PMA Monthly approvals from 3/1/2018 to 3/31/2018

Original

Data as of 04/05/2018 10:35 AM

Submission	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160007	03/08/2018	PMAO - PMA Origi	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for the Guardian Connect system. The Guardian Connect system is indicated for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin, in patients (14 to 75 years of age) with diabetes mellitus. The Guardian Connect system provides real-time glucose values and trends through a Guardian Connect app installed on a compatible consumer electronic mobile device. It allows users to detect trends and track patterns in glucose concentrations. The Guardian Connect app alerts if a Guardian Sensor (3) glucose level reaches, falls below, rises above, or is predicted to surpass set values. The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3). The Guardian Connect system is comprised of the following devices: Guardian Connect app, Guardian Sensor (3), and the Guardian Connect transmitter. Guardian Sensor (3): The Guardian Sensor (3) is intended for use with Medtronic Diabetes glucose-sensing systems, to continuously monitor glucose levels in persons with diabetes. The Guardian Sensor (3) is indicated for 7 days of continuous use. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. Guardian Connect Transmitter: The Guardian Connect transmitter is intended for use with the Guardian Connect system. The Guardian Connect transmitter powers the glucose sensor, collects and calculates sensor data, and sends the data via Bluetooth version 4.0 to the Guardian Connect app installed on a compatible mobile device. The transmitter is only compatible with the Guardian Sensor (3). The transmitter is indicated for multiple uses on a single patient as a component of the Guardian Connect system. The Guardian Connect transmitter requires a prescription. Guardian Connect App: The Guardian Connect app is intended for use only by patients using a compatible mobile device, and who have sufficient experience to adjust mobile device audio and notification settings. The app displays sensor glucose data, and also provides a user interface for sensor calibration, entering data such as exercise and meals, and uploading information to the CareLink Personal website. It allows users to detect trends and track patterns in glucose concentrations. The Guardian Connect app provides alerts if a Guardian Sensor (3) glucose level reaches, falls below, rises above, or is predicted to surpass set values. The Guardian Connect app is available over-the-counter (OTC) but requires the Guardian Sensor (3) and Guardian Connect transmitter to function.

P160013	03/22/2018	PMAO - PMA Origi	ORGAN CARE SYSTEM (OCS) LUNG SYSTEM	TRANSMEDICS, INC	Approval for the OCS Lung System, indicated for the preservation of standard criteria donor lungs in a near physiologic, ventilated, and perfused state for double lung transplantation.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S028	03/01/2018	N - Normal 180 Day	GELFOAM	PFIZER, INC.	Approval for an alternative packaging configuration for GELFOAM Sterile Powder under the trade name FLOSTAT NT as well as approval of the associated new manufacturing site for GELFOAM Sterile Powder manufacture (solely for FLOSTAT NT), kit assembly, secondary packaging, and sterilization at Vascular Solutions, Inc., 6464 Sycamore Court, Minneapolis, Minnesota.
N970003/S224	03/26/2018	R - Real-Time Proc	ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT	BOSTON SCIENTIFIC CORP.	Approval for a Software Maintenance Release (SMR) for the Model 3922 Pacing System Analyzer (PSA) Software Application that functions within Model 3300 LATITUDE Programming System (LPS).
P810002/S101	03/06/2018	N - Normal 180 Day	SJM MASTERS SERIES MECHANICAL HEART VALVE, 15MM HP	ST. JUDE MEDICAL, INC.	Approval for the addition of the 15-mm HP valve, models 15 AHPJ-505 and 15 MHPJ-505, to the Masters Series Mechanical Heart Valve with Hemodynamic Performance Sewing Cuff product line.
P830055/S195	03/07/2018	S - Special CBE	ATTUNE REVISION RP TIBIA BASE/LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a Delrin fixture that is attached to the end of the ATTUNE Revision RP Tibial Base to elevate the device out of contact with the ultrasonic basket during the ultrasonic cleaning process.
P830061/S153	03/01/2018	R - Real-Time Proc	CAPSURE SENSE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the addition of the Primo MRI SureScan and Mirro MRI SureScan ICDs to the Evera MRI Conditional family of devices.
P840001/S376	03/11/2018	O - Normal 180 Day	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for a manufacturing site located at Medronic Puerto Rico Operations Company, Villalba, Rd. 149, Km 56.3 , Cal box 6001, Villaba, Puerto Rico for manufacture of the 1x4 Pocket Adaptors (models 74001 and 64001) and 2x4 Pocket Adaptors (models 74002 and 64002).
P850007/S038	03/07/2018	R - Real-Time Proc	PHYSIOSTIM AND SPINALSTIM	ORTHOFIX, INC.	Approval for updates to the STIM onTrack mobile application for compatibility with Android OS. The optional mobile application is identical in functionality to the previously approved iOS version. The application is compatible with the CervicalStim Model 5505, SpinalStim Model 5212, and PhysioStim Models 5302, 5303, 5313, 5314, and 5315.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900033/S065	03/01/2018	Y - 135 Review Tra	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIEN CE S	Approval for modifications to the Water for Injection and Clean Steam Distribution Systems
P900056/S166	03/19/2018	N - Normal 180 Day	ROTAPRO ADVANCER; ROTAPRO; ROTAPRO CONSOLE	BOSTON SCIENTIFIC CORP.	Approval to modify and rebrand the Rotablator Rotational Atherectomy system devices and accessories.
P910077/S165	03/26/2018	R - Real-Time Proc	LATITUDE PROGRAMMING SYSTEM	BOSTON SCIENTIFIC	Approval for a Software Maintenance Release (SMR) for the Model 3922 Pacing System Analyzer (PSA) Software Application that functions within the Model 3300 LATITUDE Programming System (LPS).
P920015/S204	03/01/2018	R - Real-Time Proc	SPRINT QUATTRO SECURE S MRI SURESCAN LEAD & SPRINT QUATTRO SECURE MRI SURESCAN LEAD	MEDTRONIC INC.	Approval for the addition of the Primo MRI SureScan and Mirro MRI SureScan ICDs to the Evera MRI Conditional family of devices.
P930029/S058	03/06/2018	R - Real-Time Proc	RF CONDUCTR MC; RF MARINR 5FR; RF MARINR 7FR; AND UNIPOLAR MAPPING RF MARINR 7FR	MEDTRONIC INC.	Approval for removal of the wiper component from the handle sub-assembly.
P930039/S179	03/01/2018	R - Real-Time Proc	CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC, INC.	Approval for the addition of the Primo MRI SureScan and Mirro MRI SureScan ICDs to the Evera MRI Conditional family of devices.
P950005/S069	03/28/2018	Y - 135 Review Tra	WEBSTER CATHETER / CELSIUS CATHETER	CORDIS CORP.	Approval of transfer of extrusion process for non-braided dual lumen subcomponent catheter part from Cordis Miami to Biosense Webster in Juarez, Mexico.
P950029/S118	03/11/2018	R - Real-Time Proc	REPLY SR / ESPRIT SR / REPLY DR / ESPRIT DR	LIVANOVA USA, INC.	Approval for software updates to the embedded device and remote monitoring system.
P960009/S293	03/11/2018	O - Normal 180 Day	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for a manufacturing site located at Medronic Puerto Rico Operations Company, Villalba, Rd. 149, Km 56.3 , Cal box 6001, Villaba, Puerto Rico for manufacture of the 1x4 Pocket Adaptors (models 74001 and 64001) and 2x4 Pocket Adaptors (models 74002 and 64002).
P960011/S029	03/15/2018	S - Special CBE	BVI 1% OVD (FORMERLY BD 1% OVD AND BIOLON)	AMRING PHARMACEUT ICALS	Approval for revisions to the labeling trade name from BVI 1% OVD® (1% sodium hyaluronate viscoelastic surgical aid fluid) to BIOLON, distributor, and Instructions for Use for the inclusion of a tamper-evident tip cap closure system.
P960040/S418	03/26/2018	R - Real-Time Proc	TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILANT, PERCIVA	BOSTON SCIENTIFIC	Approval for a Software Maintenance Release (SMR) for the Model 3922 Pacing System Analyzer (PSA) Software Application that functions within Model 3300 LATITUDE Programming System (LPS).
P960040/S421	03/22/2018	R - Real-Time Proc	RESONATE, MOMENTUM, VIGILANT, AND PERCIVA NG4 ICDS	BOSTON SCIENTIFIC	Approval for an update to the Programmer Application Software Model 2868.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S653	03/01/2018	R - Real-Time Proc	PRIMO MRITM SURESCAN TM & MIRRO MRITM SURESCAN TM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the addition of the Primo MRI SureScan and Mirro MRI SureScan ICDs to the Evera MRI Conditional family of devices.
P980044/S039	03/15/2018	Y - 135 Review Tra	SUPARTZ FX AND VISCO-3	SEIKAGAKU CORP.	Approval for a change to the water classification scheme for controls of the quality of the water used to manufacture SUPARTZ FX and VISCO-3.
P980049/S128	03/11/2018	R - Real-Time Proc	PLATINIUM VR / DR / CRT-D	LIVANOVA USA, INC.	Approval for software updates to the embedded device and remote monitoring system.
P000025/S094	03/07/2018	N - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval order should be issued for the reinforced electrode variant +FLEXSOFT and the Insertion Electrode (IE) variant FLEXSOFT.
P010012/S477	03/26/2018	R - Real-Time Proc	COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILIANT, PERCIVA	BOSTON SCIENTIFIC CORP.	Approval for a Software Maintenance Release (SMR) for the Model 3922 Pacing System Analyzer (PSA) Software Application that functions within Model 3300 LATITUDE Programming System (LPS).
P010012/S480	03/22/2018	R - Real-Time Proc	RSONATE, MOMENTUM AND VIGILANT NG4 CRT-DS	BOSTON SCIENTIFIC CORP.	Approval for an update to the Programmer Application Software Model 2868.
P010014/S070	03/05/2018	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for updates to work instructions for inspection step of sterile and nonsterile packaging components.
P010032/S132	03/11/2018	O - Normal 180 Day	PROCLAIM FAMILY OF IMPLANTABLE PULSE GENERATORS	ST. JUDE MEDICAL	Approval for a manufacturing site located at St. Jude Medical-Puerto Rico, Lot A Interior-No. 2 St. Km 67.5, Santana Industrial Park, Arecibo, Puerto Rico for manufacturing and sterilization of the Proclaim and Infinity neurostimulation systems.
P020012/S019	03/21/2018	S - Special CBE	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for the improvement of the Instructions for Use to ensure that end users are aware that these medical devices should be stored in refrigerated conditions until ready to use.
P020047/S067	03/05/2018	O - Normal 180 Day	MULTI-LINK 8 CORONARY, 8 LL CORONARY, AND 8 SV CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for an alternate contract sterilizer site located at Synergy Heath Ireland Ltd, IDA Business & Technology Park, Sragh Industrial Estate, Tullamore, Co. Offaly, Ireland. To perform as an alternate ethylene oxide sterilization vendor for the GRAFTMASTER Coronary Stent Graft System, MULTI-LINK 8 Coronary, 8 LL Coronary, and 8 SV Coronary Stent System, XIENCE V and Nano Everolimus Eluting Coronary Stent System, and XIENCE Prime/Xpedition/Alpine/Sierra Everolimus Eluting Coronary Stent System (SV, LL).
P020049/S005	03/22/2018	O - Normal 180 Day	PROCOL VASCULAR BIOPROSTHESIS	LEMAITRE VASCULAR INC	Approval for a manufacturing site located at Le Maitre Vascular Inc., 63 Second Ave, Burlington, Massachusetts, for manufacturing operations for ProCol Vascular Bioprosthesis.

