PMA Monthly approvals from 4/1/2017 to 4/30/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160024	04/24/2017	PMAO - PMA Origi	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Approval for the LifeStream Balloon Expandable Vascular Covered Stent. This device is indicated for the treatment of atherosclerotic lesions in common and external iliac arteries with reference vessel diameters between 4.5 mm and 12.0 mm, and lesion lengths up to 100 mm.
P160040	04/28/2017	PMAO - PMA Origi	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Approval for the LeukoStrat® CDx FLT3 Mutation Assay is a PCR-based, in vitro diagnostic test designed to detect internal tandem duplication (ITD) mutations and the tyrosine kinase domain mutations D835 and I836 in the FLT3 gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia (AML). The LeukoStrat® CDx FLT3 Mutation Assay is used as an aid in the selection of patients with AML for whom RYDAPT (midostaurin) treatment is being considered. The Leukostrat® CDx FLT3 Mutation Assay is to be performed only at Laboratory for Personalized Molecular Medicine (LabPMM) LLC, a single site laboratory located at 6330 Nancy Ridge Dr., San Diego, CA 92121.
P160043	04/28/2017	PMAO - PMA Origi	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC INC.	Approval for the Resolute Onyx Zotarolimus-Eluting Coronary Stent System. This device is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus, with symptomatic ischemic heart disease due to de novo lesions of length less than or equal to 35 mm in native coronary arteries with reference vessel diameters of 2.25 mm to 5.0 mm.

