PMA Monthly approvals from 2/1/2018 to 2/28/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160032	02/01/2018	PMAO - PMA Origi	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Approval of the Lifeline/ReviveR DDU-100, Lifeline/ReviveR AUTO DDU-120, Lifeline/ ReviveR VIEW DDU-2300, Lifeline/ReviveR VIEW AUTO DDU-2200, Lifeline/ReviveR ECG DDU-2450, and Lifeline/ReviveR ECG+ DDU-2475 Automated External Defibrillators. The Lifeline/ReviveR DDU-100 series Automated External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are: 1) Unconscious and unresponsive; and 2) Not breathing or not breathing normally. Lifeline/ReviveR DDU-100 series AEDs may be used with Defibtech adult defibrillation pads (model number DDP-100). For patients under 8 years old, or weighing less than 55 lbs (25 kg), use Defibtech child/infant defibrillation pads (model number DDP-200P), if available. The Lifeline/ReviveR DDU-2000 series Automated External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are: 1) Unconscious and unresponsive; and 2) Not breathing or not breathing normally. Lifeline/ReviveR DDU-2000 series AEDs may be used with Defibtech adult defibrillation pads (model number DDP-2001). For patients under 8 years old, or weighing less than 55 lbs (25 kg), use Defibtech child/infant defibrillation pads (model number DDP-2002), if available.

Data as of 03/05/2018 03:54 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160037	02/12/2018	PMAO - PMA Origi	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Approval for the BD Onclarity HPV Assay. The BD Onclarity HPV Assay is a qualitative in vitro test for the detection of Human Papillomavirus in cervical specimens collected by a clinician using an endocervical brush/spatula combination or broom and placed in BD SurePath vial. The test utilizes amplification of target DNA by Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types 16, 18 and 45 while concurrently detecting the other HR HPV types that include 31, 33, 35, 39, 51, 52, 56, 58, 59, 66 and 68. The BD Onclarity HPV Assay is indicated: 1) In women 21 years and older with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results, the BD Onclarity HPV Assay can be used to determine the need for referral to colposcopy; 2) In women 21 years and older with ASC-US cervical cytology test results, the BD Onclarity HPV assay can be used to detect high-risk HPV genotypes 16, 18 and 45. This information together with physicians assessment of screening history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy; 3) In women 30 years and older, the BD Onclarity HPV Assay can be used together with cervical cytology to adjunctively screen to detect high risk HPV types. This information, together with the physicians assessment of screening history, other factors, and professional guidelines, may be used to guide patient management; 4) In women 30 years and older, the BD Onclarity HPV Assay can be used to detect high-risk HPV genotypes 16, 18 and 45. This information, together with the physicians assessment of screening history, other factors, and professional guidelines, may be used to guide patient management; and 5) In women 25 years and older, the BD Onclarity HPV Assay can be used as a first-line primary cervical cancer screening test to detect high risk HPV, including 16 and 18. Women who test negative for the high risk HPV types by the BD Onclarity HPV Assay should be followed up in accordance with the physicians assessment of screening and medical history, other risk factors, and professional guidelines. Women who test positive for HPV genotypes 16 and/or 18 by the BD Onclarity HPV Assay should be referred to colposcopy. Women who test high risk HPV positive and 16 and 18 negative by the BD Onclarity HPV Assay (12 other HR HPV Positive) should be evaluated by cervical cytology to determine the need for referral to colposcopy.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S046	02/23/2018	S - Special CBE	SURGICEL POWDER ABSORBABLE HEMOSTATIC POWDER	ETHICON, INC.	Approval for strengthening two contraindication statements for SURGICEL Powder Absorbable Hemostat.
N970003/S223	02/02/2018	R - Real-Time Proc	INGENIO PACEMAKERS (ADVANTIO, INGENIO, VITALIO, FORMIO / INGENIO 2 PACEMAKERS (ALTRUA 2, ESSENTIO, PROPONENT, ACCOLADE)	BOSTON SCIENTIFIC CORP.	Approval for labeling updates to the pulse generator replacement guide.
P890003/S384	02/23/2018	R - Real-Time Proc	CARELINK PROGRAMMER AND ENCORE PROGRAMMER SOFTWARE	MEDTRONIC, INC.	Approval for updates to the Medtronic CareLink Software Model 9986 and Encore Model SW028 Programmer Baseline Operating System Software.
P910077/S164	02/02/2018	R - Real-Time Proc	VENTAK PRX AND VENTAK MINI AICDS	BOSTON SCIENTIFIC	Approval for labeling updates to the pulse generator replacement guide.
P920047/S104	02/09/2018	N - Normal 180 Day	INTELLANAV ST CARDIAC ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for design changes to the Blazer II Ablation Catheter.
P930016/S054	02/09/2018	R - Real-Time Proc	STAR EXCIMER LASER SYSTEM	AMO MANUFACTURING USA, LLC	Approval for 1) the replacement of the existing photo interrupter (3703-0124, manufactured by Hamamatsu) in the Hyperopia Moving assembly (0030-2166) used in the Hyperopia Module (0030-3593) of the STAR S4 IR, with a replacement photo interrupter (3703-0157- L, manufactured by Sharp Microelectronics); 2) the replacement of the existing Hall Effect sensor (sensor) (SS21PE) used in the L2 Rotating Cable Assembly (0030-2714) of the STAR S4 IR L2 Rotating Assembly (0030-2508), with a replacement sensor (0035-1010); and 3) the replacement of the existing L2 Cable (0030-2714), with a replacement cable (0030-2035).
P950037/S183	02/15/2018	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEM	BIOTRONIK, INC.	Approval for MR Conditional labeling for additional system configurations when used under specific conditions with full body 1.5 T MRI scans.
P960040/S414	02/02/2018	R - Real-Time Proc	NG3 FAMILY OF ICDS (AUTOGEN, DYNAGEN, INOGEN AND ORIGEN) NG4 FAMILY OF ICDS (RESONATE, VIGILANT AND PERCIVA)	BOSTON SCIENTIFIC	Approval for labeling updates to the pulse generator replacement guide.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960043/S097	02/16/2018	P - Panel Track	PERCLOSE PROGLIDE SUTURE-MEDIATED CLOSURE SYSTEM	ABBOTT VASCULAR INC.	Approval for the Perclose ProGlide SMC System which is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures. The Perclose ProGlide SMC System is used without or, if required, with adjunctive manual compression. 1) for access sites in the common femoral artery using 5F to 21F sheaths. For sheath sizes greater than 8F, at least two devices and the pre-close technique are required; and 2) for access sites in the common femoral vein using 5F to 24F sheaths.