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P030005/S172	03/26/2018	R - Real-Time Proc	INVIVE, INTUA, VISIONIST, VALITUDE	GUIDANT CORP.	Approval for a Software Maintenance Release (SMR) for the Model 3922 Pacing System Analyzer (PSA) Software Application that functions within Model 3300 LATITUDE Programming System (LPS).
P030017/S308	03/12/2018	R - Real-Time Proc	PRECISION MONTAGE MRI SPINAL CORD STIMULATOR SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for an update to the Precision Montage and Precision Montage MRI Spinal Cord Stimulator (SCS) System firmware to adjust the temperature sensor calibration with an aim to improve the accuracy of the sensor reading, associated changes to the Printed Circuit Board Assembly and device level Automated Test Equipment software, and rework of the IPG devices that failed the device level temperature sensor test.
P030022/S039	03/20/2018	O - Normal 180 Day	REFLECTION CERAMIC ACETABULAR HIP SYSTEM (RCHS)	SMITH & NEPHEW, INC.	Approval for the updated physician and patient labeling based on post approval study data.
P030034/S011	03/07/2018	R - Real-Time Proc	CERVICALSTIM	ORTHOFIX, INC.	Approval for updates to the STIM onTrack mobile application for compatibility with Android OS. The optional mobile application is identical in functionality to the previously approved iOS version. The application is compatible with the CervicalStim Model 5505, SpinalStim Model 5212, and PhysioStim Models 5302, 5303, 5313, 5314, and 5315.
P030036/S098	03/01/2018	R - Real-Time Proc	SELECTSECURE MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the addition of the Primo MRI SureScan and Mirro MRI SureScan ICDs to the Evera MRI Conditional family of devices.
P030039/S020	03/22/2018	O - Normal 180 Day	COSEAL SURGICAL SEALANT	BAXTER BIO SCIENCE	Approval for a manufacturing site located at Baxter S.A., Boulevard Rene Branquart 80 7860 Lessines, Belgium for final release testing and product release functions of the Coseal Surgical Sealant Spray Set (Coseal Spray Set).
P040033/S033	03/02/2018	S - Special CBE	BIRMINGHAM HIP RESURFACING (BHR) SYSTEM	SMITH&NEPHEW ORTHOPAEDICS	Approval for modifications to the device labeling.
P040034/S027	03/21/2018	O - Normal 180 Day	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for manufacturing sites located at Avail/Med S.A. De C.V., C.Industrial Lt.001 Mz 105, No. 206905 Int.a.Col. Cd. Industrial, Tijuana, Baja California, Mexico 22444 for manufacture of the DuraSeal® Dural Sealant System and DuraSeal® Exact Spine Sealant System, and Synergy Health AST, LLC, 9020 Activity Road, Suite D, San Diego, California for sterilization of the devices.
P040047/S046	03/28/2018	O - Normal 180 Day	COAPTITE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval of the alternate manufacturing facility located at 13900 W. Grandview Parkway Sturtevant.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050006/S060	03/30/2018	P - Panel Track	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval for the GORE CARDIOFORM Septal Occluder. The GORE CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: 1) ostium secundum atrial septal defects (ASDs); and 2) patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.
P050037/S082	03/28/2018	O - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval of the alternate manufacturing facility located at 13900 W. Grandview Parkway Sturtevant.
P050052/S098	03/28/2018	O - Normal 180 Day	RADIESSE HANDS, RADIESSE (+) LIDOCAINE	MERZ NORTH AMERICA, INC	Approval of the alternate manufacturing facility located at 13900 W. Grandview Parkway Sturtevant.
P060027/S093	03/11/2018	R - Real-Time Proc	PLATINIUM 4LV CRT-D	LIVANOVA USA, INC.	Approval for software updates to the embedded device and remote monitoring system.
P060038/S031	03/28/2018	Y - 135 Review Tra	MITROFLOW AORTIC PERICARDIAL HEART VALVE	LIVANOVA CANADA CORP.	Approval for modifications to the molding process parameters for the Model DL and Crown PRT stent frames.
P060039/S083	03/15/2018	O - Normal 180 Day	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Approval for an update to the labeling to include a summary of the Attain StarFix Model 4195 Lead Chronic Performance Study data.
P070015/S139	03/05/2018	O - Normal 180 Day	XIENCE V/NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Approval for an alternate contract sterilizer site located at Synergy Heath Ireland Ltd, IDA Business & Technology Park, Sragh Industrial Estate, Tullamore, Co. Offaly, Ireland. To perform as an alternate ethylene oxide sterilization vendor for the GRAFTMASTER Coronary Stent Graft System, MULTI-LINK 8 Coronary, 8 LL Coronary, and 8 SV Coronary Stent System, XIENCE V and Nano Everolimus Eluting Coronary Stent System, and XIENCE Prime/Xpedition/Alpine/Sierra Everolimus Eluting Coronary Stent System (SV, LL).
P080003/S006	03/23/2018	N - Normal 180 Day	SELENIA DIMENSIONS/ 3DIMENSIONS 3D SYSTEM	HOLOGIC, INC.	Approval for a change to the Selenia Dimensions/3Dimensions 3D System with 15 projection angles for approval of the high resolution tomosynthesis and synthesized 2D feature, SmartCurve compression paddles, as well as a new linear grid for the Full-field Digital Mammography System.
P080013/S015	03/21/2018	O - Normal 180 Day	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Approval for manufacturing sites located at Avail/Med S.A. De C.V., C.Industrial Lt.001 Mz 105, No. 206905 Int.a.Col. Cd. Industrial, Tijuana, Baja California, Mexico 22444 for manufacture of the DuraSeal® Dural Sealant System and DuraSeal® Exact Spine Sealant System, and Synergy Health AST, LLC, 9020 Activity Road, Suite D, San Diego, California for sterilization of the devices.
P080020/S026	03/15/2018	Y - 135 Review Tra	GEL-ONE	SEIKAGAKU CORP.	Approval for a change to the water classification scheme for controls of the quality of the water used to manufacture Gel-One.
P090013/S269	03/01/2018	R - Real-Time Proc	CAPSUREFIX MRI SURESCAN LEAD	MEDTRONIC, INC	Approval for the addition of the Primo MRI SureScan and Mirro MRI SureScan ICDs to the Evera MRI Conditional family of devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090016/S025	03/28/2018	O - Normal 180 Day	BELOTERO BALANCE DERMAL FILLER	MERZ NORTH AMERICA, INC	Approval of the alternate manufacturing facility located at 13900 W. Grandview Parkway Sturtevant.
P100045/S022	03/06/2018	O - Normal 180 Day	CARDIOMEMS PATIENT AND HOSPITAL ELECTRONICS	ST. JUDE MEDICAL	Approval for an alternate manufacturing site located at St. Jude Medical LLC, SJM Technology Center, One St. Jude Medical Drive, Saint Paul, Minnesota.
P100047/S111	03/15/2018	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for an elongated HVAD Coring Tool and an elongated HVAD Sewing Ring Wrench.
P100047/S114	03/15/2018	O - Normal 180 Day	HEARTWARE HVAD SYSTEM	MEDTRONIC	Approval of the protocol for the post-approval study (PAS) protocol.
P100049/S021	03/15/2018	N - Normal 180 Day	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Approval for updating the precautions statement to state that use of the LINX Reflux Management System in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update the patient information booklet to align with the instructions for use and include 5 year clinical study results.
P110004/S024	03/07/2018	O - Normal 180 Day	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Approval for a manufacturing site located at Creganna Medical, 8 Admiralty Street, #07-10 Admirax Building, Singapore, for the manufacturing of D-Catheter delivery system.
P110013/S087	03/15/2018	R - Real-Time Proc	RESOLUTE INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Approval to introduce changes to the annual stability study design for the Resolute Onyx Coronary Stent System and Resolute Integrity Coronary Stent System.
P110016/S050	03/22/2018	Y - 135 Review Tra	FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for changes to the current thermal bond manufacturing equipment and process used for the deflectable to proximal shaft bond.
P110019/S096	03/05/2018	O - Normal 180 Day	XIENCE PRIME/XPEDITION/ ALPINE/SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM (SV, LL)	ABBOTT VASCULAR	Approval for an alternate contract sterilizer site located at Synergy Heath Ireland Ltd, IDA Business & Technology Park, Sragh Industrial Estate, Tullamore, Co. Offaly, Ireland. To perform as an alternate ethylene oxide sterilization vendor for the GRAFTMASTER Coronary Stent Graft System, MULTI-LINK 8 Coronary, 8 LL Coronary, and 8 SV Coronary Stent System, XIENCE V and Nano Everolimus Eluting Coronary Stent System, and XIENCE Prime/Xpedition/Alpine/Sierra Everolimus Eluting Coronary Stent System (SV, LL).
P120010/S113	03/07/2018	R - Real-Time Proc	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for a minor design change to the introducer needle component of the Guardian Sensor (3) and the Enlite Sensor and the addition of an alternate needle supplier.