Total: 3

Data as of 05/02/2017 04:08 AM

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S197	04/17/2017	N - Normal 180 Day	ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT, (INSIGNIA AND ALTRUA 2 PACEMAKER'S	BOSTON SCIENTIFIC CORP.	Approval for the LATITUDE NXT Patient Management System Release 5.0.
N970012/S128	04/27/2017	R - Real-Time Proc	AMS 700 IMPLANTED PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for modification of engineering drawings.
N970012/S129	04/07/2017	Y - 135 Review Tra	AMS 700 PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for change of molding lubricant and molding process for the suture-tie connector.
P830061/S137	04/25/2017	N - Normal 180 Day	CAPSURE SENSE MRI SURESCAN LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P830061/S143	04/25/2017	R - Real-Time Proc	CAPSURE SENSE MRI SURESCAN LEAD MODEL 4574	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.
P850064/S032	04/24/2017	R - Real-Time Proc	LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Approval for changes to the electrical design of the ventilator.
P860003/S087	04/27/2017	N - Normal 180 Day	THERAKOS CELLEX PHOTOPHERESIS SYSTEM, INSTRUMENT, LIGHT ASSEMBLY, PROCEDURAL KIT.	THERAKOS, INC.	Approval for changes to the software, circuit board, drive tube bearing retainer, power supply, and labeling.
P860004/S261	04/03/2017	N - Normal 180 Day	SYNCHROMED II MOTOR GEAR TRAIN SHAFTS	MEDTRONIC INC.	Approval for a design and associated manufacturing process changes for the Motor Gear Train Shafts of the SynchroMed II implantable infusion pump. The design change involves applying a thin layer (~1.5?m) of DLC coating, to the three jewel interfacing shafts of the SynchroMed II motor to reduce the sensitivity of the interface to loss of lubrication.
P860004/S270	04/13/2017	S - Special CBE	SYNCHROMED IMPLANTABLE INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling changes to Medtronic SynchroMed® II and IsoMed® Implant Infusion system labeling associated with Over-infusion, Allergic Reaction, Tunneling Risks, Priapism, Magnetic Resonance Imaging.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910001/S092	04/24/2017	S - Special CBE	ECLA GLIDELIGHT CATHETER	SPECTRANETICS CORP.	Approval to add an additional in-process endotoxin test to the extruded components of the catheters.
P910077/S156	04/17/2017	N - Normal 180 Day	LATITUDE NXT RELEASE 5.0	BOSTON SCIENTIFIC	Approval for the LATITUDE NXT Patient Management System Release 5.0.
P910077/S158	04/21/2017	R - Real-Time Proc	LATITUDE¿ NXT PATIENT MANAGEMENT SYSTEM/ LATITUDE NXT G2 COMMUNICATOR	BOSTON SCIENTIFIC	Approval for a software update to improve the boot up process.
P920015/S188	04/25/2017	N - Normal 180 Day	SPRINT QUATTRO SECURE S MRI & MRI SURESCAN LEADS	MEDTRONIC INC.	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P920015/S196	04/25/2017	R - Real-Time Proc	SPRINT QUATTRO MRI SURESCAN LEAD MODEL 6946M	MEDTRONIC INC.	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.
P930036/S007	04/26/2017	Y - 135 Review Tra	ADVIA CENTAUR IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for wetcake manufacturing process changes to the ADVIA Centaur AFP Solid Phase reagent to achieve the current hook specification of >1,000 ng/mL with an AFP containing sample that is between 1,000,000 to 1,150,000 ng/mL.
P930039/S162	04/25/2017	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P930039/S168	04/25/2017	R - Real-Time Proc	CAPSURE FIX NOVUS MRI SURESCAN LEAD MODELS 5076 AND 4076	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.
P960004/S078	04/11/2017	N - Normal 180 Day	FINELINE II STEROX & FINELINE II STEROX EZ, SUTURE SLEEVE ACCESSORY(FOR FINELINE II LEADS)	BOSTON SCIENTIFIC	Approval for the addition of 3T MR Conditional labeling for the Image Ready MR Conditional Pacing System consisting of an Accolade MRI pacemaker with one or two INGEVITY MRI leads. In addition, you requested approval to expand the Image Ready System to include 1.5T MR Conditional labeling for the FINELINE II Sterox and Sterox EZ leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960040/S384	04/17/2017	N - Normal 180 Day	TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILANT, PERCIVA ICD'S	BOSTON SCIENTIFIC	Approval for the LATITUDE NXT Patient Management System Release 5.0.
P960040/S389	04/21/2017	R - Real-Time Proc	TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN ICD DEVICES	BOSTON SCIENTIFIC	Approval for a software update to improve the boot up process.
P960042/S056	04/24/2017	S - Special CBE	ELCA AND SLS/ GLIDELIGHT CATHETER	SPECTRANETICS CORP.	Approval to add an additional in-process endotoxin test to the extruded components of the catheters.
P970003/S198	04/28/2017	O - Normal 180 Day	VNS THERAPY SYSTEM	CYBERONICS, INC.	Approval for labeling changes based on the post-approval study (PAS) results.
P980016/S609	04/25/2017	N - Normal 180 Day	EVERA MRI XT DR /VR SURESCAN; EVERA MRI S DR/VR SURESCAN; VISIA AF MRI XT SURESCAN; VISIA AF MRI S VR SURESCAN DVFC3D4 AND DVFC3D1 IMPLANTABLE CARDIOVETER DEFIBRILLATORS (ICDS)	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P980016/S618	04/25/2017	R - Real-Time Proc	EVERA MRI XT DR SURESCAN MODELS DDMB1D4, EVERA MRI ST VR SURESCAN MODEL DVMB1D4, VISIA AF MRI VR SURESCAN DVFC3D4 IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS)	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.
P980016/S624	04/14/2017	R - Real-Time Proc	EVERA MRI DF-I 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	Approval for changes to the battery design and corresponding manufacturing changes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S481	04/25/2017	N - Normal 180 Day	ADVISA MRI DR /SR SURESCAN IMPLANTABLE PULSE GENERATORS (IPGS)	MEDTRONIC INC.	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P990034/S036	04/13/2017	S - Special CBE	ISOMED IMPLANTABLE INFUSION SYSTEM	MEDTRONIC INC.	Approval for labeling changes to Medtronic SynchroMed® II and IsoMed® Implant Infusion system labeling associated with Over-infusion, Allergic Reaction, Tunneling Risks, Priapism, Magnetic Resonance Imaging.
P000029/S081	04/07/2017	Y - 135 Review Tra	DEFLUX INJECTABLE GEL	VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	Approval for a new supplier for the 0.9% NaCl raw material.
P000053/S075	04/28/2017	R - Real-Time Proc	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Approved for changes to the design dimensions for the cuff assembly concerning the overall cuff shell thickness and crease height is approved.
P000053/S076	04/07/2017	Y - 135 Review Tra	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for change of molding lubricant and molding process for the suture-tie connector.
P010012/S435	04/17/2017	N - Normal 180 Day	COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VIGILIANT CRT-D'S RESYNCHRONIZATION DEVICES	BOSTON SCIENTIFIC CORP.	Approval for the LATITUDE NXT Patient Management System Release 5.0.
P010012/S445	04/21/2017	R - Real-Time Proc	COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN CRT-D RESYNCHRONIZATION DEVICES	BOSTON SCIENTIFIC CORP.	Approval for a software update to improve the boot up process.
P010030/S086	04/25/2017	O - Normal 180 Day	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 3000, 3100, 4000.	ZOLL MANUFACTURING CORPORATION	Approval to modify the Zoll Wearable Cardioverter Defibrillator (WCD) 3000, 3100, and 4000 Operators Manuals to reflect the results of the Post-Approval Study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S569	04/25/2017	N - Normal 180 Day	AMPLIA MRI AND AMPLIA MRI QUAD CRT-D SURESCAN , COMPIA MRI AND COMPIA MRI QUAD CRT-D SURESCAN, CLARIA MRI AND CLARIA MRI QUAD CRT-D SURESCAN IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFRILLATORS (CRT-DS)	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P010031/S577	04/25/2017	R - Real-Time Proc	AMPLIA MRI AND AMPLIA MRI QUAD CRT-D SURESCAN MODELS DTMB1D4, DTMB1QQ. COMPIA MRI, CLARIA MRI	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.
P010031/S583	04/14/2017	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 QUAD CRT-D/ COMPIA MRI CRT-D/ COMPIA MRI QUAD CRT-D/ VIVA QUAD S CRT-D & XT CRT-D/ VIVA S CRT-D/ VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for changes to the battery design and corresponding manufacturing changes.
