PMA Monthly approvals from 5/1/2018 to 5/31/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170013	05/30/2018	PMAO - PMA Origi	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval for the Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr. This device is indicated for use with neurovascular embolization coils in patients >= 18 years of age for the treatment of wide-neck (neck width >= 4 mm or dome to neck ratio < 2) saccular intracranial aneurysms arising from a parent vessel with a diameter >= 2.0 mm and <= 4.5 mm.
P170016	05/08/2018	PMAO - PMA Origi	SYNOJOYNT	TEVA PHARMACEUTICALS USA, INC.	Approval for SYNOJOYNT. SYNOJOYNT is indicated for use in the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).
P170039	05/30/2018	PMAO - PMA Origi	CUSTOMFLEX ARTIFICIAL IRIS	CLINICAL RESEARCH CONSULTANTS, INC.	Approval for the CustomFlex Artificial Iris. The CustomFlex Artificial Iris is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860004/S294	05/18/2018	O - Normal 180 Day	SYNCHROMED INFUSION SYSTEM / ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for a alternate manufacturing site located at Medtronic Puerto Rico Operations Company, Junccos, Road 31, Km. 24, Hm 4, Deiba Norte Industrial Park, Juncos, PR 00777 for manufacturing and sterilization of the Ascenda Catheter and accessories.
P890003/S390	05/30/2018	R - Real-Time Proc	MYCARELINK MONITOR 4G CELLULAR MODEM	MEDTRONIC, INC.	Approval for updates to the Medtronic MyCareLink Patient Monitor Models 24950 and 24952.

Data as of 06/04/2018 04:48 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910073/S145	05/04/2018	N - Normal 180 Day	RELIANCE 4- FRONT LEAD FAMILY AND SUTURE SLEEVE ACCESSORY	BOSTON SCIENTIFIC	Approval for the RELIANCE 4-FRONT lead family and suture sleeve accessory (Model 6403).
P930036/S008	05/04/2018	N - Normal 180 Day	ATELLICA IM ALPHA FETOPROTEIN (AFP)	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the migration of the ADVIA Centaur AFP Assay to the Atellica IM Analyzer.
P940010/S015	05/18/2018	R - Real-Time Proc	OPTIGUIDE FIBER OPTIC DIFFUSER	CONCORDIA LABORATORIES, INC	Approval of shelf life for the OPTIGUIDE Fiber Optic Diffuser, DCYL 700 Cylindrical Diffuser Series for four (4) years in all sizes of the DCYL 700 Series fibers (DCYL 710, 715, 720, 725, 750).
P960009/S304	05/26/2018	N - Normal 180 Day	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for Medtronics new model A610 Activa Clinician Programmer application and Model 8880T2 Communicator intended for programming DBS systems and for a field-implementable update to the Model 37612 Activa RC implantable neurostimulator to extend the service life from 9 years to 15 years.
P970051/S179	05/24/2018	S - Special CBE	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM (NUCLEUS 7 SOUND PROCESSOR)	COCHLEAR AMERICAS	Approval for Labeling Enhancements for the Nucleus 7 Sound Processor.
P980016/S670	05/30/2018	R - Real-Time Proc	EVERA MRI, EVERA, MARQUIS, SECURA, MAXIMO II, INTRINSIC, PROTECTA, PROTECTA XT, VIRTUOSO II AND VISIA AF	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updates to the Medtronic MyCareLink Patient Monitor Models 24950 and 24952.
P980035/S550	05/30/2018	R - Real-Time Proc	ADAPTA, VERSA, SENSIA, ADVISA, ADVISA MRI, ENPULSE AND KAPPA	MEDTRONIC INC.	Approval for updates to the Medtronic MyCareLink Patient Monitor Models 24950 and 24952.
P000025/S099	05/15/2018	R - Real-Time Proc	RONDO 2 AUDIO PROCESSOR & WATERWEAR FOR RONDO 2	MED-EL CORP.	Approval for the RONDO 2 Audio Processor and WaterWear for RONDO 2.
P010015/S357	05/21/2018	R - Real-Time Proc	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLAR BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, APPLICATION SOFTWARE	MEDTRONIC INC.	Approval for a minor firmware design change for the Percepta/Percepta Quad CRT-P MRI SureScan devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S369	05/30/2018	R - Real-Time Proc	CONSULTA CRT-P, SYNCRA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Approval for updates to the Medtronic MyCareLink Patient Monitor Models 24950 and 24952.
P010031/S628	05/30/2018	R - Real-Time Proc	VIVA, BRAVA, PROTECTA, PROTECTA XT, CONCERTO, CONCERTO II, CONSULTA, MAXIMO II, INSYNC II PROTECT, AMPLIA, COMPIA AND CLARIA	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updates to the Medtronic MyCareLink Patient Monitor Models 24950 and 24952.
P010054/S034	05/17/2018	O - Normal 180 Day	ELECSYS ANTI-HBS, PRECICONTROL ANTI-HBS AND ANTI-HBS CALCHECK	ROCHE DIAGNOSTICS CORP.	Approval for change of the proprietary names of Elecsys Anti-HBs Immunoassay, Elecsys PreciControl Anti-HBs, and Elecsys Anti-HBs CalCheck to Elecsys Anti-HBs, PreciControl Anti-HBs, and Anti-HBs CalCheck.
P020045/S087	05/04/2018	R - Real-Time Proc	GEN V CRYOCONSOLE	MEDTRONIC CRYOCATH LP	Approval for catheter recognition files to be downloaded to the CryoConsole for recognition of two new cryoablation catheters, Arctic Front Advance Pro, models AFAPRO23 and AFAPRO28.
P020050/S029	05/11/2018	N - Normal 180 Day	WAVELIGHT EX500 LASER SYSTEM	ALCON LABORATORIES, INC.	Approval for Platform Enhancement Refractive Suite Phase I (¿PERS I¿) hardware changes (color concept, update to head-up display, keyboard, control panel and console updates), and include software release Green SP4 (SP = Service Pack) with changes to the graphical user interface.
P030008/S025	05/11/2018	N - Normal 180 Day	WAVENET PLANNING SOFTWARE	ALCON LABORATORIES, INC.	Approval for Platform Enhancement Refractive Suite Phase I (¿PERS I¿) hardware changes (color concept, update to head-up display, keyboard, control panel and console updates), and include software release Green SP4 (SP = Service Pack) with changes to the graphical user interface.
P030011/S051	05/02/2018	Y - 135 Review Tra	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for a component sub-supplier change.
P030040/S012	05/03/2018	N - Normal 180 Day	ATELLICA IM HEPATITIS B CORE ANTIGEN (AHBCM)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur HBc IgM (aHBcM) assay to the Atellica IM Analyzer.
P030050/S028	05/01/2018	O - Normal 180 Day	SCULPTRA AESTHETIC (INJECTABLE POLY-L LACTIC ACID)	Q-MED AB	Approval of the revised protocol for the post-approval study (PAS) protocol.
P030056/S011	05/09/2018	N - Normal 180 Day	ATELLICA IM HEPATITIS C (AHCV)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur HCV (aHCV) assay and ADVIA Centaur HCV Quality Control Material onto the Atellica IM Analyzer.
P040024/S099	05/18/2018	P - Panel Track	RESTYLANE LYFT WITH LIDOCAINE	Q-MED AB	Approval for the Restylane Lyft with Lidocaine for expanding the indications to include injection into the subcutaneous plane in the dorsal hand to correct volume deficit in patients over the age of 21

