PMA Monthly approvals from 2/1/2017 to 2/28/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150039	02/21/2017	PMAO - PMA Origi	TRYTON SIDE BRANCH STENT	TRYTON MEDICAL, INC.	Approval for the TRYTON Side Branch Stent. This device is indicated for improving the side branch luminal diameter of de novo native coronary artery bifurcation lesions (Medina Classification 1.1.1; 0.1.1; 1.0.1) with a side branch diameter stenosis of >=50% and a lesion length <=5.0 mm, along with reference vessel diameters >=2.5 mm to <=3.5 mm in the side branch and >=2.5 mm to <=4.0 mm in the main branch. The device is intended for use in conjunction with commercially available balloon expandable drug-eluting coronary stents in the main branch.
P160003	02/14/2017	PMAO - PMA Origi	PRO-KINETIC ENERGY COBALT CHROMIUM (COCR) CORONARY STENT SYSTEM	BIOTRONIK, INC.	Approval for the PRO-Kinetic Energy Cobalt Chromium (CoCr) Coronary Stent System. This device is indicated for improving coronary luminal diameter in patients with de novo or restenotic lesions in native coronary arteries with a reference vessel diameter ranging from 2.25 mm to 4.0 mm and lesion length <= 31 mm.
P160014	02/21/2017	PMAO - PMA Origi	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES , INC.	Approval for the COBRA PzF NanoCoated Coronary Stent System is indicated for improving coronary luminal diameter in patients, including patients with diabetes mellitus, with symptomatic ischemic heart disease due to do novo lesions in native coronary arteries. The COBRA PzF Stent System is intended for use in patients eligible for percutaneous transluminal coronary angioplasty (PTCA) with a reference vessel diameter of 2.5-4.0 mm and lesion length of <24 mm.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160023	02/13/2017	PMAO - PMA Origi	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Approval for the Aptima HCV Quant Dx. This device is indicated for: The Aptima HCV Quant Dx Assay is a real-time transcription mediated amplification test (TMA) used for both detection and quantitation of hepatitis C virus (HCV) RNA in fresh and frozen human serum and plasma from HCV-infected individuals. Plasma may be prepared in ethylenediaminetetraacetic acid (EDTA), anticoagulant citrate dextrose (ACD) solution, and plasma preparation tubes (PPT). Serum may be prepared in serum tubes and serum separator tubes (SST). Specimens are tested using the Panther system for automated specimen processing, amplification, detection, and quantitation. Specimens containing HCV genotypes 1 to 6 are validated for detection and quantitation in the assay. The Aptima HCV Quant Dx Assay is indicated for use as an aid in the diagnosis of active HCV infection in the following populations: individuals with antibody evidence of HCV infection with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and, therefore, is evidence of active infection. Detection of HCV RNA does not discriminate between acute and chronic state of infection. The Aptima HCV Quant Dx Assay is also indicated for use as an aid in the management of HCV infected patients undergoing HCV antiviral drug therapy. The assay can be used to measure HCV RNA levels periodically prior to, during, and after treatment to determine sustained virological response (SVR) or nonsustained virological response (NSVR). Assay performance characteristics have been established for individuals infected with HCV and treated with certain direct acting antiviral agents (DAA) regimens. No information is available on the assay¿s predictive value when other therapies are used. The results from the Aptima HCV Quant Dx Assay must be interpreted within the context of all relevant clinical and laboratory findings. The Aptima HCV Quant Dx Assay is not approved for use as a screening test for the presence of HCV RNA in blood or blood products.
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Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement

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N970003/S200	02/16/2017	R - Real-Time Proc	ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT, INSIGNIA, ALTRUA 2	BOSTON SCIENTIFIC CORP.	Approval for Model 6290 Patient Communicator software update to version 2.22.00.
N970012/S121	02/10/2017	R - Real-Time Proc	AMBICOR INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Approval for minor changes to dimensions and tolerances on the Ambicor device engineering drawings as part of ongoing remediation activities to align the engineering drawings with historical design intent and current manufacturing.
P810025/S038	02/17/2017	N - Normal 180 Day	AMVISC & AMVISC PLUS OVD	BAUSCH & LOMB, INC.	Approval for the addition of a cannula retention clip to be packaged with both the Amvisc and Amvisc Plus sodium hyaluronate (NaHy) solutions.
P840001/S352	02/07/2017	S - Special CBE	RESTORE ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for labeling changes which identify new potential adverse reactions, improve instructions for avoiding device inversion, and update radiation safety labeling.
P860047/S033	02/21/2017	N - Normal 180 Day	OCUCOAT OVD	BAUSCH & LOMB, INC.	Approval for the addition of a cannula retention clip to be packaged with both the Amvisc and Amvisc Plus sodium hyaluronate (NaHy) solutions.
P870076/S022	02/21/2017	N - Normal 180 Day	FALOPE RING BAND AND APPLICATOR SYSTEMS	GYRUS ACMI, INC.	Approval for a manufacturing site located at Ethox International, Inc., 2710 Northridge Drive NW Suite A, Grand Rapids, MI 49544-9112, as a packaging facility.
P890003/S369	02/17/2017	R - Real-Time Proc	MEDTRONIC MYCARELINK PATIENT MONITOR MODEL	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware changes (version M8.0) to the MyCareLink Patient Monitor Model 24950.
P890003/S371	02/14/2017	R - Real-Time Proc	VISIA AF SOFTWARE SW035 VERSION 8.1	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a software update to address minor output anomolies.
P910077/S157	02/16/2017	R - Real-Time Proc	LATITUDE¿ NXT PATIENT MANAGEMENT SYSTEM, LATITUDE WAVE COMMUNICATOR	BOSTON SCIENTIFIC	Approval for Model 6290 Patient Communicator software update to version 2.22.00.
P930014/S097	02/14/2017	N - Normal 180 Day	ACRYSOF IQ TORIC IOL WITH THE ULTRASERT PRE LOADED DELIVERY SYSTEM MODELS	ALCON RESEARCH, LTD.	Approval for the edits to the physician labeling for the AcrySof® IQ Toric IOL with the UltraSert ¿ Pre-Loaded Delivery System, Models AU00T3, AU00T4, AU00T5, AU00T6, AU00T7, AU00T8, AU00T9.