P970003/S215	02/14/2018	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for updates to the Model 3000 Programming Software (from v1.0 to v1.0.2 and then to v1.0.2.4) based on a field events which revealed that the M3000 v1.0 Software does not interrogate or program certain generator memory locations when used with Model 103, Model 104, Model 105 and Model 106 Generators.
P970004/S253	02/07/2018	O - Normal 180 Day	INTERSTIM® SACRAL NERVE STIMULATION THERAPY SYSTEM (URINARY CONTROL)	MEDTRONIC NEUROMODULATION	Approval for labeling updates to incorporate 5 year data from the InSite Post-Approval Study (Single Tined Lead (protocol 1634).
P970004/S261	02/06/2018	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM; SNM URINARY LEADS	MEDTRONIC NEUROMODULATION	Approval for changes to the instructions for use contained in the Model 3093 Lead / Model 3889 Lead Implant Manual.
P970051/S170	02/14/2018	Y - 135 Review Tra	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the use of coupons for residual gas analysis (RGA) testing for hermeticity and to remove the requirement of batch release based on RGA testing.
P980022/S201	02/14/2018	R - Real-Time Proc	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for design changes to the battery component of the GST1 transmitter. The GST1 transmitter is a component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System.
P980023/S082	02/15/2018	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for MR Conditional labeling for additional system configurations when used under specific conditions with full body 1.5 T MRI scans.
P980037/S068	02/08/2018	S - Special CBE	ANGIOJET ULTRA THROMBECTOMY SYSTEM CONSOLE	BOSTON SCIENTIFIC CORP.	Approval for changes to the Directions for Use (DFU) Operators Manual to enhance the safety of the device.
P000015/S026	02/14/2018	Y - 135 Review Tra	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the use of coupons for residual gas analysis (RGA) testing for hermeticity and to remove the requirement of batch release based on RGA testing.
P010012/S473	02/02/2018	R - Real-Time Proc	NG3 FAMILY OF CRT-DS (AUTOGEN, DYNAGEN, INOGEN, ORIGEN) / NG4 FAMILY OF CRT-DS (RESONATE, VIGILANT)	BOSTON SCIENTIFIC CORP.	Approval for labeling updates to the pulse generator replacement guide.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010019/S062	02/06/2018	R - Real-Time Proc	AIR OPTIX PLUS HYDRAGLYDE / AIR OPTIX PLUS HYDRAGLYDE FOR ASTIGMATISM / AIR OPTIX PLUS HYDRAGLYDE MULTIFOCAL / AIR OPTIX PLUS HYDRAGLYDE MULTIFOCAL TORIC	ALCON LABORATORIES, INC.	Approval for minor design modification and related minor labeling update.
P010030/S098	02/07/2018	N - Normal 180 Day	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for design changes to the battery charger.
P010032/S137	02/13/2018	R - Real-Time Proc	SCS ACCESSORY AND A127 EXTENSION KITS	ST. JUDE MEDICAL	Approval for removal of the Trial cable (also called ETE) from the SCS Accessory Kit and A127 Lead Extension Kit.
P030005/S171	02/02/2018	R - Real-Time Proc	INGENIO CRT-P DEVICES (INVIVE, INTUA), INGENIO 2 CRT-P DEVICES (VALITUDE, VALITUDE X4, VISIIONIST, VISIONIST X4)	GUIDANT CORP.	Approval for labeling updates to the pulse generator replacement guide.
P030017/S307	02/05/2018	R - Real-Time Proc	PRECISION NOVI SPINAL CORD STIMULATOR (SCS) SYSTEM FLASH MEMORY COMPONENT UPDATE	BOSTON SCIENTIFIC CORP.	Approval to replace the flash memory component used on the Printed Circuit Board Assembly (PCBA) with the Precision Novi Implantable Pulse Generator (IPG).
P030027/S005	02/16/2018	O - Normal 180 Day	CERAMIC TRANSCEND® HIP ARTICULATION SYSTEM	MICROPORT ORTHOPEDICS INC.	Approval of product labeling which was updated after the completion of post-approval study protocol.
P030031/S082	02/02/2018	S - Special CBE	THERMOCOOL SMARTTOUCH BI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for modifications to the THERMOCOOL SMARTTOUCH Catheter Instructions for Use to align with the safety information in the THERMOCOOL SMARTTOUCH SF Catheter Instructions for Use.
P030039/S021	02/07/2018	S - Special CBE	COSEAL SURGICAL SEALANT	BAXTER BIO SCIENCE	Approval to add endotoxin Limulus Amebocyte Lysate (LAL) testing for stand-alone Replacement and Extended Applicators.
P040033/S031	02/22/2018	Y - 135 Review Tra	BIRMINGHAM HIP RESURFACING (BHR) SYSTEM	SMITH&NEPHEW ORTHOPAEDICS	Approval for a change to the sterilization parameters that will be used for the BHR components from the previously approved dose range of 25-35 kGy to 25-50 kGy.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040036/S060	02/02/2018	S - Special CBE	THERMOCOOL SMARTTOUCH UNI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for modifications to the THERMOCOOL SMARTTOUCH Catheter Instructions for Use to align with the safety information in the THERMOCOOL SMARTTOUCH SF Catheter Instructions for Use.
P050023/S114	02/15/2018	R - Real-Time Proc	TUPOA LV/ATX & KRONOS LV-T / CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for MR Conditional labeling for additional system configurations when used under specific conditions with full body 1.5 T MRI scans
P050027/S011	02/15/2018	N - Normal 180 Day	KARL STORZ D-LIGHT C PDD SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for additional subsystem and manufacturing site.
