PMA Monthly approvals from 1/1/2018 to 1/31/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170025	01/23/2018	PMAO - PMA Origi	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Approval for the Aptima HBV Quant assay is an in vitro nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human plasma and serum on the fully automated Panther® system. Plasma may be prepared in ethylenediaminetetraacetic acid (EDTA), anticoagulant citrate dextrose (ACD) solution, and plasma preparation tubes (PPTs). Serum may be prepared in serum tubes and serum separator tubes (SSTs). Specimens are tested using the fully automated Panther system for sample processing, amplification, and quantitation. Specimens containing HBV genotypes A, B, C, D, E, F, G, and H are validated for quantitation in the assay. The Aptima HBV Quant assay is intended for use as an aid in the management of patients with chronic HBV infections undergoing HBV antiviral drug therapy. The assay can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing viral response to treatment. The results from the Aptima HBV Quant assay must be interpreted within the context of all relevant clinical and laboratory findings. Assay performance for determining the clinical stage of HBV infection has not been established. Clinical performance characteristics have been established for individuals treated with tenofovir disoproxil fumarate or entecavir. The Aptima HBV Quant assay is not approved for use as a screening test for the presence of HBV DNA in blood or blood products or as a diagnostic test to confirm the presence of HBV infection.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S029	01/02/2018	Y - 135 Review Tra	GELFOAM (ABSORBABLE GELATIN)STERILE SPONGE	PFIZER, INC.	Approval to monitor the water absorption prior to the final device compression manufacturing step.
N970003/S217	01/07/2018	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for multiple software upgrades and updates for the Model 3300 Latitude Programming System.
P810031/S063	01/26/2018	N - Normal 180 Day	SODIUM HYALURONATE OPHTALMIC VISCOELASTC DEVICES (OVD); HEALON PRO, HEALON5 PRO, AND HEALON DUET PRO DUAL PACK	ABBOTT MEDICAL OPTICS INC	Approval for the following: 1. change in the derivation process of the sodium hyaluronate (HA), which is the rheological active component in the above-mentioned OVDs, from rooster comb derivation to bacterial fermentation; 2. change in the supplier of the HA raw material from AMO Uppsala to HTL S.A.S. (Paris, France); 3. change in the composition and supplier of the buffer solution, which is used to reconstitute the dried HA into its final intended form; 4. change in the buffer solution supplier from Fresenius Kabi Norway AS (Halden, Norway) to Biochrom GMbH (Berlin, Germany); 5. change in the silicone emulsion supplier used to siliconize the inner glass cylinder from TriboTec AB (MölInlycke, Sweden) to Bisterfeld Spezialchemie GmbH (Hamburg, Germany); and 6. minor changes to the primary packaging components: a. change in the rubber used in the subject devices¿ plunger and aluminum cap from chlorobutyl rubber supplied by West Pharmaceutical Services, Inc. (Eschweiler, DE) to bromobutyl rubber supplied by Datwyler Pharma Packaging International (Alken, Belgium); and b. reduction in the dimensions of the inner diameter and head height of the glass cylinder.
P860003/S093	01/28/2018	N - Normal 180 Day	THERAKOS CELLEX PHOTOPHERESIS SYSTEM	THERAKOS, INC.	Approval for manufacturing site located at Harmac Medical Products Limited , I.D.A Industrial Estate Castlerea Roscommon, Ireland for the manufacture and finished product release testing for CELLEX Procedural Kits ; Synergy Health Ireland Ltd , IDA Industrial Estate , Tullamore, Offaly, Ireleand for the sterilization of CELLEX Procedural Kits; and Synergy Health (Steris), Thorne, UK Ltd , Alpha Court Capitol Park, Thorne, South Yorkshire DN8 5TZ, United Kingdom, as the alternate sterilization location for the CELLEX Procedural Kits
P860003/S097	01/26/2018	R - Real-Time Proc	THERAKOS CELLEX PHOTOPHERESIS SYSTEM	THERAKOS, INC.	Approval for a design change to the air detector used in the CELLEX Photopheresis System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860004/S262	01/31/2018	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for a change in the finished kit contract manufacturer for the Implantable Infusion System Refill and Catheter Access Port (CAP) Kits as well as component, design, labeling and packaging changes to the Refill and CAP kits.
P860004/S281	01/05/2018	N - Normal 180 Day	SYNCHROMED INFUSION SYSTEM, SYNCHROMED II INFUSION PUMP	MEDTRONIC INC.	Approval for the Model A810 SynchroMed II Clinician Programmer Application and Model 8880T2 Communicator intended for programming a SynchroMed II implantable infusion pump, and associated labeling and alarm changes.
P860057/S169	01/30/2018	Y - 135 Review Tra	CARPENTIER-EDWARDS PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS, MODEL 3300TFX	EDWARDS LIFESCIENCES, LLC.	Approval for the addition of a new modular cleanroom for surgical heart valve stent sub-assemblies in the Cartago, Costa Rica facility.
P910077/S163	01/07/2018	R - Real-Time Proc	LATITUDE PROGRAMMING SYSTEM	BOSTON SCIENTIFIC	Approval for multiple software upgrades and updates for the Model 3300 Latitude Programming System.