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P120011/S009	03/13/2018	O - Normal 180 Day	IDEAL IMPLANT STRUCTURED BREAST IMPLANT	IDEALIMPLANT	Approval for a manufacturing site located at Vesta Intermediate Funding Inc., 9900 S 57th Street, Franklin, Wisconsin.
P120016/S021	03/30/2018	N - Normal 180 Day	VASCADE VASCULAR CLOSURE SYSTEM (VCS)	CARDIVA MEDICAL, INC.	Approval to expand the indication of the VASCADE VCS to include femoral venous access site closure.
P120021/S006	03/08/2018	R - Real-Time Proc	AMPLATZER PFO OCCLUDER	ST. JUDE MEDICAL, INC.	Approval for changes to the sizing guidelines and the inclusion of the long-term follow-up clinical data from the RESPECT trial in the Instructions for Use.
P130015/S013	03/02/2018	N - Normal 180 Day	ELECSYS HBEAG AND PRECICONTROL HBEAG	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for the migration of claims from the FDA approved Elecsys HBeAg assay and PreciControl HBeAg on the MODULAR ANALYTICS E170 immunoassay analyzer to the cobas e 801 immunoassay analyzer.
P130022/S014	03/21/2018	N - Normal 180 Day	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for MR Conditional Labeling changes.
P130022/S017	03/19/2018	O - Normal 180 Day	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for a manufacturing site located at Pro-Tech Design & Mfg, Inc., 13719 Borate St, Santa Fe Springs, California.
P130026/S028	03/26/2018	Y - 135 Review Tra	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for changes to receiving inspection and manufacturing procedures for tests related to the FISO module and force testing.
P130027/S004	03/13/2018	Y - 135 Review Tra	ARTUS CMV RGQ MDX KIT AND ARTUS CMV QS-RGQ MDX KIT	QIAGEN, INC.	Approval for relocation of a manufacturing process.
P140003/S026	03/22/2018	N - Normal 180 Day	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for Impella CP ® Optical which incorporates a new pressure sensor and changes to Abiomed Impella Controller.
P140003/S026	03/22/2018	N - Normal 180 Day	IMPELLA CP SYSTEM	ABIOMED, INC.	Approval for Impella CP ® Optical which incorporates a new pressure sensor and changes to Abiomed Impella Controller.
P140004/S012	03/26/2018	O - Normal 180 Day	SUPERION INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORATED	Approval for a manufacturing site located at Model Solution Co, Ltd, 24, Beottkot-ro 20-gil, Geumcheogu, Seoul, Republic of Korea for manufacture of instrumentation.
P140009/S027	03/11/2018	O - Normal 180 Day	INFINITY FAMILY OF IMPLANTABLE PULSE GENERATORS	ST. JUDE MEDICAL NEUROMODULATION	Approval for a manufacturing site located at St. Jude Medical-Puerto Rico, Lot A Interior-No. 2 St. Km 67.5, Santana Industrial Park, Arecibo, Puerto Rico for manufacturing and sterilization of the Proclaim and Infinity neurostimulation systems.
P140009/S034	03/14/2018	R - Real-Time Proc	LEGACY MDT POCKET ADAPTER	ST. JUDE MEDICAL NEUROMODULATION	Approval for the Legacy MDT Pocket Adapter.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140033/S023	03/13/2018	R - Real-Time Proc	TENDRIL MRI	ST. JUDE MEDICAL, INC.	Approval for a shelf life extension from 12 months to 18 months.
P150001/S039	03/07/2018	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for a minor design change to the introducer needle component of the Guardian Sensor (3) and the Enlite Sensor and the addition of an alternate needle supplier.
P150003/S032	03/23/2018	N - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHRONIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for an extension in shelf life from 12 months to 24 months and approval for new stent coating integrity test methods.
P150012/S052	03/26/2018	R - Real-Time Proc	INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI, ACCOLADE MRI	BOSTONSCIENTIFIC	Approval for a Software Maintenance Release (SMR) for the Model 3922 Pacing System Analyzer (PSA) Software Application that functions within Model 3300 LATITUDE Programming System (LPS).
P150019/S039	03/07/2018	R - Real-Time Proc	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval for a minor design change to the introducer needle component of the Guardian Sensor (3) and the Enlite Sensor and the addition of an alternate needle supplier.
P150021/S012	03/20/2018	O - Normal 180 Day	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for a manufacturing site located at Flextronics Manufacturing Aguascalientes, Boulevard a Zacatecas Km. 9.5 Jesus Maria, Aguascalientes, Mexico 20900 for final assembly of the Freestyle Libre Pro Reader
P150029/S016	03/07/2018	R - Real-Time Proc	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Approval for a minor design change to the introducer needle component of the Guardian Sensor (3) and the Enlite Sensor and the addition of an alternate needle supplier.
P150034/S005	03/27/2018	N - Normal 180 Day	RAINDROP NEAR VISION INLAY	REVISION OPTICS, INCORPORATED	Approval to update the device labeling with the 36-month results for the Raindrop® Near Vision Inlay. In addition, the labeling includes minor changes (changing the temperature limit symbol maximum from 55°C to 25°C, removal of translations, updates to the Instructions for Use).
P150039/S003	03/28/2018	O - Normal 180 Day	TRYTON SIDE BRANCH STENT	TRYTON MEDICAL, INC.	Approval for updates to the labeling to include complete follow-up for the Pivotal RCT and EA Confirmatory Studies.
P150048/S009	03/16/2018	Y - 135 Review Tra	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS AND INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Approval for a modification to the magnification used to conduct particulate and fiber inspections.
P160001/S013	03/23/2018	S - Special CBE	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for changes to physician and patient labeling in response to a reported case of gastric perforation.
P160017/S037	03/07/2018	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for a minor design change to the introducer needle component of the Guardian Sensor (3) and the Enlite Sensor and the addition of an alternate needle supplier.
P160038/S002	03/26/2018	S - Special CBE	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Approval for the implementation of 100% visual volume inspection of the filled containers.
P160043/S011	03/15/2018	R - Real-Time Proc	RESOLUTE ONYX CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval to introduce changes to the annual stability study design for the Resolute Onyx Coronary Stent System and Resolute Integrity Coronary Stent System.