P010031/S584	04/12/2017	R - Real-Time Proc	AMPLIA MRI CRT-D, CLARIA MRI CRT-D, COMPIA MRI CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for minor software and firmware changes to software model SW034.
P030005/S145	04/17/2017	N - Normal 180 Day	INVIVE, INTUA, VISIONIST, VALITUDE CRT-P'S RESYNCHRONIZATION DEVOCES	GUIDANT CORP.	Approval for the LATITUDE NXT Patient Management System Release 5.0.
P030017/S278	04/28/2017	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a change to the packaging used for all Implantable Pulse Generators.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030036/S088	04/25/2017	N - Normal 180 Day	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P030036/S093	04/25/2017	R - Real-Time Proc	SELECTSECURE MRI SURESCAN LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.
P030052/S020	04/12/2017	R - Real-Time Proc	UROVYSION BLADDER CANCER KIT	ABBOTT MOLECULAR	Approval for upgrades to the VP 2000 Processor.
P030053/S037	04/13/2017	R - Real-Time Proc	MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR CORP.	Approval of a product line extension to the currently marketed MemoryGel® Silicone Gel-Filled Breast Implants Smooth product line involving additional breast implant options with increased fill volume but within approved dimension and volume ranges.
P050039/S021	04/03/2017	O - Normal 180 Day	NOVATION CERAMIC ARTICULATION HIP SYSTEM	EXACTECH, INC.	Approval to changes to the active surveillance study.
P050052/S090	04/26/2017	O - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for changes to the protocol for the post-approval study (PAS) protocol.
P050052/S091	04/26/2017	O - Normal 180 Day	RADIESSE INJECTABLE IMPLANT (DERMAL FILLERS)	MERZ NORTH AMERICA, INC	Approval for changes to the protocol for the post-approval study (PAS) protocol.
P060040/S066	04/11/2017	R - Real-Time Proc	HEARTMATE II LVAS	THORATEC CORP.	Approval for revisions to the warning statement related to body surface area (BSA) in the HeartMate II LVAS labeling.
P080003/S004	04/20/2017	S - Special CBE	3DIMENSIONS	HOLOGIC, INC.	Approval for a change to the Selenia Dimensions name to 3Dimensions.
P080006/S101	04/25/2017	N - Normal 180 Day	ATTAIN ABILITY MRI / PLUS / STRAIGHT SURESCAN LEADS; ATTAIN PERFORMA MRI / STRAIGHT / S MRI SURESCAN LEADS	MEDTRONIC INC.	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P080006/S107	04/25/2017	R - Real-Time Proc	4598MEDTRONIC ATTAIN ABILITY MODEL 4196, ATTAIN PERFORMA S MRI SURESCAN LEAD MODEL	MEDTRONIC INC.	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090013/S240	04/25/2017	N - Normal 180 Day	REVO MRI SURESCAN IPG & CAPSUREFIX MRI SURESCAN LEAD MRI	MEDTRONIC, INC	Approval of 1.5 and 3T MR Conditional Labeling for SelectSecure MRI SureScan Lead Model 3830.
P090013/S248	04/25/2017	R - Real-Time Proc	CAPSUREFIX MRI SURESCAN LEAD MODEL 5086MRI	MEDTRONIC, INC	Approval for 1.5 and 3T MR Conditional labeling for MRI SureScan Lead Model 6946M.
P090029/S007	04/03/2017	N - Normal 180 Day	PRESTIGE LP CERVICAL DISC STREAMLINED INSTRUMENTS	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for the Prestige LP Cervical Disc streamlined instrument set, which primarily includes updates to the implant trial, drill guide, and rail punch instruments.
P100014/S018	04/07/2017	Y - 135 Review Tra	SOLESTA INJECTABLE GEL	VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	Approval for a new supplier for the 0.9% NaCl raw material.
P100016/S003	04/18/2017	S - Special CBE	AARIS INTRAOCULAR LENS MODEL EC-3 AND EC-3 PAL	AAREN SCIENTIFIC INC	Approval for a new cosmetic inspection requirement to detect and reject intraocular lenses with Flat Optic Aberration.
P100047/S082	04/06/2017	N - Normal 180 Day	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for electrical, hardware, and software modifications to the controller, monitor, and AC/DC adapters.
P110004/S018	04/26/2017	N - Normal 180 Day	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Approval for modifications to the NIRxcell CoCr Coronary Stent on RX System.
P110012/S013	04/12/2017	R - Real-Time Proc	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Approval for upgrades to the VP 2000 Processor.
P110042/S068	04/17/2017	N - Normal 180 Day	EMBLEM SUBCUTANEOUS ICD'S	BOSTON SCIENTIFIC CORPORATION	Approval for the LATITUDE NXT Patient Management System Release 5.0.
P120024/S005	04/26/2017	O - Normal 180 Day	AESCULAP IMPLANT SYSTEMS	AESCULAP IMPLANT SYSTEMS, LLC	Approval of changes to the protocol for the post-approval study (PAS) protocol.
P130009/S068	04/03/2017	O - Normal 180 Day	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Approval of the statistical plan for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130021/S028	04/11/2017	N - Normal 180 Day	MEDTRONIC COREVALVE (TM) EVOLUT(TM) R SYSTEM	MEDTRONIC COREVALVE LLC	Approval for an alternative material for use in the EnVeo R Delivery Catheter System and alignment of the capsule fuse process across delivery system models.
P140003/S014	04/14/2017	R - Real-Time Proc	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for a modification to the printed circuit assembly capacitors for Impella 2.5.
P140003/S016	04/17/2017	Y - 135 Review Tra	IMPELLA VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Approval for an additional supplier for the pressure lumen kink protector for the Impella 2.5 and CP Systems.
P140012/S009	04/20/2017	S - Special CBE	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	Approval for changes to the ReShape Integrated Dual Balloon System Instructions for Use and Patient Information Guide for the ReShape Procedure.
P140026/S006	04/13/2017	O - Normal 180 Day	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for changes to the protocol for the post-approval study (PAS) protocol.
P140028/S021	04/07/2017	O - Normal 180 Day	INNOVA(TM)VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for manufacturing site located at Synergy Health Ireland, Ltd., IDA Business and Technology Park, Sragh, Tullamore, Co. Offaly, Ireland , for sterilization of the Innova Vascular Self-Expanding Stent System.
P140029/S001	04/12/2017	Y - 135 Review Tra	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for the addition of a second dialysis equipment to complement the current vessel used in the bulk manufacturing process for Restylane Refyne and Restylane Defyne.
P140031/S033	04/03/2017	S - Special CBE	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for implementing a new in-process inspection for the disc valve component of the Certitude delivery system.
P150001/S013	04/14/2017	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for design changes to the battery component of the GST3A transmitter. The GST3A transmitter is a component of the MiniMed 630G System.
P150005/S013	04/20/2017	O - Normal 180 Day	METRIQ IRRIGATION PUMP	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corporation, 150 Baytech Drive, San Jose, California, 95134.
P150012/S021	04/11/2017	N - Normal 180 Day	ESSENTIO, PROPONENT, ACCOLADE, INGEVITY MRI'S & SLIT SUTURE SLEEVE ACCESSORY (FOR INGEVITY MRI LEADS)	BOSTONSCIENTIFIC	Approval for the addition of 3T MR Conditional labeling for the Image Ready MR Conditional Pacing System consisting of an Accolade MRI pacemaker with one or two INGEVITY MRI leads. Approval to expand the Image Ready System to include 1.5T MR Conditional labeling for the FINELINE II Sterox and Sterox EZ leads.
P150033/S018	04/21/2017	R - Real-Time Proc	MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Approval for design changes to the tether retainer pin of the Micra Transcatheter Pacing System.
P150034/S003	04/05/2017	S - Special CBE	RAINDROP NEAR VISION INLAY	REVISION OPTICS, INCORPORATED	Approval for revisions to the Postoperative Care Following Inlay Implantation section of Instructions for Use (IFU) and Surgical Planning and Procedures¿ of the Professional Use Information Brochure for the Raindrop Near Vision Inlay.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150038/S002	04/17/2017	N - Normal 180 Day	EXABLATE	INSIGHTEC	Approval for a new Magnetic Resonance (MR) Head Coil for compatibility and use with the 1.5 Tesla (T) MR scanner environment when used with the ExAblate Model 4000 Type 1.0 System.
P160001/S003	04/25/2017	N - Normal 180 Day	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for the additional of a plant-based capsule material option.

