JT 45/53;	BIOTRONIK, INC.	Approval for MR conditional labeling for ProMRI DX systems with a partially capped DX lead.
P950037/S199	04/15/2019	O - Normal 180 Day	SIELLO S45, S53, S60 AND SOLIA S45, S53, S60	BIOTRONIK, INC.	Approval of the revised protocol for the Siello Pacing Lead Study.
P960009/S344	04/15/2019	S - Special CBE	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for changes to the Medtronic Communicator Model 8880T2 Technical Manual and Clinician Programmer Application labeling.
P960058/S133	04/12/2019	N - Normal 180 Day	HIRESOLUTION BIONIC EAR SYSTEM/AIM SYSTEM	ADVANCED BIONICS	Approval for the AIM System components (with model numbers): AIM System (tablet) CI-6126, AIM Power Adapter CI-6132, AIM Sterile Inserts CI-6120, AIM Tablet Power Cord (US) CI-6127, AIM Programming Cable CI-6125, AIM Software CI-6056-001, AIM Insert Earphone CI-6129, and AIM Rechargeable Battery CI-6130.
P980023/S087	04/29/2019	N - Normal 180 Day	PLEXA PROMRI DF- S DX 65/15/17; IIIVIA 7 DR-T; INRICA 5 DTR-T	BIOTRONIK, INC.	Approval for MR conditional labeling for ProMRI DX systems with a partially capped DX lead.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980023/S090	04/15/2019	O - Normal 180 Day	PERMANENT DEFIBRILLATOR ELECTRODES: PROTEGO SD, PROTEGO TD, PROTEGO S AND PROTEGO T	BIOTRONIK, INC.	Approval of the revised protocol for the Protego DF4 Post Approval Registry.
P990009/S053	04/18/2019	R - Real-Time Proc	FLOSEAL NT	BAXTER HEALTHCARE CORP.	Approval for the removal of the co-packaging configuration of the 5,000 I.U. Thrombin-JMI component from the 5 mL Floseal Hemostatic Matrix.
P990010/S008	04/12/2019	R - Real-Time Proc	STAR S4 IR EXCIMER LASER SYSTEM, WAVESCAN WAVEFRONT SYSTEM, AND IDESIGN ADVANCED WAVESCAN STUDIO SYSTEM	AMO MANUFACTURING USA, LLC	Approval for four edits in engineering drawing of "Beam Splitter, Energy Detector" and change of the material in the Beam Splitter component of the Energy Detector from Corning Fused Silica Code 7940 to Corning 7980 HPFS.
P990012/S033	04/24/2019	O - Normal 180 Day	ELECSYS HBSAG IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P990056/S035	04/24/2019	O - Normal 180 Day	ELECSYS TOTAL PSA	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P990071/S042	04/29/2019	R - Real-Time Proc	SMARTABLATE IRRIGATION PUMP, NGEN PUMP DEVICES	BIOSENSE WEBSTER, INC.	Approval for a change to the user manuals of the SmartAblate Irrigation Pump and nGEN Pump to claim compatibility with the ThermoCool SmartTouch Catheter family.
P000027/S033	04/24/2019	O - Normal 180 Day	ELECSYS FREE PSA	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P010014/S084	04/17/2019	R - Real-Time Proc	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for several packaging changes to the Oxford Partial Knee System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S385	04/10/2019	N - Normal 180 Day	PERCEPTA QUAD CRT-P MRI SURESCAN, SERENA QUAD CRT-P MRI SURESCAN, SOLARA QUAD CRT-P MRI SURESCAN AND IMPLANTABLE PULSE GENERATORS WITH CARDIAC RESYNCHRONIZATION THERAPY	MEDTRONIC INC.	Approval for the Attain Stability¿ Quad MRI SureScan¿ Model 4798 left ventricular (LV) lead.
P010019/S069	04/24/2019	Y - 135 Review Tra	LOTRAFILCON A SOFT CONTACT LENSES; LOTRAFILCON B SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Approval for a qualification of an additional primary packaging line.
P010031/S654	04/10/2019	N - Normal 180 Day	AMPLIA MRI QUAD CRT-D SURESCAN, COMPIA MRI QUAD CRT-D SURESCAN, CLARIA MRI QUAD CRT-D SURESCAN AND IMPLANTABLE DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION THERAPY	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Attain Stability¿ Quad MRI SureScan¿ Model 4798 left ventricular (LV) lead.
P010033/S045	04/29/2019	R - Real-Time Proc	QUANTIFERON - TB GOLD PLUS TEST	QIAGEN	Approval for changes to the stability/handling of whole blood specimens collected in lithium heparin (LiHep) blood collection tubes held at 2-8C, prior to transfer to the Quantiferon-TB Gold Plus blood collection tubes.
P010054/S038	04/15/2019	N - Normal 180 Day	ELECSYS ANTI-HBS; PRECICONTROL ANTI-HBS; ANTI-HBS CALCHECK	ROCHE DIAGNOSTICS CORP.	Approval for the migration of claims from the FDA approved Elecsys Anti-HBs, Anti-HBs CalCheck and PreciControl Anti-HBs on the cobas e 601 immunoassay analyzer to the cobas e 801 immunoassay analyzer.
P010054/S040	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HBS	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P030011/S068	04/17/2019	R - Real-Time Proc	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Approval for extension of the use by date for the External Battery of the Companion 2 Driver.
P030016/S036	04/15/2019	O - Normal 180 Day	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Approval for modification to the labeling for the Visian® Implantable Collamer® Lens, Models MICL and TMICL to reflect the findings of the Adverse Event Post-approval Study for the Visian® MICL

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030023/S006	04/30/2019	R - Real-Time Proc	RINGJECT	OPHTEC USA, INC.	Approval for design changes and a new supplier, Elbo Technics, for the RingJect.