P930014/S104	01/23/2018	Y - 135 Review Tra	ACRYSOF® SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Approval for the use of the membrane filtration bioburden recovery method for the AcrySof Intraocular Lenses.
P940010/S012	01/17/2018	R - Real-Time Proc	OPTIGUIDE FIBER OPTIC DIFFUSER (DCYL CYLINDRICAL DIFFUSER SERIES)	CONCORDIA LABORATORIES, INC	Approval for replacement resin for the manufacturing of "heat shrink" tubing used in all sizes of the DCYL 200 Series fibers (DCYL 210, 215,220,225, 250).
P960040/S408	01/07/2018	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETR DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for multiple software upgrades and updates for the Model 3300 Latitude Programming System.
P970018/S035	01/12/2018	O - Normal 180 Day	BD TOTALYS SLIDEPREP	BD DIAGNOSTIC SYSTEMS	Approval for labeling changes to the BD Totalys MultiProcessor and SlidePrep.
P970053/S017	01/12/2018	N - Normal 180 Day	NIDEK EC-5000 EXCIMER LASER SYSTEM	NIDEK CO., LTD.	Approval for the change of laser head of the excimer laser, software upgrade to accommodate the laser head change, change of the PC and change to the power transformer.
P980016/S649	01/31/2018	R - Real-Time Proc	EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, AND EVERA XT VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for design changes to printed wiring boards and a supplier change for a select diode used in certain ICD and CRT-D devices.
P990021/S004	01/17/2018	N - Normal 180 Day	PHOTOFRIN 630 PDT LASER	CONCORDIA LABORATORIES, INC	Approval for the PHOTOFRIN 630 PDT Laser to be manufactured by UnionMed Tech, Inc. Bridgewater, New Jersey.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S467	01/07/2018	R - Real-Time Proc	CONTAK CD, EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILL	BOSTON SCIENTIFIC CORP.	Approval for multiple software upgrades and updates for the Model 3300 Latitude Programming System.
P010031/S610	01/31/2018	R - Real-Time Proc	BRAVA CRT-D, BRAVA QUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for design changes to printed wiring boards and a supplier change for a select diode used in certain ICD and CRT-D devices.
P020047/S066	01/25/2018	Y - 135 Review Tra	MULTI-LINK 8 CORONARY STENT SYSTEM / SV / LL CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval to change the ethylene oxide (EO) sterilization release process for the affected products from using the traditional method of biological indicator testing to a parametric release process.
P030005/S165	01/07/2018	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for multiple software upgrades and updates for the Model 3300 Latitude Programming System.
P030017/S300	01/19/2018	O - Normal 180 Day	PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Approval for the addition of an alternate Ethylene Oxide sterilization site at the Boston Scientific St. Paul manufacturing site at 4100 Hamline Avenue North, St. Paul, Minnesota and new sterilization cycle parameters for that facility.
P030017/S306	01/31/2018	R - Real-Time Proc	PRECISION SPECTRA SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a modification of the Precision Spectra Implantable Pulse Generator (IPG) firmware to adjust temperature sensor calibration with an aim to improve the accuracy of the sensor reading.
P030031/S085	01/05/2018	O - Normal 180 Day	BIOSENSE WEBSTER NAVISTAR THERMOCOOL CATHETER	BIOSENSE WEBSTER, INC.	Approval of the sponsors request to close out the OSB Lead-Atrial Fibrillation Registry PAS for the post-approval study (PAS).
P040020/S071	01/23/2018	Y - 135 Review Tra	ACRYSOF® IQ RESTOR® INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Approval for the use of the membrane filtration bioburden recovery method for the AcrySof Intraocular Lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040020/S073	01/10/2018	R - Real-Time Proc	ACRYSOF ASPHERIC UV ABSORBING RESTOR TORIC IOL +2.5 AND +3.0	ALCON RESEARCH, LTD.	Approval for AcrySof Aspheric UV Absorbing ReSTOR Toric Intraocular Lens to be manufactured with the Clear AcrySof® material.
P040038/S032	01/25/2018	Y - 135 Review Tra	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Approval to change the ethylene oxide (EO) sterilization release process for the affected products from using the traditional method of biological indicator testing to a parametric release process.
P050037/S078	01/02/2018	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for changes in the rinse process of CaHA particles and the oven drying temperature of CaHA particles after rinse
P050050/S011	01/08/2018	R - Real-Time Proc	S.T.A.R. ANKLE SYSTEM	STRYKER CORPORATIO N	Approval for new labeling materials.
P050052/S092	01/02/2018	Y - 135 Review Tra	RADIESSE LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Approval for changes in the rinse process of CaHA particles and the oven drying temperature of CaHA particles after rinse
P060023/S006	01/31/2018	O - Normal 180 Day	BRYAN (TM) CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for manufacturing sites located at MedTorque, Inc., 612 W. Lamont Road, Elmhurst, Illinois, for instrument machining and laser marking of the BRYAN¿ and PRESTIGE LP instruments, and at Medtronic Sofamor Danek USA, Inc., 4340 Swinnea Road, Memphis, Tennessee, for the manufacturing of PRESTIGE LP Streamlined Instrument.