P070008/S088	02/15/2018	R - Real-Time Proc	STRATOS LV CRT-P / STRATOS LV-T CRT-P / COROX OTW BP LEAD / COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for MR Conditional labeling for additional system configurations when used under specific conditions with full body 1.5 T MRI scans
P080025/S148	02/07/2018	O - Normal 180 Day	INTERSTIM® SACRAL NERVE STIMULATION THERAPY SYSTEM / BOWEL CONTROL	MEDTRONIC NEUROMODULATION	Approval for labeling updates to incorporate 5 year data from the InSite Post-Approval Study (Single Tined Lead (protocol 1634).
P080025/S156	02/06/2018	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM; SNM BOWEL LEADS	MEDTRONIC NEUROMODULATION	Approval for changes to the instructions for use contained in the Model 3093 Lead / Model 3889 Lead Implant Manual.
P080030/S020	02/06/2018	N - Normal 180 Day	GLAUKOS ISTENT TRABECULAR MICRO-BYPASS STENT SYSTEM	GLAUKOS, CORPORATION	Approval for modifications to the Models GTS100R and GTS100L stents, which are part of the iStent® Trabecular Micro- Bypass Stent System and approval for an alternate supplier for the stents.
P090029/S009	02/13/2018	O - Normal 180 Day	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P100010/S071	02/28/2018	R - Real-Time Proc	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Approval for catheter check valve material change.
P100031/S020	02/09/2018	N - Normal 180 Day	ELECSYS ANTI-HBC II TEST SYSTEM	ROCHE DIAGNOSTICS CORP.	Approval for the migration of the Elecsys Anti-HBc II Immunoassay to the cobas e 801 immunoassay analyzer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100042/S013	02/28/2018	N - Normal 180 Day	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval for the use of the Aptima HPV Assay on Panther Systems equipped with the Panther Fusion Module. The changes required for addition of the Panther Fusion Module that are subject of this approval include reconfiguration of the Panther system hardware and updates to the Panther System and Aptima HPV Assay software.
P110038/S017	02/06/2018	O - Normal 180 Day	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval of the changes in the protocol to allow for completion of the postapproval study (PAS) protocol.
P120007/S011	02/23/2018	N - Normal 180 Day	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval for the use of the Aptima HPV 16 18/45 Genotype Assay on Panther Systems equipped with a Panther Fusion Module. The changes required for addition of the Panther Fusion Module that are subject to this approval include reconfiguration of the Panther System hardware, and updates to the Panther System and Aptima HPV 16 18/45 Genotype Assay software.
P120010/S108	02/14/2018	R - Real-Time Proc	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for design changes to the battery component of the GST1 transmitter. The GST1 transmitter is a component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System.
P120018/S001	02/16/2018	O - Normal 180 Day	SHARPS TERMINATOR	SHARPS TERMINATOR, LLC	Approval for a manufacturing site located at Global Machining Industries, 28 Xinchang Road, 2nd Floor, Suzhou Industrial Park, Suzhou 21500, China, Manufacturing.
P130005/S019	02/09/2018	N - Normal 180 Day	DIAMOND BACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for a change in design of the Orbital Atherectomy System Pump (OAS Pump Model SIP-3000).
P130013/S017	02/21/2018	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for a new plasticizer used in the side-port tubing of the WATCHMAN LAA Access Sheath.
P130024/S021	02/06/2018	O - Normal 180 Day	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval of the revised protocol for the post-approval study (PAS) protocol.
P140002/S009	02/15/2018	Y - 135 Review Tra	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Approval for the addition of new analytical equipment used for residual testing of the MISAGO RX Self-Expanding Peripheral Stent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140003/S018	02/07/2018	P - Panel Track	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for the Impella Ventricular Support Systems. The device is indicated for the treatment of ongoing cardiogenic shock that occurs: 1) immediately (<48 hours) following acute myocardial infarction or open heart surgery; or 2) in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis. As a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures.* The intent of the Impella Support Systems therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function. *Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without IABP.
P140003/S027	02/08/2018	N - Normal 180 Day	IMPELLA 2.5 & IMPELLA CP SYSTEMS	ABIOMED, INC.	Approval for removing the reference to ¿depressed left ventricular ejection fraction¿ from the indications for use statement.
P140004/S009	02/22/2018	O - Normal 180 Day	SUPERION INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORATED	Approval for a manufacturing site located at Apex Tools & Orthopedics Company, 22 Xinzhuang Road 2,Yonghe, GETDD, Guangzhou 511356, China for manufacture of surgical instrumentation.
P140033/S018	02/02/2018	N - Normal 180 Day	ACCENT MRI PACEMAKER	ST. JUDE MEDICAL, INC.	Approval for Single and Dual-chamber pacemaker models for the Accent MRI pacemaker.
P150001/S021	02/13/2018	P - Panel Track	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Approval for adding the upper arm as an alternate insertion site for the Guardian Sensor (3).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150001/S031	02/14/2018	R - Real-Time Proc	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Approval for design changes to the drive motor assembly in the MiniMed 630G pump and the MiniMed 670G pump. The MiniMed 630G/670G pump is a component of the MiniMed 630G/670G system, respectively.
P150001/S033	02/22/2018	S - Special CBE	MINIMED 630G PUMP	MEDTRONIC MINIMED	Approval for the addition of 100% visual inspection to the manufacturing protocol for P-cap O-rings (Part Number D5022027-001) and addition of a second de-flashing procedure to remove excess flash in out-of-spec (OOS) O-rings having flash >0.003.
P150011/S011	02/08/2018	Y - 135 Review Tra	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for a new manufacturing assembly tool and changes to the tissue sewing process.
P150012/S051	02/02/2018	R - Real-Time Proc	ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI PACEMAKERS	BOSTONSCIENTIFIC	Approval for labeling updates to the pulse generator replacement guide.
P150019/S034	02/14/2018	R - Real-Time Proc	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for design changes to the battery component of the GST1 transmitter. The GST1 transmitter is a component of the Paradigm REAL-Time System, the Paradigm REAL-Time Revel System, and the MiniMed 530G System.
P150021/S016	02/26/2018	R - Real-Time Proc	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for design changes to the puck carrier, applicator cap, and container tray of the Freestyle Libre Flash Glucose Monitoring System and Freestyle Libre Pro Flash Glucose Monitoring System, as well as manufacturing changes in increase production capacity for the same components.
P150022/S004	02/07/2018	S - Special CBE	CLOSER VASCULAR SEALING SYSTEM	REX MEDICAL, L.P.	Approval to modify the magnetic resonance imaging safety labeling.