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P160049/S002	03/12/2018	R - Real-Time Proc	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval for process changes related to the coating process.

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N18033/S097	03/14/2018	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Alternate test method for package integrity of the finished VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lens packages.
N970003/S226	03/12/2018	X - 30-Day Notice	ACCOLADE NON-MRI PACEMAKERS: ADVANTIO, INGENIO, VITALIO, ALTRUA 2, ESSENTIO, PROPONENT, AND ACCOLADE	BOSTON SCIENTIFIC CORP.	Alternate test method system for battery electrolyte inspection.
P790002/S037	03/30/2018	X - 30-Day Notice	BIOMET EBI BONE HEALING SYSTEM	EBI, LLC	Qualification of an alternate-secondary, contract service provider to provide calibration, maintenance, and rental services of instrumentation and equipment used during qualification and validation activities for the EBI OsteoGen Implantable Gone Growth Stimulators, SpF Implantable Spinal Fusion Stimulators, Biomet EBI Bone Healing System, Biomet SpinalPak, and the Biomet OrthoPak.
P790005/S057	03/14/2018	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Change in sterile packaging validation testing method for the SpF and EBI OsteoGen Bone Growth Stimulators.

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P790005/S058	03/14/2018	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Addition of an alternate supplier to provide clean room contract certification services and High Efficiency Particulate Air (HEPA) filter distribution services for both the SpF Implantable Spinal Fusion System and the EBI OsteoGen Implantable Bone Growth Stimulator.
P790005/S059	03/30/2018	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Qualification of an alternate-secondary, contract service provider to provide calibration, maintenance, and rental services of instrumentation and equipment used during qualification and validation activities for the EBI OsteoGen Implantable Gone Growth Stimulators, SpF Implantable Spinal Fusion Stimulators, Biomet EBI Bone Healing System, Biomet SpinalPak, and the Biomet OrthoPak.
P790005/S060	03/29/2018	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Addition of an alternate supplier to provide laboratory services for both the SpF Implantable Spinal Fusion System and the EBI OsteoGen Implantable Bone Growth Stimulator.
P830055/S194	03/02/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Changes to the current in-process inspections for the ATTUNE CR Femoral Implants.
P830061/S154	03/16/2018	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD, AND VITATRON EXCELLENCE + LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P850022/S029	03/30/2018	X - 30-Day Notice	BIOMET ORTHOPAK NON-INVASIVE BONE GROWTH STIMULATOR SYSTEM; BIOMET SPINALPAK NON-INVASIVE SPINE FUSION STIMULATOR SYSTEM	EBI, LLC	Qualification of an alternate-secondary, contract service provider to provide calibration, maintenance, and rental services of instrumentation and equipment used during qualification and validation activities for the EBI OsteoGen Implantable Gone Growth Stimulators, SpF Implantable Spinal Fusion Stimulators, Biomet EBI Bone Healing System, Biomet SpinalPak, and the Biomet OrthoPak.
P850035/S046	03/14/2018	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Change in sterile packaging validation testing method for the SpF and EBI OsteoGen Bone Growth Stimulators.
P850035/S047	03/14/2018	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Addition of an alternate supplier to provide clean room contract certification services and High Efficiency Particulate Air (HEPA) filter distribution services for both the SpF Implantable Spinal Fusion System and the EBI OsteoGen Implantable Bone Growth Stimulator.
P850035/S048	03/30/2018	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Qualification of an alternate-secondary, contract service provider to provide calibration, maintenance, and rental services of instrumentation and equipment used during qualification and validation activities for the EBI OsteoGen Implantable Gone Growth Stimulators, SpF Implantable Spinal Fusion Stimulators, Biomet EBI Bone Healing System, Biomet SpinalPak, and the Biomet OrthoPak.
P850035/S049	03/29/2018	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Addition of an alternate supplier to provide laboratory services for both the SpF Implantable Spinal Fusion System and the EBI OsteoGen Implantable Bone Growth Stimulator.

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P850079/S078	03/14/2018	X - 30-Day Notice	METHAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	New labeling line at the CooperVision Manufacturing, Ltd. labeling and packaging facility at Delta Park, United Kingdom.
P850089/S130	03/16/2018	X - 30-Day Notice	CAPSURE SP AND Z NOVUS LEAD, VITATRON EXCELLENCE SS+ LEAD AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P860003/S098	03/08/2018	X - 30-Day Notice	THERAKOS CELLEX PROCEDURAL KIT	MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED	Implementation of a modified CELLEX Procedural Kit assembly line.
P860004/S298	03/01/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Change in the sterilization process for the impacted catheter access and refill accessory kits.
P860057/S174	03/12/2018	X - 30-Day Notice	CARPENTIER - EDWARDS PERIMOUNT MAGNA EAST PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Increase in the number of personnel in a cleanroom in the Costa Rica facility.

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P860057/S175	03/27/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, CARPENTIER-EDWARDS PERIMOUNT THEON PERCARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, CARPENTIER-EDWARDS PERIMOUNT RSR PERICARDIAL AORTIC BIOPROSTHESIS, CARPENTIER-EDWARDS PERIMOUNT THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMALFIX TISSUE PROCESS, CARPENTIER-EDWARDS PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS, CARPENTIER-EDWARDS PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, CARPENTIER-EDWARDS PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, CARPENTIER-EDWARDS PERIMOUNT PLUS PERICARDIAL MITRAL BIOPROSTHESIS, CARPENTIER-EDWARDS PERIMOUNT THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, CARPENTIER-EDWARDS PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Addition of a new eddy current tester.

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P860057/S176	03/29/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS/WITH THERMAFIX TISSUE PROCESS; CARPENTIER-EDWARDS PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; CARPENTIER-EDWARDS PERIMOUNT PLUS PERICARIDIAL MITRAL BIOPROSTHESIS; CARPENTIER-EDWARDS PERIMOUNT THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS AND CARPENTIER-EDWARDS PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Implementation of the Valve Identity Verification System (VIVS) to verify the correctness of valve serial numbers.
P880086/S296	03/05/2018	X - 30-Day Notice	ASSURITY, ENDURITY	ST. JUDE MEDICAL, INC.	Alternate supplier for connector block components.
P890003/S387	03/16/2018	X - 30-Day Notice	CAPSURE VDD 2 LEAD, SERVUCE KIT-PACEMAKER REPAIR KIT, AND VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P890064/S038	03/14/2018	X - 30-Day Notice	DIGENE HC2 HIGH-RISK HPB DNA TEST AND DIGENE HC2 HPV DNA TEST	QIAGEN GAITHERSBURG, INC	Change in-process QC testing and sampling of a raw material used to manufacture kit subcomponents.