P070004/S009	01/30/2018	O - Normal 180 Day	SIENTRA SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for a manufacturing site located at 9900 Vesta, Inc., South 57th Street, Franklin, Wisconsin, a contract manufacturer.
P070015/S138	01/25/2018	Y - 135 Review Tra	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM / XIENCE NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Approval to change the ethylene oxide (EO) sterilization release process for the affected products from using the traditional method of biological indicator testing to a parametric release process.
P080013/S014	01/24/2018	O - Normal 180 Day	DURASEAL EXACT SPINE SEALANT SYSTEM 3ML & 5ML	INTEGRA LIFESCIENCE S CORPORATIO N	Approval for labeling changes based on the Postmarket Approval Study results.
P090029/S008	01/31/2018	O - Normal 180 Day	PRESTIGE: LP(TM) CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for manufacturing sites located at MedTorque, Inc., 612 W. Lamont Road, Elmhurst, Illinois, for instrument machining and laser marking of the BRYAN¿ and PRESTIGE LP instruments, and at Medtronic Sofamor Danek USA, Inc., 4340 Swinnea Road, Memphis, Tennessee, for the manufacturing of PRESTIGE LP Streamlined Instrument.
P100022/S026	01/11/2018	N - Normal 180 Day	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORAT ED	Approval for a 140 mm stent length.

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P100045/S025	01/05/2018	R - Real-Time Proc	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for the addition of a cover for the back of the i3 Patient Electronics System.
P100047/S057	01/18/2018	N - Normal 180 Day	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for implementation of the Lavare Cycle.
P100049/S020	01/29/2018	O - Normal 180 Day	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	
P110019/S095	01/25/2018	Y - 135 Review Tra	XIENCE PRIME EVEROLIMUS ELUTING CORONARY STENT SYSTEM / SV / LL ; XIENCE XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM /SV/ LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM; XIENCE ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval to change the ethylene oxide (EO) sterilization release process for the affected products from using the traditional method of biological indicator testing to a parametric release process.
P110033/S033	01/04/2018	Y - 135 Review Tra	JUVEDERM VOLUMA XC, JUVEDERM VOLLURE XC, AND JUVEDERM VOLBELLA XC	ALLERGAN	Approval for implementation of a scaled-up manufacturing process for the Juvederm Voluma XC, Juvederm Vollure XC, and Juvederm Volbella XC dermal fillers
P110039/S008	01/25/2018	N - Normal 180 Day	EXABLATE 2100/2100 VI SYSTEM	INSIGHTEC	Approval for 1) Software maintenance update to the currently approved clinical software (SW) Versions 6.24 (Windows-XP)/6.241 (Windows-7) used in the Exablate Model 2100/ 2100V1 Type 1.1 / Type 1.11 System (referred to as Exablate Bone or the system). The new software revision will be Version 6.57 (Windows-XP)/6.58 (Windows-7) (6.57 is a set of enhancements to the SW; 6.58 is an update to Windows 7 OS compatibility); and 2) Addition of a water bag as an accessory for acoustic coupling. The water bag will be provided as an optional accessory to be used as an alternative to the previously-approved gel pad.
P120020/S017	01/25/2018	Y - 135 Review Tra	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Approval to change the ethylene oxide (EO) sterilization release process for the affected products from using the traditional method of biological indicator testing to a parametric release process.
P120022/S016	01/12/2018	N - Normal 180 Day	THERASCREEN EGFR RGQ PCR KIT	QIAGEN MANCHESTER LTD	Approval for extending the labeling claim of the therascreeen® EGFR RGQ PCR Kit to include detection of EGFR mutations L681Q, G719X and S768I, to aid in identifying patients with NSCLC for whom safety and efficacy of GILOTRIF® (afatininb) has been established.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130019/S015	01/24/2018	O - Normal 180 Day	MAESTRO RECHARGEABLE SYSTEM	RESHAPE LIFESCIENCES, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P130021/S043	01/17/2018	N - Normal 180 Day	ENVEO PRO DELIVERY CATHETER SYSTEM, ENVEO PRO LOADING SYSTEM	MEDTRONIC COREVALVE LLC	Approval for various modifications to the EnVeo R Delivery Catheter System and EnVeo R Loading System.
P130022/S013	01/04/2018	N - Normal 180 Day	NEVRO CORP. SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for changes made for the Senza Implantable Pulse Generator, IPG2000.
P140008/S011	01/12/2018	S - Special CBE	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGERY INC	Approval for two additional inspections to the manufacture of the vulcanized balloon.
P140010/S033	01/05/2018	Y - 135 Review Tra	IN.PACT ADMIRAL PACLITAXEL-COATED BALLOON CATHETER	MEDTRONIC INC.	Approval to implement an alternate drug coater for the manufacturing of the IN.PACT Admiral Paclitaxel-Coated Balloon Catheter.
P140018/S008	01/30/2018	N - Normal 180 Day	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for modifications to the Instructions for Use and patient brochure.