P030031/S091	04/12/2019	O - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR THERMOCOOL CATHETER	BIOSENSE WEBSTER, INC.	Approval for a labeling update to incorporate post-approval study data from the AFIB Registry Study
P030031/S092	04/02/2019	O - Normal 180 Day	VISTAG SURPOINT EXTERNAL PROCESS UNIT (EPU)	BIOSENSE WEBSTER, INC.	Approval of a manufacturing site located at Flextronics, Ltd., Ramat Gavriel Industrial Zone, 2 Hamatechet St., Migdal Haemek 23108, P.O.B 867, Israel for the VISITAG SURPOINT External Processing Unit.
P030031/S095	04/29/2019	R - Real-Time Proc	THERMOCOOL SMARTTOUCH CATHETER	BIOSENSE WEBSTER, INC.	Approval for a change to the user manuals of the SmartAblate Irrigation Pump and nGEN Pump to claim compatibility with the ThermoCool SmartTouch Catheter family.
P030036/S106	04/10/2019	N - Normal 180 Day	SELECTSECURE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for the Attain Stability¿ Quad MRI SureScan¿ Model 4798 left ventricular (LV) lead.
P040036/S065	04/29/2019	R - Real-Time Proc	THERMOCOOL SMARTTOUCH SF CATHETER	BIOSENSE WEBSTER, INC.	Approval for a change to the user manuals of the SmartAblate Irrigation Pump and nGEN Pump to claim compatibility with the ThermoCool SmartTouch Catheter family.
P050023/S126	04/29/2019	N - Normal 180 Day	IIIVIA, 7 HF-T,QP; INTICA 7,5 HF-T,QP	BIOTRONIK, INC.	Approval for MR conditional labeling for ProMRI DX systems with a partially capped DX lead.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050023/S128	04/15/2019	O - Normal 180 Day	ILESTO 7 VR-T, IFORIA 7 VR-T, ILESTO 5 VR-T, IFORIA 5 VR-T, INVENTRA 7 VR-T, IPERIA 7 VR-T, ITREVIA 7 VR-T, IPERIA 5 VR-T, ITREVIA 5 VR-T, ILIVIA 7 DF4 VR-T, INTICA 7 DF4 VR-T, INTICA 5 DF4 VR-T, INLEXA 7 VR-T DF4, INLEXA 3 VR-T DF4, ILESTO 7 DR-T, IFORIA 7 DR-T, ILESTO 5 DR-T, IFORIA 5 DR-T, INVENTRA 7 DR-T, IPERIA 7 DR-T, ITREVIA 7 DR-T, IPERIA 5 DR-T, ITREVIA 7 DR-T, IPERIA 5 DR-T, ITREVIA 5 DR-T, ILIVIA 7 DR-T DF4, INTICA 7 DR-T DF4, INTICA 5 DR-T DF4, INLEXA 7 DR-T DF4, INLEXA 3 DR-T DF4, ILESTO 7 HF-T, IFORIA 7 HT-F, ILESTO 5 HF-T, IFORIA 5 HF-T, INVENTRA 7 HF-T, IPERIA 7 HF-T, ITREVIA 7 HF-T, IPERIA 5 HF-T, ITREVIA 5 HF-T, ILIVIA 7 HF-T DF4 IS-1, INTICA 7 HF-T DF4 IS-1, INTICA 5 HF-T DF4 IS-1, ILIVIA 7 HF-T QP DF4 IS4, INTICA 7 HF-T QP DF4 IS4, INTICA 5 HF-T QP DF4 IS4, INLEXA 7 HF-T DF4 IS-1, INLEXA 3 HF-T DF4 IS-1, INLEXA 7 HF-T QP DF4 IS4 AND INLEXA 3 HF-T QP DF4 IS4	BIOTRONIK, INC.	Approval of the revised protocol for the Protego DF4 Post Approval Registry.
P050047/S068	04/04/2019	S - Special CBE	JUVEDERM ULTRA XC AND ULTRA PLUS XC	ALLERGAN	Approval for the addition of a specification for the lidocaine-related impurity, 2,6-dimethylaniline (DMA).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060011/S015	04/12/2019	R - Real-Time Proc	RAYNER C-FLEX 570C, C-FLEX ASPHERIC 970C AND 600C ASPHERIC INTRAOCULAR LENSES	RAYNER INTRAOCULAR LENSES LTD.	Approval for revisions to the labeling to include the use of the Medicel Viscoject Injector as a delivery option, update the manufacturer address, and the item identifier.
P070004/S015	04/17/2019	R - Real-Time Proc	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for new round implant styles 10621-XP, 10721-XP, 20621- XP, and 20721-XP.
P070008/S099	04/29/2019	N - Normal 180 Day	COROX (PROMRI0 OTW, 75,85,S75,L75,LB85 BP; SENTUS (PROMRI) OTW, 75,85,S75,S85,L75,L85,QP S75S85,S95,L75,L85,L95,S75/49,S75/49,S95/49,L75/49,L85/49,L95/49	BIOTRONIK, INC.	Approval for MR conditional labeling for ProMRI DX systems with a partially capped DX lead.
P070026/S057	04/24/2019	S - Special CBE	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for a change to a component at a raw material supplier site, which is added to a silicone emulsion used as a denest agent.
P080006/S129	04/10/2019	N - Normal 180 Day	ATTAIN STABILITY QUAD MRI SURESCAN LEAD	MEDTRONIC INC.	Approval for the Attain Stability Quad MRI SureScan Model 4798 left ventricular (LV) lead.
P090007/S020	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P090008/S021	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P090009/S018	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P090013/S293	04/10/2019	N - Normal 180 Day	CAPSUREFIX MRI SURESCAN LEAD	MEDTRONIC, INC	Approval for the Attain Stability¿ Quad MRI SureScan¿ Model 4798 left ventricular (LV) lead.
P090029/S011	04/26/2019	O - Normal 180 Day	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for labeling updated to include post-approval study results from the continued follow-up of the IDE cohort.