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P890064/S039	03/16/2018	X - 30-Day Notice	DIGENE HC2 HIGH-RISK HPV DNA TEST AND DIGENE HC2 HPV DNA TEST	QIAGEN GAITHERSBURG, INC	Modification of QC testing for a critical subcomponent of the test.
P890064/S040	03/27/2018	X - 30-Day Notice	HC2 HIGH-RISK HPV DNA TEST AND DIGENE / HC2 HPV DNA TEST	QIAGEN GAITHERSBURG, INC	Update in-process QC-testing procedures for a critical component.
P900061/S148	03/16/2018	X - 30-Day Notice	END CAP AND UPSIZING SLEEVE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P910001/S103	03/29/2018	X - 30-Day Notice	ELCA LASER CATHETERS	SPECTRANETICS CORP.	Outsourcing of some tubing components to an already approved supplier and an update of dimensional inspection test methods to implement use of a non-contact measurement system.
P910018/S024	03/26/2018	X - 30-Day Notice	LIPOSORBER LA-15 SYSTEM	KANEKA PHARMA AMERICA CORP.	Replacement of the annealing oven used in the manufacturing process of the hollow fibers for the SULFLUX® KP-05 device.
P910023/S404	03/05/2018	X - 30-Day Notice	ELLIPSE	ST. JUDE MEDICAL	Alternate supplier for connector block components.
P910023/S405	03/05/2018	X - 30-Day Notice	CURRENT, FORTIFY, FORTIFY ASSURA, ELLIPSE	ST. JUDE MEDICAL	Use of an alternate silicone oil tube.
P920015/S207	03/16/2018	X - 30-Day Notice	DF-1 CONNECTOR PORT PIN PLUG, IS-1 CONNECTOR PORT PIN PLUG KIT, SPRINGT QUATTRO LEAD, SUBCUTANEOUS LEAD, AND TRANSVENE CS0SVC LEAD	MEDTRONIC INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P920015/S208	03/20/2018	X - 30-Day Notice	6996T TUNNELING TOOL STERILE BARRIER SYSTEM	MEDTRONIC INC.	Addition of packaging and sterilization processes at the Rice Creek facility as well as minor process and sterilization changes for the Model 6996T tunneling tool.
P920015/S209	03/13/2018	X - 30-Day Notice	ULTRASONIC CLEANING MACHINE	MEDTRONIC INC.	Implementation of a new ultrasonic cleaning machine.

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P930029/S059	03/16/2018	X - 30-Day Notice	RF MARINR, UNIPOLAR MAPPING RF MARINR, RF CONDUCTR MC, RF ENHANCR, AND RF CONTACTR	MEDTRONIC INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P930039/S180	03/16/2018	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD, AND VITATRON PIROUET LEAD	MEDTRONIC, INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P950020/S089	03/16/2018	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON MONORAIL (MR) AND OVER-THE-WIRE (OTW)	BOSTON SCIENTIFIC CORP.	Move the cleaning of the blade components used on Wolverine from BSC Maple Grove, Minnesota to BSC Arden Hills, Minnesota.
P950022/S116	03/27/2018	X - 30-Day Notice	DURATA AND OPTISRE FAMILY OF HIGH VOLTAGE LEADS	ST. JUDE MEDICAL, INC.	Minor inspection tool and process equipment changes for lead connector pins.
P950022/S117	03/20/2018	X - 30-Day Notice	DURATA, OPTISURE	ST. JUDE MEDICAL, INC.	Implement a change to the Dexamethasone impurity limit for steroid eluting cardiac leads.
P950022/S118	03/21/2018	X - 30-Day Notice	DURATA, OPTISURE	ST. JUDE MEDICAL, INC.	Change to the elution testing for legacy leads.
P950024/S078	03/16/2018	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P950029/S120	03/15/2018	X - 30-Day Notice	PACEMAKERS REPLY SR/ DR AND ESPRIT SR/DR	LIVANOVA USA, INC.	Implementation of manufacturing changes on Zener diodes used in the electronic hybrid module in the Reply and Esprit families of pacemakers.
P950034/S050	03/09/2018	X - 30-Day Notice	SEPRAFILM ADHESION BARRIER	GENZYME CORP.	Implementation of a new casting machine.
P960013/S096	03/20/2018	X - 30-Day Notice	OPTISENSE; TENDRIL STS, TENDRIL SDX, TENDRIL ST	ST JUDE MEDICAL	Implement a change to the Dexamethasone impurity limit for steroid eluting cardiac leads.
P960013/S097	03/21/2018	X - 30-Day Notice	TENDRIL SDX, OPTISENSE, TENDRIL STS, TENDRIL ST	ST JUDE MEDICAL	Change to the elution testing for legacy leads.
P960016/S071	03/06/2018	X - 30-Day Notice	LIVEWIRE TC STEERABLE ELECTROPHYSIOLOGY CATHETER, SAFIRE BI-DIRECTIONAL ABLATION CATHETER	ST. JUDE MEDICAL	Alternative Electrical Safety Test for the Ampere Generator, Ampere Remote Control and TactiSys Quartz Equipment.

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P960016/S072	03/12/2018	X - 30-Day Notice	LIVEWIRE TC ABLATION CATHETER / SAFIRE BI-DIRECTIONAL CATHETER	ST. JUDE MEDICAL	Implementation of parametric release method at specified cycles and chambers.
P960016/S073	03/29/2018	X - 30-Day Notice	LIVEWIRE TC STEERABLE ELECTROPHYSIOLOGY CATHETER	ST. JUDE MEDICAL	Change the Anchor Sleeve Assembly Manufacturing Procedure.
P960030/S057	03/20/2018	X - 30-Day Notice	ISOFLEX	ST. JUDE MEDICAL	Implement a change to the Dexamethasone impurity limit for steroid eluting cardiac leads.
P960030/S058	03/21/2018	X - 30-Day Notice	ISOFLEX	ST. JUDE MEDICAL	Change to the elution testing for legacy leads.
P960040/S422	03/12/2018	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD): PUNCTUA, ENERGEN, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, PERCIVA, AND RESONATE	BOSTON SCIENTIFIC	Alternate test method system for battery electrolyte inspection.
P960058/S128	03/14/2018	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Supplier relocation for a process challenge device used during sterilization of the HiRes Ultra cochlear implant and accessories.
P970051/S176	03/02/2018	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Relocation of four subassembly manufacturing processes from the Macquarie facility to the Lane Cove facility.
P970051/S177	03/16/2018	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of a supplier for the CP900 Series Standard Tamper Resistant Battery Cover.
P980006/S026	03/29/2018	X - 30-Day Notice	PUREVISION (BALAFILCON A) VISIBILITY TINTED CONTACT LENS	BAUSCH & LOMB, INC.	Change to the tear strength specification for the PureVision (balafilcon A) product family.
P980016/S659	03/27/2018	X - 30-Day Notice	PRIMO MRI DR/VR SURESCAN; MIRRO MRI DR/VR SURESCAN	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of previously accepted changes to align manufacturing of Primo MRI and Mirro MRI ICDs with existing manufacturing processes.
P980024/S017	03/12/2018	X - 30-Day Notice	PATH VYSION HER-2 DNA PROBE KIT	ABBOTT MOLECULAR, INC.	Changes to the manufacturing process and manufacturing site of a suppliers product.