P150024/S009	02/23/2018	S - Special CBE	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval for a workbook for patients, Pathway to a healthier you.
P150034/S007	02/15/2018	O - Normal 180 Day	RAINDROP NEAR VISION INLAY	REVISION OPTICS, INCORPORATED	Approval for proposed reporting changes to the Post-Approval Study (PAS) protocol.
P160016/S001	02/08/2018	R - Real-Time Proc	VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA)	SIEMENS HEALTHCARE DIAGNOSTICS, INC.	Approval for a modification to the assay procedure to allow the VERSANT kPCR Molecular System Sample Preparation module to automatically set up the PCR plate following the RNA extraction step.
P160017/S017	02/13/2018	P - Panel Track	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for adding the upper arm as an alternate insertion site for the Guardian Sensor (3).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160017/S028	02/14/2018	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for design changes to the ball bearing components of the drive motor assembly used in the MiniMed 630G pump and the MiniMed 670G pump. The MiniMed 630G and 670G pumps are components of the MiniMed 630G System and the MiniMed 670G System, respectively.
P160017/S030	02/22/2018	S - Special CBE	MINIMED 670G PUMP	MEDTRONIC MINIMED, INC.	Approval for addition of 100% visual inspection to the manufacturing protocol for P-cap O-rings (Part Number D5022027-001) and addition of a second de-flashing procedure to remove excess flash in out-of-spec (OOS) O-rings having flash >0.003.
P160022/S001	02/07/2018	R - Real-Time Proc	ZOLL X SERIES	ZOLL MEDICAL CORPORATION	Approval for a replacement FPGA component to address obsolescence of the current component.
P160023/S001	02/23/2018	N - Normal 180 Day	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Approval for the use of the Aptima HCV Quant Dx Assay on the Panther System with the attachment of the Panther Fusion Module. The changes being approved include the addition of new hardware and updated software.
P160030/S007	02/26/2018	R - Real-Time Proc	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for design changes to the puck carrier, applicator cap, and container tray of the Freestyle Libre Flash Glucose Monitoring System and Freestyle Libre Pro Flash Glucose Monitoring System, as well as manufacturing changes in increase production capacity for the same components.
P170003/S001	02/26/2018	O - Normal 180 Day	LUTONIX DRUG COATED BALLOON	LUTONIX	Approval of the protocol for the post-approval study (PAS) protocol.
P170011/S002	02/16/2018	O - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170011/S003	02/16/2018	O - Normal 180 Day	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.

Total: 71

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S225	02/08/2018	X - 30-Day Notice	ACCOLADE; PROPONENT; ESSENTIO; ALTRUA 2 PACEMAKER	BOSTON SCIENTIFIC CORP.	New controlled environment area (CEA) level VIII for battery testing.
N970012/S144	02/13/2018	X - 30-Day Notice	INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Removal of heavy metals receiving inspection for acetal and fluorosilicone raw materials.
P810002/S106	02/27/2018	X - 30-Day Notice	MECHANICAL HEART VALVES AND VLAVED GRAFTS	ST. JUDE MEDICAL, INC.	Additional data loggers for use with an automated environmental monitoring system.
P810006/S080	02/09/2018	X - 30-Day Notice	COLLASTAT ABSORABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORABLE COLLAGEN HEMOSTATIC AGENT MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Implement a peristaltic pump for use as a manufacturing aid in the Dispersion Preparation Process for 0.77% or 0.85% Alkali Dispersion at the Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, New Jersey.
P810031/S064	02/27/2018	X - 30-Day Notice	SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES (OVD), HEALON, HEALON GV, HEALON5, HEALON ULTIMATE DUAL PACK, HEALON DUET DUEL PACK PRODUCTS	ABBOTT MEDICAL OPTICS INC	Tightening of the endotoxin specification from 0.5 EU/ml to 0.2 EU/ml, an alternate Limulus Amebocyte Lysate (LAL) testing method, and a change to the sampling method for LAL testing for the Healon®, Healon5®, Healon GV®, Healon® Ultimate Dual Pack and Healon Duet® Dual Pack Ophthalmic Viscoelastic Devices (OVDs).
P820033/S012	02/15/2018	X - 30-Day Notice	PLASMAFLO OP-05W(A)	ASAHI KASEI MEDICAL CO., LTD.	Change in the bioburden recovery procedure for the Plasmaflo OP-05W(A).
P820076/S026	02/21/2018	X - 30-Day Notice	DIPLOS MODEL 05 A & B	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process for implantable leads and accessories.
P840062/S064	02/08/2018	X - 30-Day Notice	COLLACOTE, COLLA TAPE, COLLAPLUG, ABSORABLE COLLAGEN WOUND DRESSING FOR DENTAL SURGERY	COLLA-TEC, INC.	Peristaltic pump for use as a manufacturing aid in the Dispersion Preparation Process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850010/S079	02/09/2018	X - 30-Day Notice	HELISTAT ABSORABLE COLLAGEN HEMOSTATIC AGENT AND HELITENE ABSORABLE COLLAGEN HEMOSTATIC AGENT FIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Implement a peristaltic pump for use as a manufacturing aid in the Dispersion Preparation Process for 0.77% or 0.85% Alkali Dispersion at the Collagen Manufacturing Center located at 105 Morgan Lane, Plainsboro, New Jersey.
P860057/S173	02/03/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS; THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; RSR PERICARDIAL AORTIC BIOPROSTHESIS; THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PLUS PERICARDIAL MITRAL BIOPROSTHESIS; THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Increase in the maximum allowable number of personnel in Cleanroom #1 of the Singapore facility.
P880086/S294	02/01/2018	X - 30-Day Notice	ASSURITY, ASSURITY+, ENDURITY, ACCENT, IDENTITY ADX XL, SUSTAIN XL, VERITY ADX XL, VICTORY XL, AND ZEPHYR XL	ST. JUDE MEDICAL, INC.	Relocation of supplier manufacturing of certain battery components and use of an alternate component welding machine.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P880086/S295	02/22/2018	X - 30-Day Notice	VICTORY, ZEPHYR, ACCENT, ASSURITY, ASSURITY+, ENDURITY,	ST. JUDE MEDICAL, INC.	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P890064/S036	02/08/2018	X - 30-Day Notice	DIGENE HYBIRD CAPTURE 2 (HC2) HPV DNA TEST	QIAGEN GAITHERSBURG, INC	Update and tighten final kit release criteria.