P100012/S008	04/03/2019	O - Normal 180 Day	NUVASIVE PCM CERVICAL DISC	NUVASIVE, INC.	Approval for labeling updated to include post-approval study results.
P100026/S065	04/09/2019	S - Special CBE	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for changes to the labeling to strengthen instructions intended to enhance the safe use of the NeuroPace® Magnet.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100031/S026	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P100032/S020	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P100034/S021	04/12/2019	Y - 135 Review Tra	OPTUNE SYSTEM	NOVOCURE, LTD.	Approval for an additional ceramic disc supplier with no changes to electrical specifications.
P100042/S022	04/28/2019	R - Real-Time Proc	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval for an alternate cleaning recommendation for the sample racks used on the Panther and Tigris instruments.
P100045/S036	04/04/2019	R - Real-Time Proc	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for updates to the software contained in the CardioMEMS I2 Hospital Electronic System and I3 Patient Electronics System.
P110022/S027	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P110025/S023	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P110031/S024	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P110033/S043	04/04/2019	S - Special CBE	JUVEDERM VOLUMA XC, VOLLURE XC AND VOLBELLA XC	ALLERGAN	Approval for the addition of a specification for the lidocaine-related impurity, 2,6-dimethylaniline (DMA).
P120005/S081	04/24/2019	R - Real-Time Proc	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for minor design changes to the firmware installed on the transmitter component of the Dexcom G5 Mobile Continuous Glucose Monitoring System.
P120007/S019	04/22/2019	R - Real-Time Proc	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval to revise the release criteria for specificity testing of the Negative QC Panel Internal Control RLU parameter
P120007/S020	04/28/2019	R - Real-Time Proc	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval for an alternate cleaning recommendation for the sample racks used on the Panther and Tigris instruments.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130005/S025	04/10/2019	R - Real-Time Proc	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY DEVICE (OAD); ORBITAL ATHERECTOMY SYSTEM PUMP (OAS PUMP) VIPERWIRE ADVANCE CORONARY GUIDE WIRE; VIPERSLIDE	CARDIOVASCULAR SYSTEMS, INC.	Approval for a change to the motor gear material and the addition of a new motor tester.
P130013/S020	04/02/2019	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for an alternate PET fabric filter resin material and knitting vendor as well as modifications to various device specifications.
P130026/S043	04/10/2019	S - Special CBE	TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL	Approval for the reduction of the concentration of IPA in all TactiCath SE manufacturing.
P140003/S044	04/17/2019	N - Normal 180 Day	IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0, IMPELLA LD	ABIOMED, INC.	Approval for modifications to the Instructions for Use (IFU) to add the option to use either bivalirudin or argatroban to achieve the recommended level of systemic anticoagulation for Impella patients.
P140003/S047	04/17/2019	R - Real-Time Proc	IMPELLA 2.5, IMPELLA CP, IMPELLA CP WITH SMARTASSIST, IMPELLA 5.0, AND IMPELLA LD SYSTEMS	ABIOMED, INC.	Approval for a replacement battery pack for the Automated Impella Controller.
P140017/S014	04/18/2019	O - Normal 180 Day	MELODY TPV SYSTEM	MEDTRONIC INC.	Approval for an update to labeling based on the results of your Post-Approval Study.
P140021/S016	04/24/2019	O - Normal 180 Day	ELECSYS ANTI-HCV II	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement

P150013/S012	04/16/2019	N - Normal 180 Day	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3. The device is intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction (GEJ) adenocarcinoma, cervical cancer and urothelial carcinoma tissues using EnVision FLEX visualization system on Autostainer Link 48. Non-Small Cell Lung Cancer (NSCLC) PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. The specimen should be considered to have PD-L1 expression if TPS ? 1%. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). See KEYTRUDA® product label for specific clinical circumstances guiding PD-L1 testing. Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma PD-L1 protein expression in gastric or GEJ adenocarcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS ? 1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab). Cervical Cancer PD-L1 protein expression in cervical cancer is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS ? 1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying cervical cancer patients for treatment with KEYTRUDA® (pembrolizumab). Urothelial Carcinoma PD-L1 protein expression in urothelial carcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. The specimen should be considered to have PD-L1 expression if CPS ? 10. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying urothelial carcinoma patients for treatment with KEYTRUDA® (pembrolizumab). See the KEYTRUDA® product label for specific clinical circumstances guiding PD-L1 testing. For in vitro diagnostic use.
P150021/S036	04/05/2019	N - Normal 180 Day	FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for the implementation of individual sensor calibration (ISC) and incorporation of the ISC methodology in the performance monitoring sampling process
P150026/S005	04/08/2019	N - Normal 180 Day	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for the replacement of the single board computer and hard drive with validated equivalent alternate components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160003/S006	04/25/2019	Y - 135 Review Tra	PRO-KINETIC ENERGY CORONARY STENT SYSTEM	BIOTRONIK, INC.	Approval for automation of an existing inspection process.
P160019/S009	04/24/2019	O - Normal 180 Day	ELECSYS HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for a manufacturing site for the cobas e 411 Analyzer located at Hitachi High-Technologies Corp., 1892-1, Oazategama, Omuta, Fukuoka, 836-0004 Japan
P160021/S016	04/09/2019	R - Real-Time Proc	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for new device inspection equipment and modified stent profile acceptance criteria.
P160023/S011	04/28/2019	R - Real-Time Proc	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Approval for an alternate cleaning recommendation for the sample racks used on the Panther and Tigris instruments.
P160030/S028	04/05/2019	N - Normal 180 Day	FREESTYLE LIBRE PRO	ABBOTT DIABETES CARE INC.	Approval for the implementation of individual sensor calibration (ISC) and incorporation of the ISC methodology in the performance monitoring sampling process.
P170011/S009	04/17/2019	R - Real-Time Proc	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a replacement battery pack for the Automated Impella Controller.
