PMA Monthly approvals from 12/1/2017 to 12/31/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140032	12/22/2017	PMAO - PMA Origi	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval or the Implantable System for Remodulin®. This device is indicated for adult patients with Class I, II and III pulmonary arterial hypertension (PAH) receiving intravenous delivery of Remodulin.
P150031	12/08/2017	PMAO - PMA Origi	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the Vercise DBS System. The device is indicated for use in bilateral stimulation of the subthalamic nucleus (STN) in the treatment of patients with moderate to advanced levodopa-responsive Parkinsons disease (PD), which is not adequately controlled with medication.
P160012	12/21/2017	PMAO - PMA Origi	LIFEPAK CR® PLUS DEFIBRILLATOR, LIFEPAK EXPRESS® DEFIBRILLATOR, AND CHARGE-PAK® BATTERY CHARGER	PHYSIO-CONTROL. INC.	Approval for the LIFEPAK CR® Plus Defibrillator, LIFEPAK EXPRESS® Defibrillator, and CHARGE-PAK® Battery Charger. The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are indicated for use on patients in cardiac arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement). The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The defibrillators may be used with QUIK-PAK defibrillations pads only on adults and children who are 8 years old or more, or who weigh more than 25kg (55lbs). The defibrillators may be used on children who are less than 8 years old or weigh less than 25k (55lbs) with Infant/Child Reduced Energy Defibrillation Electrodes. The defibrillators may be used with the CHARGE-PAK battery charger.
P160022	12/27/2017	PMAO - PMA Origi	X SERIES®, R SERIES®, AED PRO®, AED 3 BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER BATTERY PACK, SUREPOWER II BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3	ZOLL MEDICAL CORPORATION	Approval for the X Series Defibrillator Function. The X Series system is indicated for defibrillation on victims of cardiac arrest where there is apparent lack of circulation as indicated by: 1) Unconsciousness.; 2) Absence of breathing; and 3) Absence of pulse. The X Series system in the Manual mode is indicated for synchronized cardioversion of certain atrial or ventricular arrhythmias. A qualified physician must decide when synchronized cardioversion is appropriate.

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			BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER SINGLE BAY CHARGER		The X Series system Semiautomatic and Manual mode is indicated for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol. The X Series system Semiautomatic and Manual mode is indicated for adult and pediatric patients. R Series Defibrillator Function. The R Series system is indicated for defibrillation on victims of cardiac arrest where there is apparent lack of circulation as indicated by: 1) Unconsciousness; 2) Absence of breathing; and 3) Absence of pulse. The R Series system in the Manual mode is indicated for synchronized cardioversion of certain atrial or ventricular arrhythmias. A qualified physician must decide when synchronized cardioversion is appropriate. The R Series system Semiautomatic and Manual mode is indicated for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol. The R Series system Semiautomatic and Manual mode is indicated for adult and pediatric patients. AED Pro. The AED Pro system is indicated for use on victims of cardiac arrest with apparent lack of circulation as indicated by: 1) Unconsciousness; 2) Absence of breathing; and 3) Absence of pulse and other signs of circulation. The device is also indicated for use when ECG monitoring is indicated to evaluate the patients heart rate or ECG morphology. The AED Pro system is indicated for adult and pediatric patients. AED 3 BLS. The ZOLL AED 3 system is indicated for use when a suspected cardiac arrest victim has an apparent lack of circulation as indicated by: 1) Unconsciousness;

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					2) Absence of breathing; and 3) Absence of pulse and other signs of circulation. The AED 3 system is indicated for adult and pediatric patients. ...
P170012	12/15/2017	PMAO - PMA Origi	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Approval of the Hemoblast Bellows. This device is indicated for surgical procedures as an adjunct to hemostasis when control of minimal, mild, and moderate bleeding by conventional procedures is ineffective or impractical, except in neurosurgical, ophthalmic, and urological procedures.

Total: 5

Supplements

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N970003/S213	12/13/2017	R - Real-Time Proc	ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT, INSIGNIA, ALTRUA 2	BOSTON SCIENTIFIC CORP.	Approval for server and communicator software updates necessary for LATITUDE NXT Release 6.0.
P790007/S052	12/13/2017	Y - 135 Review Tra	HANCOCK MODIFIED ORIFICE VALVED CONDUIT	MEDTRONIC HEART VALVES	Approval for a transfer of manufacturing operations to a new controlled environment area within the same manufacturing site.
P830055/S192	12/22/2017	R - Real-Time Proc	LCS TOTAL KNEE SYSTEM TRUMATCH PERSONALIZED SOLUTIONS SURGICAL TECHNIQUE WITH ATTUNE KNEE SYSTEM INTUITION SOLO INSTRUMENTS SURGICAL TECHNIQUE	DEPUY, INC.	Approval for labeling modifications to allow use of the TRUMATCH Personalized Solutions instruments with the INTUITION SOLO instruments during the ATTUNE Knee surgical process.
P840024/S089	12/14/2017	S - Special CBE	NUCLEUS 22 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a change in clinical guidance for programming Nucleus cochlear implant recipients in bipolar mode.

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P850064/S035	12/20/2017	R - Real-Time Proc	LIFEPULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Approval for adding a ¿Funnel¿ shape to the machine end of the LifePort Adapter via the molding process. The disposable LifePort Adapters were approved for use with the LifePulse High Frequency Ventilator Model 204 in 1995.
P860004/S268	12/05/2017	N - Normal 180 Day	SYNCHROMED II PUMP REMEDIATION	MEDTRONIC INC.	Approval for design changes and related manufacturing and labeling changes to the Model 8637 SynchroMed II R Implantable Infusion Pump (SM II pump implant kit).
P860004/S275	12/21/2017	N - Normal 180 Day	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Approval for changes made to the design history file and device master record of the motor component of the SynchroMed II Programmable Drug Infusion Pump (Model 8637), the associated parts of the motor (i.e. assemblies, subassemblies, components, subcomponents, and materials used in the manufacturing of the motor assembly), and the pumphead assembly material specifications.
P870078/S037	12/13/2017	Y - 135 Review Tra	HANCOCK VALVED CONDUIIS	MEDTRONIC, INC.	Approval for a transfer of manufacturing operations to a new controlled environment area within the same manufacturing site.
P890003/S381	12/01/2017	R - Real-Time Proc	CARELINK EXPRESS MONITOR, MONITOR CARDIOSIGHT READER, MY CARELINK PATIENT MONITOR.	MEDTRONIC, INC.	Approval for firmware changes to the CareLink Express Monitor Model 2020B and CardioSight Reader Model 2020A.
P890023/S028	12/19/2017	R - Real-Time Proc	OCUFILCON D SIFT (HYDROPHILIE) CONTACT LENSES	THE COOPER COMPANIES	Approval for a change in the test specifications of the saline solutions that are manufactured at the CooperVision Caribbean Corporation manufacturing facility in Juana Diaz, Puerto Rico and used in the packaging of ocufilcon D Soft (Hydrophilic) Contact Lenses in blister containers.
P890027/S058	12/14/2017	S - Special CBE	NUCLEUS 22 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a change in clinical guidance for programming Nucleus cochlear implant recipients in bipolar mode.
P910023/S388	12/19/2017	N - Normal 180 Day	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)	ST. JUDE MEDICAL	Approval for MR Conditional labeling for Fortify Assura ICDs, Quadra Assura and Quadra Assura MP CRT-Ds, Durata, Optisure, Tendril MRI and Quartet lead systems.
P910077/S162	12/13/2017	R - Real-Time Proc	LATITUDE NXT PATIENT MANAGEMENT SYSTEM, WAVE COMMUNICATOR, G2 COMMUNICATOR, CONSULT COMMUNICATOR, NXT SYSTEM SERVER SOFTWARE	BOSTON SCIENTIFIC	Approval for server and communicator software updates necessary for LATITUDE NXT Release 6.0.
P950022/S109	12/19/2017	N - Normal 180 Day	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D)	ST. JUDE MEDICAL, INC.	Approval for MR Conditional labeling for Fortify Assura ICDs, Quadra Assura and Quadra Assura MP CRT-Ds, and Durata, Optisure, Tendril MRI and Quartet lead systems.
P950037/S182	12/12/2017	R - Real-Time Proc	PSW 1704.U	BIOTRONIK, INC.	Approval for the PSW 1704.U programmer software update.