Total: 76

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S089	04/19/2017	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Modification to the raw material testing for the senofilcon A and etafilcon A brand contact lenses.
N970012/S132	04/06/2017	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESIS (WITH AND WITHOUT INHIBIZONE TREATMENT)	BOSTON SCIENTIFIC CORP.	Changes in the molding and post-cure process parameters and work instructions of silicone molded components.
N970012/S133	04/14/2017	X - 30-Day Notice	AMBICOR INFLATABLE PENILE PROSTHESIS.	BOSTON SCIENTIFIC CORP.	Removal of an inspection step, removal of an in-process verification step, and the moving of four additional manufacturing steps.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S134	04/28/2017	X - 30-Day Notice	AMS 700 IMPLANTABLE PENILE PROSTHESIS WITH INHIBIZONE TREATMENT, AMS 700 IMPLANTABLE PENILE PROSTHESIS WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Change to the cylinder tip bond inspection and a change to the cylinder straightness inspection.
P810006/S076	04/24/2017	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT-MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Change in the tissue grinder.
P830055/S181	04/20/2017	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Reduction of cycle time for the drag finishing process.
P840001/S354	04/04/2017	X - 30-Day Notice	MASTER ITREL SPINAL CORD STIMULATION SYSTEM	MEDTRONIC NEUROMODULATION	Addition of automated feedthrough electrical test and change in test procedure.
P840001/S355	04/26/2017	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Replacing the coil winder equipment and mandrels and updating processes for the manufacture of the helical coil subcomponents of the impacted products.
P840001/S356	04/25/2017	X - 30-Day Notice	RESTORE SPINAL CORD STIMULATION SYSTEMS	MEDTRONIC NEUROMODULATION	Additions to the Argon Gas Resistant Spot Welding (RSW) manufacturing process to ensure proper setup and the availability of Argon Gas at Medtronics internal supplier, Medtronic Energy and Component Center (MECC).
P840062/S062	04/24/2017	X - 30-Day Notice	COLLACOTE, COLLATAPE, COLLAPLUG, ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	COLLA-TEC, INC.	Change in the tissue grinder.
P850010/S075	04/24/2017	X - 30-Day Notice	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT AND HELITENE-FIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Change in the tissue grinder.
P860057/S158	04/07/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Additional bovine abattoir.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S134	04/28/2017	X - 30-Day Notice	AMS 700 IMPLANTABLE PENILE PROSTHESIS WITH INHIBIZONE	BOSTON SCIENTIFIC	Change to the cylinder tip bond inspection and a change to the cylinder straightness inspection.
P910073/S141	04/19/2017	X - 30-Day Notice	ACUITY X4 LEAD	BOSTON SCIENTIFIC	Updates to potency and elution acceptance criteria for finished leads.
P930016/S050	04/05/2017	X - 30-Day Notice	IDESIGN ADVANCED WAVESCAN STUDIO	AMO MANUFACTURING USA, LLC	Manufacturing improvements to the iDesign Advanced WaveScan Studio fixation target.
P960004/S079	04/19/2017	X - 30-Day Notice	FINELINE II STEROX AND STEROX EZ LEAD	BOSTON SCIENTIFIC	Updates to potency and elution acceptance criteria for finished leads.
P960009/S272	04/04/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of automated feedthrough electrical test and change in test procedure.
P960009/S274	04/26/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Replacing the coil winder equipment and mandrels and updating processes for the manufacture of the helical coil subcomponents of the impacted products.
P960009/S275	04/25/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Additions to the Argon Gas Resistant Spot Welding (RSW) manufacturing process to ensure proper setup and the availability of Argon Gas at Medtronics internal supplier, Medtronic Energy and Component Center (MECC).
P970004/S238	04/04/2017	X - 30-Day Notice	SNS URINARY NEUROSTIMULATOR IMPLANTABLE INTERSTIM	MEDTRONIC NEUROMODULATION	Addition of automated feedthrough electrical test and change in test procedure.
P970004/S239	04/26/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Replacing the coil winder equipment and mandrels and updating processes for the manufacture of the helical coil subcomponents of the impacted products.
P970051/S159	04/21/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of an alternate Printed Circuit Board (PCB) supplier for the CP800 and CP900 sound processor coils for the Nucleus 24 Cochlear Implant system, the Nucleus Hybrid L24 implant system and the Nucleus ABI541 Auditory Brainstem Implant system.
P980016/S627	04/12/2017	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the inspection criteria for certain feedthrough components.
P980016/S628	04/26/2017	X - 30-Day Notice	EVERA, VISIA MRI ICD, S VR ICD, XT VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of mixing equipment used in battery manufacturing.