P170011/S010	04/12/2019	S - Special CBE	IMPELLA RP	ABIOMED, INC.	Approval for modifications to the Instructions for Use to add a section about patient selection.
P170019/S005	04/10/2019	N - Normal 180 Day	FOUNDATIONONE CDX ASSAY	FOUNDATION MEDICINE, INC.	Approval for FoundationOne CDx (F1CDx) for reporting of homologous recombination deficiency (HRD) status in ovarian cancer patients.
P170025/S010	04/28/2019	R - Real-Time Proc	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Approval for an alternate cleaning recommendation for the sample racks used on the Panther and Tigris instruments.
P170043/S001	04/16/2019	O - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATIO N	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170043/S002	04/16/2019	O - Normal 180 Day	ISTENT INJECT TRABECULAR MICRO-BYPASS SYSTEM (MODEL G2-M-IS)	GLAUKOS CORPORATIO N	Approval of the revised protocol for the post-approval study (PAS) protocol.

Total: 88

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S054	04/12/2019	X - 30-Day Notice	SURGICEL ABSORBABLE HEMOSTATS	ETHICON, INC.	Extension of the Clean Manufacturing Environment at the Ethicon SARL, Neuchatel Switzerland site.
N18033/S102	04/05/2019	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Manufacturer recommended like-for-like replacement part used during the manufacturing process of VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lenses.
N970003/S237	04/08/2019	X - 30-Day Notice	ACCESSORY WRENCH SOCKET CAP BRADY/ TACHY	BOSTON SCIENTIFIC CORP.	Modifications to the frequency, equipment and method for monitoring airborne particulates.
N970012/S160	04/03/2019	X - 30-Day Notice	AMS AMBICOR INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Changing the supplier of the Deflation Block Filter component.
N970012/S162	04/18/2019	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/ IMPLANTABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Change the milling and molding process of the silicone rear tip extenders used with the AMS 700 CXR models and move the process to a dedicated molding room.
P810006/S085	04/19/2019	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC-MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Implementation of data integrity and security controls for the Quality Control (QC) Analytical Laboratory Instruments at the Collagen Manufacturing Center (CMC).
P810006/S086	04/26/2019	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORBABLE HEMOSTATIC AGENT - MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Splitting an existing Clean Compressed Air (CCA) Point of Use (POU) within Room 105. You split the existing POU into two (2) POUs with one POU dedicated to filter integrity testing and the other POU dedicated to equipment drying.
P810032/S068	04/22/2019	X - 30-Day Notice	PMMA MULTI-PIECE POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES	Application and coding of a Radio-Frequency Identification (RFID) label to the device packaging.
P810032/S069	04/22/2019	X - 30-Day Notice	PMMA MULTI-PIECE POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON LABORATORIES	Use the membrane filtration recovery method for bioburden testing of the AcrySof® Intraocular Lenses.
P830055/S228	04/30/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Change the inspection method of the Attune Anatomic Patella component..

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830060/S083	04/08/2019	X - 30-Day Notice	ACCESSORY MEDICAL ADHESIVE, ACCESSORY MINERAL OIL, ACCESSORY VEIN PICK, ACCESSORY KIT LEAD CAP, ACCESSORY STYLET TAPER 0.016, ACCESSORY STYLET TAPER 0.014, ACCESSORY LEAD ANCHOR, ACCESSORY TUNNELER TOOL, ACCESSORY STYLET J.014 100CM, ACCESSORY STYLEY J .016 100CM, ACCESSORY TOOL TUN/ TIP 6.1 AND 3.2	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.
P840001/S423	04/01/2019	X - 30-Day Notice	MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODU LATION	Manufacturing transfer of A10504002, Pin-Crimp Core, 316L SST Thru Hole, Transition Fitting, from the current supplier Lake Region Medical to RMS.
P840001/S424	04/02/2019	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODU LATION	Change of a sub-tier raw material supplier and to include a lower bound to the particle size of Vanadium Pentoxide
P840001/S429	04/29/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODU LATION	Removal of a redundant cleaning process of stylet components at the Medtronic Puerto Rico Operations Company in Villabla, Puerto Rico.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S430	04/29/2019	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Rearrange the manufacturing process flow for the Restore Extension family at the Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P840060/S045	04/22/2019	X - 30-Day Notice	PMMA SINGLE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES	Application and coding of a Radio-Frequency Identification (RFID) label to the device packaging.
P840060/S046	04/22/2019	X - 30-Day Notice	PMMA SINGLE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON LABORATORIES	Use the membrane filtration recovery method for bioburden testing of the AcrySof® Intraocular Lenses.
P840062/S072	04/19/2019	X - 30-Day Notice	COLLACOTE(TM), COLLATAPE, AND COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Implementation of data integrity and security controls for the Quality Control (QC) Analytical Laboratory Instruments at the Collagen Manufacturing Center (CMC).
P840062/S073	04/26/2019	X - 30-Day Notice	COLLACOTE, COLLATAPE, AND COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERGY	INTEGRA LIFESCIENCES CORP.	Splitting an existing Clean Compressed Air (CCA) Point of Use (POU) within Room 105. You split the existing POU into two (2) POUs with one POU dedicated to filter integrity testing and the other POU dedicated to equipment drying.
P840068/S054	04/08/2019	X - 30-Day Notice	ACCESSORY HEX WRENCH	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.
P850010/S085	04/19/2019	X - 30-Day Notice	HELISTAT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Implementation of data integrity and security controls for the Quality Control (QC) Analytical Laboratory Instruments at the Collagen Manufacturing Center (CMC).
P850010/S086	04/26/2019	X - 30-Day Notice	HELISTAT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENT	INTEGRA LIFESCIENCES CORPORATION	Splitting an existing Clean Compressed Air (CCA) Point of Use (POU) within Room 105. You split the existing POU into two (2) POUs with one POU dedicated to filter integrity testing and the other POU dedicated to equipment drying.