P890064/S037	02/21/2018	X - 30-Day Notice	DIGENE HC2 HIGH-RISK HPV DNA TEST AND DIGENE HC2 HPV DNA TEST	QIAGEN GAITHERSBURG, INC	Modify the in-process QC methods as described and alter the component specifications for the specified reagent.
P900056/S169	02/16/2018	X - 30-Day Notice	ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to a sterilization cycle.
P910023/S401	02/06/2018	X - 30-Day Notice	FORTIFY ASSURA	ST. JUDE MEDICAL	Alternate supplier of the vibratory patient notifier assembly.
P910023/S402	02/01/2018	X - 30-Day Notice	CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, AND QUADRA ASSURA MP	ST. JUDE MEDICAL	Relocation of supplier manufacturing of certain battery components and use of an alternate component welding machine.
P910023/S403	02/22/2018	X - 30-Day Notice	CURRENT+, FORTIFY, FORTIFY ASSURA, ELLIPSE	ST. JUDE MEDICAL	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P920047/S107	02/16/2018	X - 30-Day Notice	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Updates to a sterilization cycle.
P950020/S088	02/08/2018	X - 30-Day Notice	FLEXTOME CORONARY CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Move the blade manufacturing processes from the Boston Scientific Maple Grove, Minneapolis manufacturing facility to the Boston Scientific Arden Hills, Minneapolis manufacturing facility for the atherotome microsurgical blades component used on the Flextome Coronary Cutting Balloon.
P950022/S114	02/08/2018	X - 30-Day Notice	DURATA AND OPTISURE HIGH VOLTAGE LEADS	ST. JUDE MEDICAL, INC.	Minor manufacturing changes to the polyvinylpyrrolidone coating process.
P950022/S115	02/22/2018	X - 30-Day Notice	DURATA, OPTISURE	ST. JUDE MEDICAL, INC.	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P950037/S185	02/21/2018	X - 30-Day Notice	SELOX ST/JT; SIELLO S; SETROX S, SOLIA S, SAFIO S	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process for implantable leads and accessories.
P960004/S082	02/08/2018	X - 30-Day Notice	FINELINE II LEAD FAMILY	BOSTON SCIENTIFIC	Implementation of serial number reading stations with optical character recognition equipment and software for use in lead manufacturing.
P960013/S094	02/08/2018	X - 30-Day Notice	TENDRIL AND OPTISENSE F LOW VOLTAGE LEADS	ST JUDE MEDICAL	Minor manufacturing changes to the polyvinylpyrrolidone coating process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960013/S095	02/22/2018	X - 30-Day Notice	TENDRIL SDX LEAD, TENDRIL ST LEAD, OPTISENSE, TENTRIL STS LEAD	ST JUDE MEDICAL	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P960030/S055	02/08/2018	X - 30-Day Notice	ISOFLEX LOW VOLTAGE LEAD	ST. JUDE MEDICAL	Minor manufacturing changes to the polyvinylpyrrolidone coating process.
P960030/S056	02/22/2018	X - 30-Day Notice	ISOFLEX OPTIM	ST. JUDE MEDICAL	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P960040/S419	02/08/2018	X - 30-Day Notice	DYNAGEN EL/MINI; INOGEN EL/MINI; ORIGEN EL/MINI; AUTOGEN EL; VIGILIANT EL; PERCIVA; RESONATE EL/HF; PERCIVA HF; MOMENTUM EL; PUNCTUA; ENERGEN; INCEPTA ICD	BOSTON SCIENTIFIC	New controlled environment area (CEA) level VIII for battery testing.
P960040/S420	02/21/2018	X - 30-Day Notice	NG3 IMPLANTABLE CARDIOVERTER DEFIBRILLATORS - ORIGEN, INOGEN, DYNAGEN, AUTOGEN / NG4 - MOMENTUM, VIGILANT, RESONATE, PERCIVA	BOSTON SCIENTIFIC	Modify the taping process for capacitors by adding a new equipment.
P970013/S077	02/22/2018	X - 30-Day Notice	MICRONY	ST. JUDE MEDICAL, INC.	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P970051/S174	02/01/2018	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Change in inspection criteria to accept brazed chassis parts.
P970051/S175	02/01/2018	X - 30-Day Notice	NECLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Removal of the Laminar Flow Units from cleanrooms.
P980003/S084	02/16/2018	X - 30-Day Notice	CHILLI II COOLED ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Updates to a sterilization cycle.
P980016/S656	02/08/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Removal of certain visual inspection criteria and addition of a visual inspection upstream during feedthrough manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S657	02/21/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DDR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD< SECURA ICD, VISIA AF, MRI, DFI ICD, VISIA AF MRI VR ICD< VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Increase to the upper concentration limit of an additive used during electroplating.
P980018/S024	02/08/2018	X - 30-Day Notice	HERCEP TEST	DAKO A/S	Changes to the manufacturing process of a buffer.
P980022/S202	02/28/2018	X - 30-Day Notice	PARADIGM REAL TIME INSULIN PUMP / PARADIGM REAL TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Change of O-ring supplier for MiniMed 630G, 670G, and Paradigm REAL-Time family of insulin pumps, which are components of the MiniMed 670G System, MiniMed 630G System with SmartGuard, MiniMed Paradigm Real-Time Revel System with Enlite Sensor, MiniMed 530G System, and MiniMed Paradigm Real-Time Revel System.
P980022/S203	02/28/2018	X - 30-Day Notice	PARADIGM REAL TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Changes to the test method for the bolus accuracy and timing test that is performed for the insulin pump component of the Paradigm Real-time system, Paradigm Real-Time REVEL system, MiniMed 530G system, MiniMed 630G system, and MiniMed 670G system.