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P960040/S406	12/13/2017	R - Real-Time Proc	TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILANT, PERVICA	BOSTON SCIENTIFIC	Approval for server and communicator software updates necessary for LATITUDE NXT Release 6.0.
P970031/S058	12/13/2017	Y - 135 Review Tra	FREESTYLE BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a transfer of manufacturing operations to a new controlled environment area within the same manufacturing site.
P970051/S157	12/14/2017	S - Special CBE	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a change in clinical guidance for programming Nucleus cochlear implant recipients in bipolar mode.
P980016/S640	12/01/2017	R - Real-Time Proc	EVERA MRI DF-I ICD,EVERA MRI ICD, EVERA S DR/S VR/XT DR/ XT VR ICD, INTRINSIC 30 ICD, MARQUIS VR ICD, MAXMO II ICD,	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for firmware changes to the CareLink Express Monitor Model 2020B and CardioSight Reader Model 2020A.
P980035/S519	12/01/2017	R - Real-Time Proc	ADAPTA, VERSA, SENSIA IPG, ADAPTA, VERSA SENSIA IPG, ADVISA DR IPG, ADVISA DR /SR MRI IPG, ASTRA S DR/S SR XTDR/ XT SR MRI IPG; AZURE S DR/ S SRXT DR/ XT SR MRI, ENPULSE E1./ E2IPG ; KAPPA DR IPG ,	MEDTRONIC INC.	Approval for firmware changes to the CareLink Express Monitor Model 2020B and CardioSight Reader Model 2020A.
P980043/S062	12/13/2017	Y - 135 Review Tra	HANCOCK II BIOPROSTHESIS & HANCOCK ULTRA II BISPROSTHESIS	MEDTRONIC, INC.	Approval for a transfer of manufacturing operations to a new controlled environment area within the same manufacturing site.
P990012/S029	12/20/2017	R - Real-Time Proc	ELECSYS HBSAG IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P990046/S050	12/13/2017	Y - 135 Review Tra	OPEN PIVOT HEART VALVE / AORTIC VALVED GRAFT	MEDTRONIC ATS MEDICAL, INC.	Approval for a transfer of manufacturing operations to a new controlled environment area within the same manufacturing site.
P990056/S029	12/20/2017	R - Real-Time Proc	ELECSYS TOTAL PSA	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P990064/S070	12/13/2017	Y - 135 Review Tra	MOSAIC BIOPROSTHESIS & ULTRA BIOPROSTHESIS	MEDTRONIC, INC.	Approval for a transfer of manufacturing operations to a new controlled environment area within the same manufacturing site.

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P990075/S043	12/06/2017	S - Special CBE	MENTOR-SALINE-FILLED AND SPECTRUM BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval for changes to the labeling including modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P000009/S075	12/12/2017	R - Real-Time Proc	PSW 1704.U	BIOTRONIK, INC.	Approval for the PSW1704.U programmer software update.
P000027/S028	12/20/2017	R - Real-Time Proc	ELECSYS FREE PSA	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P000037/S050	12/05/2017	Y - 135 Review Tra	ON-X (R) PROSTHETIC HEART VALVE, MODEL ONXA	ON-X LIFE TECHNOLOGIES, INC.	Approval for an additional manufacturing lathe and a new coolant for the leaflet substrate grinding process.
P000037/S051	12/14/2017	O - Normal 180 Day	ON-X ASCENDING AORTIC PROSTHESIS	ON-X LIFE TECHNOLOGIES, INC.	Approval for an additional ethylene oxide sterilization site located at 1300 East Anderson Lane, Building B, Austin, Texas.
P010012/S465	12/13/2017	R - Real-Time Proc	COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILANT	BOSTON SCIENTIFIC CORP.	Approval for server and communicator software updates necessary for LATITUDE NXT Release 6.
P010014/S068	12/13/2017	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM - FEMORAL AND TIBIAL TRAY COMPONENTS	BIOMET MANUFACTURING CORP.	Approval for modifications to the instructions for the cosmetic inspection process.
P010015/S343	12/01/2017	R - Real-Time Proc	CONSULTA CRT-P, PERCEPTA BIPLOAR CRT-P. PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P; SOLAR BIPOLAR / QUADRIPOLAR CRT-P; SYNCRA QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for firmware changes to the CareLink Express Monitor Model 2020B and CardioSight Reader Model 2020A.
P010029/S025	12/28/2017	O - Normal 180 Day	EUFLEXXA (1% SODIUM HYALURONATE)	FERRING PHARMACEUTICALS, INC.	Approval for BTG (Ferring) to manufacture, package and release Euflexxa at both the BTG (Ferring) and Lifecore facilities.

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P010031/S601	12/01/2017	R - Real-Time Proc	AMPLIA MRI CRT-D/ AMPLIA MRI QUAD CRT-D; BRAVA CRT-D/ BRAVA QUAD CRT-D; CLARIA MRI CRT-D. CLARIA MRI CRT-D; COMPIA MRI CRT-D. CONCERTO ICD, CONCERTO II CRT-D ; CONSULAT CRT-D; MAXIMO II CRT-D.PROTECTA 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	Approval for firmware changes to the CareLink Express Monitor Model 2020B and CardioSight Reader Model 2020A.
P010032/S134	12/09/2017	R - Real-Time Proc	PROCLAIM ELITE FAMILY OF SCS IPGS	ST. JUDE MEDICAL	Approval for updated versions of the Clinician Programmer and Patient Controller software (v 3.6) that include new methods for calculating battery status and recovering system functions after exposure to power disturbances.
P010032/S135	12/09/2017	N - Normal 180 Day	EONC AND EON MINI NEUROSTIMULATION SYSTEM	ST. JUDE MEDICAL	Approval for enabling the BurstDR¿ stimulation feature on the already-implanted Eon family devices (two models: EonC and Eon Mini) for a short evaluation period (30 days).
P010054/S032	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HBS	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P020047/S065	12/15/2017	O - Normal 180 Day	MULTI-LINK 8 CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for a manufacturing site located at Sterigenics UK Limited, Cotes Park Estate, Somercotes, Derbeyshire DE55 4NJ, United Kingdom, for sterilization of Multi-Link 8 / Multi-Link 8LL / Multi-Link 8SV Coronary Stent System manufactured at Abbott Vascular¿s Clonmel, Ireland facility.
P020050/S027	12/21/2017	R - Real-Time Proc	WAVELIGHT EX500 LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for changes to RAS-board by adding two LEDs to ease troubleshooting during manufacturing and service.
P030005/S161	12/13/2017	R - Real-Time Proc	INVIVE, INTUA, VISIONIST, VALITUDE	GUIDANT CORP.	Approval for server and communicator software updates necessary for LATITUDE NXT Release 6.0.
P030008/S023	12/21/2017	R - Real-Time Proc	WAVELIGHT EX500 LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for changes to RAS-board by adding two LEDs to ease troubleshooting during manufacturing and service.
P030011/S050	12/06/2017	Y - 135 Review Tra	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Approval for a change in the sub-supplier of the cannula velour component of the TAH-t.