P860004/S327	04/02/2019	X - 30-Day Notice	SYNCHROMED® INFUSION SYSTEM, ASCENDA® INTRATHECAL CATHETERS	MEDTRONIC INC.	Change of a sub-tier raw material supplier and to include a lower bound to the particle size of Vanadium Pentoxide

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P880047/S031	04/12/2019	X - 30-Day Notice	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Extension of the Clean Manufacturing Environment at the Ethicon SARL, Neuchatel Switzerland site.
P880087/S027	04/22/2019	X - 30-Day Notice	PMMA SINGLE-PIECE ANTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES	Application and coding of a Radio-Frequency Identification (RFID) label to the device packaging.
P880087/S028	04/22/2019	X - 30-Day Notice	PMMA SINGLE-PIECE ANTERIOR CHAMBER INTRAOCULAR LENSES	ALCON LABORATORIES	Use the membrane filtration recovery method for bioburden testing of the AcrySof® Intraocular Lenses.
P890003/S409	04/16/2019	X - 30-Day Notice	CARELINK SMARTSYNC DEVICE MANAGER PROGRAMMER	MEDTRONIC, INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) release 9.6.
P900033/S077	04/19/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Implementation of data integrity and security controls for the Quality Control (QC) Analytical Laboratory Instruments at the Collagen Manufacturing Center (CMC).
P900033/S078	04/26/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Splitting an existing Clean Compressed Air (CCA) Point of Use (POU) within Room 105. You split the existing POU into two (2) POUs with one POU dedicated to filter integrity testing and the other POU dedicated to equipment drying.
P900056/S177	04/17/2019	X - 30-Day Notice	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM GUIDEWIRE WITH WIRECLIP TORQUER	BOSTON SCIENTIFIC CORP.	Add an existing EO sterilization cycle to an additional chamber in order to increase cycle capacity.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910073/S154	04/08/2019	X - 30-Day Notice	LV LEAD QUADPOLE CONNECTOR IS4, ACCESSORY KIT LEAD CAP, ACCESSORY STYLET TAPER FIX SOFT 64CM, 70CM, AND 100CM, ACCESSORY STYLET TAPER FIX FIRM 64CM, ACCESSORY STYLET TAPER FIX FRT 70CM AND 100CM, ACCESSORY STYLET STR .016 90CM AND .014 90CM, ACCESSORY LEAD REPAIR KIT, ACCESSPRY STYLET TAPER 0.017 70CM, 0.016 70CM, AND 0.014 70CM, ACCESSORY STYLET STR . 016 64CM AND .014 64CM, ACCESSORY 4-SITE TERMINAL TOOL/FIXATION HANDLE, ACCESSORY LEAD PULLING TIP AND ACCESSORY KIT LEAD CAP	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.
P910077/S170	04/08/2019	X - 30-Day Notice	ZOOM LATTITUDE PROGRAMMER SYSTEM ACCESSORY KIT, ADAPTER POWER RF COMMUNICATOR, ACCESSORY KIT LEAD CAP, ACCESSORY WAND TELEMETRY TOOL, ACCESSORY DISK PATIENT DATA, ACCESSORY POUCH PROGRAMMER, ACCESSORY BI-DIRECTIONAL TORQUE WRENCH, DF-1 PORT PLUG	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920047/S114	04/16/2019	X - 30-Day Notice	INTELLATIP MIFI XP ABLATION CATHETERS, INTELLANSV MIFI XP ABLATION CATHETERS AND INTELLANAV ST ABLATION CATHETERS	BOSTON SCIENTIFIC CORP.	Addition of two Thermistor Temperature Accuracy Test Systems for use during the final inspection.
P930014/S121	04/22/2019	X - 30-Day Notice	ACRYSOF® POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Application and coding of a Radio-Frequency Identification (RFID) label to the device packaging.
P930014/S122	04/22/2019	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Use the membrane filtration recovery method for bioburden testing of the AcrySof® Intraocular Lenses.
P930031/S063	04/17/2019	X - 30-Day Notice	WALLSTENT TIPS ENDOPROSTHESIS WITH UNISTEP PLUS	BOSTON SCIENTIFIC CORP.	Add an existing EO sterilization cycle to an additional chamber in order to increase cycle capacity.
P930035/S030	04/08/2019	X - 30-Day Notice	ACCESSORY WRENCH	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.
P930038/S094	04/19/2019	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATIO N	New testing facilities for quarterly bioburden monitoring, a new testing facility for sample pre-sterilization preparation, and a new testing facility for sterility testing.
P940019/S054	04/17/2019	X - 30-Day Notice	WALLSTENT ILIAC ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC SCIMED, INC.	Add an existing EO sterilization cycle to an additional chamber in order to increase cycle capacity.
P940031/S078	04/08/2019	X - 30-Day Notice	ACCESSORY KIT	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960004/S089	04/08/2019	X - 30-Day Notice	ACCESSORY STYLET TAPER .014 45CM, .014 52CM, .014 58CM, .016 45CM, .016 52CM, AND .016 58CM, ACCESSORY STYLET TAPER .013 45CM, .013 52CM, .013 52CM, AND .013 58CM, ACCESSORY STYLET .014 J 45CM,.014 J 52CM, .014 J 58CM, .016 J 45CM, .016 J 52CM, .016 J 58CM, .013 J 45CM, 52CM, AND J 58CM, ACCESSORY STR .013 45CM, 52CM AND 58CM, ACCESSORY STR .014 45CM, 52CM, AND 58CM, ACCESSORY STR .016 45CM, 52CM AND 58CM ACCESSORY KIT SUTURE SLEEVE STABLIZER, AND ACESSORY STYLET	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.