P140020/S012	01/12/2018	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for the BRACAnalysis CDx®. The device is an in vitro diagnostic device intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes using genomic DNA obtained from whole blood specimens collected in EDTA. Single nucleotide variants and small insertions and deletions (indels) are identified by polymerase chain reaction (PCR) and Sanger sequencing. Large deletions and duplications in BRCA1 and BRCA2 are detected using multiplex PCR. Results of the test are used as an aid in identifying breast and ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants, who are or may become eligible for treatment with Lynparza® (olaparib). Detection of deleterious or suspected deleterious germline BRCA variants by the BRACAnalysis CDx® test in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) maintenance therapy. This assay is for professional use only and is to be performed only at 320 Wakara Way, Salt Lake City, Utah.
P140029/S004	01/31/2018	O - Normal 180 Day	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for a manufacturing site located at Q-Med AB, Seminariegatan 31, SE-752 58 Uppsala, Sweden, for manufacturing and sterilization of Restylane Refyne and Restylane Defyne.
P140033/S019	01/07/2018	R - Real-Time Proc	TENDRIL MRI CARDIAC LEAD	ST. JUDE MEDICAL, INC.	Approval for shelf life extension from 6 months to 12 months.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S044	01/07/2018	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for multiple software upgrades and updates for the Model 3300 Latitude Programming System.
P150022/S003	01/31/2018	R - Real-Time Proc	CLOSER VASCULAR SEALING SYSTEM (VSS)	REX MEDICAL, L.P.	Approval for design changes to the delivery system as well as packaging changes to the delivery system and access kit.
P150026/S003	01/17/2018	R - Real-Time Proc	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for an alternate sterilization process STERRAD 100NX to the current STERRAD NX process for endoscope sterilization.
P150034/S002	01/24/2018	O - Normal 180 Day	REVISION OPTICS RAINDROP NEAR VISION INLAY	REVISION OPTICS, INCORPORATED	Approval of the protocol for the post-approval study (PAS) protocol.
P150036/S019	01/30/2018	Y - 135 Review Tra	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval for the addition of a new modular cleanroom for surgical heart valve stent sub-assemblies in the Cartago, Costa Rica facility.
P150048/S003	01/08/2018	O - Normal 180 Day	INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Approval for protocol for the post-approval study (PAS) protocol. The PAS protocol (Version A:) for the OSB Lead-Model 11500A Prospective PAS.
P150048/S006	01/30/2018	Y - 135 Review Tra	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Approval for the addition of a new modular cleanroom for surgical heart valve stent sub-assemblies in the Cartago, Costa Rica facility.
P160017/S027	01/03/2018	O - Normal 180 Day	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval of the revised protocol for the post-approval study (PAS).
P160019/S003	01/18/2018	N - Normal 180 Day	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS, INC.	Approval for migration of the Elecsys HBsAg II, Elecsys HBsAg Confirmatory Test, and PreciControl HBsAg II onto the cobas e 411 immunoassay analyzer.

Total: 61

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16837/S023	01/18/2018	X - 30-Day Notice	ARTEGRAFT COLLAGEN VASCULAR GRAFT	ARTEGRAFT, INC.	Addition of an alternate supplier for bovine carotid arteries.
N16837/S024	01/26/2018	X - 30-Day Notice	ARTEGRAFT COLLAGEN VASCULAR GRAFT	ARTEGRAFT, INC.	Addition of an alternate supplier for L-cysteine, C.P.
N970012/S143	01/30/2018	X - 30-Day Notice	AMS 700 IMPLANTABLE/ INFLATABLE PENILE PROSTHESIS WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Use of new molding equipment; relocation of and changes to the milling and molding process of the valve block.
P790007/S055	01/12/2018	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE VALVED CONDUIT	MEDTRONIC HEART VALVES	Addition of five new porcine tissue suppliers.
P820033/S011	01/17/2018	X - 30-Day Notice	PLASMAFLO	ASAHI KASEI MEDICAL CO., LTD.	Replacement of the annealing oven used in the manufacturing process of the hollow fibers for the Plasmaflo device.
P840001/S387	01/11/2018	X - 30-Day Notice	MASTER INTELLIS SPINAL CORD STIMULATION SYSTEM	MEDTRONIC NEUROMODULATION	Change the accelerometer offset test from a pass/fail to a process monitor for the AdaptiveStim feature of the Intellis Model 97715/97716 devices.
P840001/S388	01/09/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Qualification of plasma treatment of Neuro molded components on additional plasma reactor at Medtronic Energy and Component Center (MECC), internal supplier of plasma treated polysulfone components for Medtronic Neuromodulation.
P840001/S389	01/11/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Software updates to a final functional test performed on Medtronic Restorative Therapies Group (RTG) therapies' recharging systems. This change is to allow the final functional test software to correctly measure the standby current for the Current Drain Standby Mode Test.
P860004/S295	01/16/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Adding an alternate printer wheel equipment for the application of ink markings to silicone tubing to improve the ink handling and storage process for the SynchroMed II Infusion System and Ascenda Intrathecal Catheters.
P860004/S296	01/12/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Relocation of the manufacturing site of a resonator component of the alarm system in the SynchroMed II Implantable Infusion System Model 8637.

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P870078/S040	01/12/2018	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE VALVED CONDUIT	MEDTRONIC, INC.	Addition of five new porcine tissue suppliers.
P880086/S291	01/03/2018	X - 30-Day Notice	ASSURITY, ASSURITY+, ENDURITY	ST. JUDE MEDICAL, INC.	Use of an additional solder material allowing for the rework of pacemaker and CRT-P hybrid circuits.