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P930021/S017	02/17/2017	Y - 135 Review Tra	STRAUMANN EMDOGAIN	THE STRAUMANN COMPANY	Approval for design changes to the syringe packaging and manufacturing changes for in-house secondary packaging by Biora AB.
P950020/S079	02/09/2017	O - Normal 180 Day	WOLVERINE CORONARY CUTTING BALLOON (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corporation, Two Scimed Place, Maple Grove, Minnesota, for the ZGlide manufacturing process and application.
P950037/S164	02/08/2017	N - Normal 180 Day	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for the ProMRI VR-T System.
P950037/S169	02/10/2017	R - Real-Time Proc	PULSE GENERATOR, PERMANENT, IMPLANTABLE	BIOTRONIK, INC.	Approval of minor modifications to the SAW filter and antenna.
P960040/S386	02/16/2017	R - Real-Time Proc	TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN	BOSTON SCIENTIFIC	Approval for Model 6290 Patient Communicator software update to version 2.22.00.
P970031/S054	02/07/2017	R - Real-Time Proc	MEDTRONIC FREESTYLE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Approval for changes to the labeling content and format for the Mosaic, Hancock II, and Freestyle Bioprostheses.
P980016/S610	02/02/2017	R - Real-Time Proc	EVERA MRI DF-1 ICD, EVERA MRI IDC, 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 a minor design change and associated manufacturing changes to the Medtronic Advanced Valve Metal (AVM) Capacitor Feedthrough.
P980016/S613	02/17/2017	R - Real-Time Proc	EVERA MRI, EVERA, MARQUIS, SECURA, MAXIMO II, INTRINSIC, PROTECTA, PROTECTA XT,	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware changes (version M8.0) to the MyCareLink Patient Monitor Model 24950.
P980016/S615	02/14/2017	R - Real-Time Proc	VISIA AF SOFTWARE SW035 VERSION 8.1	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for software updates to address negative artifacts.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980023/S076	02/08/2017	N - Normal 180 Day	LINOX SMART/PROTEGO (PROMRI) S 65;LINOX SMART/PROTEGO (PROMRI) S 75;LINOX SMART/PROTEGO (PROMRI) SD 65/16;LINOX SMART/PROTEGO (PROMRI) SD 65/18;LINOX SMART/PROTEGO (PROMRI) SD 75/18	BIOTRONIK, INC.	Approval for the ProMRI VR-T System.
P980035/S485	02/17/2017	R - Real-Time Proc	ADAPTA, VERSA, SENSIA, ADVISA, ADVISA MRI, ENPULSE, KAPPA	MEDTRONIC INC.	Approval for firmware changes (version M8.0) to the MyCareLink Patient Monitor Model 24950.
P980037/S059	02/23/2017	Y - 135 Review Tra	ANGIOJET ULTRA XMI/ SPIROFLEX/SPIROFLEX VG/DISTAFLEX THROMBECTOMY SET'S	BOSTON SCIENTIFIC CORP.	Approval for modified silicone o-ring formulation.
P980043/S056	02/07/2017	R - Real-Time Proc	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Approval for changes to the labeling content and format for the Mosaic, Hancock II, and Freestyle Bioprostheses.
P990009/S044	02/10/2017	N - Normal 180 Day	FLOSEAL HEMOSTATIC MATRIX	BAXTER HEALTHCARE CORP.	Approval for modifications to the device design, material, labeling, and packaging, including: replacement of the 10 mL syringe assembly to align with the current 5 mL syringe design, removal of bowel for thrombin, removal of thrombin stickers, removal of malleable tip applicator (10 mL configuration only), removal of luer connector (10 mL configuration only), modification to the needle-free vial access device (VAD), incorporation of thrombin pouch assembly, modification of diluent container, removal of plastic component tray, modification to kit box (5 mL configuration only), and labeling modifications corresponding to the aforementioned modifications.
P990064/S065	02/07/2017	R - Real-Time Proc	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC HEART VALVES	Approval for changes to the labeling content and format for the Mosaic, Hancock II, and Freestyle Bioprostheses.
P990074/S036	02/17/2017	R - Real-Time Proc	NATRELLE SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for minor design modifications to previously approved packaging configurations and the use of this packaging with additional devices.
P000009/S067	02/08/2017	N - Normal 180 Day	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for the ProMRI VR-T System.
P000025/S089	02/16/2017	N - Normal 180 Day	SONNET/SONNET EAS AUDIO PROCESSORS AND MAESTRO 6.0	MED-EL CORP.	Approval for the new front end cochlear implant signal processing features (Microphone Directionality and Wind Noise Reduction) in the SONNET and SONNET EAS audio processors and the fitting of these features with the MAESTRO 6.0 software.¿

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P000037/S048	02/07/2017	O - Normal 180 Day	ON-X (R) PROSTHETIC HEART VALVE, ON-X CONFORM-X AORTIC PROSTHETIC HEART VALVE, ON-X AORTIC PROSTHETIC HEART VALVE WITH ANATOMIC SEWING RING	ON-X LIFE TECHNOLOGIES, INC.	Approval for multiple changes, including clinical changes to the current protocol for the post-approval study (PAS) protocol.
P010003/S023	02/10/2017	Y - 135 Review Tra	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Approval for changes in the molding parameters used in the manufacturing of the 5 mL BioGlue container, as well as the addition of a new resin for molding portions of all BioGlue containers used with the BioGlue Surgical Adhesive.
P010012/S439	02/16/2017	R - Real-Time Proc	CRT D RESYNCHRONIZATION DEVICES, COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN	BOSTON SCIENTIFIC CORP.	Approval for Model 6290 Patient Communicator software update to version 2.22.00.
P010015/S315	02/17/2017	R - Real-Time Proc	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for firmware changes (version M8.0) to the MyCareLink Patient Monitor Model 24950.
P010030/S067	02/24/2017	N - Normal 180 Day	HOSPITAL WEARABLE DEFIBRILLATOR (HWD 1000)	ZOLL MANUFACTURING CORPORATION	Approval for the HWD 1000 System. This is a wearable defibrillation for hospital use that is based on the previously approved LifeVest Wearable Cardioverter Defibrillator (WCD) 4000 design as a platform and incorporates design features from the previously approved WCD 3000S.