P960006/S049	04/08/2019	X - 30-Day Notice	ACCESSORY KIT SUTURE SLEEVE STABILIZER AND ACCESSORY TERMINAL PIN FIXATION TOOL	BOSTON SCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.
P960009/S342	04/01/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Manufacturing transfer of A10504002, Pin-Crimp Core, 316L SST Thru Hole, Transition Fitting, from the current supplier Lake Region Medical to RMS.
P960009/S343	04/02/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Change of a sub-tier raw material supplier and to include a lower bound to the particle size of Vanadium Pentoxide
P960009/S346	04/29/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	approval to rearrange the manufacturing process flow for the Restore Extension family at the Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico
P970004/S285	04/02/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Change of a sub-tier raw material supplier and to include a lower bound to the particle size of Vanadium Pentoxide
P970055/S019	04/17/2019	X - 30-Day Notice	PARVOVIRUS B19 IGM IMMUNOASSY (V619IMUS)	DIASORIN	Add a process for a manual setting of a lot specific constant value for specific kit lots.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S703	04/16/2019	X - 30-Day Notice	EVERA, MIRRO, PRIMO, PROTECTA, SECURA, VISIA, S DR, VR XT DF1 MRI ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) release 9.6.
P980023/S091	04/16/2019	X - 30-Day Notice	PROTEGO TD, SD 75/18, 65/18, 65/16 AND SD 60/16 PROTEGO T 65, AND S 75, 65, 60 PLEXA S 60, PLEXA SD 60/16, PLEXA PROMRI S 65, 75, PLEXA PROMRI SD 65/16, 65/18, 75/18AND SENTUS (PROMRI) OTW QP S-75, 85, 95, QP L-75, 85, 95 QP S-75/49, 85/49, 95/49, QP L-75/49, 85/49, 95/49, SENTUS OTW QP S/L-75, 85, 95 AND SENTUS OTW QP S-75/49, 85/49	BIOTRONIK, INC.	Changes to in-process quality inspection criteria.
P980033/S053	04/17/2019	X - 30-Day Notice	WALLSTENT VENOUS ENDOPROSTHESIS WITH UNISTEP PLUS	BOSTON SCIENTIFIC CORPORATION	Add an existing EO sterilization cycle to an additional chamber in order to increase cycle capacity.
P980035/S580	04/04/2019	X - 30-Day Notice	IMPLANTABLE PULSE GENERATORS (IPG) ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG; AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	Modification to the resistance spot welding process to the B+ electrical connector to the battery.
P980035/S585	04/16/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA, ADVISA, ASTRA, ATTESTA, AZURE, RELIA, SPHERA, DR S XT SR MRI IPG	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) release 9.6.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980040/S102	04/01/2019	X - 30-Day Notice	SENSAR 1-PIECE IOL, TECNIS 1-PIECE IOL, TECNIS 1-PIECE OPTIBLUE IOL, PRELOADED TECNIS 1-PIECE IOL, TECNIS MULTIFOCAL 1-PIECE IOL, TECNIS SYMFONY EXTENDED AND TORIC EXTENDED RANGE OF VISION IOL, SENSAR 3-PIECE MONOFOCAL AND TECNIS TORIC 1-PIECE	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding a new system to cool the lens blanks during manufacturing.
P990080/S050	04/01/2019	X - 30-Day Notice	TECNIS 3-PIECE ACRYLIC MONOFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Adding a new system to cool the lens blanks during manufacturing.
P000039/S066	04/18/2019	X - 30-Day Notice	AMPLATZER SEPTAL OCCLUDER	ABBOTT MEDICAL	Add two higher capacity sterilization chambers at the Costa Rica sterilization site and add two new sterilization process challenge devices.
P010012/S500	04/08/2019	X - 30-Day Notice	ACUITY X4 STRAIGHT 86CM ,95CM, ACUITY X4 SPIRAL S 86CM, 95CM, ACUITY X4 SPIRAL L 86CM, L95CM, ACCESSORY SUTURE SLEEVES SLITE, FLUSHING TOOL WITH WIRE GUIDE, UNIVERSL HF FINISH WIRE 72CM, ACCESSORY SLIT SUTURE SLEEVE, ADAPTER POWER IND COMMUNICATOR, ACCESSORY BI-DIRECTIONAL TORQUE WRENCH, ACCESSORY STABILIZER AND ACCESORY LEAD CAP LV1	BOSTON SCIENTIFIC CORP.	Modifications to the frequency, equipment and method for monitoring airborne particulates.
P010014/S085	04/17/2019	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Introduce Paramelt F30-53 pattern-wax and Paramelt ¿Zimmer¿ Sprue Wax into the casting process at Biomet Fair Lawn. This wax is used during the casting process of the metallic femoral and tibial components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S396	04/04/2019	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY PACEMAKERS (CRT-P) PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADTRIPOLAR CRT-P; SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P; SOLARA BIPOLAR CRT-P, SOLARA QUADTRIPOLAR CRT-P	MEDTRONIC INC.	Modification to the resistance spot welding process to the B+ electrical connector to the battery.
P010015/S401	04/16/2019	X - 30-Day Notice	CONSULTA; PERCEPTA BIPOLAR, QUADRIPOLAR; SERENA BIPOLAR, QUADRIPOLAR; SYNCRA; VIVA CRT-P	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) release 9.6.
P010031/S663	04/16/2019	X - 30-Day Notice	AMPLIA, AMPLIA BRAVA ,BRAVA QUAD, CLARIA CLARIA QUARD, COMPIA, CONSULTA, PROTECTA, VIVA MRI XT S CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) release 9.6.
P010033/S044	04/29/2019	X - 30-Day Notice	QUANTIFERON- TB GOLD TEST AND QUANTIFERON-TB GOLD PLUS TEST	QIAGEN	Scale-up bulk and sub-bulk manufacturing processes for a kit component.