P980023/S084	02/21/2018	X - 30-Day Notice	PROTEGO SD/TD/S/T; PROTEGO DF-1 SD/DF-1S; PROTEGO PROMRI SDX/ DF-1 PROMRI SDX; PROTEGO DF-1 PROMRI SD/DF-1 PROMRI S; PLEXA SD/S; PLEXA PRO MRI SD/ PROMRI S; PLEXA DF-1 SD/ DF-1 S; PLEXA DF-1 SDX/ PRO MRI DF-1 S DX; PLEXA PROMRI DF-1 SD/PROMRI DF-1S; BK-IS4/DF4; DH DF4; IS4/DF4 ADAPTER; DH IS-1/ DF4	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process for implantable leads and accessories.
P980035/S531	02/21/2018	X - 30-Day Notice	ASTRA XT DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR 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.	Increase to the upper concentration limit of an additive used during electroplating.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980037/S069	02/08/2018	X - 30-Day Notice	ANGIOJET ULTRA CONSOLE	BOSTON SCIENTIFIC CORP.	Replace an obsolete component that monitors the position of the AngioJet Ultra Console roller pump.
P980044/S042	02/09/2018	X - 30-Day Notice	SUPARTZ FX AND VISCO-3	SEIKAGAKU CORP.	Change to the bacterial endotoxins testing system used in the manufacture of SUPARTZ FX and VISCO-3.
P000015/S028	02/01/2018	X - 30-Day Notice	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Change in inspection criteria to accept brazed chassis parts.
P000015/S029	02/01/2018	X - 30-Day Notice	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Removal of the Laminar Flow Units from cleanrooms.
P000053/S086	02/01/2018	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM 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 calendared cuff adapter.
P000053/S087	02/13/2018	X - 30-Day Notice	URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of heavy metals receiving inspection for acetal and fluorosilicone raw materials.
P000053/S088	02/01/2018	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Addition of annealing step and residual stress test for Y-connector component.
P010012/S478	02/08/2018	X - 30-Day Notice	DYNAGEN X4; INOGEN X4; ORIGEN X4; AUTOGEN X4; MOMENTUM X4; VIGILIANT X4; RESONATE X4/HF; PUNCTUA; ENERGEN; INCEPTA CRT-D	BOSTON SCIENTIFIC CORP.	New controlled environment area (CEA) level VIII for battery testing.
P010012/S479	02/21/2018	X - 30-Day Notice	NG3 CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS - ORIGEN, INOGEN, DYNAGEN, AUTOGEN / NG4 CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS - MOMENTUM, VIGILANT, RESONATE	BOSTON SCIENTIFIC CORP.	Modify the taping process for capacitors by adding a new equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010014/S069	02/22/2018	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Replace use of a cotton bud stick with a shim stock for aiding in the cosmetic irregularity inspection steps for the Oxford Partial Knee metal components.
P010015/S352	02/21/2018	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Increase to the upper concentration limit of an additive used during electroplating.
P010031/S616	02/08/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S AND XT CRT-D, VIVA S AND XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Removal of certain visual inspection criteria and addition of a visual inspection upstream during feedthrough manufacturing.
P010031/S617	02/21/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONSULTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Increase to the upper concentration limit of an additive used during electroplating.
P010033/S038	02/23/2018	X - 30-Day Notice	QUANTIFERON TB GOLD AND QUANTIFERON TB GOLD PLUS	QIAGEN	Establishment of an outside firm as an additional manufacturing site for a portion of the production for a kit component.
P010047/S053	02/01/2018	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT (PALS)	NEOMEND, INC.	Change to the acceptance testing of the outer pouch used to package the extended tip accessory
P010047/S055	02/05/2018	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Expand the use of the Lighthouse Monitoring System (LMS) to additional cleanroom and product storage areas.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020025/S110	02/16/2018	X - 30-Day Notice	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Updates to a sterilization cycle.
P020045/S085	02/06/2018	X - 30-Day Notice	FREEZOR CARDIAC CRYOABLATION CATHETER (4-MM TIP), FREEZOR XTRA SURGICAL CARDIAC CRYOABLATION DEVICE (6-MM TIP), FREEZOR MAX SURGICAL CARDIAC CRYOABLATION DEVICE (8-MM TIP), COAXIAL UMBILICAL CABLE	MEDTRONIC CRYOCATH LP	Change in the sub-tier supplier of a polyimide resin product.
P020047/S068	02/21/2018	X - 30-Day Notice	MULTI-LINK 8 CORONARY STENT SYSTEM AND SV/LL CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change the time point when pyrogen testing for ethylene oxide (EO) sterilized products is conducted for products manufactured at its facility located in Clonmel, Ireland.
P030004/S014	02/06/2018	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Change in the supplier of the Biological Indicator used in the dry heat sterilization of Onyx Liquid Embolic System.
P030005/S173	02/08/2018	X - 30-Day Notice	VALITUDE CRT-P; VALITUDE X4 CRT-P; VISIONIST	GUIDANT CORP.	New controlled environment area (CEA) level VIII for battery testing.
P030026/S033	02/23/2018	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC IGM REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Remove the requirement to functionally test an incoming raw material and release it based on supplier data in the Certificate of Analysis.
P030035/S165	02/01/2018	X - 30-Day Notice	ALLURE, ALLURE QUADRA, QUADRA ALLURE MP, ANTHEM, AND FRONTIER II	ST. JUDE MEDICAL, INC.	Relocation of supplier manufacturing of certain battery components and use of an alternate component welding machine.
P030035/S166	02/22/2018	X - 30-Day Notice	ANTHEM, ALLURE, ALLURE RF, ALLURE QUADRA, ALLURE QUADRA RF	ST. JUDE MEDICAL, INC.	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P030054/S345	02/06/2018	X - 30-Day Notice	UNIFY ASSURA, QUADRA ASSURA, QUADRA ASSURA MP	ST. JUDE MEDICAL	Alternate supplier of the vibratory patient notifier assembly.
P030054/S346	02/08/2018	X - 30-Day Notice	QUICKFLEX U AND QUARTET CRT LEADS	ST. JUDE MEDICAL	Minor manufacturing changes to the polyvinylpyrrolidone coating process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030054/S347	02/01/2018	X - 30-Day Notice	PROMOTE+, QUADRA ASSURA, UNIFY, UNIFY ASSURA, AND UNIFY QUADRA	ST. JUDE MEDICAL	Relocation of supplier manufacturing of certain battery components and use of an alternate component welding machine.