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P980035/S533	03/02/2018	X - 30-Day Notice	AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	Changes to the Quasar Hybrid Test.
P980035/S535	03/09/2018	X - 30-Day Notice	ASTRA XT DR, ASTRA S DR, ASTRA S SR, ASTRA XT SR MIR IPG AND AZURE S DR, AZURE S SR, AZURE XT DR, AZURE XT SR MRI IPG	MEDTRONIC INC.	Removal of the visual inspection criteria for raised insulators from the Orion and CRT-P subassembly inspection process.
P980035/S537	03/21/2018	X - 30-Day Notice	ATTESTA DR MRI SUESCAN, ATTESTA L DR MRI SURESCAN, ATTESTA S DR MRI SURESCAN, ATTESTA SR MRI SURESCAN, SPHERA DR MRI SURESCAN, SPHERA L DR MRI SURESCAN, SPHERA SR MRI SURESCAN	MEDTRONIC INC.	Implementation of an updated weld inspection process.
P980044/S043	03/14/2018	X - 30-Day Notice	SUPARTZ FX AND VISCO-3	SEIKAGAKU CORP.	Sharing the facility and equipment used to manufacture SUPARTZ FX and VISCO-3 for the purpose of the manufacturing of an investigational drug product.
P980049/S129	03/20/2018	X - 30-Day Notice	PLATINIUM VR 1240; PLATINIUM DR 1540	LIVANOVA USA, INC.	Supplier manufacturing change for contact spring components assembled into headers.
P980050/S114	03/16/2018	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P990034/S038	03/01/2018	X - 30-Day Notice	ISOMED INFUSION SYSTEM	MEDTRONIC INC.	Change in the sterilization process for the impacted catheter access and refill accessory kits.
P990038/S025	03/14/2018	X - 30-Day Notice	ETI-MAK-2 PLUS AND HBSAG CONFIRMATORY TEST ASSAYS	DIASORIN, INC.	Add a filtration step and an in-process bioburden control to a raw material process, and to relocate a QC-testing process within the site.
P990041/S024	03/14/2018	X - 30-Day Notice	ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Add a filtration step and an in-process bioburden control to a raw material process, and to relocate a QC-testing process within the site.
P990042/S021	03/14/2018	X - 30-Day Notice	ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Add a filtration step and an in-process bioburden control to a raw material process, and to relocate a QC-testing process within the site.
P990043/S025	03/14/2018	X - 30-Day Notice	ETI-EBK PLUS ASSAY	DIASORIN, INC.	Add a filtration step and an in-process bioburden control to a raw material process, and to relocate a QC-testing process within the site.
P990044/S022	03/14/2018	X - 30-Day Notice	ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Add a filtration step and an in-process bioburden control to a raw material process, and to relocate a QC-testing process within the site.

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P990045/S022	03/14/2018	X - 30-Day Notice	ETI-AB-COREK PLUS ASSAY	DIASORIN, INC.	Add a filtration step and an in-process bioburden control to a raw material process, and to relocate a QC-testing process within the site.
P000015/S030	03/02/2018	X - 30-Day Notice	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Relocation of four subassembly manufacturing processes from the Macquarie facility to the Lane Cove facility.
P000015/S031	03/16/2018	X - 30-Day Notice	NUCLEUS AB1541 AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Addition of a supplier for the CP900 Series Standard Tamper Resistant Battery Cover.
P000039/S062	03/12/2018	X - 30-Day Notice	AMPLATZER SEPTAL OCCLUDER / AMPLATZER MULTI-FENESTRATED SEPTAL OCCLUDER-"CRIBRIFORM" OCCLUDER	AGA MEDICAL CORPORATIO N	Implementation of parametric release method at specified cycles and chambers.
P010012/S481	03/12/2018	X - 30-Day Notice	IMPLANTABLE CARDIAC RESYNCHRONIZATION THERPY DEFIBRILLATOR (CRT-D): PUNCTUA, ENERGEN, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, AND RESONATE	BOSTON SCIENTIFIC CORP.	Alternate test method system for battery electrolyte inspection.
P010015/S354	03/02/2018	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLAR QUADRIPOLAR CRT-P	MEDTRONIC INC.	Changes to the Quasar Hybrid Test.
P010015/S356	03/09/2018	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P AND SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Removal of the visual inspection criteria for raised insulators from the Orion and CRT-P subassembly inspection process.

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P010019/S063	03/02/2018	X - 30-Day Notice	LOTRAFILCON A SOFT CONTACT LENSES FOR EXTENDED WEAR	ALCON LABORATORIES, INC.	Startup of lotrafilcon A back end finishing production at the Johor, Malaysia facility including technology transfer from the Batam Indonesia manufacturing facility to the production facility in Johor, Malaysia.
P010033/S039	03/27/2018	X - 30-Day Notice	QUANTIFERON-TB GOLD AND QUANTIFERON-TB GOLD PLUS	QIAGEN	Update the QC testing for critical components of the test.
P020004/S150	03/21/2018	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of a film wrapping machine for the manufacture of the sealing cuffs of the GORE EXCLUDER AAA Endoprosthesis and the GORE Conformable TAG Thoracic Endoprosthesis.
P020004/S151	03/22/2018	X - 30-Day Notice	EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of transfer of manufacturing processes for the 36 mm Aortic Extender from Phoenix 1 facility to Silicon Valley facility.
P020014/S050	03/22/2018	X - 30-Day Notice	ESSURE SYSTEM FOR PERMANENT BIRTH CONTROL	BAYER PHARMA AG	Increase of the production lot quantity of ESS305 to a full production lot size of 468 kits.
P020024/S051	03/12/2018	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER / AMPLATZER DUCT OCCLUDER II	AGA MEDICAL CORP.	Implementation of parametric release method at specified cycles and chambers.
P020036/S038	03/20/2018	X - 30-Day Notice	S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Modification to a supplier processing aid.
P030005/S174	03/12/2018	X - 30-Day Notice	ACCOLADE CARDIAC RESYNCHRONIZATION THERAPY-PACEMAKER (CRT-P) DEVICES: INVIVE TM, INTUA TM, VALITUDE, VALITUDE X4, VISIONIST, AND VISIONIST X4	GUIDANT CORP.	Alternate test method system for battery electrolyte inspection.
P030011/S060	03/16/2018	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Change in location for a component supplier.
P030017/S311	03/12/2018	X - 30-Day Notice	PRECISION, PRECISION SPECTRA, PRECISION NOVI, PRECISION MONTAGE, PRECISION MONTAGE MRI AND SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Adding an additional Ethylene Oxide (EO) sterilization chamber (Getinge G1) and associated sterilization process at the Boston Scientific Dorado manufacturing site (BSC-DOR) to sterilize the BSC Precision SCS products.

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P030035/S167	03/05/2018	X - 30-Day Notice	ASSURE CRT-P	ST. JUDE MEDICAL, INC.	Alternate supplier for connector block components.
P030036/S099	03/16/2018	X - 30-Day Notice	ANCHORING SLEEVE KIT AND SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P030039/S022	03/22/2018	X - 30-Day Notice	COSEAL SURGICAL SEALANT SPRAY SET	BAXTER BIO SCIENCE	Change the resin used to mold the side clip and spray head parts of the Coseal Spray Set.
P030047/S035	03/20/2018	X - 30-Day Notice	PRECISE NITINOL STENT SYSTEMS	CORDIS CORP.	Modification to a supplier processing aid.
P030052/S022	03/12/2018	X - 30-Day Notice	UROVYSION BLADDER CANCER KIT	ABBOTT MOLECULAR	Changes to the manufacturing process and manufacturing site of a suppliers product.
P030054/S349	03/20/2018	X - 30-Day Notice	QUICKFLEX, QUARTET	ST. JUDE MEDICAL	Implement a change to the Dexamethasone impurity limit for steroid eluting cardiac leads.
P030054/S350	03/21/2018	X - 30-Day Notice	QUICKFLEX U, QUARTET	ST. JUDE MEDICAL	Change to the elution testing for legacy leads.
P040014/S034	03/06/2018	X - 30-Day Notice	THERAPY ABLATION CATHETERS	IRVINE BIOMEDICAL, INC.	Alternative Electrical Safety Test for the Ampere Generator, Ampere Remote Control and TactiSys Quartz Equipment.
P040037/S110	03/06/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implement changes to the VIABAHN Stent Graft Stripping Machine used in the manufacture of the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface.
P040037/S111	03/08/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Modifications to an analytical test method.
P040040/S033	03/12/2018	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	AGA MEDICAL CORPORATION	Implementation of parametric release method at specified cycles and chambers.
P040042/S040	03/06/2018	X - 30-Day Notice	THERAPY DUAL 8, THERAPY 8MM THERMISTOR, SAFIRE TX ABLATION CATHETERS, 1500T6 RF GENERATORS, 1500T9 RF GENERATORS	IRVINE BIOMEDICAL,INC.(IBI)	Alternative Electrical Safety Test for the Ampere Generator, Ampere Remote Control and TactiSys Quartz Equipment.
P040043/S098	03/21/2018	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of a film wrapping machine for the manufacture of the sealing cuffs of the GORE EXCLUDER AAA Endoprosthesis and the GORE Conformable TAG Thoracic Endoprosthesis.