P020011/S013	04/26/2019	X - 30-Day Notice	APTIMA HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Change in plastic resin used for reagent storage containers.
P020012/S028	04/05/2019	X - 30-Day Notice	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Implementation of a new quality control oven.
P020025/S117	04/16/2019	X - 30-Day Notice	BLAZERE II ABLATION CATHETERS, BLAZER II XP ABLATION CATHETERS, BLAZER PRIME ABLATION CATHETERS	BOSTON SCIENTIFIC	Addition of two Thermistor Temperature Accuracy Test Systems for use during the final inspection.
P020036/S040	04/30/2019	X - 30-Day Notice	CORDIS S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Process improvement to upgrade the sterilization vessel control system and associated mechanical components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S325	04/05/2019	X - 30-Day Notice	PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND SPEXCTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Environmental monitoring control change and sampling plan update at the Boston Scientific Corporation, St. Paul, Minnesota facility.
P030031/S097	04/19/2019	X - 30-Day Notice	THERMACOOL SMARTTOUCH SF BI-DIRECTIONAL AND THERMOCOOL SMARTTOUCH SF UNI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Add a semi-automated prep shaft machine as an alternate manufacturing process for the ThermoCool SmartTouch and ThermoCool SmartTouch SF catheters.
P030047/S038	04/30/2019	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS CORP.	Process improvement to upgrade the sterilization vessel control system and associated mechanical components
P040014/S036	04/11/2019	X - 30-Day Notice	ELECTROPHYSIOLOGY CABLE, THERAPY ABLATION CATHETER	IRVINE BIOMEDICAL, INC.	Implementation of a new biological indicator as a monitoring control.
P040020/S089	04/22/2019	X - 30-Day Notice	ACRYSOF® IQ RESTOR® POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Application and coding of a Radio-Frequency Identification (RFID) label to the device packaging.
P040020/S090	04/22/2019	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Use the membrane filtration recovery method for bioburden testing of the AcrySof® Intraocular Lenses.
P040029/S007	04/11/2019	X - 30-Day Notice	EUCLID SYSTEMS ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR; EUCLID SYSTEMS ORTHOKERATOLOGY (TISILFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	Change to the lens order input process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040036/S067	04/19/2019	X - 30-Day Notice	THERMOCOOL SMARTTOUCH UNI-DIRECTIONAL AND THERMOCOOL SMARTTOUCH BI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Add a semi-automated prep shaft machine as an alternate manufacturing process for the ThermoCool SmartTouch and ThermoCool SmartTouch SF catheters.
P040037/S131	04/17/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an automated verification process of endoprosthesis loading.
P040042/S042	04/11/2019	X - 30-Day Notice	ELECTROPHYSIOLOGY CABLE; SE-SAFIRE TX, CATHETER EXTENSION CABLE; THERAPY 8MM, THERMISTOR, DUAL 8, SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Implementation of a new biological indicator as a monitoring control.
P040045/S105	04/05/2019	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Manufacturer recommended like-for-like replacement part used during the manufacturing process of VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lenses.
P040045/S106	04/16/2019	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate supplier for a raw material used in VISTAKON (senofilcon A) Brand Contact Lenses.
P050006/S076	04/18/2019	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Remove cytotoxicity and IR inspections for the GORE CARDIOFORM Septal Occluder incoming components.
P050027/S017	04/22/2019	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC (PDD) D-LIGHT C SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Change for the two circuit board components of the D-Light C Light Source.
P050028/S074	04/10/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HBV, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Removal of redundant visual inspection of components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060011/S017	04/12/2019	X - 30-Day Notice	C-FLEX INTRAOCULAR, C-FLEX ASPHERIC INTRAOCULAR, ASPHERIC INTRAOCULAR AND RAYONE ASPHERIC LENS	RAYNER INTRAOCULAR LENSES LTD.	Change to the lens blocking arbors and wax.
P060019/S045	04/11/2019	X - 30-Day Notice	THERAPY COOL PATH ABLATION CATHETER	IRVINE BIOMEDICAL, INC.	Implementation of a new biological indicator as a monitoring control.
P060030/S073	04/10/2019	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Removal of redundant visual inspection of components.
P070008/S102	04/16/2019	X - 30-Day Notice	SENTUS PROMRI OTW QP S-75, 85, 95, L-75, 85, 95, SENTUS PROMRI OTW QP S-75/49, 85/49, 95/49, L-75/49, 85/49, 9/49 AND SENTUS OTW QP S-95/49 AND QP L-75/49, 85/49, 95/49	BIOTRONIK, INC.	Changes to in-process quality inspection criteria.
P070026/S056	04/12/2019	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Additional inspection technique.
P070026/S058	04/17/2019	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Changes to dye penetrant formulation.
P070026/S060	04/26/2019	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Increasing the high sealing temperature parameter for the Blister Sealer.
P080011/S091	04/09/2019	X - 30-Day Notice	BIOFINITY XR TORIC LENSES	COOPERVISION MANUFACTURING, LTD.	Introduction of a second Biofinity MTO manufacturing line at the Hamble, United Kingdom facility.
P080025/S180	04/02/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Change of a sub-tier raw material supplier and to include a lower bound to the particle size of Vanadium Pentoxide.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090003/S045	04/17/2019	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Add an existing EO sterilization cycle to an additional chamber in order to increase cycle capacity.
P090015/S007	04/11/2019	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Addition of a new supplier of reagents.
P100010/S089	04/03/2019	X - 30-Day Notice	ARCTIC FRON ADVANCE AND ARCTIC FRONT ADVANCE PRO CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Addition of an alternate outer balloon bond manual measurement fixture.
P100026/S067	04/26/2019	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Eliminate the parylene coating process of the internal surface of contacts / electrodes of the NeuroPace Leads.
P100042/S023	04/26/2019	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Change in plastic resin used for reagent storage containers.