P030054/S348	02/22/2018	X - 30-Day Notice	PROMOTE+, UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, QUADRA ASSURA MP, QUICKFLEX U, QUARTET, QUARTET (MR CONDITIONAL)	ST. JUDE MEDICAL	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P040037/S109	02/20/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Addition of automated packaging dispensing equipment.
P040045/S092	02/13/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Implementation of an alternate quality control testing method for a raw material.
P040045/S093	02/09/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification of the monomer dose volume.
P040047/S049	02/12/2018	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Update to the test method for determining the pH of calcium hydroxyapatite (CaHA) particles.
P050019/S029	02/22/2018	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Update the visual acceptance criteria of a thermal bond for a delivery system component.
P050023/S115	02/21/2018	X - 30-Day Notice	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process for implantable leads and accessories.
P050037/S086	02/12/2018	X - 30-Day Notice	RADIESSEE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Update to the test method for determining the pH of calcium hydroxyapatite (CaHA) particles.
P050047/S062	02/21/2018	X - 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Addition of a syringe filling line.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050052/S102	02/12/2018	X - 30-Day Notice	RADIESSE LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Update to the test method for determining the pH of calcium hydroxyapatite (CaHA) particles.
P060006/S090	02/16/2018	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to a sterilization cycle.
P070008/S089	02/21/2018	X - 30-Day Notice	COROX OTW BP/OTW-S BP; COROX OTW-L BP/ PROMRI OTW-L BP; COROX PROMRI OTW BP/ PROMRI OTW-SBP; SENTUS PROMRI OTW QP S/PROMRI OTW QP L; SENTUS PROMRI OTW QP S/PROMRI OTW QP-L	BIOTRONIK, INC.	Use of supplemental sterilization equipment and a new sterilization process for implantable leads and accessories.
P070015/S140	02/21/2018	X - 30-Day Notice	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Change the time point when pyrogen testing for ethylene oxide (EO) sterilized products is conducted for products manufactured at its facility located in Clonmel, Ireland.
P080004/S021	02/01/2018	X - 30-Day Notice	HOYA ISERT AND CLARISERT INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Modifications to the Final Inspection Work Instruction for haptic scratches at the HOYA Surgical Optics manufacturing site located in Singapore for the HOYA iSert® and Clarisert Intraocular lens (IOLs).
P080011/S070	02/26/2018	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Reduction in the injection molding machine cycle time for Biofinity Multifocal and Biofinity Energys (comfilcon A) Extended Wear Soft Contact Lenses.
P080020/S028	02/09/2018	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Change to the bacterial endotoxins testing system used in the manufacture of Gel-One.
P080027/S032	02/01/2018	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Manufacture additional lateral flow platform devices in a common production area and to share manufacturing equipment.
P090028/S014	02/16/2018	X - 30-Day Notice	HBEAG REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Add an additional supplier and introduce a manufacturing process for plasma.
P100001/S013	02/16/2018	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS	Add an additional supplier and introduce a processing step to the manufacturing of plasma.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100010/S072	02/06/2018	X - 30-Day Notice	FREEZOR MAX	MEDTRONIC CRYOCATH LP	Change in the sub-tier supplier of a polyimide resin product.
P100021/S069	02/01/2018	X - 30-Day Notice	ENDURANT, ENDURANT II, ENDURANT LLS TALENT OCCLUDER	MEDTRONIC VASCULAR	Relocation of stent graft manufacturing operations at a Medtronic manufacturing facility.
P100026/S053	02/20/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the automated test equipment (ATE) test flow and PXI Vader ATE hardware, software as well as test database to support the manufacture of the RNS® Neurostimulator (model RNS-320).
P100029/S030	02/27/2018	X - 30-Day Notice	TRIFECTA AND TRIFECTA GT	ST. JUDE MEDICAL, INC.	Additional data loggers for use with an automated environmental monitoring system.
P100029/S031	02/23/2018	X - 30-Day Notice	TRIFECTA VALVE AND TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Add a new inspection criterion to the pre-package inspection of the bovine pericardial leaflets.
P100040/S034	02/01/2018	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM	MEDTRONIC VASCULAR	Relocation of stent graft manufacturing operations at a Medtronic manufacturing facility.
P100045/S028	02/26/2018	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Addition of second supplier for the catheter sub-assembly of the Pulmonary Artery (PA) Delivery catheter.
P100047/S117	02/22/2018	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Addition of an alternate battery supplier, Inventus Power, Inc.
P110010/S152	02/16/2018	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-EIUTING STENT SYSTEM/ PROMUS PREMIER EVEROLIMUS-EIUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to a sterilization cycle.
P110010/S153	02/23/2018	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM AND PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the incoming verification of Everolimus.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110019/S097	02/21/2018	X - 30-Day Notice	XIENCE PRIME/SV/LL AND XIENCE/SV/LL AND XIENCE ALPINE AND XIENCE SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change the time point when pyrogen testing for ethylene oxide (EO) sterilized products is conducted for products manufactured at its facility located in Clonmel, Ireland.
P110033/S036	02/21/2018	X - 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Addition of a syringe filling line.
P110042/S103	02/08/2018	X - 30-Day Notice	EMBLEM S-ICD; EMBLEM MRI S-ICD	BOSTON SCIENTIFIC CORPORATIO N	New controlled environment area (CEA) level VIII for battery testing.
P120010/S110	02/28/2018	X - 30-Day Notice	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	Change of O-ring supplier for MiniMed 630G, 670G, and Paradigm REAL-Time family of insulin pumps, which are components of the MiniMed 670G System, MiniMed 630G System with SmartGuard, MiniMed Paradigm Real-Time Revel System with Enlite Sensor, MiniMed 530G System, and MiniMed Paradigm Real-Time Revel System.
P120010/S111	02/28/2018	X - 30-Day Notice	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	Changes to the test method for the bolus accuracy and timing test that is performed for the insulin pump component of the Paradigm Real-time system, Paradigm Real-Time REVEL system, MiniMed 530G system, MiniMed 630G system, and MiniMed 670G system.
P120022/S017	02/22/2018	X - 30-Day Notice	THERASCREEN EGFR RGQ PCR KIT	QIAGEN MANCHESTER LTD	Transfer of the sub-process of standards manufacturing to another manufacturing site.
P130006/S048	02/20/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Addition of automated packaging dispensing equipment.