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P070015/S141	05/30/2018	N - Normal 180 Day	EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Approval for implementation of everolimus BHT manufactured at a new manufacturing site.
P080030/S021	05/29/2018	N - Normal 180 Day	ISTENT TRABECULAR MICRO-BYPASS STENT SYSTEM	GLAUKOS, CORPORATION	Approval for two alternate packaging configurations that include an ophthalmic clip.
P090013/S282	05/30/2018	R - Real-Time Proc	REVO MRI	MEDTRONIC, INC	Approval for updates to the Medtronic MyCareLink Patient Monitor Models 24950 and 24952.
P100009/S025	05/23/2018	N - Normal 180 Day	MITRACLIP SYSTEM (NTR AND XTR)	ABBOTT VASCULAR INC.	Approval for several design and manufacturing changes to the clip delivery system and implant as well as minor changes to device packaging.
P100010/S070	05/04/2018	N - Normal 180 Day	ARCTIC FRONT ADVANCE PRO CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Approval for two new models to be added to the Arctic Front family of Cardiac Cryoablation Catheters, AFAPRO23 and AFAPRO28.
P100010/S076	05/04/2018	R - Real-Time Proc	GEN V CRYOCONSOLE ROHS COMPLIANT	MEDTRONIC CRYOCATH LP	Approval for catheter recognition files to be downloaded to the CryoConsole for recognition of two new cryoablation catheters, Arctic Front Advance Pro Models AFAPRO23 and AFAPRO28.
P100026/S054	05/16/2018	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for an alternate smaller size NeuroPace Magnet, a new carabiner style convenience clip to carry the magnet, and minor labeling changes to incorporate new artwork depicting a more generic looking magnet and to add the clip to the contents on the label.
P100039/S005	05/23/2018	N - Normal 180 Day	ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2), ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 QUALITY CONTROL (AHBS2 QC)	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Aproval for the migration of the ADVIA Centaur Anti-HBs2 (aHBs2) assay to the Atellica IM Analyzer.
P110002/S020	05/30/2018	O - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS	LDR SPINE USA	Approval for an update of labeling with 84 month data.
P110005/S003	05/07/2018	S - Special CBE	GELSYN-3	IBSA INSTITUT BIOCHIMIQUE SA	Approval for a labeling change to the Product Information leaflet for GELSYN-3 for incorporation of additional details in the instructions for removal of the syringe cap, securing of the needle to the syringe, and removal of the needle shield in preparation for injection of the product.
P110006/S009	05/11/2018	N - Normal 180 Day	INVENIA ABUS 2.0 AUTOMATED BREAST ULTRASOUND SYSTEM	U-SYSTEMS, INC.	Approval for changes to the Invenia ABUS 2.0 Automated Breast Ultrasound System include hardware updates which include a new ultrasound beam former, ultrasound engine, and computer components. This supplement also requests approval for removal of the current review software from the PMA, and proposes that the images will now be reviewed on a workstation.

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P110009/S020	05/30/2018	O - Normal 180 Day	MOBI-C CERVICAL DISC PROSTHESIS	LDR SPINE USA INC.	Approval for an update of labeling with 84 month data.
P110019/S094	05/22/2018	N - Normal 180 Day	XIENCE SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for changes to the stent geometry, delivery system, and packaging materials.
P110019/S098	05/30/2018	N - Normal 180 Day	XIENCE XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM, SV (2.25), LL; XIENCE ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM; XIENCE SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for the implementation of everolimus BHT manufactured at a new manufacturing site.
P120005/S067	05/07/2018	O - Normal 180 Day	DEXCOM G4 PLATINUM CONTINUOUS GLUCOSE MONITORING SYSTEM AND DEXCOM 5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for the addition of a Manufacturing Site for components of the G4 Platinum and G5 Mobile Continuous Glucose Monitoring Systems at your facility located at 232 South Dobson Rd., Mesa, Arizona.
P120006/S030	05/08/2018	R - Real-Time Proc	OVATION IX ABDOMINAL STENT GRAFT SYSTEM	TRIVASCULAR INC	Approval for the modification of the inner handle of the Ovation iX aortic body delivery system.
P130008/S029	05/11/2018	O - Normal 180 Day	INSPIRE UPPER AIRWAY STIMULATION THERAPY	INSPIRE MEDICAL SYSTEMS	Approval for updates to the labeling with the results of the Extended Follow Up of the Premarket Cohort post approval study.
P130008/S033	05/15/2018	R - Real-Time Proc	INSPIRE UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for proposed changes to the Inspire systems MRI Guidelines Manual.
P130013/S019	05/18/2018	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Approval for changes to the hub cap component of the WATCHMAN access system.
P130026/S032	05/16/2018	R - Real-Time Proc	TATICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for elimination of a field service procedure for the TactiSys Quartz equipment, and minor IFU revisions to reflect the removal of the service procedure.
P130028/S020	05/21/2018	R - Real-Time Proc	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Approval for a change to Model 2412 and 2408 Algovita Implantable Pulse Generator (IPG) software.