P010031/S570	02/02/2017	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 SQUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a minor design change and associated manufacturing changes to the Medtronic Advanced Valve Metal (AVM) Capacitor Feedthrough.

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P010031/S573	02/17/2017	R - Real-Time Proc	VIVA, BRAVA, PROTECTA, PROTECTA XT, CONCERTO, CONCERTO II, CONSULTA, MAXIMO II,	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware changes (version M8.0) to the MyCareLink Patient Monitor Model 24950.
P010032/S127	02/03/2017	N - Normal 180 Day	LGW	ST. JUDE MEDICAL	Approval for an updated version (v 3.4) of Clinician Programmer and Patient Controller software to enable the Surgery Mode and Device Status check feature in the Proclaim Elite, Infinity, and Proclaim DRG family of implanted pulse generators (IPGs).
P020025/S094	02/09/2017	R - Real-Time Proc	INTELLANAV XP TEMPERATURE ABLATION CATHETERS	BOSTON SCIENTIFIC	Approval for a design change to the thermistor wire insulating material
P020056/S038	02/17/2017	R - Real-Time Proc	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for minor design modifications to previously approved packaging configurations and the use of this packaging with additional devices.
P030005/S148	02/16/2017	R - Real-Time Proc	CRT-P RESYNCHRONIZATION DEVICES, INVIVE, INTUA, VISIONIST, VALITUDE	GUIDANT CORP.	Approval for Model 6290 Patient Communicator software update to version 2.22.00.
P030009/S089	02/01/2017	Y - 135 Review Tra	INTEGRITY CORONARY STENT SYSTEM	MEDTRONIC IRELAND	Approval for updated in-process sampling requirements and to remove redundant inspections.
P040046/S019	02/17/2017	R - Real-Time Proc	NATRELLE HIGHLY COHESIVE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for minor design modifications to previously approved packaging configurations and the use of this packaging with additional devices.
P050023/S101	02/08/2017	N - Normal 180 Day	IPERIA 7 VR-T/INVENTRA 7 VR-T (DF-1); IPERIA 7 VR-T/ INVENTRA 7 VR-T (DF4)	BIOTRONIK, INC.	Approval for the ProMRI VR-T System.
P070008/S074	02/08/2017	N - Normal 180 Day	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for the ProMRI VR-T System.
P070008/S077	02/10/2017	R - Real-Time Proc	PULSE GENERATOR, PACEMAKER, IMPLANTABLE, WITH CARDIAC RESYNCHRONIZATION (CRT-P)	BIOTRONIK, INC.	Approval of minor modifications to the SAW filter and antenna.
P070015/S134	02/21/2017	Y - 135 Review Tra	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM; XIENCE NANO EECSS	ABBOTT VASCULAR INC.	Approval for the use of an alternate test method, Fourier Transform Near Infra-Red Spectroscopy (FT-NIR), for the testing of in-process drug coating solution. This method will be used as an alternate to the current High Performance Liquid Chromatography (HPLC) methods.

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P070027/S048	02/01/2017	Y - 135 Review Tra	TALENT OCCLUDER WITH OCCLUDER DELIVERY SYSTEM	MEDTRONIC VASCULAR	Approval for updated in-process sampling requirements and to remove redundant inspections.
P090006/S019	02/01/2017	Y - 135 Review Tra	COMPLETE SE VASCULAR STENT SYSTEM¿ ILIAC	MEDTRONIC VASCULAR	Approval for updated in-process sampling requirements and to remove redundant inspections.
P090013/S243	02/17/2017	R - Real-Time Proc	REVO MRI	MEDTRONIC, INC	Approval for firmware changes (version M8.0) to the MyCareLink Patient Monitor Model 24950.
P100021/S057	02/01/2017	Y - 135 Review Tra	ENDURANT/ENDURANT II/ ENDURANT IIS STENT GRAFT	MEDTRONIC VASCULAR	Approval for updated in-process sampling requirements and to remove redundant inspections.
P100021/S058	02/23/2017	N - Normal 180 Day	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval to transfer device component of the Talent Occluder to Endurant Stent Graft System.
P100040/S028	02/01/2017	Y - 135 Review Tra	VALIANT THORACIC STENT GRAFT SYSTEM WITH CAPTIVIA DELIVERY SYSTEM	MEDTRONIC VASCULAR	Approval for updated in-process sampling requirements and to remove redundant inspections.
P100044/S023	02/23/2017	P - Panel Track	PROPEL CONTOUR SINUS IMPLANT	INTERSECT ENT	Approval of the PROPEL Contour Sinus Implant. This device is indicated for use in patients greater than or equal to 18 years of age to maintain patency of the frontal and maxillary sinus ostia following sinus surgery and locally deliver steroids to the sinus mucosa. The PROPEL Contour Sinus Implant separates/dilates mucosal tissues, prevents obstruction by adhesions/ scarring, and reduces edema. The implant reduces the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids.
P100045/S014	02/14/2017	R - Real-Time Proc	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for use of the i3 (CM1100) of the Patient Electronics System, a subsystem of the CardioMEMS HF System
P100045/S018	02/14/2017	O - Normal 180 Day	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for changes to the protocol, such as Quality of Life evaluations as well as minor clarifications for the post-approval study (PAS) protocol.
P110004/S021	02/10/2017	O - Normal 180 Day	NIRXCELL PMS US STUDY NIRTRAKS	MEDINOL LTD.	Approval for cessation of patient enrollment in this PAS for the post-approval study (PAS).
P110011/S013	02/01/2017	Y - 135 Review Tra	ASSURANT COBALT ILIAC BALLOON-EXPANDABLE STENT SYSTEM	MEDTRONIC IRELAND	Approval for updated in-process sampling requirements and to remove redundant inspections.
P110013/S075	02/01/2017	Y - 135 Review Tra	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Approval for updated in-process sampling requirements and to remove redundant inspections.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110016/S025	02/17/2017	N - Normal 180 Day	FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC.	Approval for the FlexAbility Ablation Catheter, Sensor Enabled is intended for use with the compatible irrigation pump and a compatible RF cardiac ablation generator. The catheter is intended for creating focal endocardial lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of typical atrial flutter.