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P030011/S057	12/08/2017	S - Special CBE	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM / COMPANION 2 DRIVER SYSTEM	SYNCARDIA SYSTEMS, LLC	Approval for changes to the labeling of the Companion 2 Driver System.
P030017/S297	12/21/2017	N - 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 labeling changes associated with the demonstrated safety and effectiveness of subperception therapy.
P030017/S302	12/22/2017	R - Real-Time Proc	SPECTRA WAVEWRITER SPINAL CORD STIMULATOR SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for minor updates to firmware/software and microcontroller on the Printed Circuit Board Assembly (PCBA) of Boston Scientific's Freelink Remote Control (RC) associated with their Spectra WaveWriter SCS system, and updates to support the addition of two new features as well as enhancement to existing features in their Clinician Programming software.
P030053/S044	12/06/2017	S - Special CBE	MENTOR MEMORYGEL BREAST IMPLANTS	MENTOR CORP.	Approval for changes to the labeling including modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P030054/S332	12/19/2017	N - Normal 180 Day	HIGH VOLTAGE ACTIVE FIXATION LEAD,	ST. JUDE MEDICAL	Approval for MR Conditional labeling for Fortify Assura ICDs, Quadra Assura and Quadra Assura MP CRT-Ds, and Durata, Optisure, Tendril MRI and Quartet lead systems.
P050023/S113	12/12/2017	R - Real-Time Proc	PSW 1704.U	BIOTRONIK, INC.	Approval for the PSW1704.U programmer software update.
P060028/S027	12/06/2017	S - Special CBE	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval for changes to the labeling including modifications to the language in the physician and patient labeling regarding the potential risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).
P070004/S010	12/01/2017	O - Normal 180 Day	SIENTRA OPUS SILICONE GEL BREAST IMPLANTS	SIENTRA, INC	Approval for a trade name change from Sientra Silicone Gel Breast Implants to Sientra OPUS¿ Silicone Gel Breast Implants.
P070008/S087	12/12/2017	R - Real-Time Proc	PSW 1704.U	BIOTRONIK, INC.	Approval for the PSW1704.U programmer software update.
P070026/S050	12/14/2017	R - Real-Time Proc	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for a minor design change of the 28mm and 36mm ceramic liners.

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P080012/S047	12/19/2017	R - Real-Time Proc	PROMETRA PROGRAMMABLE IMPLANTABLE PUMP / PROMETRA II PROGRAMMABLE IMPLANTABLE PUMP	FLOWONIX MEDICAL, INC.	Approval for modifications of product labeling as a result of MRI testing conducted on the Flowonix Prometra Programmable Infusion Pump System.
P090007/S017	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P090008/S019	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P090009/S017	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HCV IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P090013/S263	12/01/2017	R - Real-Time Proc	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Approval for firmware changes to the CareLink Express Monitor Model 2020B and CardioSight Reader Model 2020A.
P100013/S015	12/14/2017	O - Normal 180 Day	CORDIS EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS CORPORATION	Approval to add Steri-Tek as a new E-beam sterilization site for the Exoseal Vascular Closure Device.
P100026/S050	12/09/2017	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for modifications to the printed circuit assembly of the RNS® Neurostimulator model RNS-320 to remove Long Range Telemetry (LRT) components.
P100030/S008	12/21/2017	P - Panel Track	PREVELEAK SURGICAL SEALANT	MALLINCKRODT PHARMA IP TRADING DAC	Approval for Preveleak Surgical Sealant. The device is indicated for use in vascular and cardiac reconstructions (excluding application to arterial and venous grafts used in coronary artery bypass graft surgery) to achieve adjunctive hemostasis by mechanically sealing areas of potential leakage.
P100031/S021	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P100032/S017	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HBC II	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P100047/S101	12/15/2017	N - Normal 180 Day	HEARTWARE HVAD SYSTEM	MEDTRONIC	Approval for the addition of cleaning specifications and ongoing controls and monitoring requirements to verify compliance to the new cleanliness specifications.
P110022/S022	12/21/2017	N - Normal 180 Day	ELECSYS ANTI-HBC IGM TEST SYSTEM	ROCHE DIAGNOSTICS CORP.	Approval for migration of the Elecsys Anti-HBc IgM Immunoassay and Elecsys PreciControl Anti-HBc IgM to the cobas e 801 immunoassay analyzer.

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P110022/S024	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P110025/S021	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P110031/S020	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HBC IGM	ROCHE DIAGNOSTICS CORP.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P110038/S016	12/08/2017	S - Special CBE	RELAYPLUS THORACIC STENT-GRAFT SYSTEM	BOLTON MEDICAL, INC.	Approval for updates to the Instructions for Use including clarifications regarding device deployment directions, as well as other minor administrative and editorial changes.
P110042/S092	12/13/2017	R - Real-Time Proc	EMBLEM	BOSTON SCIENTIFIC CORPORATION	Approval for server and communicator software updates necessary for LATITUDE NXT Release 6.0.
P130015/S014	12/20/2017	R - Real-Time Proc	ELECSYS HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P130020/S003	12/28/2017	R - Real-Time Proc	SENOGRAPHE PRISTINA 3D	GE HEALTHCARE	Approval for a change to Senographe Pristina 3D to add a new Digital Breast Tomosynthesis (DBT) Automatic Optimization of Parameters (AOP) table, called 3D STD+. This new AOP table enables the acquisition of DBT datasets at a dose equivalent to 2D STD+, already enabled on Senographe Pristina for 2D examination. As in 2D, the user will be able to choose which AOP table to use for 3D acquisitions: 3D STD or 3D STD+.
P140004/S006	12/28/2017	O - Normal 180 Day	SUPERION INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORATED	Approved for site change.
P140009/S030	12/09/2017	R - Real-Time Proc	INFINITY FAMILY OF DBS IPGS	ST. JUDE MEDICAL NEUROMODULATION	Approval for updated versions of the Clinician Programmer and Patient Controller software (v 3.6) that include new methods for calculating battery status and recovering system functions after exposure to power disturbances.
P140015/S021	12/21/2017	O - Normal 180 Day	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Approval for a manufacturing site change of the t:Slim G4 Insulin Pump, which is used with the Dexcom G4 Platinum CGM, from their old facility at 11045 Roselle St, San Diego, California to their new facility at 10151 Barnes Canyon Rd, San Diego, California.
P140021/S012	12/20/2017	R - Real-Time Proc	ELECSYS ANTI-HCV II	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation

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P140033/S010	12/19/2017	N - Normal 180 Day	LOW VOLTAGE ACTIVE FIXATION LEAD	ST. JUDE MEDICAL, INC.	Approval for MR Conditional labeling for Fortify Assura ICDs, Quadra Assura and Quadra Assura MP CRT-Ds, and Durata, Optisure, Tendril MRI and Quartet lead systems.
P140033/S014	12/12/2017	Y - 135 Review Tra	TENDRIL MRI LEADS	ST. JUDE MEDICAL, INC.	Approval for updates to the elution test methods for Tendril MRI leads.
P150001/S028	12/20/2017	N - Normal 180 Day	MINIMED 630G INSULIN PUMP	MEDTRONIC MINIMED	Approval for 1) minor design changes to the electronics board stack used in the 630G insulin pump; 2) a new supplier for the electronics board stack; 3) an updated pump software version; and 4) an extension to the 630G insulin pump shelf life from 185 days to 1095 days.
P150004/S014	12/09/2017	R - Real-Time Proc	PROCLAIM DRG FAMILY OF DRG IPGS	ST. JUDE MEDICAL	Approval for updated versions of the Clinician Programmer and Patient Controller software (v 3.6) that include new methods for calculating battery status and recovering system functions after exposure to power disturbances.
P150005/S014	12/21/2017	P - Panel Track	BLAZER OPEN-IRRIGATED ABLATION CATHETER AND INTELLANAV OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the Blazer and IntellaNav Open-Irrigated Ablation Catheters. The Blazer and IntellaNav Open-Irrigated Ablation Catheters, when used with a compatible Radiofrequency Controller and Irrigation Pump, are indicated for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, radiofrequency ablation of sustain or recurrent Type 1 Atrial Flutter in patients age 18 or older, and treatment of drug refractory, recurrent, symptomatic, paroxysmal atrial fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system.
P150012/S043	12/13/2017	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for server and communicator software updates necessary for LATITUDE NXT Release 6.0.
P150033/S027	12/01/2017	R - Real-Time Proc	MICRA TPS	MEDTRONIC INC.	Approval for firmware changes to the CareLink Express Monitor Model 2020B and CardioSight Reader Model 2020A.
P150037/S008	12/18/2017	N - Normal 180 Day	CYPASS ULTRA SYSTEM	ALCON RESEARCH, LTD	Approval for design changes to the CyPass System 241-S and inclusion of an additional sterilization vendor. The modified design will be marketed as the CyPass Ultra System.
P150043/S001	12/14/2017	N - Normal 180 Day	QVCAD SYSTEM (VERSION 3.3)	QVIEW MEDICAL, INC.	Approval for QVCAD System (Version 3.3). The QVCAD System is indicated for use as an aid to the reader during screening procedures in searching images of female breasts produced by the somo¿v and Invenia Automated Breast Ultrasound Systems (screening mammography BIRADS® Assessment Category 1 or 2, and BI-RADS Composition/ Density c or d) to detect mammography-occult lesions in regions not known to have suspicious findings. The indicators produced by the QVCAD System are not intended to be used for diagnostic characterization of suspicious findings.
P160017/S020	12/08/2017	N - Normal 180 Day	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for 1) minor design changes to the electronics board stack used in the 670G insulin pump; 2) a new supplier for the electronics board stack; 3) an updated pump software version; and 4) an extension to the 670G insulin pump shelf life from 185 days to 1095 days.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160019/S004	12/29/2017	N - Normal 180 Day	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for Migration of Elecsys HBsAg II, Elecsys HBsAg Confirmatory Test and PreciControl HBsAg II on the cobas e 801 immunoassay analyzer
P160019/S006	12/20/2017	R - Real-Time Proc	ELECSYS HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for implementation of system software 06-04 on the cobas e 602 to address a software limitation
P160030/S001	12/08/2017	O - Normal 180 Day	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P160039/S001	12/21/2017	O - Normal 180 Day	REMEDE® SYSTEM	RESPICARDIA	Approval of the protocol for the post-approval study (PAS).
P160043/S007	12/06/2017	R - Real-Time Proc	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Approval for a material change to the distal inner shaft of the Resolute Onyx Zotarolimus-Eluting Coronary Stent Systems (RX & OTW).
P170011/S001	12/13/2017	R - Real-Time Proc	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for a design change to the USB cable in the Automated Impella Controller (AIC).