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P130030/S049	05/21/2018	N - Normal 180 Day	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL)	BOSTON SCIENTIFIC CORP.	Approval for design changes to the stent delivery catheter, including corresponding changes to the product labeling, and removal of the accessory package from the product packaging.
P140003/S030	05/02/2018	O - Normal 180 Day	IMPELLA CP WITH SMARTASSIST	ABIOMED, INC.	Approval for change in trade name from Impella CP Optical to Impella CP with SmartAssist.
P140008/S012	05/31/2018	S - Special CBE	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGERY INC	Approval for labeling updates to inform users about current risks associated with device use and adverse event information.
P140010/S039	05/25/2018	N - Normal 180 Day	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PT A) BALLOON CATHETER	MEDTRONIC INC.	Approval for the 200 mm and 250 mm balloon lengths for the IN.PACT Admiral Paclitaxel-Coated Percutaneous-Transluminal Angioplasty Balloon Catheter.
P140012/S012	05/30/2018	O - Normal 180 Day	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	Approval of the revised protocol of the post-approval study protocol.
P140012/S013	05/31/2018	S - Special CBE	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	Approval for labeling updates to inform users about current risks associated with device use and adverse event information.
P140013/S009	05/01/2018	R - Real-Time Proc	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for the co-packaging of the Minerva Cervical Dilator with the Minerva Disposable Handpiece, modifications to the packaging design to accommodate said co-packaging, and the addition of a manufacturing supplier for the thermoformed tray and insert used in packaging said co-packaged devices.
P140015/S025	05/02/2018	R - Real-Time Proc	T:SLIM X2 INSULIN PUMP WITH DEXCOMG5 MOBILE CGM SYSTEM	TANDEM DIABETES CARE, INC.	Approval for a design change to the insulin cartridge.
P140029/S006	05/11/2018	Y - 135 Review Tra	RESTYLANE REFYNE, RESTYLANE DEFYNE INJECTABLE GELS	Q-MED AB	Approval for a replacement of a compressor for compressed air used in the manufacture of Restylane Refyne and Restylane Defyne.
P140032/S006	05/18/2018	S - Special CBE	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for changes to the Implantable System for Remodulin Technical Manual and Implantable System for Remodulin Patient Manual.
P150023/S010	05/30/2018	N - Normal 180 Day	ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for implementation of everolimus BHT manufactured at a new manufacturing site.
P150026/S002	05/02/2018	N - Normal 180 Day	HEART LIGHT CATHETER WITH EXCALIBUR BALLOON	CARDIOFOCUS, INC.	Approval for the HeartLight Endoscopic Ablation System with Excalibur Balloon, which represents design and labeling changes to the HeartLight Endoscopic Ablation System, including changes to the balloon component and cooling loop, and the addition of a balloon remote.

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P150033/S036	05/30/2018	R - Real-Time Proc	MICRA	MEDTRONIC INC.	Approval for updates to the Medtronic MyCareLink Patient Monitor Models 24950 and 24952.
P150037/S007	05/29/2018	O - Normal 180 Day	CYPASS SYSTEM 241-S	ALCON RESEARCH, LTD	Approval for a manufacturing site located at Alcon Research, Ltd, 714 Columbia Avenue, Sinking Spring, Pennsylvania.
P150040/S002	05/02/2018	R - Real-Time Proc	VISUMAX FEMTOSECOND LASER SYSTEM	CARL ZEISS MEDITEC, INC.	Approval for the replacement of the fiber-optic laser source hardware module.
P160035/S001	05/21/2018	O - Normal 180 Day	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval of the protocol for the post-approval study protocol.
P160054/S006	05/31/2018	R - Real-Time Proc	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for updating the packaging materials for the existing Modular Cable Cap and Coring Knife standalone packaging configurations, and introducing a standalone packaging configuration for the Apical Cuff, Skin Coring Punch, Thread Protectors, and Tunneling Adapter.
P160054/S010	05/18/2018	S - Special CBE	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for an update to the Instructions for Use regarding Outflow Graft twist obstruction.
P170012/S001	05/02/2018	R - Real-Time Proc	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Approval for a modified design of the Hemoblast Bellows device applicator.