P110019/S087	02/21/2017	Y - 135 Review Tra	XIENCE PRIME,XIENCE XPEDITION,XIENCE ALPINE,EVEROLIMUS ELUTING CORONARY STENT SYSTEM, SV (2.25) LL	ABBOTT VASCULAR	Approval for Fourier Transform Near Infra-Red Spectroscopy (FT-NIR), which will be used as an alternate test method to high performance liquid chromatography (HPLC) methods for drug coating solution analysis.
P110022/S020	02/28/2017	R - Real-Time Proc	COBAS E 601	ROCHE DIAGNOSTICS CORP.	Approval for the addition of K3-EDTA plasma as a specimen type for the Elecsys Anti-HBc IgM immunoassay for use on the cobas e 411, cobas e 601, cobas e 602, and MODULAR ANALYTICS E170 analyzers.
P110025/S018	02/28/2017	R - Real-Time Proc	MODULAR ANALYSTICS E170	ROCHE DIAGNOSTICS CORP.	Approval for the addition of K3-EDTA plasma as a specimen type for the Elecsys Anti-HBc IgM immunoassay for use on the cobas e 411, cobas e 601, cobas e 602, and MODULAR ANALYTICS E170 analyzers.
P110031/S017	02/28/2017	R - Real-Time Proc	COBAS E 411	ROCHE DIAGNOSTICS CORP.	Approval for the addition of K3-EDTA plasma as a specimen type for the Elecsys Anti-HBc IgM immunoassay for use on the cobas e 411, cobas e 601, cobas e 602, and MODULAR ANALYTICS E170 analyzers.
P110035/S035	02/03/2017	Y - 135 Review Tra	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for several process changes that include qualification of a new wetline, new final cleaning equipment, a new manufacturing data system, and qualification of unchanged equipment moved from the Plymouth facility to the Maple Grove facility.
P110040/S011	02/01/2017	Y - 135 Review Tra	COMPLETE SE VASCULAR STENT SYSTEM-SFA AND PPA	MEDTRONIC VASCULAR	Approval for updated in-process sampling requirements and to remove redundant inspections.
P110042/S070	02/16/2017	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM EMBLEM	BOSTON SCIENTIFIC CORPORATION	Approval for Model 6290 Patient Communicator software update to version 2.22.00.
P120020/S014	02/01/2017	Y - 135 Review Tra	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Approval for the removal of the in-process dimensional inspection of the nitinol wire diameter before and after the passivation process.
P120021/S001	02/06/2017	O - Normal 180 Day	AMPLATZER PFO OCCLUDER	ST. JUDE MEDICAL, INC.	Approval to add an alternate sterilization facility and to modify the sterilization packaging configuration.
P130005/S015	02/23/2017	O - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval for a manufacturing site located at Isomedix Operations, Inc., 1435 Isomedix Place El Paso, TX 79936, Contract sterilizer.

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P130024/S009	02/07/2017	P - Panel Track	LUTONIX 035 DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval for Lutonix DCB is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
P130028/S013	02/07/2017	S - Special CBE	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATIO N	Approval for quality control changes that impact the manufacturing process for Algovita Percutaneous Leads and Trial Leads
P130030/S031	02/23/2017	R - Real-Time Proc	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL	BOSTON SCIENTIFIC CORP.	Approval for changes to the manufacturing process and design of the Distal Outer component of the Monorail stent delivery system.
P130030/S035	02/09/2017	O - Normal 180 Day	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER THE WIRE)	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corporation, Two Scimed Place, Maple Grove, Minnesota, for the ZGlide manufacturing process and application.
P140004/S007	02/21/2017	O - Normal 180 Day	SUPERION INTERSPINOUS SPACER	VERTIFLEX (R), INCORPORAT ED	Approval of minor modifications to the protocol for the post-approval study (PAS) protocol.
P140009/S022	02/03/2017	N - Normal 180 Day	MHY	ST. JUDE MEDICAL NEUROMODU LATION	Approval of an updated version (v 3.4) of Clinician Programmer and Patient Controller software to enable the Surgery Mode and Device Status Check features in the Proclaim Elite, Infinity, and Proclaim DRG family of implanted pulse generators (IPGs).
P140010/S024	02/01/2017	Y - 135 Review Tra	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for the introduction of new in-line degasser.
P140017/S005	02/24/2017	P - Panel Track	MELODY TRANSCATHETER PULMONARY VALVE, ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM AND ENSEMBLE II TRANSCATHETER VALVE DELIVERY SYSTEM	MEDTRONIC INC.	Approval for the Melody Transcatheter Pulmonary Valve, Ensemble Transcatheter Valve Delivery System, and Ensemble II Transcatheter Valve Delivery System for expanding the indications to include patients with a dysfunctional surgical bioprosthetic pulmonary valve. The device is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has >= moderate regurgitation and/or a mean RVOT gradient >= 35 mmHg.
P150004/S006	02/03/2017	N - Normal 180 Day	PMP	SPINAL MODULATION, INC	Approval of an updated version (v 3.4) of Clinician Programmer and Patient Controller software to enable the Surgery Mode and Device Status Check features in the Proclaim Elite, Infinity, and Proclaim DRG family of implanted pulse generators (IPGs).

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P150027/S003	02/24/2017	O - Normal 180 Day	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for the updated product labeling and associated data.
P150033/S013	02/17/2017	R - Real-Time Proc	MICRA	MEDTRONIC INC.	Approval for firmware changes (version M8.0) to the MyCareLink Patient Monitor Model 24950.
P150040/S001	02/28/2017	R - Real-Time Proc	VISUMAX FEMTOSECOND LASER SYSTEM	CARL ZEISS MEDITEC, INC.	Approval for software changes.
P160017/S003	02/02/2017	N - Normal 180 Day	MINIMED 670G SYSTEM	MEDTRONIC MINIMED	Approval for a hardware design change for the ¿Lockout 2.0 Change Design¿ which affects Guardian Sensor (3), MMT-7020A, B, Guardian Link (3) Transmitter, MMT-7811, and Tester, MMT-776L.
P160017/S008	02/10/2017	R - Real-Time Proc	GUARDIAN LINK (3) TRANSMITTER	MEDTRONIC MINIMED	Approval for design changes to the battery component of the GST3C transmitter. The GST3C transmitter is a component of the MiniMed 670G System.