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P980016/S629	04/28/2017	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MAXIMO II ICD, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DR1 ICD, VISIA AF MRI VR ICD , VISIA AF VR ICD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.
P980016/S630	04/23/2017	X - 30-Day Notice	EVERA MRI DF-1/EVERA MRI/EVERA S DR/EVERA S VR/EVERA XT DR/EVERA XT VR/MAXIMO II/ PROTECTA/PROTECTA VR/ PROTECTA XT/SECURA DR/SECURA/VISIA AF MRI DF-1/VISIA MRI VR/VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition a rework process at a supplier for the barrels used in Multi Beam Contacts.
P980035/S492	04/11/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA, ADVISA DR, ADVISA DR MRI, ADVISA SR MRI, RELIA IPG	MEDTRONIC INC.	Automation of an electrical test and updates to the test procedure for feedthrough components.
P980035/S493	04/26/2017	X - 30-Day Notice	ADVISIA DR IPG, ADVISIA DR/SR MRI IPG	MEDTRONIC INC.	Addition of mixing equipment used in battery manufacturing.
P980035/S494	04/28/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ADVISA DR IPG,ADVISA DR MRI IPG, ADVISA SR MRI IPG, RELIA IPG	MEDTRONIC INC.	Changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.
P980035/S496	04/26/2017	X - 30-Day Notice	ADVISA DR IPG A4DR01; ADVISA DR MRI IPG A2DR01; ADVISA SR MRI IPG A3SR01	MEDTRONIC INC.	Additional laser welder for use in battery manufacturing.
P980037/S064	04/27/2017	X - 30-Day Notice	ANGIOJET ULTRA THROMBECOMY SYSTEM CONOSLE	BOSTON SCIENTIFIC CORP.	Establish an alternate vendor for repair of the AngioJet Ultra Console.

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P990013/S034	04/06/2017	X - 30-Day Notice	COLLAMER ULTRAVIOLET ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	STARR SURGICAL CO.	Modify the hydration step for the Collamer IOL Models CQ2015A and CC4204A and to remove the cometic inspection step for the Collamer IOL Model CC4204A that was performed as part of the hydration process.
P990075/S038	04/04/2017	X - 30-Day Notice	MENTOR SALINE-FILLED AND SPECTRUM BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Addition of Vinatoru equipment for seal strength testing of packaging components that are used for Mentor Saline-Filled and SPECTRUM® Breast Implants, MemoryGel® Silicone Gel-Filled Breast Implants and MemoryShapeTM Breast Implants and their accessories.
P990075/S039	04/10/2017	X - 30-Day Notice	MENTOR SALINE-FILLED AND SPECTRUM BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Addition of a new semi-automated secondary packaging line which will include electronic label and component verification equipment.
P000015/S019	04/21/2017	X - 30-Day Notice	NUCLEUS ABI541 AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Addition of an alternate Printed Circuit Board (PCB) supplier for the CP800 and CP900 sound processor coils for the Nucleus 24 Cochlear Implant system, the Nucleus Hybrid L24 implant system and the Nucleus ABI541 Auditory Brainstem Implant system.
P000053/S078	04/06/2017	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM PRODUCT LINE	BOSTON SCIENTIFIC CORP.	Changes to thickness measure and inspection of the cuff shell.
P010012/S447	04/19/2017	X - 30-Day Notice	ENDOTAK RELIANCE IS-1 AND ENDOTAK RELIANCE 4-SITE LEAD	BOSTON SCIENTIFIC CORP.	Updates to potency and elution acceptance criteria for finished leads.
P010015/S323	04/11/2017	X - 30-Day Notice	CONSULTA, SYNCRA, VIVA CRT-P	MEDTRONIC INC.	Automation of an electrical test and updates to the test procedure for feedthrough components.
P010015/S324	04/26/2017	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-D	MEDTRONIC INC.	Addition of mixing equipment used in battery manufacturing.
P010015/S325	04/28/2017	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.
P010015/S326	04/26/2017	X - 30-Day Notice	CONSULTA CRT-P C4TR01; SYNCRA CRT-P C2TR01; VIVA CRT-P C6TR01	MEDTRONIC INC.	Additional laser welder for use in battery manufacturing.
P010019/S054	04/21/2017	X - 30-Day Notice	AIR OPTIX PLUS HYDRAGLYDE SOFT CONTACT LENSES FOR DAILY AND EXTENDED WEAR	ALCON LABORATORIES, INC.	Update to the variable sampling plan for the lens power testing during in-process and final product quality control testing of AIR OPTIX plus HydraGlyde (lotrafilcon B) soft contact lenses for daily and extended wear.

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P010031/S587	04/12/2017	X - 30-Day Notice	MEDTRONIC CARDIAC RHYTHM AND HEART FAILURE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the inspection criteria for certain feedthrough components.
P010031/S588	04/26/2017	X - 30-Day Notice	AMPLIA, AMPLIA MRI QUAD, BRAVA, BRAVA MRI QUAD, CLARIA MRI, COMPIA, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of mixing equipment used in battery manufacturing.
P010031/S589	04/28/2017	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, 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	Changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.
P010031/S590	04/23/2017	X - 30-Day Notice	AMPLIA MRI/AMPLIA MRI QUAD/BRAVA/BRAVA QUAD/CLARIA MRI/CLARIA MRI QUAD/COMPIA MRI/ COMPAI MRI QUAD/ CONSULTA/MAXIMO II/ PROTECTA/PROTECTA XT/ VIVA QUAD S/VIVA QUAD XT/VIVA S/VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition a rework process at a supplier for the barrels used in Multi Beam Contacts.
P020012/S013	04/06/2017	X - 30-Day Notice	BELLAFILL DERMAL FILTER	SUNEVA MEDICAL, INC.	1) Changed contract test lab and associated SOP for residual monomer in unprocessed PMMA microspheres; 2) Changed contract test lab and associated SOP for residual monomer in processed non-sterile PMMA microspheres; and 3) Added reference to internal manufacturing document and clarified reject criteria for finished product specification.