P880086/S292	01/05/2018	X - 30-Day Notice	MEDICAL ADHESIVE	ST. JUDE MEDICAL, INC.	Changes to the sterilization chamber load configuration used for device accessories.
P890055/S071	01/12/2018	X - 30-Day Notice	CODMAN 3000 IMPLANTABLE INFUSION PUMP	CODMAN	Removal of the streaming potential test for the capillary tubing for the Codman 3000 Constant Flow pump.
P900033/S067	01/02/2018	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Validation of the cleaning process for the Silastic Guides and Suture Bars.
P910023/S399	01/05/2018	X - 30-Day Notice	LEAD CAP (IS-1/DF-1/SJ4/ DF/IS4) IS4/DF4 PORT PLUG; DF-1 RECEPTACLE PLUG; IS-1 RECEPTACLE PLUG	ST. JUDE MEDICAL	Changes to the sterilization chamber load configuration used for device accessories.
P910056/S029	01/11/2018	X - 30-Day Notice	ENVISTA ONE PIECE HYDROPHOBIC ACRYLIC INTRAOCULAR LENS VIAL MANUFACTURING	BAUSCH & LOMB, INC.	Replacement of a molding press.
P910073/S147	01/05/2018	X - 30-Day Notice	ENDOTAK RELIANCE S / GS /G	BOSTON SCIENTIFIC	Modify the mold tooling drawing to include additional tooling specifications.
P920015/S205	01/04/2018	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT; SPRINT QUATTRO LEAD	MEDTRONIC INC.	Updates to the manufacturing process to co-locate batch plasma processing into a single manufacturing cell.
P930014/S109	01/08/2018	X - 30-Day Notice	ACRYSOF INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Elimination of a test performed during set-up of the manufacturing of your Acrysof and AcrySof ReSTOR multi-piece intraocular lenses.
P940010/S013	01/13/2018	X - 30-Day Notice	OPTIGUIDE CYLINDRICAL FIBER OPTIC	CONCORDIA LABORATORIES, INC	Addition of a manual heating method to be added as an alternative method for the formation of the rounded tip of the cap sub-assembly using ETFE tubing.
P940010/S014	01/30/2018	X - 30-Day Notice	OPTIGUIDE FIBER OPTIC DIFFUSER (DCYL CYLINDRICAL DIFFUSER SERIES)	CONCORDIA LABORATORIES, INC	Replace the current final diffuser tip axial load test method with a test method that is currently performed as an in-process diffuser tip axial load test and to eliminate the requirement for an in-process diffuser tip axial load test.
P950022/S113	01/05/2018	X - 30-Day Notice	IS4/DF4 CONNECTOR SLEEVE; SUTURE SLEEVE; SUTURE SLEEVE KIT	ST. JUDE MEDICAL, INC.	Changes to the sterilization chamber load configuration used for device accessories.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950029/S117	01/29/2018	X - 30-Day Notice	REPLY & ESPRIT SR & DR PACEMAKERS	LIVANOVA USA, INC.	Modify the gluing process of the silicone caps, X-ray tag, and header cavities and to move the assembly sequence of the bal seal springs for the header.
P950029/S119	01/29/2018	X - 30-Day Notice	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR	LIVANOVA USA, INC.	Add a new supplier for silicone cap components for use in the device header.
P960009/S307	01/09/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Qualification of plasma treatment of Neuro molded components on additional plasma reactor at Medtronic Energy and Component Center (MECC), internal supplier of plasma treated polysulfone components for Medtronic Neuromodulation.
P960009/S308	01/11/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Software updates to a final functional test performed on Medtronic Restorative Therapies Group (RTG) therapies' recharging systems. This change is to allow the final functional test software to correctly measure the standby current for the Current Drain Standby Mode Test.
P960011/S027	01/02/2018	X - 30-Day Notice	BVI 1% OVD (1% SODIUM HYALURONATE VISCOELASTIC SURGICAL AID FLUID)	AMRING PHARMACEUTICALS	Increasing the formulation capacity for the manufacturing of BVI 1% OVD®.
P960011/S028	01/04/2018	X - 30-Day Notice	BVI 1%OVD (FONNERLY BD 1%OVD AND BIOLON)	AMRING PHARMACEUTICALS	Alternative, additional supplier for syringe components, and a tamper-evident tip cap closure system for the BVI 1% OVD®.
P960040/S415	01/10/2018	X - 30-Day Notice	DYNAGEN, INOGEN, ORIGEN, AUTOGEN EL ICD; DYNAGEN MINI, INOGEN MINI, ORIGEN MINI ICD; INCEPTA, ENERGEN, PUNCTUA ICD; MOMENTUM, VIGILANT, PERCIVA MINI AND HF ICD, RESONATE EL ICD AND RESONATE HF ICD	BOSTON SCIENTIFIC	Add an alternate supplier of titanium ribbon.
P960040/S416	01/19/2018	X - 30-Day Notice	ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, RESONATE, PERCIVA,PUNCTUA, ENERGEN, INCEPTA ICD	BOSTON SCIENTIFIC	Additional supplier of nickel materials used in the battery stack sub-assemblies.