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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S086	02/08/2017	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.
N18033/S087	02/22/2017	X - 30-Day Notice	VISTAKON® (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Implementation of changes in raw material testing used in the production of VISTAKON (etafilcon A) and (senofilcon A) Brand Contact lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S130	02/23/2017	X - 30-Day Notice	AMS 700 IMPLANTABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Replacement of a silicone dispersion viscosity measurement tool with a similar tool.
P780007/S055	02/03/2017	X - 30-Day Notice	POLYMACON SOFT (HYDROPHILIC) CONTACT LENSES	COOPERVISION, INC.	Acceptance for the implementation of Rework Processes in the Infinity QS system.
P780007/S056	02/28/2017	X - 30-Day Notice	POLYMACON SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Alternate Packaging and Labeling Site at the West Henrietta, New York Facility.
P810002/S100	02/02/2017	X - 30-Day Notice	MASTERS VALVED GRAFT WITH HEMASHIELD GRAFT TECHNOLOGY	ST. JUDE MEDICAL, INC.	Minor process modifications to the graft and to relocate the graft weaving process to a different facility.
P830055/S180	02/21/2017	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of a new material supplier.
P830061/S142	02/14/2017	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD, VITATRON EXCELLENCE PS+ LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P840001/S351	02/06/2017	X - 30-Day Notice	RESTORE ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of alternate supplier and manufacturing method for connector and electrodes used in quadripolar leads.
P840062/S060	02/16/2017	X - 30-Day Notice	COLLACOTE(TM)	COLLA-TEC, INC.	Various installation, operation and environmental monitoring of anti-static bars, stainless steel shroud, vacuum port, and particle trap in the Integra Packaging Room.
P850048/S044	02/14/2017	X - 30-Day Notice	ACCESS PSA CALIBRATORS ON THE ACCESS IMMUNOASSAY ANALYZER	BECKMAN COULTER, INC.	Add another filling line for the filling, sealing, and labeling of calibrator bottles using the new Bottle/Vial Filler.
P850079/S072	02/13/2017	X - 30-Day Notice	METHAFILCON A SOFT HYDROPHILIC EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Use of Getinge autoclave A as back up equipment for the sterilization of lathing produced products (3 pack Blisters and Vials) in the event of breakdown or service of lathing autoclaves K and M at the CooperVision, Inc. Hamble UK manufacturing facility.
P850079/S073	02/28/2017	X - 30-Day Notice	METHAFILCON A AND METHAFILCON B SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Alternate Packaging and Labeling Site at the West Henrietta, New York Facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850089/S123	02/14/2017	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P860004/S265	02/24/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	New supplier of the retaining ring component within the Drug Delivery Catheters (model 8780, 8781, 8731SC) and Drug Delivery Kits for Revisions (model 8578, 8596SC, 8784).
P860004/S267	02/21/2017	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED II WELDING PROCESSES MONITORS AND CONTROLS	MEDTRONIC INC.	Addition of process monitors of the weld hardness, penetration, pull strength; as well as the addition of a process control that ensures the focus of the z-axis location at the laser welding process is locked on predefined tolerances; to the SynchroMed II weld processes.
P860004/S267	02/21/2017	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED II WELDING PROCESSES MONITORS AND CONTROLS	MEDTRONIC INC.	Addition of process monitors of the weld hardness, penetration, pull strength; as well as the addition of a process control that ensures the focus of the z-axis location at the laser welding process is locked on predefined tolerances; to the SynchroMed II weld processes.
P880086/S277	02/24/2017	X - 30-Day Notice	AFFINITY/ INTEGRITY/ VICTORY/ ZEPHYR/ ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.
P880086/S278	02/24/2017	X - 30-Day Notice	PM1160, PM1240, PM1260, PM2160, PM2240, PM2260, PM1152, PM2152	ST. JUDE MEDICAL, INC.	Modifications to the dry buffing process used on device headers.
P890023/S026	02/03/2017	X - 30-Day Notice	OCUFILCON D SOFT (HYDROPHILIC) CONTACT LENSES	THE COOPER COMPANIES	Acceptance for the implementation of Rework Processes in the Infinity QS system.
P890023/S027	02/28/2017	X - 30-Day Notice	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Alternate Packaging and Labeling Site at the West Henrietta, New York Facility.
P890055/S066	02/21/2017	X - 30-Day Notice	INFUSION PUMP AND MEDSTREAM PROGRAMMABLE INFUSION SYSTEM	CODMAN	Changing the manufacturing of blister lids from Smith Print to Mangar Medical Packaging. This change applies to the: Codman Pump Catheter (602914US) and SureStream Intraspinal Catheter kit (70020US).
P900061/S145	02/14/2017	X - 30-Day Notice	EPICARDIAL PATCH LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910023/S379	02/24/2017	X - 30-Day Notice	CURRENT+, FORTIFY, FORTIFY ASSURA AND ELLIPSE FAMILY OF ICDS	St. Jude Medical	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.
P910023/S379	02/24/2017	X - 30-Day Notice	CURRENT+, FORTIFY, FORTIFY ASSURA AND ELLIPSE FAMILY OF ICDS	ST. JUDE MEDICAL	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.
P910023/S379	02/24/2017	X - 30-Day Notice	CURRENT+, FORTIFY, FORTIFY ASSURA AND ELLIPSE FAMILY OF ICDS	ST. JUDE MEDICAL	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.
P910023/S380	02/24/2017	X - 30-Day Notice	CD1231-40, CD1231-40Q, CD2231-40, CD2231-40Q, CD1257-40, CD1257-40Q, CD2257-40, CD2257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC	St. Jude Medical	Modifications to the dry buffing process used on device headers.
P910023/S380	02/24/2017	X - 30-Day Notice	CD1231-40, CD1231-40Q, CD2231-40, CD2231-40Q, CD1257-40, CD1257-40Q, CD2257-40, CD2257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC	ST. JUDE MEDICAL	Modifications to the dry buffing process used on device headers.
P910023/S380	02/24/2017	X - 30-Day Notice	CD1231-40, CD1231-40Q, CD2231-40, CD2231-40Q, CD1257-40, CD1257-40Q, CD2257-40, CD2257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC	ST. JUDE MEDICAL	Modifications to the dry buffing process used on device headers.