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P020045/S082	04/17/2017	X - 30-Day Notice	FREEZER CARDIAC CRYOABLATION, FREEZER XTRA SURGICAL CARDIAC, FREEZER MAX SURGICAL CARDIAC	MEDTRONIC CRYOCATH LP	New soldering tool for Freezor and Arctic Front family of catheters.
P020050/S026	04/11/2017	X - 30-Day Notice	ALLEGRO TOPOLYZER VARIO	ALCON LABORATORIES, INC.	Improvement of the electromagnetic compatibility shielding on the housing of the Allegro Topolyzer Vario.
P030008/S022	04/11/2017	X - 30-Day Notice	ALLEGRO TOPOLYZER VARIO	ALCON LABORATORIES, INC.	Improvement of the electromagnetic compatibility shielding on the housing of the Allegro Topolyzer Vario.
P030011/S052	04/04/2017	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	New supplier of the cooling fan for the Freedom AC power supply.
P030053/S038	04/04/2017	X - 30-Day Notice	MENTOR MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR CORP.	Addition of Vinatoru equipment for seal strength testing of packaging components that are used for Mentor Saline-Filled and SPECTRUM® Breast Implants, MemoryGel® Silicone Gel-Filled Breast Implants and MemoryShapeTM Breast Implants and their accessories.
P030053/S039	04/10/2017	X - 30-Day Notice	MEMORYGEL SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR CORP.	Addition of a new semi-automated secondary packaging line which will include electronic label and component verification equipment.
P030053/S040	04/19/2017	X - 30-Day Notice	MENTOR MEMORYGEL SILICONEGEL-FILLED BREAST IMPLANTS	MENTOR CORP.	Changes to the routine batch auditing plans for measurement of shell properties and gel cohesion performance for the MemoryShape and MemoryGel breast implants.
P040005/S014	04/12/2017	X - 30-Day Notice	HER2 IQFISH PHARMDX	DAKO DENMARK A/S	Changes to the in-process control fluorescent labeling process.
P040012/S059	04/07/2017	X - 30-Day Notice	RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	Change to the frequency of routine bacterial endotoxin testing.
P040045/S069	04/19/2017	X - 30-Day Notice	VISTAKON (SENOFILCON) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification to the raw material testing for the senofilcon A and etafilcon A brand contact lenses.
P050017/S015	04/06/2017	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK INCORPORATED	Supplier modifications to the stent component processing.
P050018/S024	04/17/2017	X - 30-Day Notice	ANGIOSCULPT RX PTCA SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Change to the biological indicator utilized to build the internal process challenge device.

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P050047/S057	04/06/2017	X - 30-Day Notice	JUVEDERM 24 HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Change of supplier for raw materials used in the manufacture of Juvederm dermal filler products.
P060028/S020	04/04/2017	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Addition of Vinatoru equipment for seal strength testing of packaging components that are used for Mentor Saline-Filled and SPECTRUM® Breast Implants, MemoryGel® Silicone Gel-Filled Breast Implants and MemoryShapeTM Breast Implants and their accessories.
P060028/S021	04/10/2017	X - 30-Day Notice	MENTOR MEMORY SHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Addition of a new semi-automated secondary packaging line which will include electronic label and component verification equipment.
P060028/S022	04/19/2017	X - 30-Day Notice	MENTOR MENORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Changes to the routine batch auditing plans for measurement of shell properties and gel cohesion performance for the MemoryShape and MemoryGel breast implants.
P070015/S136	04/25/2017	X - 30-Day Notice	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Add a replicate sterilization chamber at the Sterigenics UK facility.
P080011/S056	04/17/2017	X - 30-Day Notice	BIOFINITY (COMFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Addition of GEO Specialty Chemicals (GEO) as a secondary supplier of a handling tint for use in the manufacture of Biofinity (comfilcon A) soft contact lenses at both the United Kingdom (UK) and Puerto Rico manufacturing sites.
P080011/S057	04/10/2017	X - 30-Day Notice	BIOFINITY XR TORIC	COOPERVISION MANUFACTURING, LTD.	Use of Biofinity Line 3 for the production of Biofinity XR Toric lenses with a sphere power range of 0.00D to +10.00D and cylinder powers of -2.75D to -4.25D.
P080025/S133	04/04/2017	X - 30-Day Notice	SNS BOWEL NEUROSTIMULATORS IMPLANTABLE INTERSTIM	MEDTRONIC NEUROMODULATION	Addition of automated feedthrough electrical test and change in test procedure.
P080025/S134	04/26/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Replacing the coil winder equipment and mandrels and updating processes for the manufacture of the helical coil subcomponents of the impacted products.
P090013/S252	04/26/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Addition of mixing equipment used in battery manufacturing.
P090013/S253	04/28/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.
P090013/S255	04/26/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG RVDR01	MEDTRONIC, INC	Additional laser welder for use in battery manufacturing.
P090016/S023	04/14/2017	X - 30-Day Notice	BELOTERO BALANCE DERMAL FILLER	MERZ NORTH AMERICA, INC	Change to incoming inspection requirements for the 27G 1/2" and 30G 1/2" needles.