P960040/S417	01/15/2018	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR / MOMENTUR, VIGILANT, RESONATE, PERCIVA	BOSTON SCIENTIFIC	Update to the final pack electrical test.

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P970003/S216	01/24/2018	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Changes that are being made to the Electrical Test System (ETS) used during the production of the SenTiva Model 1000 Generator and the Model 2000 Programming Wand.
P970031/S062	01/12/2018	X - 30-Day Notice	FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Addition of five new porcine tissue suppliers.
P980016/S655	01/03/2018	X - 30-Day Notice	EVERA MRI ICD / EVERA S DR / S VR /XT DR / XT VR ICD; VISIA AF MRI VR ICD / VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of manufacturing equipment for use during the interconnect ribbon trim process.
P980043/S065	01/12/2018	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Addition of five new porcine tissue suppliers.
P980049/S127	01/25/2018	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR ICDS	LIVANOVA USA, INC.	Replace the solder mask material, to allow for rework of RF modules on hybrids, and to incorporate use of alternate thermosealing equipment during the packaging process.
P990064/S074	01/12/2018	X - 30-Day Notice	MOSAIC PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Addition of five new porcine tissue suppliers.
P000008/S040	01/16/2018	X - 30-Day Notice	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Changes to the adhesive strip tolerance limits and an additional cavity in the Outer Tray Sealing Nest Tool.
P000008/S041	01/18/2018	X - 30-Day Notice	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Installation and qualification of the primary equipment for performing the Lap-Band primary packaging thermoform tray peel test.
P000008/S042	01/23/2018	X - 30-Day Notice	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Change of a suppliers manufacturing site location for production of the thermoform trays used in primary packaging of the Lap-Band system.
P010003/S029	01/03/2018	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Implement use of an additional resin in the manufacture of the mixing tip of the BioGlue Surgical Adhesive.
P010012/S474	01/10/2018	X - 30-Day Notice	DYNAGEN CRT-D AND X4 CRT-D; INOGEN CRT-D AND X4 CRT-D; ORIGEN CRT-D AND X4 CRT-D; AUTOGEN CRT-D AND X4 CRT-D; INCEPTA, ENERGEN AND PUNCTUA CRT-D; MOMENTUM CRT-D AND X4 CRT-D; VIGILANT CRT-D AND X4 CRT-D; RESONATE CRT-D, X4 CRT-D AND HF CRT-D	BOSTON SCIENTIFIC CORP.	Add an alternate supplier of titanium ribbon.

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P010012/S475	01/19/2018	X - 30-Day Notice	ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, RESONATE, PUNCTUA, ENERGEN, INCEPTA CRT-D	BOSTON SCIENTIFIC CORP.	Additional supplier of nickel materials used in the battery stack sub-assemblies.
P010012/S476	01/15/2018	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR MOMENTUM, VIGILANT, RESONATE	BOSTON SCIENTIFIC CORP.	Update to the final pack electrical test.
P010013/S069	01/12/2018	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Changes to the inspection of the Disposable Device array.
P010015/S351	01/17/2018	X - 30-Day Notice	CONSULTA, SYNCRA, VIVA CRT-P	MEDTRONIC INC.	Use of an alternate laser seam welder.
P010031/S615	01/03/2018	X - 30-Day Notice	AMPLIA MRI CRT-D / AMPLIA MRI QUAD CRT-D / BRAVA CRT-D / BRAVA QUAD CRT-D / CLARIA MRI & QUAD QUAD CRT-D / COMPIA MRI & QUAD CRT-D / VIVA QUAD S & XT CRT-D / VIVA S CRT_D / VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of manufacturing equipment for use during the interconnect ribbon trim process.
P010032/S139	01/12/2018	X - 30-Day Notice	SCS AND DBS LEADS, EXTENSIONS, ANCHORS, ADAPTERS AND ACCESSORIES	ST. JUDE MEDICAL	Change in the Process Challenge Devices (PCDs) that are used in St. Jude Medicals current sterilization process for products sterilized at Medline Industries (Medline).
P010032/S140	01/10/2018	X - 30-Day Notice	PROCLAIM ELITE IPG	ST. JUDE MEDICAL	Alternate supplier manufacturing location for the drilling process for the Bluetooth (BLE) antenna (this also included new equipment models). The BLE antenna is a component of the spinal cord stimulation (SCS) and deep brain stimulation (DBS) implantable pulse generator (IPGs) headers.
P020012/S017	01/02/2018	X - 30-Day Notice	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Modification of the Bellafill tray by adding: 1) a stop shelf in the molded tray at a slight diagonal orientation to align the plunger end of the syringes; and 2) a flange indentation for placement of each syringe flange.

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P030017/S309	01/17/2018	X - 30-Day Notice	PRECISION WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEM / WAVEWRITER IPG TEST EQUIPMENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the test equipment system software used for testing the Precision Spectra WaveWriter IPG units.
P030017/S310	01/19/2018	X - 30-Day Notice	PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Replace the Tracer Summit Environmental Monitoring System (EMS) with the Vaisala Central Monitoring System (CMS) at Boston Scientific Dorado, Puerto Rico (BSC-DOR) facility, which manufactures the Spinal Cord Stimulator (SCS) Lead Product Families (Leads, Lead Extensions, Connectors, Adapters and Splitters).