P920015/S194	02/01/2017	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implementation of inspection and rework process instructions for the overlay joint assembly process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S194	02/01/2017	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Implementation of inspection and rework process instructions for the overlay joint assembly process.
P920015/S195	02/14/2017	X - 30-Day Notice	IS-1 CONNECTOR PORT PIN PLUG KIT, SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P920015/S195	02/14/2017	X - 30-Day Notice	IS-1 CONNECTOR PORT PIN PLUG KIT, SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P930039/S167	02/16/2017	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD ; VITATRON CRYSTALLLINE ACTIVE FIXATION LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the inspection criteria for the laser welding process of the weld sleeve and connector ring.
P940035/S014	02/27/2017	X - 30-Day Notice	MATRITECH NMP22(TM) TEST KIT	ALERE SCARBOROUGH, INC	New vendor for the resin contained in the nitrocellulose membrane, and extend expiry of the antigen and purified antibodies used in the test.
P950022/S099	02/21/2017	X - 30-Day Notice	DURATA AND OPTISURE LEADS (HV ACTIVE AND PASSIVE)	ST. JUDE MEDICAL, INC.	Changes to sample preparation for the HPLC test method.
P950022/S100	02/24/2017	X - 30-Day Notice	DURATA AND OPTISURE LEADS (HV ACTIVE AND PASSIVE)	ST. JUDE MEDICAL, INC.	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.
P950024/S072	02/14/2017	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P950024/S072	02/14/2017	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P960009/S270	02/06/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of alternate supplier and manufacturing method for connector and electrodes used in quadripolar leads.
P960009/S270	02/06/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of alternate supplier and manufacturing method for connector and electrodes used in quadripolar leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960013/S088	02/21/2017	X - 30-Day Notice	TENDRIL SDX/ST/STS AND OPTISENSE LEADS (LV ACTIVE)	PACESETTER, INC.	Changes to sample preparation for the HPLC test method.
P960030/S050	02/21/2017	X - 30-Day Notice	ISOFLEX OPTIM LEADS (LV PASSIVE)	PACESETTER, INC.	Changes to sample preparation for the HPLC test method.
P960040/S388	02/14/2017	X - 30-Day Notice	DYNAGEN, INOGEN, ORIGEN, AUTOGEN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)	BOSTON SCIENTIFIC	Implementation of an optional process to reduce moisture during battery manufacturing.
P960043/S096	02/15/2017	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Implementation of an automated blade insertion process.
P970003/S209	02/16/2017	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Updated environmental monitoring equipment.
P970004/S237	02/06/2017	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM DBS LEADS	MEDTRONIC NEUROMODULATION	Addition of alternate supplier and manufacturing method for connector and electrodes used in quadripolar leads.
P970038/S032	02/14/2017	X - 30-Day Notice	ACCESS FREE PSA CALIBRATORS ON THE ACCESS IMMUNOASSAY ANALYZER	BECKMAN COULTER, INC.	Add another filling line for the filling, sealing, and labeling of calibrator bottles using the new Bottle/Vial Filler.
P980016/S617	02/07/2017	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New supplier for material used in battery manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S619	02/21/2017	X - 30-Day Notice	EVERA MRI DF-1ICD DDMB1D1, DDMC3D1 L; EVERA MRI ICD DDMB1D4, DDMC3D4, DVMB1D4, DVMC3D4; EVERA S DR ICD DDBC3D1, DDBC3D4; EVERA S VR ICD DVBC3D1, DVBC3D4; EVERA XT DR ICD DDBB1D1, DDBB1D4; EVERA XT VR ICD DVBB1D1, DVBB1D4; MAXIMO II ICD D264DRM, D264VRM, D284VRC, D284DRG; PROTECTA ICD D334DRG, D334VRG, D334DRM; PROTECTA VR ICD D334VRM; PROTECTA XT ICD D314DRG, D314VRG, D314DRM, D314VRM; SECURA DR ICD D224DRG; SECURA ICD D204DRM, D204VRM, D224VRC; VIRTUOSO II DR/ VR ICD D274DRG, D274VRC; VISIA AF MRI DF1 ICD DVFB1D1, DVFC3D1; VISIA AF MRI VR ICD DVFB1D4, DVFC3D4; VISIA AF VR ICD DVAB1D1, DVAB1D4, DVAC3D1, DVAC3D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Additional wirebond equipment for use in hybrid manufacturing at Medtronic Tempe Campus.
P980016/S621	02/28/2017	X - 30-Day Notice	EVERA MRI DF-1/EVERA MRI/EVERA S DR/EVERA S VR/EVERA XT DR/EVERA XT VR/MAXIMO II/SECURA DR/SERURA/VIRTUOSO II DR/VR/VISIA AF MRI DFI/ VISIA AF MRI VR/VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Implementation of an updated weld inspection process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S487	02/07/2017	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	New supplier for material used in battery manufacturing.
P980035/S487	02/07/2017	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	New supplier for material used in battery manufacturing.
P980035/S488	02/28/2017	X - 30-Day Notice	ADVISA DR IPG A4DR01, ADVISA DR MRI IPG A2DR01, ADVISA SR MRI IPG A3SR01	MEDTRONIC INC.	Implementation of a test solution update, Next Generation Hybrid Tester Release 43.0.
P980035/S488	02/28/2017	X - 30-Day Notice	ADVISA DR IPG A4DR01, ADVISA DR MRI IPG A2DR01, ADVISA SR MRI IPG A3SR01	MEDTRONIC INC.	Implementation of a test solution update, Next Generation Hybrid Tester Release 43.0.
P980035/S489	02/28/2017	X - 30-Day Notice	ADVISA DR/ADVISA DR MRI/ADVISA SR MRI IPG	MEDTRONIC INC.	Implementation of an updated weld inspection process.
P980035/S489	02/28/2017	X - 30-Day Notice	ADVISA DR/ADVISA DR MRI/ADVISA SR MRI IPG	MEDTRONIC INC.	Implementation of an updated weld inspection process.
P980037/S063	02/08/2017	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Manufacturing process change to the AngioJet outlet adaptor nut.