P110004/S032	04/12/2019	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Utilization of two identical welding machines for the welding of the D-Catheter Distal spring tip, as an alternative to the already approved welding machines used for this purpose.
P110016/S060	04/11/2019	X - 30-Day Notice	THERAPY COOL FLEX, PATH DUO, SAFIRE DUO, MEDIGUIDE ENABLED ABLATION CATHETER; MEDIGUIDE ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Implementation of a new biological indicator as a monitoring control.
P110016/S061	04/23/2019	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER, FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Addition of chambers 3 and 4 at the approved sterilization vendor and addition of new sterilization process challenge devices.
P110037/S045	04/10/2019	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS TAQMAN CV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Removal of redundant visual inspection of components.
P110038/S023	04/19/2019	X - 30-Day Notice	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Specification change for the amount of adhesive allowed on the Delivery Tube.
P110042/S124	04/08/2019	X - 30-Day Notice	EMBLEM S-ICD ELECTRODE 45CM	BOSTON SCIENTIFIC CORPORATION	Modifications to the frequency, equipment and method for monitoring airborne particulates.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120002/S015	04/30/2019	X - 30-Day Notice	CORDIS S.M.A.R.T. CONTROL / S.M.A.R.T. VASCULAR	CORDIS CORP.	Process improvement to upgrade the sterilization vessel control system and associated mechanical components.
P120006/S032	04/24/2019	X - 30-Day Notice	OVATION IX ABDOMINAL STENT GRAFT SYSTEM	TRIVASCULAR INC	Implement a change of the surfactant in the FEP dispersion.
P120007/S021	04/26/2019	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Change in plastic resin used for reagent storage containers.
P130006/S070	04/17/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of an automated verification process of endoprosthesis loading.
P130013/S028	04/01/2019	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE DEVICE AND DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Modify the implant frame ultrasonic cleaning and laser window removal process.
P130026/S044	04/23/2019	X - 30-Day Notice		ST. JUDE MEDICAL	Addition of chambers 3 and 4 at the approved sterilization vendor and addition of new sterilization process challenge devices.
P140026/S012	04/30/2019	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Rrocess improvement to upgrade the sterilization vessel control system and associated mechanical components.
P140032/S030	04/02/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Change of a sub-tier raw material supplier and to include a lower bound to the particle size of Vanadium Pentoxide
P150005/S042	04/18/2019	X - 30-Day Notice	INTELLANAV OI AND INTELLANAV MIFI OI ABLATION CATHETERS	BOSTON SCIENTIFIC CORP.	Alternate vendor for Printed Circuit Board Assembly (PCBA) components within the handles of the IntellaNav OI and IntellaNav MiFi OI Ablation Catheters.
P150012/S074	04/08/2019	X - 30-Day Notice	ACCESSORY STYLET STR 0.013 45CM, ACCESSORY STYLET STR 0.013 52CM,ACCESSORY STYLET STR 0.013 59CM, ACCESSORY STYLET LTPR STR 0.014 45CM, ACCESSORY STYLET LTPR STR 0.014 52CM, ACCESSORY STYLET LTPR STR 0.014 59CM AND INGEVITY SLIT SUTURE SLEEVE	BOSTONSCIENTIFIC	Modifications to the frequency, equipment and method for monitoring airborne particulates.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150015/S024	04/25/2019	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Implement an additional purification step for an oligonucleotide probe.
P150031/S017	04/05/2019	X - 30-Day Notice	VERCISE VERCISE PC, AND VERCISE GEVIA, DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Environmental monitoring control change and sampling plan update at Boston Scientific St. Paul, Minnesota facility.
P150033/S053	04/16/2019	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) release 9.6.
P150038/S011	04/25/2019	X - 30-Day Notice	EXABLATE 4000 SYSTEM	INSIGHTEC	Introduction of a US based warehouse and distribution facility for the purpose of receipt, handling, storage, shipping, and distributing of Exablate Treatment Kits and for storing replacement parts.
P150048/S032	04/04/2019	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, EDWARDS INSPIRIS RESILIA AORTIC VALVE, EDWARDS PERICARDIAL MITRAL BIOPROTHESIS	EDWARDS LIFESCIENCES, LLC.	Implementation of manufacturing changes to the Model 11500A, Model 11000A, and Model 11000M products.
P160001/S035	04/12/2019	X - 30-Day Notice	OBALON NAVIGATION BALLOON KIT	OBALON THERAPEUTICS, INC.	Addition of a component inspection step in the manufacturing process
P160001/S036	04/26/2019	X - 30-Day Notice	OBALON TOUCH DISPENSER	OBALON THERAPEUTICS, INC.	Add an inspection step for the Touch Dispenser¿s manifold.
P160016/S003	04/05/2019	X - 30-Day Notice	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)	SIEMENS HEALTHCARE DIAGNOSTICS, INC.	Relocation of reagent manufacture from one building to another within the same establishment.
P160023/S012	04/26/2019	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Change in plastic resin used for reagent storage containers.
P160043/S023	04/26/2019	X - 30-Day Notice	RESOLUTE ONYX OVER-THE-WIRE (OTW) ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Addition of an alternate manufacturing site for the Resolute Onyx OTW catheter subassembly.
P160055/S004	04/05/2019	X - 30-Day Notice	RXSIGHT LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Expansion of the manufacturing to an additional building under the same FDA establishment registration, addition of a large humidity chamber, and a modification to the optic surface molds.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170002/S003	04/10/2019	X - 30-Day Notice	RHA 2, RHA 3, RHA 4 DERMAL FILLERS	TEOXANE S.A.	Change in the sterilization method of the empty syringe by the syringe supplier
P170008/S015	04/12/2019	X - 30-Day Notice	ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Utilization of two identical welding machines for the welding of the D-Catheter Distal spring tip, as an alternative to the already approved welding machines used for this purpose.
P170025/S011	04/26/2019	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Change in plastic resin used for reagent storage containers.

Total: 124