Total: 62

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S098	05/24/2018	X - 30-Day Notice	VISTAKON (ETAFILCON A) ACUVUE 2 BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Conversion of an existing production line to produce VISTAKON® (etafilcon A) ACUVUE® 2 Brand Contact Lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P790005/S063	05/04/2018	X - 30-Day Notice	EBI OSTEOGEN IMPANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Modifying and upgrading the Compressed Contact Air Utility System to replace the existing, legacy, compressed contact air system to conform to the company's newly adopted global engineering specification.
P790005/S064	05/07/2018	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Qualify and implement redesigned, manufacturing, work area layouts, installation of a new environmental monitoring (HEMS) system and complementary clean room equipment within the ISO Class 8 Environmentally Controlled Clean Room Area (CEA) and its corresponding ISO Class 8 Adjacent Gowning Room at Guaynabo, Puerto Rico Manufacturing and Distribution Facility.
P810006/S082	05/17/2018	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE, COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC - MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Change in the environmental monitoring procedures for detection of bioburden at the main cleanroom manufacturing area.
P830055/S199	05/02/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of cleaning agents for use in passivation and clean-line processing.
P830055/S200	05/29/2018	X - 30-Day Notice	ATTUNE REVISION TIBIAL AUGMENTS	DEPUY, INC.	New machining equipment for the ATTUNE Revision Tibial Augments and increased inspection frequency.
P830055/S201	05/22/2018	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Introduction of a new laser for marking the Femoral casting components of the LCS® Total Knee System that are casted at the DePuy Ireland Foundry manufacturing facility.
P830061/S158	05/31/2018	X - 30-Day Notice	CAPSURE SENSE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to process parameters for the blister process and acceptance criteria for minimum blister sealed width.
P840001/S395	05/11/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS, SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS, SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Change in supplier of battery electrolytes and cleaning agent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S396	05/24/2018	X - 30-Day Notice	MASTER RESTORE, ITREL, SYNERGY SND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Dimensional change, a dimensional system change, and a clarification of design intent on specifications for the manufacture and inspection of the Patient Programmers in response to complaints of battery compartment heating.
P840001/S397	05/31/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Removal of bias voltage during cool-down and removal of transfer time requirement for hybrid burn-in test.
P840062/S066	05/16/2018	X - 30-Day Notice	COLLACOTE, COLLATAPE, COLLAPLUG, ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	COLLA-TEC, INC.	Change in the environmental monitoring procedures for detection of bioburden at the main cleanroom manufacturing area.
P850010/S081	05/17/2018	X - 30-Day Notice	HELISTAT, HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Change in the environmental monitoring procedures for detection of bioburden at the main cleanroom manufacturing area.
P850035/S052	05/04/2018	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Modifying and upgrading the Compressed Contact Air Utility System to replace the existing, legacy, compressed contact air system to conform to the company's newly adopted global engineering specification.
P850035/S053	05/07/2018	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Qualify and implement redesigned, manufacturing, work area layouts, installation of a new environmental monitoring (HEMS) system and complementary clean room equipment within the ISO Class 8 Environmentally Controlled Clean Room Area (CEA) and its corresponding ISO Class 8 Adjacent Gowning Room at Guaynabo, Puerto Rico Manufacturing and Distribution Facility.
P860004/S303	05/11/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Change in supplier of battery electrolytes and cleaning agent.
P860004/S304	05/24/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Changes to the surface treatment used on select components of the SynchroMed II pumphead.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860004/S305	05/24/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Dimensional change, a dimensional system change, and a clarification of design intent on specifications for the manufacture and inspection of the Patient Programmers in response to complaints of battery compartment heating.
P860004/S306	05/31/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Removal of bias voltage during cool-down and removal of transfer time requirement for hybrid burn-in test.
P860057/S178	05/07/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Additional supplier of bovine pericardial tissue.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S179	05/31/2018	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS; THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; RSR PERICARDIAL AORTIC BIOPROSTHESIS; THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS; MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS; PLUS PERICARDIAL MITRAL BIOPROSTHESIS; THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS AND CARPENTIER-EDWARDS PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Increase the number of production personnel in Clean Room 4-1 at the Edwards Changi, Singapore facility.
P880081/S041	05/09/2018	X - 30-Day Notice	TECNIS CL	JOHNSON & JOHNSON SUGICAL VISION, INC.	Sterilization of the intraocular lens products manufactured at the Johnson & Johnson Vision Care manufacturing facility in Puerto Rico using vessel #4 and hot cell #5.
P880086/S298	05/03/2018	X - 30-Day Notice	ASSURITY, ASSURITY +, ENDURITY	ST. JUDE MEDICAL, INC.	Alternate supplier for organic substrate components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900009/S043	05/22/2018	X - 30-Day Notice	EXOGEN ULTRASOUND BONE HEALING SYSTEM	BIOVENTUS LLC	Add a new supplier of the transducer.
P900033/S070	05/17/2018	X - 30-Day Notice	DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Change in the environmental monitoring procedures for detection of bioburden at the main cleanroom manufacturing area.
P900060/S057	05/24/2018	X - 30-Day Notice	CARBOMEDICS PROSTHETIC HEART VALVE	SORIN GROUP ITALIA S.R.L	Use of automatic equipment to assess the integrity and functional characteristics of heart valves.
P910001/S104	05/08/2018	X - 30-Day Notice	CVX-300 EXCIMER LASER SYSTEM/ELCA CORONARY ATHERECTOMY CATHETER	SPECTRANETICS CORP.	Reduction of routine monitoring of the purified water system.
P910073/S149	05/16/2018	X - 30-Day Notice	ENDOTAK RELIANCE IS-1 LEAD FAMILY, ENDOTAK RELIANCE IS4 LEAD FAMILY, RELIANCE 4-FRONT LEAD FAMILY	BOSTON SCIENTIFIC	Add alternate drug identifying equipment.
P930039/S187	05/31/2018	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD	MEDTRONIC, INC.	Updates to process parameters for the blister process and acceptance criteria for minimum blister sealed width.
P940035/S015	05/17/2018	X - 30-Day Notice	ALERE NMP22 BLADDERCHEK TEST	ALERE SCARBOROUGH, INC	Change in the manufacturing process of the Alere NMP22® BladderChek® Test, in which standard parameter adjustments are needed in the manufacture of the stock conjugate due to the biological nature of the antibodies used
P950029/S122	05/14/2018	X - 30-Day Notice	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR	LIVANOVA USA, INC.	Addition of an alternate automated visual inspection for incoming inspection of die after dicing.
P960004/S084	05/16/2018	X - 30-Day Notice	FINELINE LL LEAD FAMILY	BOSTON SCIENTIFIC	Add alternate drug identifying equipment.
P960009/S312	05/11/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Change in supplier of battery electrolytes and cleaning agent.
P960009/S313	05/24/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Dimensional change, a dimensional system change, and a clarification of design intent on specifications for the manufacture and inspection of the Patient Programmers in response to complaints of battery compartment heating.
P960009/S314	05/31/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Removal of bias voltage during cool-down and removal of transfer time requirement for hybrid burn-in test.

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P960042/S060	05/08/2018	X - 30-Day Notice	SPECTRANETICS LASER SHEATHS SLS (SLS LL/ GLIDELIGHT)	SPECTRANETICS CORP.	Reduction of routine monitoring of the purified water system.
P960042/S061	05/31/2018	X - 30-Day Notice	SLS II/GLIDE LIGHT CATHETERS	SPECTRANETICS CORP.	Updates to the extrusion process and a new vendor for tubing components.
P970004/S269	05/11/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Change in supplier of battery electrolytes and cleaning agent.
P970004/S270	05/24/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Dimensional change, a dimensional system change, and a clarification of design intent on specifications for the manufacture and inspection of the Patient Programmers in response to complaints of battery compartment heating.
P970004/S271	05/31/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Removal of bias voltage during cool-down and removal of transfer time requirement for hybrid burn-in test.
P970051/S178	05/11/2018	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Change to the upper limit of a quality control test to check implant antenna tuning parameters.
P980016/S665	05/03/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICD< PRIMO MRI VR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduce the number of loop height measurements during laser ribbon bonding process monitoring.