Total: 92

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S218	12/01/2017	X - 30-Day Notice	ACCOLADE, ALTRUA 2, ESSENTIO, PROPONENT (ACCOLADE), ADVANTIO, INGENIO, VITALIO, FORMIO (INGENIO)	BOSTON SCIENTIFIC CORP.	Upgrade device header overmolding equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S219	12/11/2017	X - 30-Day Notice	ACCOLADE NON-MRI PACEMAKERS: ALTRUA 2, ESSENTIO, PROPONENT AND ACCOLADE	BOSTON SCIENTIFIC CORP.	Modifications to a suppliers cleaning process used in the manufacture of the MICS module component of the pulse generators hybrid.
N970003/S220	12/06/2017	X - 30-Day Notice	ALTRUA 2, ESSONTIO, PROPONENT, ACCOLADE, ADVANTIO, INGENIO, VITALIO, NON-MRI PACEMAKERS	BOSTON SCIENTIFIC CORP.	Additional electrolyte supplier for pulse generator batteries, an approved manufacturing location for the existing battery electrolyte supplier, and updates to associated acceptance activities.
N970003/S221	12/06/2017	X - 30-Day Notice	ALTRUA 2 / ESSENTIO / PROPONENT / ACCOLADE / ACCOLADE NON-MRI PACEMAKERS	BOSTON SCIENTIFIC CORP.	Modifications to the titanium can manufacturing process at the supplier.
N970003/S222	12/19/2017	X - 30-Day Notice	ACCOLADE, ADVANTIO, ALTRUA, ALTRUA 2, ESSENTIO, FORMIO, INGENIO, INSIGNIA, PROPONENT, VITALIO PACEMAKERS	BOSTON SCIENTIFIC CORP.	Change in the bacterial endotoxin test sampling plan and frequency.
N970012/S140	12/18/2017	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/ INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Removal of outer diameter inspections of the kink resistant tubing in the preconnect assembly process.
N970012/S141	12/15/2017	X - 30-Day Notice	AMS 700 IMPLANTABLE PENILE PROSTHESIS (WITH AND WITHOUT INHIBIZONE TREATMENT) / AMS AMBICOR IMPLANTABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Changes to the manufacturing process to the platen orientation of the trays and addition of polyethylene slip sheets between the trays.
N970012/S142	12/12/2017	X - 30-Day Notice	AMS 700 IMPLANTABLE PENILE PROSTHESIS WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Change of the receiving inspection from manual to automatic poppet inspection.
P830061/S152	12/14/2017	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S382	12/06/2017	X - 30-Day Notice	MASTER RESTORE, ITREL AND INTELLIS SPINAL CORD STIMULATION SYSTEMS ADN PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Implement a new catalyst (Catalyst 23LV) in the tantalum capacitor encapsulation process at AVX Tantalum Corporation.
P840001/S383	12/13/2017	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Transfer of the injection molding of the TIP-QUAD LEAD, part number 117167001, from Medtronic Energy and Component Center (MECC) to Donatelle Plastics, Inc.
P840001/S385	12/14/2017	X - 30-Day Notice	SPINAL CORD STIMULATION LEADS; MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS ADN PISCES, SPECIFYAND VECTRIS	MEDTRONIC NEUROMODULATION	Updates of the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.4.
P840001/S386	12/12/2017	X - 30-Day Notice	MASTER RESTORE, ITREL, AND INTELLIS SPINAL CORD STIMULATION SYSTEMS	MEDTRONIC NEUROMODULATION	Manufacturing process change at a 2nd-tier supplier of capacitors used in the manufacture of hybrids contained in Medtronic implantable neurostimulators.
P850089/S129	12/14/2017	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD, VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P860004/S292	12/14/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Updates of the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.4.
P860004/S293	12/17/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Include the addition of a new Medium Rate (MR) Battery COS production line.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S171	12/08/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS; THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PERIMOUNT RSR PERICARDIAL AORTIC BIOPROSTHESIS; PERIMOUNT THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS; PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PERIMOUNT PLUS PERICARDIAL MITRAL BIOPROSTHESIS; PERIMOUNT THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; AND PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Addition of new manufacturing equipment to an existing cleanroom.
P890003/S383	12/14/2017	X - 30-Day Notice	CAPSURE VDD 2 LEAD, VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890064/S035	12/21/2017	X - 30-Day Notice	DIGENE HC2 HPV DNA TEST / DIGENE HC2 HIGH RISK HPV DNA TEST	QIAGEN GAITHERSBURG, INC	Modify current quality control in-process testing procedures for three kit components.
P900056/S168	12/01/2017	X - 30-Day Notice	ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P900061/S147	12/14/2017	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P910001/S102	12/22/2017	X - 30-Day Notice	CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Use of an alternate Joulemeter for laser-light measurement during production.
P910023/S397	12/07/2017	X - 30-Day Notice	FORTIFY ASSURA , ELLIPSE	ST. JUDE MEDICAL	Elimination of certain non-destructive pull testing of wires on hybrid circuits.
P910023/S398	12/11/2017	X - 30-Day Notice	FORTIFY; FORTIFY ASSURA	ST. JUDE MEDICAL	Alternate high voltage capacitor stack process with automated inspection and placement.
P910056/S028	12/04/2017	X - 30-Day Notice	ENVISTA ONE PIECE HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL), MODEL MX60E LENS HOLDER	BAUSCH & LOMB, INC.	Modification of the lens holder surface finish.
P910073/S144	12/01/2017	X - 30-Day Notice	PLASMA TREATMENT SYSTEM	BOSTON SCIENTIFIC	Add an alternate plasma treatment system for treatment of PEEK lead components.
P920015/S203	12/14/2017	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT, IS-1 CONNECTOR PORT PIN PLUG KIT, LEAD ADAPTOR, SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P920047/S106	12/01/2017	X - 30-Day Notice	BLAZER II CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P930014/S107	12/21/2017	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of an automated cleaning system for initial cleaning of the AcrySof Intraocular Lenses at the Alcon Ireland manufacturing site