P030031/S087	01/11/2018	X - 30-Day Notice	THERMOCOOL SMART TOUCH	BIOSENSE WEBSTER, INC.	Add a rework process for the ThermoCool SmartTouch and ThermoCool SmartTouch SF catheters to correct an incorrect calibration.
P030035/S163	01/03/2018	X - 30-Day Notice	ALLURE, ALLURE QUADRA, QUADRA ALLURE MP	ST. JUDE MEDICAL, INC.	Use of an additional solder material allowing for the rework of pacemaker and CRT-P hybrid circuits.
P030044/S004	01/22/2018	X - 30-Day Notice	EGFR PHARMDX	DAKO NORTH AMERICA, INC.	Changed manufacturing process (order of addition) of components in two diluent solutions.
P030053/S045	01/30/2018	X - 30-Day Notice	MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR CORP.	Elimination of the oven-based patch curing step from the assembly process.
P030054/S343	01/05/2018	X - 30-Day Notice	SLIT SUTURE SLEEVE; VEIN PICK	ST. JUDE MEDICAL	Changes to the sterilization chamber load configuration used for device accessories.
P040020/S077	01/08/2018	X - 30-Day Notice	ACRYSOF RESTOR INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Elimination of a test performed during set-up of the manufacturing of your Acrysof and AcrySof ReSTOR multi-piece intraocular lenses.
P040021/S034	01/30/2018	X - 30-Day Notice	BIOCOR AND EPIC HEART VALVES	ST. JUDE MEDICAL, INC.	Removal of a manual inspection step in the final packaging inspection process.
P040036/S062	01/11/2018	X - 30-Day Notice	THERMOCOOL SMART TOUCH SF CATHETERS	BIOSENSE WEBSTER, INC.	Add a rework process for the ThermoCool SmartTouch and ThermoCool SmartTouch SF catheters to correct an incorrect calibration.
P060027/S092	01/25/2018	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR CRT-DS	LIVANOVA USA, INC.	Replace the solder mask material, to allow for rework of RF modules on hybrids, and to incorporate use of alternate thermosealing equipment during the packaging process.

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P070004/S012	01/10/2018	X - 30-Day Notice	SIENTRA SILICONE BREAST IMPLANTS	SIENTRA, INC	Change in the implant marking process.
P070004/S014	01/19/2018	X - 30-Day Notice	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Changes to sterilization equipment and dry heat sterilization cycle, and packaging features for Sientra OPUS Silicone Gel Breast Implants at the following manufacturing facility: Vesta, Inc., 9900 South 57th Street, Franklin, Wisconsin.
P080006/S117	01/04/2018	X - 30-Day Notice	ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Updates to the manufacturing process to co-locate batch plasma processing into a single manufacturing cell.
P080007/S021	01/16/2018	X - 30-Day Notice	BARD E-LUMINEXX AND LIFESTAR VASCULAR STENTS	BARD PERIPHERAL VASCULAR, INC.	Addition of alternate laser cutting equipment.
P080027/S031	01/03/2018	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Alternate supplier of a component used to collect specimen for use with the test.
P100026/S051	01/09/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Two changes to occur at NeuroPaces approved battery supplier: 1) to replace an aging Lid Assembly Machine (LAM) welding equipment with equivalent equipment; and 2) to change the sourcing location of the battery ferrules (same supplier, different location).
P100026/S052	01/08/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Implement an alternate inspection method using the Vertex Measurement System (Vertex System).
P100029/S029	01/30/2018	X - 30-Day Notice	TRIFECTA HEART VALVES	ST. JUDE MEDICAL, INC.	Removal of a manual inspection step in the final packaging inspection process.
P100042/S015	01/18/2018	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Transfer bulk manufacturing and filling operations for specified reagents to an existing manufacturing facility.
P110042/S099	01/16/2018	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Additional human visual inspection acceptance activity to the overmolded header inspection step.
P110042/S100	01/12/2018	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Addition of a second high-potential (HiPot) tester and to retro-fit the current HiPot tester on high voltage capacitors.
P110042/S101	01/10/2018	X - 30-Day Notice	EMBLEM MRI S-ICD; EMBLEM S-ICD	BOSTON SCIENTIFIC CORPORATION	Add an alternate supplier of titanium ribbon.

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P120005/S069	01/10/2018	X - 30-Day Notice	DEXCON G4 PLATINUM AND G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Additional manufacturing line for the transmitter component of the Dexcom G4 PLATINUM and G5 Mobile continuous glucose monitoring systems.
P120007/S013	01/18/2018	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Transfer bulk manufacturing and filling operations for specified reagents to an existing manufacturing facility.
P120010/S109	01/19/2018	X - 30-Day Notice	MEDTRONIC MINIMED 530G SYSTEM	MEDTRONIC INC.	Adding a new ISO Class 8 Cleanroom for the manufacturing of Enlite Sensors and Guardian Sensors at Medtronics Northridge facility. The Enlite sensors are components of the MiniMed 530G, Paradigm Real-Time Revel, and iPro2 CGM systems and the Guardian Sensors are components of the MiniMed 630G and MiniMed 670G systems.