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P090018/S035	04/14/2017	X - 30-Day Notice	MODEL 7010 SENSOR AND MODEL 7510 DRIVER TRANSDUCERS	ENVOY MEDICAL CORPORATION	Change in a component supplier and a manufacturing process change for the Model 7010 Sensor and Model 7510 Driver transducers.
P090024/S003	04/25/2017	X - 30-Day Notice	ADVIA CENTAUR HBEAG	SIEMENS HEALTHCARE DIAGNOSTICS	Addition of a new reference material to the in-process Quality Control testing.
P100009/S022	04/13/2017	X - 30-Day Notice	MITRACLIP NT CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Addition of two new pieces of equipment used for the riveting process.
P100009/S023	04/28/2017	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Add an alternate supplier for the molded key component.
P100010/S063	04/17/2017	X - 30-Day Notice	ARCTIC FRONT FAMILY OF CATHETERS	MEDTRONIC CRYOCATH LP	New soldering tool for Freezor and Arctic Front family of catheters.
P100010/S064	04/21/2017	X - 30-Day Notice	ARCTIC FRONT AND ARCTIC FRONT ADVANCE CARDIAC CRYOALBATION CATHETERS	MEDTRONIC CRYOCATH LP	Automated pressure sensor testing equipment.
P100021/S062	04/12/2017	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Implementation of a new stent ring cutting (trimming) machine during manufacturing of the Endurant Stent Graft System, Endurant II Stent Graft System, Endurant II Aorto-Uni-Iliac Stent Graft System and Endurant IIs Stent Graft System.
P100022/S023	04/06/2017	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Supplier modifications to the stent component processing.
P100022/S024	04/11/2017	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Add a specification for a component and new equipment at a supplier.
P100024/S012	04/12/2017	X - 30-Day Notice	HER2 CISH PHARMDX KIT	DAKO DENMARK A/S	Changes to the in-process control fluorescent labeling process.
P100024/S013	04/03/2017	X - 30-Day Notice	HER2 CISH PHARMDX KIT	DAKO DENMARK A/S	Change in the mixing process for preparation of a probe component.
P100026/S048	04/05/2017	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Add a workmanship requirement to the molded distal tip of the NeuroPace Depth Leads.
P100029/S025	04/03/2017	X - 30-Day Notice	TRIFECTA VALVE WITH GLIDE	ST. JUDE MEDICAL, INC.	Change to the machining lubricant used to manufacture a component of the Trifecta GT valve.

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P110001/S013	04/07/2017	X - 30-Day Notice	RX HERCULINK ELITE RENAL AND BILIARY STENT SYSTEM	ABBOTT VASCULAR	Change to the frequency of routine bacterial endotoxin testing.
P110010/S139	04/11/2017	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Update the proximal bond process.
P110016/S039	04/10/2017	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER AND FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC.	Acceptance of modified adhesive cure parameters for the plunger assembly and lower handle assembly processes.
P110016/S040	04/17/2017	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER, SENSOR ENABLED (BI-DIRECTIONAL) & FLEXABILITY ABLATION CATHETER, SENSOR ENABLED (UNI-DIRECTIONAL)	ST. JUDE MEDICAL, INC.	Supplier manufacturing changes (facility, welding equipment, and cleaning solvent) for a component of the FlexAbility Sensor Enabled Ablation Catheters.
P110016/S041	04/24/2017	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC.	Add Sterigenics as an alternate ethylene oxide sterilization vendor for the FlexAblity Ablation Catheter, Sensor Enabled (Flex SE) and corresponding connecting cable.
P110019/S090	04/06/2017	X - 30-Day Notice	XIENCE V XIENCE NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEM; XIENCE PRIMME / XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM; XIENCE ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change to the balloon blow process parameters.
P110019/S092	04/25/2017	X - 30-Day Notice	XIENCE PRIME EVEROLIMUS ELUTING CORONARY STENT SYSTEM, SV, LL	ABBOTT VASCULAR	Add a replicate sterilization chamber at the Sterigenics UK facility.

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P110028/S017	04/14/2017	X - 30-Day Notice	ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYSTEM.	ABBOTT VASCULAR INC.	Addition of new equipment for stent laser cutting operations and modifications to associated manufacturing processes.
P110028/S018	04/07/2017	X - 30-Day Notice	ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYSTEM	ABBOTT VASCULAR INC.	Change to the frequency of routine bacterial endotoxin testing.
P110033/S027	04/06/2017	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Change of supplier for raw materials used in the manufacture of Juvederm dermal filler products.
P110042/S081	04/13/2017	X - 30-Day Notice	EMBLEM¿ S-ICD MODEL A209; EMBLEM¿ MRI S-ICD MODEL A219	BOSTON SCIENTIFIC CORPORATION	Additional manufacturing inspection step and associated specification and inspection criteria to distinguish case half discontinuities from dents.
P110042/S082	04/23/2017	X - 30-Day Notice	ALL FLEX 4-SOCKET HI-POT/PULSE TEST SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of automated test equipment to perform leakage current and resistance acceptance activities.
P120005/S061	04/26/2017	X - 30-Day Notice	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM, DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Relocate storage and shipping activities for finished products for the Dexcom G4 Platinum Contiuous Glucose Monitoring System and the Dexcom G5 Mobile Continuous Glucose Monitoring System to a new warehouse facility.
P120010/S102	04/27/2017	X - 30-Day Notice	ARTIFICIAL PANCREAS DEVICE SYSTEM THRESHOLD SUSPEND	MEDTRONIC INC.	Additional inspections and inspection equipment by contract manufacturer of introducer needle in the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System With SmartGuard, the Paradigm Real-Time Revel System with Enlite Sensor, and iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G System.
P120016/S023	04/11/2017	X - 30-Day Notice	VASCADE 6/7F VCS & VASCADE 5F VCS	CARDIVA MEDICAL, INC.	Addition of an alternate, in-house supplier for the pad-printed Distal Outer Sleeve.
P130007/S023	04/20/2017	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Relocation of a contract manufacturing facility for the injection molding process for the Drive Housing and Dual Vent Housing components which are assembled into the Animas Vibe Insulin pump. The Animas Vibe Insulin pump is a component of the Animas Vibe System.
P130007/S024	04/21/2017	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Implementation of a pump motor refurbishment process for the Animas Vibe Insulin Pump. The refurbishment activities will be conducted in the same building where current pump manufacturing occurs. The Animas Vibe Pump is a component of the Animas Vibe System with the Dexcom G4 PLATINUM Sensor and Transmitter.