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930014/S108	12/18/2017	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Change to the molding process.
P930039/S178	12/14/2017	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE, FIXATION LEAD	MEDTRONIC, INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P950024/S077	12/14/2017	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P950037/S184	12/19/2017	X - 30-Day Notice	SIELLO, SOLIA, SETROX, AND SAFIO	BIOTRONIK, INC.	Alternate supplier for a silicone tube material used in lead manufacturing.
P960009/S301	12/06/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implement a new catalyst (Catalyst 23LV) in the tantalum capacitor encapsulation process at AVX Tantalum Corporation.
P960009/S302	12/13/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Transfer of the injection molding of the TIP-QUAD LEAD, part number 117167001, from Medtronic Energy and Component Center (MECC) to Donatelle Plastics, Inc.
P960009/S305	12/14/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Updates of the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.4.
P960009/S306	12/12/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Manufacturing process change at a 2nd-tier supplier of capacitors used in the manufacture of hybrids contained in Medtronic implantable neurostimulators.
P960013/S093	12/07/2017	X - 30-Day Notice	TENDRIL ST; TENDRIL STS; OPTISENSE	ST JUDE MEDICAL	Supplier to conduct heat treatment and passivation processes in-house.
P960040/S409	12/01/2017	X - 30-Day Notice	AUTOGEN, DYNAGEN, INOGEN, ORIGEN (NG3 ICDS), MOMENTUM, VIGILANT, PERCIVA, RESONATE (NG4 ICDS)	BOSTON SCIENTIFIC	Upgrade device header overmolding equipment.
P960040/S410	12/11/2017	X - 30-Day Notice	NG3 IMPLANTABLE CARDIAC DEFIBRILLATORS (ICDS): AUTOGEN, DYNAGEN, INOGEN AND ORIGEN; NG4 ICDS: MOMENTUM, VIGILANT, PERCIVA AND RESONATE	BOSTON SCIENTIFIC	Modifications to a suppliers cleaning process used in the manufacture of the MICS module component of the pulse generators hybrid.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960040/S411	12/06/2017	X - 30-Day Notice	ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, RESONATE, PERCIVA, PUNCTUA, ENERGEN, INCEPTA , INPLANTABLE CARDIOVERTER DEFRIBRILLATOR (ICD)	BOSTON SCIENTIFIC	Additional electrolyte supplier for pulse generator batteries, an approved manufacturing location for the existing battery electrolyte supplier, and updates to associated acceptance activities.
P960040/S412	12/19/2017	X - 30-Day Notice	AUTOGEN, DYNAGEN, ENERGEN, INCEPTA, INOGEN, MOMENTUM, ORIGEN, PERCIVA, PUNCTUA, RESONATE, VIGILIANT, VITALITY ICDS	BOSTON SCIENTIFIC	Change in the bacterial endotoxin test sampling plan and frequency.
P960040/S413	12/06/2017	X - 30-Day Notice	ORIGEN / INOGEN / DYNAGEN /AUTOGEN / MOMENTUM /VIGILANT/ PERCIVA / RESONATE/ IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)	BOSTON SCIENTIFIC	Modifications to the titanium can manufacturing process at the supplier.
P960043/S099	12/13/2017	X - 30-Day Notice	PERCLOSE PROGLIDE SUTURE-MEDIATED CLOSURE SYSTEM	ABBOTT VASCULAR INC.	Addition of a vision inspection system for inspecting the contents of the packaging tray.
P970003/S214	12/27/2017	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Change to the Leads Manufacturing Process to add the following two (2) processes on all commercially available Lead Models (302/303/304): 1) Additional use of the currently approved primer; proposed application to the Suture and along the exposed edge of the Electrode; and 2) Implementation of a Protection Aid to encapsulate the Lead Helicals, protecting them from Ribbon Damage during further processing steps. This will be removed at the end of the Lead Final assembly.
P970004/S262	12/13/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Transfer of the injection molding of the TIP-QUAD LEAD, part number 117167001, from Medtronic Energy and Component Center (MECC) to Donatelle Plastics, Inc.
P970004/S264	12/14/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Updates of the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.4.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980003/S083	12/01/2017	X - 30-Day Notice	CHILLI II COOLED ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P980016/S646	12/05/2017	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR 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 DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Manufacturing change at a supplier for capacitors used in the manufacture of hybrids.
P980016/S647	12/11/2017	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, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional catalyst material for the capacitor encapsulation process.
P980016/S648	12/12/2017	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	Implementation of a laser marking process to remove and re-mark graphics on the devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S650	12/14/2017	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, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P980016/S651	12/13/2017	X - 30-Day Notice	EVERA MRI ICD,EVERA S DR ICD,EVERA MRI DF-1 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	Manufacturing process changes at a supplier for the 3um Complementary Metal Oxide Semiconductor (CMOS) components.
P980016/S652	12/15/2017	X - 30-Day Notice	EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of manufacturing equipment for use in the connector second shot assembly process.
P980016/S654	12/21/2017	X - 30-Day Notice	EVERA MRI DF-1 ICD / EVERA S DR /VR ICD / EVERA XT VR ICD / PROTECTA ICD / PROTECTA XT ICD /VISIA AF MRI DF 1 ICD / VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Elimination of a destructive in-process manual peel test monitor performed after first shot assembly of the connector module.
P980023/S083	12/19/2017	X - 30-Day Notice	LINOX SMART, PROTEGO, AND PLEXA	BIOTRONIK, INC.	Alternate supplier for a silicone tube material used in lead manufacturing.
P980024/S016	12/06/2017	X - 30-Day Notice	PATH VYSION HER-2 DNA PROBE KIT	ABBOTT MOLECULAR, INC.	Vendors relocation of a manufacturing site for production of reagents contained in kit components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S525	12/05/2017	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, 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 ST SR MRI IPG	MEDTRONIC INC.	Manufacturing change at a supplier for capacitors used in the manufacture of hybrids.
P980035/S526	12/11/2017	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, 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.	Additional catalyst material for the capacitor encapsulation process.
P980035/S527	12/04/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG/ATTESTA IPG/RELIA IPG/SPHERA IPG	MEDTRONIC INC.	Implementation of additional weld equipment.
P980035/S528	12/14/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT SR MRI IPG, ATTESTA IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG, RELIA IPG, SPHERA IPG	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S529	12/13/2017	X - 30-Day Notice	ADAPTA,VERSA,SENSIA IPG, ADAPTA,VERSA,SENSIA IPG,ADVISA DR IPG, ADVISA DR MRI IPG,ADVISA SR MRI IPG,RELIA IPG	MEDTRONIC INC.	Manufacturing process changes at a supplier for the 3um Complementary Metal Oxide Semiconductor (CMOS) components.
P980040/S085	12/12/2017	X - 30-Day Notice	TECNIS SYMFONY 1-PIECE IOL, TECNIS MULTIFOCAL 1-PIECE IOL, AND TECNIS MULTIFOCAL 1-PIECE IOL	ABBOTT MEDICAL OPTICS INC	Utilization of an additional manufacturing site.
P980044/S041	12/14/2017	X - 30-Day Notice	SUPARTZ FX / VISCO-3	SEIKAGAKU CORP.	Change in the storage facility for the hyaluronic acid component of SUPARTZ FX and VISCO-3 and commission of back-up facilities for the weighing and preparation of components of SUPARTZ FX and VISCO-3.
P980050/S113	12/14/2017	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P000021/S035	12/15/2017	X - 30-Day Notice	DIMENSION VISTA TPSA FLEX REAGENT CARTRIDGE (K6451)	SIEMENS HEALTHCARE DIAGNOSTICS	Transfer a contract service provider to manufacture subassembly components and service spare parts, which are used in the Dimension Vista® System manufacturing process.
P000039/S061	12/26/2017	X - 30-Day Notice	AMPLATZER SEPTAL OCCLUDER	AGA MEDICAL CORPORATION	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P000053/S084	12/15/2017	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM (WITH AND WITHOUT INHIBIZONE TREATMENT)	BOSTON SCIENTIFIC CORP.	Changes to the manufacturing process to the platen orientation of the trays and addition of polyethylene slip sheets between the trays.
P000053/S085	12/12/2017	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Change of the receiving inspection from manual to automatic poppet inspection.
P000054/S049	12/13/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Source manufacturing changes to the absorbable collagen sponge component of Infuse Bone Graft.
P000058/S068	12/13/2017	X - 30-Day Notice	INFUSE BONE GRAFT / LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Source manufacturing changes to the absorbable collagen sponge component of Infuse Bone Graft.