P130019/S016	01/22/2018	X - 30-Day Notice	MAESTRO RECHARGEABLE SYSTEM	RESHAPE LIFESCIENCES, INC.	Change in manufacturing site for the contract manufacturer of the Rechargeable Neuroregulator.
P130021/S049	01/18/2018	X - 30-Day Notice	COREVALVE EVOLUT R SYSTEM AND COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Add an alternative supplier for a stopcock component of the EnVeo R Delivery Catheter System and EnVeo PRO Delivery Catheter System.
P140009/S033	01/12/2018	X - 30-Day Notice	IMPLANTABLE PULSE GENERATORS	ST. JUDE MEDICAL NEUROMODULATION	Change in the Process Challenge Devices (PCDs) that are used in St. Jude Medicals current sterilization process for products sterilized at Medline Industries (Medline).
P140009/S035	01/10/2018	X - 30-Day Notice	INFINITY IPG	ST. JUDE MEDICAL NEUROMODULATION	Alternate supplier manufacturing location for the drilling process for the Bluetooth (BLE) antenna (this also included new equipment models). The BLE antenna is a component of the spinal cord stimulation (SCS) and deep brain stimulation (DBS) implantable pulse generator (IPGs) headers.
P150001/S032	01/19/2018	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Adding a new ISO Class 8 Cleanroom for the manufacturing of Enlite Sensors and Guardian Sensors at Medtronics Northridge facility. The Enlite sensors are components of the MiniMed 530G, Paradigm Real-Time Revel, and iPro2 CGM systems and the Guardian Sensors are components of the MiniMed 630G and MiniMed 670G systems.
P150004/S019	01/10/2018	X - 30-Day Notice	PROCLAIM DRG IPG	ST. JUDE MEDICAL	Alternate supplier manufacturing location for the drilling process for the Bluetooth (BLE) antenna (this also included new equipment models). The BLE antenna is a component of the spinal cord stimulation (SCS) and deep brain stimulation (DBS) implantable pulse generator (IPGs) headers.
P150013/S008	01/22/2018	X - 30-Day Notice	PD L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Changed manufacturing process (order of addition) of components in two diluent solutions.
P150016/S008	01/02/2018	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Changes to the manufacturing of the extended applicator tip, assembly/sealing/packaging, labeling processes, and environmental controls of TRIDYNE Vascular Sealant.

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P150019/S035	01/19/2018	X - 30-Day Notice	MEDTRONIC MINIMED PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Adding a new ISO Class 8 Cleanroom for the manufacturing of Enlite Sensors and Guardian Sensors at Medtronics Northridge facility. The Enlite sensors are components of the MiniMed 530G, Paradigm Real-Time Revel, and iPro2 CGM systems and the Guardian Sensors are components of the MiniMed 630G and MiniMed 670G systems.
P150025/S008	01/22/2018	X - 30-Day Notice	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Changed manufacturing process (order of addition) of components in two diluent solutions.
P150029/S014	01/19/2018	X - 30-Day Notice	MEDTRONIC MINIMED IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Adding a new ISO Class 8 Cleanroom for the manufacturing of Enlite Sensors and Guardian Sensors at Medtronics Northridge facility. The Enlite sensors are components of the MiniMed 530G, Paradigm Real-Time Revel, and iPro2 CGM systems and the Guardian Sensors are components of the MiniMed 630G and MiniMed 670G systems.
P150033/S029	01/05/2018	X - 30-Day Notice	MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Additional catalyst material for the capacitor encapsulation process.
P150034/S006	01/12/2018	X - 30-Day Notice	RAINDROP NEAR VISION INLAY	REVISION OPTICS, INCORPORATED	Alternative shortened purification process for the Raindrop® Near Vision Inlay.
P150036/S023	01/19/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM, AORTIC VALVE AND DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Change to the manufacturing process for the malleable handle component of the delivery system.
P160001/S009	01/26/2018	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Modification to the proximal luer hub receiving inspection method and inspection sample size increase.
P160001/S010	01/16/2018	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Change to the gas dispenser final inspection to enhance leak detection.
P160017/S029	01/19/2018	X - 30-Day Notice	MEDTRONIC MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Adding a new ISO Class 8 Cleanroom for the manufacturing of Enlite Sensors and Guardian Sensors at Medtronics Northridge facility. The Enlite sensors are components of the MiniMed 530G, Paradigm Real-Time Revel, and iPro2 CGM systems and the Guardian Sensors are components of the MiniMed 630G and MiniMed 670G systems.
P160035/S003	01/31/2018	X - 30-Day Notice	EXCOR BLOOD PUMP	BERLIN HEART INC.	Process change to the blood-side layer of the triple layer membrane of the EXCOR blood pump.
P160040/S001	01/19/2018	X - 30-Day Notice	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Validation of the ABI instruments and minor corrections to the instructions for use.

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P160054/S003	01/16/2018	X - 30-Day Notice	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Add an alternative manufacturing site for a sub-assembly of the Percutaneous Cable.
P170011/S004	01/16/2018	X - 30-Day Notice	IMPELLA RP SYSTEM	ABIOMED, INC.	Modification to the acceptance criterion for a quality inspection related to the purge flow performance.

Total: 98