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P130009/S071	04/07/2017	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Additional bovine abattoir.
P130009/S072	04/20/2017	X - 30-Day Notice	NOVAFLEX+ DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Change to the depth of adhesive application in the NovaFlex+ Delivery System.
P130013/S013	04/13/2017	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Use of alternate Biological Indicators (BIs) used for routine monitoring of EO sterilization.
P130016/S024	04/21/2017	X - 30-Day Notice	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of an alternate Printed Circuit Board (PCB) supplier for the CP800 and CP900 sound processor coils for the Nucleus 24 Cochlear Implant system, the Nucleus Hybrid L24 implant system and the Nucleus ABI541 Auditory Brainstem Implant system.
P130021/S032	04/04/2017	X - 30-Day Notice	EN VEO R DCS AND EN VEO R LS	MEDTRONIC COREVALVE LLC	Reduce the sample size for in-process pouch tensile testing on the EnVeo R Delivery Catheter System and EnVeo R Loading System at the Medtronic Ireland facility.
P130021/S035	04/05/2017	X - 30-Day Notice	ENVEO R DELIVERY CATHETER SYSTEM	MEDTRONIC COREVALVE LLC	Addition of an inspection step and redesign of tooling used during the capsule bonding process of the EnVeo R Delivery Catheter System.
P130021/S036	04/13/2017	X - 30-Day Notice	MEDTRONIC COREVALVE EVOLUT R TRANSCATHER AORTIC VALVE (BIOPROSTHESIS); ENVEO R DELIVERY CATHETER SYSTEM; EN"VEO R LOADING SYSTEM	MEDTRONIC COREVALVE LLC	Automation of the cutting process for two components of the EnVeo R Delivery Catheter System.
P130021/S037	04/20/2017	X - 30-Day Notice	MEDTRONIC COREVALVE AND MEDTRONIC EVOLUT SYSTEMS	MEDTRONIC COREVALVE LLC	Transfer of valve manufacturing operations from Building 1 to Building 3 at the Medtronic Tijuana, Mexico facility.
P140031/S036	04/07/2017	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Additional bovine abattoir.
P140031/S037	04/19/2017	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of a new manufacturing aid to be used during assembly of the Commander Delivery System.
P150001/S011	04/20/2017	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM WITH ENLITE	MEDTRONIC MINIMED	Relocation of the molding process and a replacement press for the standoffs to a new manufacturing location for the 630G and 670G system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150001/S012	04/27/2017	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Additional inspections and inspection equipment by contract manufacturer of introducer needle in the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System With SmartGuard, the Paradigm Real-Time Revel System with Enlite Sensor, and iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G System.
P150003/S028	04/11/2017	X - 30-Day Notice	SYNERGY EVEROLIMUS ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER-THE-WIRE.	BOSTON SCIENTIFIC CORPORATION	Update the proximal bond process.
P150005/S018	04/07/2017	X - 30-Day Notice	INTELLANAV OPEN IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Addition of ultrasonic tip cleaning on the IntellaNav Open Irrigated (Nav OI) Ablation Catheters.
P150012/S027	04/19/2017	X - 30-Day Notice	INGEVITY LEAD	BOSTONSCIENTIFIC	Updates to potency and elution acceptance criteria for finished leads.
P150019/S028	04/27/2017	X - 30-Day Notice	PARADIGM REAL-TIME REVEAL SYSTEM	MEDTRONIC MINIMED	Additional inspections and inspection equipment by contract manufacturer of introducer needle in the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System With SmartGuard, the Paradigm Real-Time Revel System with Enlite Sensor, and iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G System.
P150021/S005	04/26/2017	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Update the Applicator Sub-Assembly manufacturing process from a manual to an automated process, and to update the Applicator Sub-Assembly drawing to include three updates to quality attributes for measurement checks to provide an additional control for the automated manufacturing process. The Applicator Sub-Assembly is a component of the Sensor Applicator for the Abbott Diabetes Care FreeStyle Libre Pro Flash Glucose Monitoring System.
P150029/S008	04/27/2017	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Additional inspections and inspection equipment by contract manufacturer of introducer needle in the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System With SmartGuard, the Paradigm Real-Time Revel System with Enlite Sensor, and iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G System.
P150033/S021	04/26/2017	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Addition of mixing equipment used in battery manufacturing.
P150033/S022	04/28/2017	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150036/S006	04/07/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCE S, LLC.	Additional bovine abattoir.
P150037/S004	04/12/2017	X - 30-Day Notice	CYPASS MICRO-STENT	ALCON RESEARCH, LTD	Removal of an in-process tensile test of the CyPass Micro-Stent.
P160017/S010	04/20/2017	X - 30-Day Notice	MEDTRONIC MINIMED HYBRID CLOSED LOOP (HCL) 670G	MEDTRONIC MINIMED	Relocation of the molding process and a replacement press for the standoffs to a new manufacturing location for the 630G and 670G system.
P160017/S011	04/27/2017	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED	Additional inspections and inspection equipment by contract manufacturer of introducer needle in the Enlite Sensor and Guardian Sensor (3). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System With SmartGuard, the Paradigm Real-Time Revel System with Enlite Sensor, and iPro2 CGM System with Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G System.

Total: 126