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P980016/S666	05/02/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICD, PRIMO MRI VR ICD, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New battery electrolyte supplier.
P980016/S667	05/03/2018	X - 30-Day Notice	EVERA NRI DF-1 ICD, EVERA MRI ICD, EVERA S DR/VR ICD, EVERA XT DR/ VR ICD, MIRRO MRI DR/VR ICD, PRIMO MRI DR/VR ICD, PROTECTA ICD, PROTECTA VR/XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the hybrid burn-in manufacturing process step.
P980016/S669	05/04/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD< EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICD, PRIMO MRI VR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the seam weld and backfill manufacturing processes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S671	05/16/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XR DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICD, PRIMO MRI VR ICD, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD, SECURA ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the TEMPO software that is used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors.
P980016/S672	05/21/2018	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI VR ICD, PRIMO MRI DR ICD, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Manufacturing and inspection changes during capacitor manufacturing.
P980022/S204	05/30/2018	X - 30-Day Notice	PARADIGM REAL-TIME INSULIN PUMP, PARADIGM REAL-TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Change from a manual to an automated pull test system to decrease variability and increase production capacity for the Paradigm and 530G insulin pumps housing. The Paradigm insulin pumps are components of the Continuous Glucose Monitoring System, Paradigm REAL-Time Revel System, and Paradigm REAL-Time System and the MiniMed 530G pumps are components of the MiniMed 530G System.
P980035/S546	05/02/2018	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	New battery electrolyte supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S547	05/08/2018	X - 30-Day Notice	ADVISA DR IPG, ADVISA DDR MRI IPG AND ADVISA SR MRI IPG	MEDTRONIC INC.	New X-ray diffraction instrumentation and an updated test method for SVO analysis for battery manufacturing.
P980035/S548	05/03/2018	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR/SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA S DR/ SR/XT MRI IPG, AZURE S DR/SR MRI IPG, AZURE XT DR/SR MRI IPG	MEDTRONIC INC.	Modify the hybrid burn-in manufacturing process step.
P980035/S551	05/16/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT SR MRI IPG, ATTESTA DR MRI IPG, ATTESTA SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG, RELIA IPG, SPHERA DR MRI IPG AND SPHERA SR MRI IPG	MEDTRONIC INC.	Update the TEMPO software that is used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors.
P980035/S552	05/18/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ATTESTA IPG, RELIA IPG, SPHERA IPG	MEDTRONIC INC.	Implementation of new battery case laser marking equipment.
P980035/S554	05/31/2018	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA SR MRI IPG, ATTESTA DR/SR MRI IPG, SPHERA DR/SR MRI IPG	MEDTRONIC INC.	Updates to process parameters for the blister process and acceptance criteria for minimum blister sealed width.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980040/S088	05/09/2018	X - 30-Day Notice	SENSAR 1-PIECE IOL, TECNIS 1-PIECE IOL, TECNIS 1-PIECE OPTIBLUE IOL, PRELOADED TECNIS 1-PIECE IOL, PRELOADED TECNIS 1-PIECE OPTIBLUE IOL, TECNIS MULTIFOCAL 1-PIECE IOL, TECNIS SYMFONY EXTENDED RANGE OF VISION IOL, TECNIS ITEC PRELOADED DELIVERY SYSTEM, SENSAR 3-PIECE MONOFOCAL,	JOHNSON & JOHNSON SURGICAL VISION, INC.	Sterilization of the intraocular lens products manufactured at the Johnson & Johnson Vision Care manufacturing facility in Puerto Rico using vessel #4 and hot cell #5.
P980044/S045	05/25/2018	X - 30-Day Notice	SUPARTZ FX, VISCO-3	SEIKAGAKU CORP.	Installation of a clean booth to be used in the processing of a syringe component for SUPARTZ FX and VISCO-3.
P980049/S131	05/14/2018	X - 30-Day Notice	PARADYM VR, PARADYM DR, PARADYM RF VR, PARADYM RF DR (ZL 102) INTENSIA VR ICD, INTENSIA DR, PLATINIUM VR, PLATINIUM DR	LIVANOVA USA, INC.	Addition of an alternate automated visual inspection for incoming inspection of die after dicing.
P990056/S032	05/03/2018	X - 30-Day Notice	ELECSYS TOTAL PSA, TOTAL PSA CALSET LL	ROCHE DIAGNOSTICS CORP.	Add the cobas e 602 analyzer e-barcode for the associated lots of tPSA 200-test kit and the PreciControl Universal with the current target values.
P990080/S046	05/09/2018	X - 30-Day Notice	TECNIS 3-PIECE ACRYLIC MONOFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Sterilization of the intraocular lens products manufactured at the Johnson & Johnson Vision Care manufacturing facility in Puerto Rico using vessel #4 and hot cell #5.
P000015/S032	05/11/2018	X - 30-Day Notice	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Change to the upper limit of a quality control test to check implant antenna tuning parameters.
P000021/S037	05/14/2018	X - 30-Day Notice	DIMENSION TPSA FLEX REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Add an alternate Surlyn 1601-2 resin to manufacture Surlyn¿ Film used in the production of Dimension® Cuvette Canister Consumable.
P000053/S089	05/11/2018	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Work instruction changes and use of a cuff KRT bonding nest.
P000053/S090	05/14/2018	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Changes to the fluid resistor component manufacturing process, movement to a sampling plan, and removal of an incoming cleaning step.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S483	05/16/2018	X - 30-Day Notice	ACUITY SPIRAL LEAD FAMILY, ACUITY X4 LEAD FAMILY	BOSTON SCIENTIFIC CORP.	Add alternate drug identifying equipment.
P010013/S070	05/17/2018	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRAIL ABLATION DEVICE	HOLOGIC, INC.	Addition of the second supplier for the Thumb Pusher Component of the Novasure Disposable Device and the addition of the second supplier for the CO2 Cartridge 5-Pack Assembly.
P010014/S075	05/04/2018	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Upgrade from a manual cleaning procedure to an automated cleaning procedure and cold Nitric upgrade.
P010015/S365	05/02/2018	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	New battery electrolyte supplier.
P010015/S366	05/03/2018	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P, VIVA CRT-P,	MEDTRONIC INC.	Modify the hybrid burn-in manufacturing process step.
P010015/S367	05/08/2018	X - 30-Day Notice	CONSULTA, SYNCRA AND VIVA CRT-P	MEDTRONIC INC.	New X-ray diffraction instrumentation and an updated test method for SVO analysis for battery manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S370	05/16/2018	X - 30-Day Notice	CONSULTA CRT-P, PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P, SYNCRA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Update the TEMPO software that is used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors.
P010019/S065	05/22/2018	X - 30-Day Notice	LOTRAFILCON A SOFT CONTACT LENSES FOR EXTENDED WEAR	ALCON LABORATORIES, INC.	Expansion of front-end manufacturing capacity for lotrafolcon A lenses at the Alcon Malaysia production plant with an additional production line.
P010030/S105	05/18/2018	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Addition of a manual Pulse Screening Test to the device manufacturing and servicing processes.
P010031/S623	05/03/2018	X - 30-Day Notice	AMPLIA MR CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT_D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Reduce the number of loop height measurements during laser ribbon bonding process monitoring.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S624	05/02/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONSULTA CRT-D, PROTECTA 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	New battery electrolyte supplier.
P010031/S625	05/03/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, CONSULTA CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the hybrid burn-in manufacturing process step.
P010031/S627	05/04/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the seam weld and backfill manufacturing processes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S629	05/16/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONSULTA CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA XT CRT-D, VIVA S CRT-D AND VICA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the TEMPO software that is used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors.
P010031/S630	05/21/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Manufacturing and inspection changes during capacitor manufacturing.
P010047/S056	05/04/2018	X - 30-Day Notice	PROGEL PLEURAL AIR LEAK SEALANT	NEOMEND, INC.	Use of calibrated spray tips ('standards') in the flow rate testing process.
P020004/S152	05/24/2018	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS AND GORE EXCLUDER ILIAC BRANCH ENDOPRSTHESIS	W.L. GORE & ASSOCIATES,INC	Alternate test lab for impurities testing.
P020027/S032	05/14/2018	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Add an alternate Surlyn 1601-2 resin to manufacture Surlyn¿ Film used in the production of Dimension® Cuvette Canister Consumable.
P030035/S169	05/03/2018	X - 30-Day Notice	ALLURE, ALLURE QUADRA, QUADRA ALLURE MP	ST. JUDE MEDICAL, INC.	Alternate supplier for organic substrate components.
P030050/S029	05/23/2018	X - 30-Day Notice	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Addition of a second autoclave for the sterilization of process equipment used in the aseptic process of Sculptra and Sculptra Aesthetic.
P040027/S060	05/18/2018	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an alternate resin and updates to the specifications and sampling plan used in manufacture of the zipper fiber component of the GORE VIATORR TIPS Endoprosthesis and GORE VIATORR TIPS Endoprosthesis with Controlled Expansion.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040027/S061	05/24/2018	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS; GORE VIATORR TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION	W. L. GORE & ASSOCIATES, INC.	Alternate test lab for impurities testing.
P040037/S112	05/24/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Alternate test lab for impurities testing.
P040043/S099	05/24/2018	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Alternate test lab for impurities testing.
P040045/S097	05/04/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of an alternate test method for finished product release for VISTAKON (senofilcon A) Brand Contact Lenses.
P040047/S051	05/15/2018	X - 30-Day Notice	COAPTITE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Alternate (in-house) source for large calcium hydroxyapatite particles.
P050006/S065	05/24/2018	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER, GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Alternate test lab for impurities testing.
P050006/S068	05/31/2018	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Implementation of automated visual inspection equipment.
P050027/S012	05/22/2018	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Relocation of manufacturing of flexible cystoscope subassemblies.
P050028/S062	05/15/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Discontinue sterilization of vials/bottles and closures for reagents.
P050028/S063	05/04/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Modification of filling operations for a kit component.