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P040045/S094	03/14/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate test method for package integrity of the finished VISTAKON® (senofilcon A) and (etafilcon A) Brand Contact Lens packages.
P040045/S095	03/14/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Introduce an alternate dual injection molding machine.
P050006/S062	03/26/2018	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Alternate supplier for the retaining stiffener component.
P050006/S063	03/23/2018	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Implementation of automated inspection equipment.
P050019/S030	03/13/2018	X - 30-Day Notice	CAROTID WALLSTENT	BOSTON SCIENTIFIC CORP.	Addition of an annealing step to the manufacturing of a delivery system component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050023/S118	03/30/2018	X - 30-Day Notice	INLEXA 7 VR-T, INLEXA 3 VR-T, LLIVIA 7 VR-T, INTICA 7 VR-T, INTICA 5 VR-T, IPERIA 7 VR-T, ITREVIA 5 VR-T, INVENTRA 7 VR-T, LLESTO 7 VR-T, LLESTO 5 VR-T, IPERIA 5 VR-T, ITREVIA 7 VR-T, INLEXA 7 DR-T, INLEXA 3 DR-T, LLIVIA 7 DR-T, INTICA 7 DR-T, INTICA 5 DR-T, IPERIA 7 DR-T, IFORIA 7 VR-T, IFORIA 5 VR-T, ITREVIA 5 DR-T, INVENTRA 7 DR-T, LLESTO 7 DR-T, LLESTO 5 DR-T, IFORIA 7 DR-T, IPERIA 5 DR-T, ITREVIA 7 DR-T, INLEXA 7 HF-T, INLEXA 3 HF-T, LLIVIA 7 HF-T, INTICA 7 HF-T, INTICA 5 HF-T, IFORIA 5 DR-T, ITREVIA 7 HF-T, ITREVIA 5 HF-T, INVENTRA 7 HF-T, LLESTO 7 HF-T, IPERIA 7 HF-T, IPERIA 5 HF-T, LLESTO 5 HF-T, IFORIA 7 HF-T, IFORIA 5 HF-T	BIOTRONIK, INC.	Addition of an inspection step during the battery manufacturing process.
P050028/S061	03/26/2018	X - 30-Day Notice	COBAS TAQMAN HBV TEST, COBAS AMPLIPEP/ COBAS, TAQMAN HBV TEST, V2.0, COBAS AMPLIPREP	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill line processes.
P060019/S042	03/06/2018	X - 30-Day Notice	THERAPY COOL PATH, SAFIRE BLU, SAFIRE BLU SP, THERAPY COOL PATH SP, 1500T9-CP GENERATORS	IRVINE BIOMEDICAL, INC.	Alternative Electrical Safety Test for the Ampere Generator, Ampere Remote Control and TactiSys Quartz Equipment.
P060027/S094	03/20/2018	X - 30-Day Notice	PLATINIUM CRT-D 1741; PLATINIUM 4LV CRT-D 1744	LIVANOVA USA, INC.	Supplier manufacturing change for contact spring components assembled into headers.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060030/S062	03/26/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V.20	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill line processes.
P060037/S054	03/05/2018	X - 30-Day Notice	NEXGEN LPS-FLEX / LPS-MOBILE BEARING KNEE	ZIMMER, INC.	Addition of a new curing oven and its associated process parameter specifications that is used during the PMMA coating process for NexGen® Complete Knee Solution, Legacy® Knee Posterior Stabilized (LPS), LPS-Flex Mobile Bearing Knee, pre-coated femoral components.
P060037/S055	03/29/2018	X - 30-Day Notice	NEXGEN LPS-FLEX / LPS MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Change in manufacturing process by the replacement of a piece of equipment (heat sealer) with a new piece of equipment of a different make and model.
P060039/S084	03/16/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P070026/S051	03/02/2018	X - 30-Day Notice	CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Implementation of 2D barcode verification.
P070026/S052	03/26/2018	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Inclusion of an additional alternate method of automated manufacturing at the porous coating process step.
P080006/S118	03/16/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD AND ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico
P080011/S071	03/14/2018	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	New labeling line at the CooperVision Manufacturing, Ltd. labeling and packaging facility at Delta Park, United Kingdom.
P080011/S072	03/29/2018	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Addition of IGM Resins as a new supplier in the manufacture of Biofinity (comfilcon A) soft contact lenses.
P080020/S029	03/14/2018	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Update of control instruments for the water systems used to manufacture Gel-One.
P100010/S074	03/09/2018	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Modification of the bonding process for two check valves.
P100010/S075	03/15/2018	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	New automated outer diameter measuring equipment for Arctic Front Advance cardiac cryoablation catheter.

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P100016/S005	03/06/2018	X - 30-Day Notice	LENS OPTIC BODY DIAMETER CUT	CARL ZEISS MEDITEC PRODUCTION LLC	Addition of an alternate lathing machine.
P100020/S029	03/26/2018	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill line processes.
P100029/S032	03/29/2018	X - 30-Day Notice	TRIFECTA VALVE/ TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Create a new controlled access environment room for the manufacture of the Trifecta/ Trifecta GT valves.
P100033/S008	03/07/2018	X - 30-Day Notice	PROGENSA PCA3 ASSAY	GEN-PROBE INCORPORATED	Change of subcomponent manufacturing location.
P100042/S016	03/08/2018	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Duplication for manufacture of reagent components at an approved manufacturing site.
P110012/S015	03/12/2018	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Changes to the manufacturing process and manufacturing site of a suppliers product.
P110016/S053	03/06/2018	X - 30-Day Notice	THERAPY COOL PATH DUO, SAFIRE BLU DUO, COOL PATH DUO, SAFIRE DUO, THERAPY COOL PATH DUO SP, SAFIRE BLU DUO SP, THERAPY COOL FLEX ABLATION CATHETERS, FLEXABILITY ABLATION CATHETERS, 1500T9 RF GENERATORS, 1500T9-CP RF GENERATORS	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Alternative Electrical Safety Test for the Ampere Generator, Ampere Remote Control and TactiSys Quartz Equipment.
P110016/S054	03/12/2018	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER / FLEXABILITY ABLATION CATHETER SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Implementation of parametric release method at specified cycles and chambers.

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P110016/S055	03/09/2018	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER AND FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Alternate supplier for the compression coil in the FlexAbility and FlexAbility SE Ablation Catheter.
P110020/S024	03/27/2018	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill-line processes
P110037/S034	03/26/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill line processes.
P110042/S104	03/12/2018	X - 30-Day Notice	SUBCUTANEOUS ICD DEVICE (S-ICD): EMBLEM, EMBLEM MRI	BOSTON SCIENTIFIC CORPORATIO N	Alternate test method system for battery electrolyte inspection.
P110042/S105	03/28/2018	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD) EMBLEM MRI S-ICD AND S-ICD PULSE GENERATOR	BOSTON SCIENTIFIC CORPORATIO N	Retro-fit the anode portion of a battery production line to align manufacturing processes between lines.
P120002/S013	03/20/2018	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL VASCULAR STENT SYSTEMS	CORDIS CORP.	Modification to a supplier processing aid.
P120005/S071	03/27/2018	X - 30-Day Notice	DEXCOM G4 PLATINUM AND G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEMS	DEXCOM, INC.	Removal of redundant inspection of the skived wire component, which will be processed further to manufacture the finished sensor probes. The sensors are components of the Dexcom G4 PLATINUM and Dexcom G5 Mobile Continuous Monitoring Systems.
P120007/S014	03/08/2018	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORAT ED	Duplication for manufacture of reagent components at an approved manufacturing site.
P120010/S112	03/09/2018	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Adding a new press, two new molds and a new quality control measurement system at the contract manufacturer. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P120017/S012	03/16/2018	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Device History Record (DHR) review optimization at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico

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P120019/S020	03/27/2018	X - 30-Day Notice	COBAS EGFR MUTATION TEST AND COBAS EGFR MUTATION TEST V2	ROCHE	Modification of manufacturing fill line processes
P120021/S007	03/12/2018	X - 30-Day Notice	AMPLATZER PATENT FORAMEN OVALE OCCLUDER	ST. JUDE MEDICAL, INC.	Implementation of parametric release method at specified cycles and chambers.
P130001/S004	03/20/2018	X - 30-Day Notice	EPI PROCOLON	EPIGENOMIC S AG	Addition of alternate suppliers of key reagents for the test system.
P130006/S049	03/06/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Implement changes to the VIABAHN Stent Graft Stripping Machine used in the manufacture of the GORE VIABAHN Endoprosthesis and GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface.
P130006/S050	03/08/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Modifications to an analytical test method.
P130007/S033	03/01/2018	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Modification to the lens curing and cover leak test for the Animas Vibe insulin pump for the Animas Vibe System.
P130007/S034	03/12/2018	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Changes to the manufacturing of the main printed circuit board assembly used in the Animas Vibe Insulin pump. The Animas Vibe Insulin pump is a component of the Animas Vibe System.
P130008/S032	03/07/2018	X - 30-Day Notice	PRESSURE SENSOR TEST LIMITS	INSPIRE MEDICAL SYSTEMS	Changes to update the Model 4323 lead gain and frequency response limits in the test specification.
P130009/S085	03/29/2018	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCE S, LLC.	Implementation of the Valve Identity Verification System (VIVS) to verify the correctness of valve serial numbers.
P130009/S086	03/07/2018	X - 30-Day Notice	ASCENDRA+ AND NOVAFLEX+ DELIVERY SYSTEM, CRIMPER AND EDWARDS EXPANDABLE INTRODUCER SHEATH SET	EDWARDS LIFESCIENCE S, LLC.	Add new controlled environment rooms for cleaning device components prior to manufacturing activities.
P130009/S088	03/28/2018	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCE S, LLC.	Addition of a verification step in the metal grain size analysis.
P130011/S006	03/07/2018	X - 30-Day Notice	SOLO SMART STENTLESS HEART VALVE	LIVANOVA CANADA CORP.	Implementation of a new sterilization and neutralization (HCSTAN) system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130013/S018	03/19/2018	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate dowel pin for use in the WATCHMAN implant.
P130016/S034	03/16/2018	X - 30-Day Notice	NUCLEUS HYBRID COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of a supplier for the CP900 Series Standard Tamper Resistant Battery Cover.
P130017/S022	03/07/2018	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATIO N	Validation of additional lab space.
P130026/S029	03/06/2018	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Alternative Electrical Safety Test for the Ampere Generator, Ampere Remote Control and TactiSys Quartz Equipment.
P130026/S030	03/07/2018	X - 30-Day Notice	TACTICATH QUARTZ ABLATION CATHETER	ST. JUDE MEDICAL	Implementation for the Cirrus Test System for the TactiCath Quartz Thermocouple Position Test.
P130026/S031	03/12/2018	X - 30-Day Notice	TATICATH QUARTZ CONTACT FORCE ABLATION CATHETER	ST. JUDE MEDICAL	Implementation of parametric release method at specified cycles and chambers.
P140018/S009	03/27/2018	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implementation of a modified sample preparation method for bacterial endotoxin testing of the VenaSeal Closure System.
P140023/S013	03/27/2018	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill-line processes
P140031/S060	03/29/2018	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCE S, LLC.	Implementation of the Valve Identity Verification System (VIVS) to verify the correctness of valve serial numbers.
P140031/S061	03/07/2018	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCE S, LLC.	Add new controlled environment rooms for cleaning device components prior to manufacturing activities.
P140031/S063	03/28/2018	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCE S, LLC.	Addition of a verification step in the metal grain size analysis.
P140033/S026	03/05/2018	X - 30-Day Notice	ASSURITY MRI, ENDURITY MRI	ST. JUDE MEDICAL, INC.	Alternate supplier for connector block components.
P140033/S027	03/20/2018	X - 30-Day Notice	TENDRIL	ST. JUDE MEDICAL, INC.	Implement a change to the Dexamethasone impurity limit for steroid eluting cardiac leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150001/S036	03/01/2018	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM WITH GUARDIAN SENSOR (3)	MEDTRONIC MINIMED	Addition of an alternative mask aligner to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G and MiniMed 670G systems.
P150001/S037	03/01/2018	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	New electroplating machine to increase manufacturing capacity for the Guardian Sensor continuous glucose monitoring sensor. The Guardian Sensor is a component of the MiniMed 630G and MiniMed 670G systems.
P150001/S038	03/09/2018	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Adding a new press, two new molds and a new quality control measurement system at the contract manufacturer. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P150001/S040	03/22/2018	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Introduce an alternative press and mold to manufacture the sensor cap components of the Guardian Sensor and implement a new configuration number for parts manufactured under this change. The Guardian Sensor is a component of the MiniMed 670G and MiniMed 630G Systems.
P150003/S038	03/28/2018	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORPORATION	Add manufacturing lines for coating and crimping.
P150011/S012	03/07/2018	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Implementation of a new sterilization and neutralization (HCSTAN) system.
P150012/S054	03/12/2018	X - 30-Day Notice	ACCOLADE MRI PACEMAKERS: ESSENTIO MRI, PROPONENT MRI, AND ACCOLADE MRI	BOSTONSCIENTIFIC	Alternate test method system for battery electrolyte inspection.
P150014/S014	03/26/2018	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill line processes.
P150015/S013	03/26/2018	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill line processes.
P150019/S038	03/09/2018	X - 30-Day Notice	REVEL SYSTEM WITH ENLITE SYSTEM	MEDTRONIC MINIMED	Adding a new press, two new molds and a new quality control measurement system at the contract manufacturer. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.

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P150021/S021	03/29/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASSH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduce a new circuit printing line for the glucose sensor of the FreeStyle Libre Flash and Libre Pro Flash Glucose Monitoring Systems.
P150021/S022	03/27/2018	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a supplier for the electrode coating polymer of the sensor. The sensor is a component of the Freestyle Libra Flash and Libra Pro Flash Glucose Monitoring System.
P150029/S015	03/09/2018	X - 30-Day Notice	IPRO SYSTEM	MEDTRONIC MINIMED	Adding a new press, two new molds and a new quality control measurement system at the contract manufacturer. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P150036/S025	03/12/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Increase in the number of personnel in a cleanroom in the Costa Rica facility.
P150036/S026	03/29/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Parametric release for the INTUITY Elite Valve System.
P150036/S027	03/27/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of a new eddy current tester.
P150041/S002	03/12/2018	X - 30-Day Notice	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Changes to the manufacturing process and manufacturing site of a suppliers product.
P150048/S014	03/07/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Extend the inner tray seal process time and remove the inner tray repair limit.
P150048/S016	03/12/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (RESILIA TISSUE)	EDWARDS LIFESCIENCES, LLC.	Increase in the number of personnel in a cleanroom in the Costa Rica facility.
P150048/S018	03/27/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Addition of a new eddy current tester.
P160017/S034	03/01/2018	X - 30-Day Notice	MEDTRONIC MINIMED 670G SYSTEM WITH GUARDIAN SENSOR (3)	MEDTRONIC MINIMED, INC.	Addition of an alternative mask aligner to increase manufacturing capacity for the Guardian Sensor (3) continuous glucose monitoring sensor. The Guardian Sensor (3) is a component of the MiniMed 630G and MiniMed 670G systems.
P160017/S035	03/01/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	New electroplating machine to increase manufacturing capacity for the Guardian Sensor continuous glucose monitoring sensor. The Guardian Sensor is a component of the MiniMed 630G and MiniMed 670G systems.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160017/S036	03/09/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Adding a new press, two new molds and a new quality control measurement system at the contract manufacturer. The changes will apply to the Enlite Sensor and Guardian Sensor (3) which are part of the MiniMed 530G, MiniMed 630G, Paradigm Real-Time Revel, iPro2 CGM, and Medtronic 670G systems.
P160017/S038	03/22/2018	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Introduce an alternative press and mold to manufacture the sensor cap components of the Guardian Sensor and implement a new configuration number for parts manufactured under this change. The Guardian Sensor is a component of the MiniMed 670G and MiniMed 630G Systems.
P160030/S011	03/29/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Introduce a new circuit printing line for the glucose sensor of the FreeStyle Libre Flash and Libre Pro Flash Glucose Monitoring Systems.
P160030/S012	03/27/2018	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of a supplier for the electrode coating polymer of the sensor. The sensor is a component of the Freestyle Libra Flash and Libra Pro Flash Glucose Monitoring System.
P160041/S006	03/16/2018	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Transfer filling of specified kit components from a manual to automated process.
P160041/S007	03/26/2018	X - 30-Day Notice	COBAS CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of manufacturing fill line processes.

Total: 191