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P010012/S468	12/01/2017	X - 30-Day Notice	AUTOGEN, DYNAGEN, INOGEN, ORIGEN (NG3 CRT-DS), MOMENTUM, RESONATE, VIGILANT (NG4 CRT-DS)	BOSTON SCIENTIFIC CORP.	Upgrade device header overmolding equipment.
P010012/S469	12/11/2017	X - 30-Day Notice	NG3 CARDIAC RESYNCHRONIZATION THERAPY-DEFIBRILLATOR (CRT-D) DEVICES: AUTOGEN, DYNAGEN, INOGEN AND ORIGEN; NG4 CRT-D DEVICES: MOMENTUM, VIGILANT, AND RESONATE	BOSTON SCIENTIFIC CORP.	Modifications to a suppliers cleaning process used in the manufacture of the MICS module component of the pulse generators hybrid.
P010012/S470	12/06/2017	X - 30-Day Notice	ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, RESONATE, PERCIVA, PUNCTUA, ENERGEN, INCEPTA , CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D)	BOSTON SCIENTIFIC CORP.	Additional electrolyte supplier for pulse generator batteries, an approved manufacturing location for the existing battery electrolyte supplier, and updates to associated acceptance activities.
P010012/S471	12/06/2017	X - 30-Day Notice	ORIGEN / INOGEN / DYNAGEN / AUTOGEN / MOMENTUM / VIGILANT / RESONATE / IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D)	BOSTON SCIENTIFIC CORP.	Modifications to the titanium can manufacturing process at the supplier.
P010012/S472	12/19/2017	X - 30-Day Notice	AUTOGEN, COGNIS, DYNAGEN, ENERGEN, INCEPTA, INOGEN, MOMENTUM, ORIGEN, PUNCTUA, RESONATE, VIGILIANT, CRT-DS	BOSTON SCIENTIFIC CORP.	Change in the bacterial endotoxin test sampling plan and frequency.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S346	12/05/2017	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Manufacturing change at a supplier for capacitors used in the manufacture of hybrids.
P010015/S347	12/11/2017	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P,PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Additional catalyst material for the capacitor encapsulation process.
P010015/S348	12/14/2017	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P010015/S349	12/13/2017	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Manufacturing process changes at a supplier for the 3um Complementary Metal Oxide Semiconductor (CMOS) components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S103	12/12/2017	X - 30-Day Notice	WCD 4000 LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Implementation of the Semi-Automated TE Resistance Test Version 3.1 software.
P010031/S607	12/05/2017	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, PROCTA 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	Manufacturing change at a supplier for capacitors used in the manufacture of hybrids.
P010031/S608	12/11/2017	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 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	Additional catalyst material for the capacitor encapsulation process.
P010031/S609	12/12/2017	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 CRT-D; VIVA QUAD XT CRT-D; VIVA S CRT-D; VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a laser marking process to remove and re-mark graphics on the devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S611	12/14/2017	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 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	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P010031/S612	12/13/2017	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 CRT-D, PROTECTA XT 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	Manufacturing process changes at a supplier for the 3um Complementary Metal Oxide Semiconductor (CMOS) components.
P010031/S613	12/15/2017	X - 30-Day Notice	AMPLIA MRI CRT-D, BRAVA CRT-D, CLARIA MRI CRT-D, COMPIA MRI CRT-D, VIVA S CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of manufacturing equipment for use in the connector second shot assembly process.
P010031/S614	12/21/2017	X - 30-Day Notice	AMPLIA MRI CRT-D / BRAVA CRT-D / CLARIA & COMPIA MRI CRT-D / PROTECTA CR-D / PROTECTA XT CRT-D / VIVA S CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Elimination of a destructive in-process manual peel test monitor performed after first shot assembly of the connector module.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010033/S036	12/07/2017	X - 30-Day Notice	QUANTIFERON-TB GOLD AND QUANTIFERON -TB GOLD PLUS.	QIAGEN	Change in-process QC testing of a raw material used to manufacture a kit subcomponent.
P020004/S149	12/13/2017	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Supplier site change.
P020014/S049	12/04/2017	X - 30-Day Notice	ESSURE SYSTEM FOR PERMANENT BIRTH CONTROL	BAYER PHARMA AG	Change in a supplier's site of manufacture of the wound coil, inner coil and outer coil critical components from Tualatin Oregon to Heredia, Costa Rica.
P020025/S109	12/01/2017	X - 30-Day Notice	BLAZER II XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P020027/S030	12/15/2017	X - 30-Day Notice	DIMENSION VISTA FPSA FLEX REAGENT CARTRIDGE (K6452)	SIEMENS HEALTHCARE DIAGNOSTICS	Transfer a contract service provider to manufacture subassembly components and service spare parts, which are used in the Dimension Vista® System manufacturing process.
P030005/S166	12/01/2017	X - 30-Day Notice	VALITUDE, VALITUDE X4, VISIONIST, VISIONIST X4 (ACCOLADE (CRT-PS), INTUA, INVIVE (INGENIO CRT-PS)	GUIDANT CORP.	Upgrade device header overmolding equipment.
P030005/S167	12/11/2017	X - 30-Day Notice	ACCOLADE CARDIAC RESYNCHRONIZATION THERAPY-PACEMAKER (CRT-P) DEVICES: VALITUDE, VALITUDE, AND VISIONIST	GUIDANT CORP.	Modifications to a suppliers cleaning process used in the manufacture of the MICS module component of the pulse generators hybrid.
P030005/S168	12/06/2017	X - 30-Day Notice	VALITUDE, VALITUDE X4, VISIONIST, VISIONIST X4, INVIVE, INTUA CARDIAC RESYNCHRONIZATION THERAPY-PACEMALER (CRT-P)	GUIDANT CORP.	Additional electrolyte supplier for pulse generator batteries, an approved manufacturing location for the existing battery electrolyte supplier, and updates to associated acceptance activities.
P030005/S169	12/06/2017	X - 30-Day Notice	VALITUDE / VALITUDE X4 / VISIONIST / VISIONIST X4 / ACCOLADE C ARDIAC RESYNCHRONIZATION THERAPY-PACEMAKER (CRT-P) DEVICES	GUIDANT CORP.	Modifications to the titanium can manufacturing process at the supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030005/S170	12/19/2017	X - 30-Day Notice	INTUA, INVIVE, VALITUDE, VISIONIST, CRT-PS	GUIDANT CORP.	Change in the bacterial endotoxin test sampling plan and frequency.
P030009/S093	12/20/2017	X - 30-Day Notice	INTEGRITY CORONARY STENT SYSTEM	MEDTRONIC IRELAND	Introduce software for monitoring the Controlled Environment Areas (CEAs) at the Empalme, Mexico manufacturing facility.
P030011/S058	12/01/2017	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM; FREEDOM DRIVER SYSTEM	SYNCARDIA SYSTEMS, LLC	Change in location for a component supplier.
P030011/S059	12/07/2017	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Change of an electrical component and to the supplier of electrical assemblies for the Companion 2 Driver.
P030017/S305	12/01/2017	X - 30-Day Notice	SPECTRA WAVEWRITER SCS SYSTEM	BOSTON SCIENTIFIC CORP.	Update the test equipment system software (to add 40 seconds delay between the Bootloader and application firmware download tests) used for testing the 'Spectra Wave Writer (SCS) External Trial Stimulator (ETS) units.
P030022/S045	12/20/2017	X - 30-Day Notice	REFLECTION CERAMIC ACETABULAR HIP SYSTEM	SMITH & NEPHEW, INC.	Modification of the in-process visual inspection criteria for the sterile packaging for the subject device.
P030036/S097	12/14/2017	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P030047/S034	12/15/2017	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS CORP.	Tighten a specification and add an in-process test.
P030050/S027	12/14/2017	X - 30-Day Notice	SCULPTRA & SCULPTRA AESTHETIC	Q-MED AB	Installation of a new sieving process hopper for PLLA particles for Sculptra and Sculptra Aesthetic.
P030052/S021	12/06/2017	X - 30-Day Notice	UROVYSION BLADDER CANCER KIT	ABBOTT MOLECULAR	Vendors relocation of a manufacturing site for production of reagents contained in kit components.
P030054/S341	12/07/2017	X - 30-Day Notice	UNIFY/ UNIFY QUADRA/ UNIFY ASSURA / QUADRA ASSURA MP	ST. JUDE MEDICAL	Elimination of certain non-destructive pull testing of wires on hybrid circuits.
P030054/S342	12/11/2017	X - 30-Day Notice	UNIFY/ UNIFY QUADRA/ UNIFY ASSURA/ QUADRA ASSURA/ QUADRA ASSURA MP	ST. JUDE MEDICAL	Alternate high voltage capacitor stack process with automated inspection and placement.
P040020/S075	12/21/2017	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBERS INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Implementation of an automated cleaning system for initial cleaning of the AcrySof Intraocular Lenses at the Alcon Ireland manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040020/S076	12/18/2017	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Change to the molding process.
P040021/S033	12/26/2017	X - 30-Day Notice	BIOCOR HEART VALVE	ST. JUDE MEDICAL, INC.	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P040033/S032	12/20/2017	X - 30-Day Notice	BIRMINGHAM HIP RESURFACING SYSTEM	SMITH&NEPHEW ORTHOPAEDICS	Modification of the in-process visual inspection criteria for the sterile packaging for the subject device.
P040037/S107	12/13/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Supplier site change.
P040037/S108	12/28/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate resin, supplied by an alternate supplier, in the manufacture of radiopaque marker components of the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface.
P040043/S097	12/13/2017	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Supplier site change.
P040045/S088	12/01/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification of an in-process control procedure for a raw material used in VISTAKON® (senofilcon A) Brand Contact Lenses.
P040045/S089	12/06/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of a purity specification for a raw material used in VISTAKON (senofilcon A) Brand Contact lenses and a new test method which will be utilized to support testing of raw material to ensure compliance with the additional purity specification.
P040045/S090	12/14/2017	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 release of VISTAKON® (senofilcon A) Brand Contact Lenses.