P980041/S035	02/14/2017	X - 30-Day Notice	ACCESS AFP CALIBRATORS ON THE ACCESS IMMUNOASSAY ANALYZER	BECKMAN COULTER, INC.	Add another filling line for the filling, sealing, and labeling of calibrator bottles using the new Bottle/Vial Filler.
P980050/S109	02/14/2017	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P980050/S109	02/14/2017	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P000039/S057	02/22/2017	X - 30-Day Notice	THE AMPLATZER SEPTAL OCCLUDER/AMPLATZER CRIBRIFORM OCCLUDER	ST. JUDE MEDICAL CARDIOVASCULAR DIVISION	Implementation of an automated environmental monitoring system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000054/S045	02/16/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Various source manufacturing changes to the absorbable collagen sponge component of Infuse Bone Graft.
P000058/S063	02/16/2017	X - 30-Day Notice	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Various source manufacturing changes to the absorbable collagen sponge component of Infuse Bone Graft.
P010012/S444	02/14/2017	X - 30-Day Notice	DYNAGEN, INOGEN, ORIGEN, AUTOGEN CARDIAC RESYNCHRONIZATION THERAPYN DEFIBRILLATOR (CRT_D)	BOSTON SCIENTIFIC CORP.	Implementation of an optional process to reduce moisture during battery manufacturing.
P010014/S060	02/27/2017	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM -MENISCAL BEARINGS	BIOMET MANUFACTURING CORP.	Transfer of the testing location and modifications to the test method for the density evaluation of the compression molded meniscal component.
P010015/S319	02/07/2017	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	New supplier for material used in battery manufacturing.
P010015/S319	02/07/2017	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	New supplier for material used in battery manufacturing.
P010015/S320	02/14/2017	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P010015/S320	02/14/2017	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P010031/S576	02/07/2017	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New supplier for material used in battery manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S578	02/21/2017	X - 30-Day Notice	AMPLIA MRI CRTD DTMB1D4, DTMB1D1; AMPLIA MRI QUAD CRT-D DTMB1QQ, DTMB1Q1; BRAVA CRT-D DTBC1D4, DTBC1D1, BRAVA QUAD CRTD DTBC1Q1, DTBC1QQ; CLARIA MRI CRT-D DTMA1D1, DTMA1D4; CLARIA MRI QUAD CRT-D DTMA1Q1, DTMA1QQ; COMPIA MRI CRTD DTMC1D4, DTMC1D1; COMPIA MRI QUAD CRT-D DTMC1QQ; CONCERTO II CRT-D D274TRK; CONSULTA CRT-D D204TRM, D224TRK; MAXIMO II CRT-D D264TRM, D284TRK; PROTECTA CRT-D D334TRM, D334TRG; PROTECTA XT CRTD D314TRM, D314TRG; VIVA QUAD S CRTD DTBB1Q1, DTBB1QQ; VIVA QUAD XT CRT-D DTBA1Q1, DTBA1QQ; VIVA S CRT-D DTBB1D1, DTBB1D4; VIVA XT CRT-D DTBA1D1, DTBA1D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional wirebond equipment for use in hybrid manufacturing at Medtronic Tempe Campus.
P010031/S580	02/28/2017	X - 30-Day Notice	AMPLIA MRI/AMPLIA MRI QUAD/BRAVA/BRAVA QUAD/CLARIA MRI/CLARIA MRI QUAD/COMPIA MRI/ CONCERTO II/CONSULTA/ MAXIMO II/VIVA QUAD S/ VIVA QUAD XT/VIVA S/VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of an updated weld inspection process.
P020024/S047	02/22/2017	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER/DUCT OCCLUDER II	AGA MEDICAL CORP.	Implementation of an automated environmental monitoring system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030005/S150	02/21/2017	X - 30-Day Notice	VISIONIST CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER (CRT-P) DEVICES	GUIDANT CORP.	Implementation of the following previously accepted changes: (1) Changes to the molding manufacturing line; (2) Changes to an acceptance limit and sampling rate during battery testing; (3) Changes to visual inspection criteria for cosmetic defects; (4) Addition of a software interface between the traceability system software and the braze oven equipment for the feedthru component braze process; (5) Addition of an alternate sterilization cycle for pulse generators; (6) Additional supplier for the raw material used in low voltage battery lids; (7) Addition of an alternate supplier of titanium for pulse generator case halves; and (8) Additional manufacturing inspection step along with associated specification and inspection criteria that will allow pulse generator case half discontinuities to be distinguished from dents.
P030009/S091	02/22/2017	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Introduce an alternate preconditioning room for the Ethylene Oxide sterilization cycle.
P030017/S276	02/14/2017	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Adding an alternate qualified supplier for the core seals used in the assembly of the Precision IPG family.
P030035/S152	02/24/2017	X - 30-Day Notice	PM3120, PM3140, PM3222, PM3242, PM3160, PM3262	ST. JUDE MEDICAL, INC.	Modifications to the dry buffing process used on device headers.
P030054/S317	02/21/2017	X - 30-Day Notice	QUICKFLEX U AND QUARTET LEADS (CRT)	St. Jude Medical	Changes to sample preparation for the HPLC test method.
P030054/S317	02/21/2017	X - 30-Day Notice	QUICKFLEX U AND QUARTET LEADS (CRT)	ST. JUDE MEDICAL	Changes to sample preparation for the HPLC test method.
P030054/S317	02/21/2017	X - 30-Day Notice	QUICKFLEX U AND QUARTET LEADS (CRT)	ST. JUDE MEDICAL	Changes to sample preparation for the HPLC test method.
P030054/S318	02/24/2017	X - 30-Day Notice	PROMOTE+, UNIFY, UNIFY QUADRA/ASSURA AND QUADRA ASSURA FAMILY OF CRT-DS	St. Jude Medical	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.
P030054/S318	02/24/2017	X - 30-Day Notice	PROMOTE+, UNIFY, UNIFY QUADRA/ASSURA AND QUADRA ASSURA FAMILY OF CRT-DS	ST. JUDE MEDICAL	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.