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P050028/S064	05/15/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Increase the scale of bulk and vialing manufacturing processes.
P050047/S064	05/01/2018	X - 30-Day Notice	JUVEDERM ULTRA, ULTRA XC, ULTRA PLUS, AND JUVEDERM ULTRA PLUS XC	ALLERGAN	New ISO Class 8 cleanroom for use during the manufacturing of Juvéderm injectable gel products.
P050047/S065	05/04/2018	X - 30-Day Notice	JUVEDERM ULTRA, ULTRA XC, ULTRA PLUS, ULTRA PLUS XC	ALLERGAN	Additional frame to be used during sterilization of Juvederm injectable gel implants.
P060027/S096	05/14/2018	X - 30-Day Notice	PARADYM CRT-D, PARADYM RF CRT-D (ZL 102), INTENSIA CRT-D, PLATINIUM CRT-D, PLATINIUM 4LV CRT-D	LIVANOVA USA, INC.	Addition of an alternate automated visual inspection for incoming inspection of die after dicing.
P060030/S063	05/15/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Discontinue sterilization of vials/bottles and closures for reagents.
P060030/S064	05/04/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Modification of filling operations for a kit component.
P060037/S056	05/23/2018	X - 30-Day Notice	NEXGEN LPS-FLEX/LPS-MOBILE BEARING KNEE	ZIMMER, INC.	Addition of IMR Laboratories, located at Lansing, New York, USA and Louisville, Kentucky, USA as approved suppliers to complete cleaning residual analysis for validations and process monitoring of the final cleaning process for the NexGen LPS-Flex/LPS-Mobile Bearing Knee System components manufactured in Warsaw, Indiana, USA and Shannon, Ireland facilities.
P070026/S053	05/02/2018	X - 30-Day Notice	CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change to the machining process for hip stem components.
P070026/S054	05/02/2018	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of cleaning agents for use in passivation and clean-line processing.
P080010/S015	05/09/2018	X - 30-Day Notice	TECNIS 3-PIECE MULTIFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Sterilization of the intraocular lens products manufactured at the Johnson & Johnson Vision Care manufacturing facility in Puerto Rico using vessel #4 and hot cell #5.