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P040045/S091	12/19/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of an alternate in-process test method used in the manufacture of VISTAKON (senofilcon A) Brand Contact Lenses. The test method is specific to the presbyopia designs of senofilcon A contact lenses.
P050028/S060	12/20/2017	X - 30-Day Notice	COBAS TAQMAN HBV TEST V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Remove a Quality Control test performed on finished analyzers.
P050053/S040	12/13/2017	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Source manufacturing changes to the absorbable collagen sponge component of Infuse Bone Graft.
P060006/S088	12/01/2017	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P060006/S089	12/15/2017	X - 30-Day Notice	EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Use of automated equipment in the packaging process.
P060011/S013	12/07/2017	X - 30-Day Notice	RAYNER C-FLEX 570C, C-FLEX ASPHERIC 970C AND 600C ASPHERIC INTRAOCULAR LENSES	RAYNER INTRAOCULAR LENSES LTD.	Addition of a supplier for repackaging the device into the approved configuration.
P060030/S061	12/20/2017	X - 30-Day Notice	COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Remove a Quality Control test performed on finished analyzers.
P060039/S082	12/14/2017	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P080004/S020	12/19/2017	X - 30-Day Notice	CLARISERT PRELOADED IOL SYSTEM	HOYA SURGICAL OPTICS, INC.	Incorporation of the Clarisert Model into the existing lathe cutting line number 4.
P080006/S116	12/14/2017	X - 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P080011/S064	12/12/2017	X - 30-Day Notice	COMFLICON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Reduction of the cycle time for the injection molding machine for Biofinity Toric (comfilcon A) extended wear soft (hydrophilic) contact lenses.

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P080011/S065	12/28/2017	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACE LENSES	COOPERVISION MANUFACTURING, LTD.	Reduction in injection molding machine cycle time for Biofinity Sphere (comfilcon A) contact lenses.
P080020/S027	12/14/2017	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Changes in the storage and main weighing facilities for the hyaluronic acid component of Gel-One and commission of a back-up facility for the weighing of the hyaluronic acid component of Gel-One.
P080025/S157	12/13/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Transfer of the injection molding of the TIP-QUAD LEAD, part number 117167001, from Medtronic Energy and Component Center (MECC) to Donatelle Plastics, Inc.
P080025/S159	12/14/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Updates of the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.4.
P090013/S265	12/05/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Manufacturing change at a supplier for capacitors used in the manufacture of hybrids.
P090013/S266	12/11/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Additional catalyst material for the capacitor encapsulation process.
P090013/S267	12/14/2017	X - 30-Day Notice	CAPSUREFIX MRI LEAD, REVO MRI SURESCAN IPG	MEDTRONIC, INC	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P090013/S268	12/13/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Manufacturing process changes at a supplier for the 3um Complementary Metal Oxide Semiconductor (CMOS) components.
P100010/S069	12/14/2017	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Addition of a visual inspection of pin alignment during the manufacturing of the Arctic Front and Arctic Front Advance catheters.
P100020/S028	12/26/2017	X - 30-Day Notice	COBAS 4800 WASH AND LYSIS REAGENTS	ROCHE MOLECULAR SYSTEMS, INC.	Increase batch range of kit components.
P100021/S068	12/20/2017	X - 30-Day Notice	ENDURANT/ENDURANT II/ ENDURANT IIS STENT GRAFT SYSTEMS, TALENT OCCLUDER WITH OCCLUDER DELIVERY SYSTEM	MEDTRONIC VASCULAR	Introduce software for monitoring the Controlled Environment Areas (CEAs) at the Empalme, Mexico manufacturing facility.
P100029/S028	12/26/2017	X - 30-Day Notice	TRIFECTA HEART VALVE	ST. JUDE MEDICAL, INC.	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P100040/S033	12/20/2017	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Introduce software for monitoring the Controlled Environment Areas (CEAs) at the Empalme, Mexico manufacturing facility.

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P110004/S026	12/19/2017	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Introduce an additional hydrophilic coating line for the NIRxcell delivery system.
P110010/S149	12/01/2017	X - 30-Day Notice	PROMUS ELEMEN PLUS EVEROLIMUS-EIUTING STENT SYSTEM/ PROMUS PREMIER EVEROLIMUS-EIUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P110010/S150	12/12/2017	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Widen an in-process specification from the proximal marker band to the balloon body transition on all catheter lengths and sizes.
P110012/S014	12/06/2017	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Vendors relocation of a manufacturing site for production of reagents contained in kit components.
P110013/S085	12/20/2017	X - 30-Day Notice	RESOLUTE INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Introduce software for monitoring the Controlled Environment Areas (CEAs) at the Empalme, Mexico manufacturing facility.
P110016/S052	12/26/2017	X - 30-Day Notice	THERAPY (FLEXABILITY) ABLATION CATHETERS	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P110033/S035	12/14/2017	X - 30-Day Notice	JUVEDERM VOLBELLA XC	ALLERGAN	Implementation of an automated visual inspection process for Juvederm Volbella XC in the 0.55 mL fill volume configuration.
P110035/S044	12/14/2017	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Upgrades to the sterilization equipment.
P110037/S033	12/20/2017	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Remove a Quality Control test performed on finished analyzers.
P110042/S096	12/01/2017	X - 30-Day Notice	EMBLEM S-ICD SYSTEM MODEL A209 / EMBLEM MRI S-ICD SYSTEM MODEL A219	BOSTON SCIENTIFIC CORPORATION	Upgrade device header overmolding equipment.

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P110042/S097	12/06/2017	X - 30-Day Notice	EMBLEM SICD GEN 2, SICD EMBLEM MRI , SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (SICD)	BOSTON SCIENTIFIC CORPORATION	Additional electrolyte supplier for pulse generator batteries, an approved manufacturing location for the existing battery electrolyte supplier, and updates to associated acceptance activities.
P110042/S098	12/19/2017	X - 30-Day Notice	EMBLEM, EMBLEM MRI S-ICDS	BOSTON SCIENTIFIC CORPORATION	Change in the bacterial endotoxin test sampling plan and frequency.
P120010/S107	12/21/2017	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of a new sterilization site for the Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of MiniMed 530G System, MiniMed Paradigm Real-Time Revel System, and MiniMed iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of MiniMed 630G System with SmartGuard and the MiniMed 670G System.
P120017/S011	12/14/2017	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P130006/S046	12/13/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Supplier site change.
P130006/S047	12/28/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of an alternate resin, supplied by an alternate supplier, in the manufacture of radiopaque marker components of the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface.
P130008/S028	12/08/2017	X - 30-Day Notice	INSPIRE IV IPG	INSPIRE MEDICAL SYSTEMS	Changes to update to software version 1.1.9 of the final functional test system for the Model 3028 IPG.
P130013/S016	12/05/2017	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the final forming temperature range of the device frame.
P130017/S021	12/18/2017	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Remove the cassette tube blocking step.