P130009/S084	02/03/2018	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCE S, LLC.	Add an alternate supplier for a ribbon used to make skirt components in the SAPIEN XT and SAPIEN 3 Transcatheter Heart Valves.
P130016/S033	02/01/2018	X - 30-Day Notice	NUCLEUS HYBRID IMPLANT SYSTEM	COCHLEAR AMERICAS	Removal of the Laminar Flow Units from cleanrooms.
P130030/S048	02/16/2018	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Updates to a sterilization cycle.
P140015/S023	02/14/2018	X - 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH DEXCOM G5 MOBILE CGM	TANDEM DIABETES CARE, INC.	Additional laser welding equipment and leak rate testing parameters for manufacturer of the t:slim insulin cartridge. The t:slim insulin cartridge is a component of the t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140026/S008	02/14/2018	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Tighten a specification and add an in-process test.
P140031/S059	02/03/2018	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Add an alternate supplier for a ribbon used to make skirt components in the SAPIEN XT and SAPIEN 3 Transcatheter Heart Valves.
P140033/S024	02/01/2018	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI	ST. JUDE MEDICAL, INC.	Relocation of supplier manufacturing of certain battery components and use of an alternate component welding machine.
P140033/S025	02/22/2018	X - 30-Day Notice	ASSURITY MRI, ENDURITY MRI, TENDRIL MRI	ST. JUDE MEDICAL, INC.	Adjust the relative humidity in the device and leads manufacturing and product packaging areas located in the Sylmar, California facility.
P150001/S034	02/28/2018	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Change of O-ring supplier for MiniMed 630G, 670G, and Paradigm REAL-Time family of insulin pumps, which are components of the MiniMed 670G System, MiniMed 630G System with SmartGuard, MiniMed Paradigm Real-Time Revel System with Enlite Sensor, MiniMed 530G System, and MiniMed Paradigm Real-Time Revel System.
P150001/S035	02/28/2018	X - 30-Day Notice	MINIMED 630G INSULIN PUMP	MEDTRONIC MINIMED	Changes to the test method for the bolus accuracy and timing test that is performed for the insulin pump component of the Paradigm Real-time system, Paradigm Real-Time REVEL system, MiniMed 530G system, MiniMed 630G system, and MiniMed 670G system.
P150003/S037	02/23/2018	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the incoming verification of Everolimus.
P150005/S034	02/16/2018	X - 30-Day Notice	BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Updates to a sterilization cycle.
P150012/S053	02/08/2018	X - 30-Day Notice	ESSENTIO; PROPONENT; ACCOLADE MRI	BOSTONSCIENTIFIC	New controlled environment area (CEA) level VIII for battery testing.
P150014/S013	02/20/2018	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Increase manufacturing scale and filling time for a material used to manufacture kit subcomponents.
P150015/S012	02/20/2018	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Increase manufacturing scale and filling time for a material used to manufacture kit subcomponents.
P150016/S011	02/05/2018	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Expand the use of the Lighthouse Monitoring System (LMS) to additional cleanroom and product storage areas.
P150019/S036	02/28/2018	X - 30-Day Notice	PARADIGM REAL TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Change of O-ring supplier for MiniMed 630G, 670G, and Paradigm REAL-Time family of insulin pumps, which are components of the MiniMed 670G System, MiniMed 630G System with SmartGuard, MiniMed Paradigm Real-Time Revel System with Enlite Sensor, MiniMed 530G System, and MiniMed Paradigm Real-Time Revel System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150019/S037	02/28/2018	X - 30-Day Notice	PARADIGM REAL TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Changes to the test method for the bolus accuracy and timing test that is performed for the insulin pump component of the Paradigm Real-time system, Paradigm Real-Time REVEL system, MiniMed 530G system, MiniMed 630G system, and MiniMed 670G system.
P150021/S018	02/15/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Replacement of a verification sensor in the vision system during manufacture of the Sharp Introducer and optimization of the vision system during manufacture of the Sensor component at the firm¿s suppliers. The Sharp Introducer and the Sensor are components of the FreeStyle Libre Pro Flash Glucose Monitoring System.
P150021/S019	02/22/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Add a new YSI instrument used for the release testing of the FreeStyle Libre Pro Flash Glucose Monitoring System sensor component.
P150033/S030	02/12/2018	X - 30-Day Notice	MICRA TPS MC1VR01	MEDTRONIC INC.	Manufacturing change at a supplier for capacitors used in hybrids.
P150033/S031	02/21/2018	X - 30-Day Notice	MICRA TPS MC1VR01	MEDTRONIC INC.	Additional supplier for the crystal oscillator component.
P150036/S024	02/03/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Increase in the maximum allowable number of personnel in Cleanroom #1 of the Singapore facility.
P150048/S013	02/03/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (RESILIA TISSUE)	EDWARDS LIFESCIENCES, LLC.	Increase in the maximum allowable number of personnel in Cleanroom #1 of the Singapore facility.
P150048/S015	02/28/2018	X - 30-Day Notice	INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Add an additional manufacturing site for the model 11500A valve.
P150048/S017	02/28/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS AND INSPIRIS RESILIA AORTIC	EDWARDS LIFESCIENCES, LLC.	Add a new clean room for the manufacture of the Edwards Integrity Preservation technology for the RESILIA tissue.
P160017/S032	02/28/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Change of O-ring supplier for MiniMed 630G, 670G, and Paradigm REAL-Time family of insulin pumps, which are components of the MiniMed 670G System, MiniMed 630G System with SmartGuard, MiniMed Paradigm Real-Time Revel System with Enlite Sensor, MiniMed 530G System, and MiniMed Paradigm Real-Time Revel System.
P160017/S033	02/28/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Changes to the test method for the bolus accuracy and timing test that is performed for the insulin pump component of the Paradigm Real-time system, Paradigm Real-Time REVEL system, MiniMed 530G system, MiniMed 630G system, and MiniMed 670G system.
P160021/S005	02/28/2018	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Alternate raw material resin and change to subcomponent processing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160041/S005	02/20/2018	X - 30-Day Notice	COBAS CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Increase manufacturing scale and filling time for a material used to manufacture kit subcomponents.
P170008/S001	02/08/2018	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Introduce an additional hydrophilic coating line for the EluNIR delivery system.

Total: 135