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P080025/S164	05/11/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Change in supplier of battery electrolytes and cleaning agent.
P080025/S165	05/24/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Dimensional change, a dimensional system change, and a clarification of design intent on specifications for the manufacture and inspection of the Patient Programmers in response to complaints of battery compartment heating.
P080025/S166	05/31/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Removal of bias voltage during cool-down and removal of transfer time requirement for hybrid burn-in test.
P090013/S278	05/02/2018	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	New battery electrolyte supplier.
P090013/S279	05/08/2018	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	New X-ray diffraction instrumentation and an updated test method for SVO analysis for battery manufacturing.
P090013/S280	05/03/2018	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Modify the hybrid burn-in manufacturing process step.
P090013/S283	05/16/2018	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Update the TEMPO software that is used to apply, collect, and record data from the Helium Leak Test on batteries and capacitors.
P090013/S284	05/31/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Updates to process parameters for the blister process and acceptance criteria for minimum blister sealed width.
P100020/S030	05/15/2018	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinue sterilization of vials/bottles and closures for reagents.
P100021/S070	05/03/2018	X - 30-Day Notice	ENDURANT, ENDURANT II, ENDURANT IIS	MEDTRONIC VASCULAR	Modifications to the stent ring finishing process for the Endurant, Endurant II and Endurant IIs Stent Graft Systems.
P100021/S071	05/03/2018	X - 30-Day Notice	TALENT OCCLUDER	MEDTRONIC VASCULAR	Modifications to the stent ring finishing process for the Talent Occluder and Valiant Captivia devices.
P100040/S035	05/03/2018	X - 30-Day Notice	VALIANT CAPTIVIA	MEDTRONIC VASCULAR	Modifications to the stent ring finishing process for the Talent Occluder and Valiant Captivia devices.
P100047/S121	05/24/2018	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change that would harmonize components used on the HVAD Controller.
P110002/S021	05/15/2018	X - 30-Day Notice	LDR SPINE MOBI-C CERVICAL DISC PROSTHESIS (ONE LEVEL)	LDR SPINE USA	Update the cutting fluid and bactericidal agent for the machines used to manufacture Mobi-C components.

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P110009/S021	05/15/2018	X - 30-Day Notice	LDR SPINE MOBI-C CERVICAL DISC PROSTHESIS (TWO LEVEL)	LDR SPINE USA INC.	Update the cutting fluid and bactericidal agent for the machines used to manufacture Mobi-C components.
P110010/S156	05/22/2018	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Implement a new laser cutting system.
P110033/S038	05/01/2018	X - 30-Day Notice	JUVEDERM VOLUMA XC, VOLLURE XC, AND JUVEDERM VOLBELLA XC	ALLERGAN	New ISO Class 8 cleanroom for use during the manufacturing of Juvéderm injectable gel products.
P110033/S039	05/04/2018	X - 30-Day Notice	VOLUMA XC, VOLLURE XC, VOLBELLA XC	ALLERGAN	Additional frame to be used during sterilization of Juvederm injectable gel implants.
P110037/S035	05/15/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Discontinue sterilization of vials/bottles and closures for reagents.
P110037/S036	05/04/2018	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN CMV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Modification of filling operations for a kit component.
P110041/S005	05/23/2018	X - 30-Day Notice	ADVIA CENTAUR HBSLL	SIEMENS CORP.	Implement second and third tier standards with more robust QC testing.
P110042/S107	05/15/2018	X - 30-Day Notice	EMBLEM MRI S-CD/ EMBLEM S-CD PULSE GENERATOR (PG)	BOSTON SCIENTIFIC CORPORATION	Add Boston Scientific as a second supplier for Digital ASIC electrical testing and to implement other minor process updates.
P110042/S109	05/08/2018	X - 30-Day Notice	S-ICD BATTERY ANODE LASER EDGE WELD PROCESS	BOSTON SCIENTIFIC CORPORATION	Modification to the S-ICD battery anode laser weld process.
P120010/S115	05/23/2018	X - 30-Day Notice	MEDTRONIC MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of contamination controls at a supplier during manufacturing of liquid glucose oxidase. The glucose oxidase is used in production of Enlite and Guardian glucose sensors.
P120010/S116	05/30/2018	X - 30-Day Notice	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	Change from a manual to an automated pull test system to decrease variability and increase production capacity for the Paradigm and 530G insulin pumps housing. The Paradigm insulin pumps are components of the Continuous Glucose Monitoring System, Paradigm REAL-Time Revel System, and Paradigm REAL-Time System and the MiniMed 530G pumps are components of the MiniMed 530G System.

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P130006/S051	05/24/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS, GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Alternate test lab for impurities testing.
P130009/S089	05/07/2018	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Additional supplier of bovine pericardial tissue.
P130009/S090	05/31/2018	X - 30-Day Notice	SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Increase the number of production personnel in Clean Room 4-1 at the Edwards Changi, Singapore facility.
P130030/S051	05/22/2018	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Implement a new laser cutting system.
P140002/S016	05/24/2018	X - 30-Day Notice	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Changes to the stent mounting and inspection processes.
P140003/S032	05/18/2018	X - 30-Day Notice	IMPELLA 2.5 AND IMPELLA CP VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC.	Addition of second supplier for a component of the Impella 2.5 and Impella CP as well as minor changes to the inspection checklist.
P140003/S034	05/24/2018	X - 30-Day Notice	IMPELLA 2.5, IMPELLA CP VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Add a second supplier for the Pressure Cube component of the Impella 2.5 System and Impella CP System.
P140003/S035	05/25/2018	X - 30-Day Notice	IMPELLA 2.5 AND IMPELLA CP VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Upgrade the laser welding workstation and associated Computer Numeric Control (CNC) program for the manufacture of the Pump Motor Assembly of the Impella 2.5 System and Impella CP System.
P140030/S006	05/16/2018	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Change to replace an extrusion machine used to produce various component tubes with a new extrusion machine.
P140030/S007	05/15/2018	X - 30-Day Notice	ASTRON PULSAR/ PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Multiple changes to the measurement and laser cutting processes for the stent component.
P140031/S065	05/07/2018	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Additional supplier of bovine pericardial tissue.