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P130021/S047	12/11/2017	X - 30-Day Notice	COREVALVE EVOLUT R SYSTEM AND COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Allow for rework of the valve for certain minor defects during the assembly process.
P130021/S048	12/12/2017	X - 30-Day Notice	CORE VALVE EVOLUT R SYSTEM AND CORE VALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Introduce a lower temperature acceptance limit inspection criterion for incoming shipment of fresh porcine pericardial tissue.
P130030/S046	12/01/2017	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P130030/S047	12/15/2017	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Use of automated equipment in the packaging process.
P140017/S010	12/14/2017	X - 30-Day Notice	MELODY TPV SYSTEM	MEDTRONIC INC.	Relocate the manufacturing of the Melody Transcatheter Pulmonary Valve to a different building within the Medtronic Mexico facility.
P140028/S030	12/14/2017	X - 30-Day Notice	INNOVA SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Upgrades to the sterilization equipment.
P140031/S057	12/11/2017	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Add the Edwards Singapore facility as a manufacturing site for the valve skirts and to add an upgraded laser cutting system.
P140031/S058	12/11/2017	X - 30-Day Notice	FINAL CRIMP STOPPER	EDWARDS LIFESCIENCES, LLC.	Change the vision systems used for receiving inspection of the crimp stopper.
P140033/S020	12/07/2017	X - 30-Day Notice	TENDRIL MRI	ST. JUDE MEDICAL, INC.	Supplier to conduct heat treatment and passivation processes in-house.
P150001/S030	12/21/2017	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Addition of a new sterilization site for the Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of MiniMed 530G System, MiniMed Paradigm Real-Time Revel System, and MiniMed iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of MiniMed 630G System with SmartGuard and the MiniMed 670G System.
P150003/S035	12/14/2017	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Upgrades to the sterilization equipment.
P150004/S016	12/08/2017	X - 30-Day Notice	AXIUM CLINICAL AND PATIENT PROGRAMMERS	ST. JUDE MEDICAL	Addition of a recharging process for the Axium Patient and Clinical Programmer at the Plano, Texas manufacturing facility to maintain battery level while the programmers are in inventory.

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P150004/S017	12/15/2017	X - 30-Day Notice	SLIMTIP DRG TRIAL LEAD KIT, 50CM & 90CM / SLIMTIP DRG IMPLANT LEAD KIT, 50CM & 90CM / DRG LEAD EXTENSION KIT.	ST. JUDE MEDICAL	Extending the duration after plasma etching and the update to the electrode weld inspection criteria on proximal terminal end of the DRG leads.
P150005/S032	12/01/2017	X - 30-Day Notice	BLAZER OPEN IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Update the BSC2000-2 cycle conducted in Chamber 5 at the BSC Coventry, RI facility with new Programmable Logic Controller (PLC) software, a replacement vacuum pump with an additional vacuum pump booster, and a new validation documentation structure used to support the system.
P150012/S045	12/01/2017	X - 30-Day Notice	ACCOLADE MRI, ESSENTIO MRI, PROPONENT MRI (ACCOLADE MRI)	BOSTONSCIENTIFIC	Upgrade device header overmolding equipment.
P150012/S046	12/11/2017	X - 30-Day Notice	ACCOLADE MRI PACEMAKERS: ESSENTIO MRI, PROPONENT MRI AND ACCOLADE MRI	BOSTONSCIENTIFIC	Modifications to a suppliers cleaning process used in the manufacture of the MICS module component of the pulse generators hybrid.
P150012/S048	12/06/2017	X - 30-Day Notice	ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI, MRI PACEMAKERS	BOSTONSCIENTIFIC	Additional electrolyte supplier for pulse generator batteries, an approved manufacturing location for the existing battery electrolyte supplier, and updates to associated acceptance activities.
P150012/S049	12/06/2017	X - 30-Day Notice	ESSENTIO MRI / PROPONENT MRI / ACCOLADE MRI / ACCOLADE MRI PACEMAKERS	BOSTONSCIENTIFIC	Modifications to the titanium can manufacturing process at the supplier.
P150012/S050	12/19/2017	X - 30-Day Notice	ACCOLADE MRI, ESSENTIO MRI, FORMIO MRI, INGENIO MRI, PROPONENT MRI, VITALIO MRI	BOSTONSCIENTIFIC	Change in the bacterial endotoxin test sampling plan and frequency.
P150014/S012	12/11/2017	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Increase the batch size of a component.
P150015/S011	12/11/2017	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Increase the batch size of a component.

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P150016/S007	12/20/2017	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT; TRIDYNE VS STANDARD SPRAY TIPS; TRIDYNE VS 6" EXTENDED SPRAY TIP	NEOMEND, INC.	Changes to the processing of the Human Serum Albumin (HSA) and Polyethylene Glycol (PEG) components of the Tridyne Vascular Sealant.
P150019/S033	12/21/2017	X - 30-Day Notice	MINIMED PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of a new sterilization site for the Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of MiniMed 530G System, MiniMed Paradigm Real-Time Revel System, and MiniMed iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of MiniMed 630G System with SmartGuard and the MiniMed 670G System.
P150021/S013	12/20/2017	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a mold and press to increase the product capacity for the sharp carrier component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P150021/S014	12/21/2017	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Changes to the molding process parameters and molding equipment used for the plastic components of the puck in the Freestyle Libre Flash Glucose Monitoring System and Freestyle Libre Pro Flash Glucose Monitoring System.
P150021/S015	12/22/2017	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of an alternate higher cavitation mold tool for the platform component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P150021/S017	12/29/2017	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a new injection molding machine and an alternative higher cavitation (16-cavity) mold tool for the sensor applicator housing component of the Freestyle Libre Flash Glucose Monitoring System and the FreeStyle Libre Pro Flash Glucose Monitoring
P150029/S013	12/21/2017	X - 30-Day Notice	MINIMED IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Addition of a new sterilization site for the Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of MiniMed 530G System, MiniMed Paradigm Real-Time Revel System, and MiniMed iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of MiniMed 630G System with SmartGuard and the MiniMed 670G System.
P150030/S004	12/20/2017	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Modification of the in-process visual inspection criteria for the sterile packaging for the subject device.
P150033/S028	12/14/2017	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Update to the manufacturing execution system to FACTORYworks (FW) Release 9.4.
P150036/S021	12/08/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of new manufacturing equipment to an existing cleanroom.
P150041/S001	12/06/2017	X - 30-Day Notice	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Vendors relocation of a manufacturing site for production of reagents contained in kit components.

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P150048/S010	12/08/2017	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS AND EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Addition of new manufacturing equipment to an existing cleanroom.
P160004/S007	12/13/2017	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Supplier site change.
P160017/S026	12/21/2017	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of a new sterilization site for the Enlite Sensor and the Guardian Sensor (3). The Enlite Sensor is a component of MiniMed 530G System, MiniMed Paradigm Real-Time Revel System, and MiniMed iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of MiniMed 630G System with SmartGuard and the MiniMed 670G System.
P160030/S003	12/20/2017	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a mold and press to increase the product capacity for the sharp carrier component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160030/S004	12/21/2017	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Changes to the molding process parameters and molding equipment used for the plastic components of the puck in the Freestyle Libre Flash Glucose Monitoring System and Freestyle Libre Pro Flash Glucose Monitoring System.
P160030/S005	12/22/2017	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of an alternate higher cavitation mold tool for the platform component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160030/S006	12/28/2017	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a new injection molding machine and an alternate higher cavitation mold tool to increase the product capacity for the Sheath component of the Freestyle Libre Flash Glucose Monitoring System.
P160030/S008	12/29/2017	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a new injection molding machine and an alternative higher cavitation (16-cavity) mold tool for the sensor applicator housing component of the Freestyle Libre Flash Glucose Monitoring System and the FreeStyle Libre Pro Flash Glucose Monitoring
P160041/S004	12/11/2017	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Increase the batch size of a component.
P160045/S002	12/06/2017	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Move the storage location of finished component materials.

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P160045/S003	12/18/2017	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Change of subcomponent vendor and removal of a QC test.
P170006/S005	12/15/2017	X - 30-Day Notice	AVALUS BIOPROSTHESIS, MODEL 400	MEDTRONIC INC.	Extension to the in-process tissue coupon storage time.

Total: 206