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P140031/S066	05/31/2018	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Increase the number of production personnel in Clean Room 4-1 at the Edwards Changi, Singapore facility.
P140032/S004	05/11/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Change in supplier of battery electrolytes and cleaning agent.
P140032/S007	05/31/2018	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Removal of bias voltage during cool-down and removal of transfer time requirement for hybrid burn-in test.
P140033/S029	05/03/2018	X - 30-Day Notice	ENDURITY MRI, ASSURITY MRI	ST. JUDE MEDICAL, INC.	Alternate supplier for organic substrate components.
P140033/S030	05/29/2018	X - 30-Day Notice	TENDRIL MRI	ST. JUDE MEDICAL, INC.	Change the test article from full leads to distal subassemblies for the attributes of identification, assay, content uniformity, impurities, degradation products, and elution for batch release testing.
P150001/S042	05/23/2018	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Addition of contamination controls at a supplier during manufacturing of liquid glucose oxidase. The glucose oxidase is used in production of Enlite and Guardian glucose sensors.
P150004/S022	05/19/2018	X - 30-Day Notice	DRG LEAD EXTENSION KIT, SLIMTIP DRG TRIAL/ IMPLANT LEAD KIT	ST. JUDE MEDICAL	Addition of the St. Jude Medical Portland facility as an alternate location for the extrusion of the conductor wires used in the Dorsal Root Ganglion (DRG) leads and extensions.
P150012/S059	05/16/2018	X - 30-Day Notice	INGEVITY LEAD FAMILY	BOSTONSCIENTIFIC	Add alternate drug identifying equipment.
P150014/S015	05/04/2018	X - 30-Day Notice	COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Modification of filling operations for a kit component.
P150015/S014	05/04/2018	X - 30-Day Notice	COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Modification of filling operations for a kit component.
P150016/S013	05/04/2018	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Use of calibrated spray tips ('standards') in the flow rate testing process.
P150019/S041	05/23/2018	X - 30-Day Notice	MEDTRONIC MINIMED PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of contamination controls at a supplier during manufacturing of liquid glucose oxidase. The glucose oxidase is used in production of Enlite and Guardian glucose sensors.
P150019/S042	05/30/2018	X - 30-Day Notice	PARADIGM REAL-TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Change from a manual to an automated pull test system to decrease variability and increase production capacity for the Paradigm and 530G insulin pumps housing. The Paradigm insulin pumps are components of the Continuous Glucose Monitoring System, Paradigm REAL-Time Revel System, and Paradigm REAL-Time System and the MiniMed 530G pumps are components of the MiniMed 530G System.

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P150029/S018	05/23/2018	X - 30-Day Notice	MEDTRONIC MINIMED IPRO2 CGM SYSTEM WITH ELITE SENSOR	MEDTRONIC MINIMED	Addition of contamination controls at a supplier during manufacturing of liquid glucose oxidase. The glucose oxidase is used in production of Enlite and Guardian glucose sensors.
P150033/S034	05/02/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	New battery electrolyte supplier.
P150033/S035	05/03/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Modify the hybrid burn-in manufacturing process step.
P150036/S029	05/07/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM, AORTIC VALVE MODEL 8300AB AND DELIVERY SYSTEM MODEL 8300DB	EDWARDS LIFESCIENCES, LLC.	Additional supplier of bovine pericardial tissue.
P150036/S030	05/31/2018	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Increase the number of production personnel in Clean Room 4-1 at the Edwards Changi, Singapore facility.
P150037/S009	05/30/2018	X - 30-Day Notice	CYPASS MICRO-STENT	ALCON RESEARCH, LTD	Addition of an alternate additional vendor for the stent cleaning step of the CyPass Micro-Stent manufacturing process.
P150038/S007	05/09/2018	X - 30-Day Notice	EXABLATE 4000 SYSTEM	INSIGHTEC	Consolidate the two connector types of the 1.5T Head Coil cables into a single connector type (P-Type). The change is being made to maintain compatibility with the GE Medical Systems (GE) Signa Artist MR scanner.
P150048/S020	05/07/2018	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS, EDWARDS INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Additional supplier of bovine pericardial tissue.
P150048/S022	05/31/2018	X - 30-Day Notice	EDWARDS INSPIRIS RESILIA AORTIC VALVE AND EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Increase the number of production personnel in Clean Room 4-1 at the Edwards Changi, Singapore facility.
P160001/S016	05/31/2018	X - 30-Day Notice	OBALON BALLOON KIT	OBALON THERAPEUTICS, INC.	Change in the adhesive dispensing process by adding an alternate syringe piston.
P160003/S004	05/16/2018	X - 30-Day Notice	PRO-KINETIC ENERGY CORONARY STENT SYSTEM	BIOTRONIK, INC.	Change to replace an extrusion machine used to produce various component tubes with a new extrusion machine.
P160004/S009	05/24/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Alternate test lab for impurities testing.

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P160007/S001	05/23/2018	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Addition of contamination controls at a supplier during manufacturing of liquid glucose oxidase. The glucose oxidase is used in production of Enlite and Guardian glucose sensors.
P160017/S040	05/23/2018	X - 30-Day Notice	MEDTRONIC MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of contamination controls at a supplier during manufacturing of liquid glucose oxidase. The glucose oxidase is used in production of Enlite and Guardian glucose sensors.
P160021/S006	05/24/2018	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Alternate test lab for impurities testing.
P160022/S002	05/29/2018	X - 30-Day Notice	ONESTEP PACING CABLE ASSEMBLY USED WIT R SERIES DEVICE	ZOLL MEDICAL CORPORATION	Change the manufacturing site location of its accessories supplier for the R Series device to another existing facility.
P160022/S003	05/18/2018	X - 30-Day Notice	MFC-CPRD CABLE ASSEMBLY USED WITH X SERIES AND R SERIES DEVICE	ZOLL MEDICAL CORPORATION	Change the manufacturing site location of its cable accessories manufacturing operations for the R Series and X Series device to another existing facility.
P160023/S003	05/17/2018	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Relocation for manufacture of a reagent sub-component to an approved manufacturing site and subsequent changes to filling operations for a reagent component.
P160025/S004	05/16/2018	X - 30-Day Notice	ASTRON PULSAR/ PULSAR-18 STENT SYSTEMS	BIOTRONIK, INC.	Change to replace an extrusion machine used to produce various component tubes with a new extrusion machine.
P160038/S003	05/01/2018	X - 30-Day Notice	MISEQDX PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Reagent supplier site change.
P160041/S008	05/04/2018	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Modification of filling operations for a kit component.
P160045/S006	05/25/2018	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Modify the current Fill/Finish activities of Ion PGM reagent kits.
P170012/S003	05/10/2018	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Change in the method to measure the in-process water content of the collagen powder component.
P170025/S003	05/17/2018	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Relocation for manufacture of a reagent sub-component to an approved manufacturing site and subsequent changes to filling operations for a reagent component.

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