P030054/S318	02/24/2017	X - 30-Day Notice	PROMOTE+, UNIFY, UNIFY QUADRA/ASSURA AND QUADRA ASSURA FAMILY OF CRT-DS	ST. JUDE MEDICAL	Alternate supplier of accessory sterile pouches and use of large size sterile pouches as outer pouches.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030054/S319	02/24/2017	X - 30-Day Notice	CD3231-40, CD3231-40Q, CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC,	St. Jude Medical	Modifications to the dry buffing process used on device headers.
P030054/S319	02/24/2017	X - 30-Day Notice	CD3231-40, CD3231-40Q, CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC,	ST. JUDE MEDICAL	Modifications to the dry buffing process used on device headers.
P030054/S319	02/24/2017	X - 30-Day Notice	CD3231-40, CD3231-40Q, CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC,	ST. JUDE MEDICAL	Modifications to the dry buffing process used on device headers.
P040021/S030	02/03/2017	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ST. JUDE MEDICAL, INC.	Addition of an alternate contract sterilizer vendor for the sterilization of the jar set assemblies.
P040040/S030	02/22/2017	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ST. JUDE MEDICAL CARDIOVASCULAR DIVISION	Implementation of an automated environmental monitoring system.
P040045/S065	02/08/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Modification to the raw material testing for the senofilcon A and etafilcon A brand contact lenses.
P040045/S066	02/14/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Implementation of an alternate test method to measure finished lens parameters of VISTAKON (senofilcon A) Brand Contact Lenses with sphere and toric lens designs.
P040045/S067	02/17/2017	X - 30-Day Notice	VISTAKON	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Alternate supplier of a raw material component of the senofilcon A monomer of VISTAKON® senofilcon A brand contact lenses.

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P040045/S068	02/22/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) CONTACT LENS, CLEAR AND VISIBILITY TINTED WITH UV BLOCKER	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Implementation of changes in raw material testing used in the production of VISTAKON (etafilcon A) and (senofilcon A) Brand Contact lenses.
P050053/S036	02/17/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Various source manufacturing changes to the absorbable collagen sponge component of Infuse Bone Graft.
P050053/S036	02/17/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Various source manufacturing changes to the absorbable collagen sponge component of Infuse Bone Graft.
P060039/S077	02/14/2017	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P060039/S077	02/14/2017	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P070026/S045	02/21/2017	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of a new material supplier.
P080006/S106	02/14/2017	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P080006/S106	02/14/2017	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Modify the electrical discharge machine used to manufacture sub-components for leads and extensions.
P080006/S108	02/21/2017	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Change to the tray and lid used to package the Attain Ability Leads.
P080006/S108	02/21/2017	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Change to the tray and lid used to package the Attain Ability Leads.
P080011/S053	02/03/2017	X - 30-Day Notice	COMFILCON A SOFT (HYDROPHILIC) CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Acceptance for the implementation of Rework Processes in the Infinity QS system.
P080011/S054	02/02/2017	X - 30-Day Notice	BIOFINITY SPHERE AND BIOFINITY XR SPHERE	COOPERVISION MANUFACTURING, LTD.	Addition of Gelest Inc. as a secondary supplier of a raw material to be used in the manufacture of Biofinity (comfilcon A) soft contact lenses at both the UK and Puerto Rico manufacturing sites.
P080011/S055	02/27/2017	X - 30-Day Notice	CONFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Acceptance for the validation of Biofinity Line 3 to manufacture Biofinity XR Toric High Minus Power Lenses at the CooperVision Inc. Hamble, UK manufacturing facility.
P080025/S132	02/06/2017	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM SNS BOWEL LEADS	MEDTRONIC NEUROMODULATION	Addition of alternate supplier and manufacturing method for connector and electrodes used in quadripolar leads.

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P080027/S026	02/28/2017	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Replacement of an instrument and purchase of purification columns used to manufacture kit subcomponents.
P090013/S246	02/07/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	New supplier for material used in battery manufacturing.
P090013/S246	02/07/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	New supplier for material used in battery manufacturing.
P090013/S247	02/16/2017	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Update the inspection criteria for the laser welding process of the weld sleeve and connector ring.
P090013/S247	02/16/2017	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Update the inspection criteria for the laser welding process of the weld sleeve and connector ring.
P090013/S249	02/28/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Implementation of an updated weld inspection process.
P090013/S249	02/28/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Implementation of an updated weld inspection process.
P090015/S004	02/15/2017	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Transfer of several items of equipment from one testing laboratory to another laboratory within the same manufacture site. The equipment is used to complete the Quality Control testing of the BOND Oracle HER2 IHC System.
P090015/S004	02/15/2017	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Transfer of several items of equipment from one testing laboratory to another laboratory within the same manufacture site. The equipment is used to complete the Quality Control testing of the BOND Oracle HER2 IHC System.
P090022/S031	02/07/2017	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Revision of the final cleaning process step in the manufacture of intraocular lenses.
P090026/S016	02/14/2017	X - 30-Day Notice	ACCESS P2PSA CALIBRATOR ON THE ACCESS IMMUNOASSAY ANALYZER	BECKMAN COULTER, INC.	Add another filling line for the filling, sealing, and labeling of calibrator bottles using the new Bottle/Vial Filler.
P090026/S017	02/21/2017	X - 30-Day Notice	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Manufacturing process change to the Working Strength Particle Batch Size process, which is used in the paramagnetic particle (PMP) for use in the Access Hybritech p2PSA Reagent.
P100021/S060	02/03/2017	X - 30-Day Notice	ENDURANT & ENDURANT II STENT GRAFT SYSTEM; ENDURANT II AORTO-UNI-LIAC (AUI) STENT GRAFT SYSTEM; ENDURANT IIS STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Manufacturing change for the hypotube component of the Endurant, Endurant II, and Endurant IIs iliac delivery systems.
P100029/S024	02/03/2017	X - 30-Day Notice	TRIFECTA VALVE, VALVE WITH GLIDE	ST. JUDE MEDICAL, INC.	Addition of an alternate contract sterilizer vendor for the sterilization of the jar set assemblies.

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P100040/S029	02/09/2017	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Change in the sterilization dose audit process.
P110042/S075	02/14/2017	X - 30-Day Notice	EMBLEM SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD)	Boston Scientific Corporation	Implementation of an optional process to reduce moisture during battery manufacturing.
P110042/S075	02/14/2017	X - 30-Day Notice	EMBLEM SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Implementation of an optional process to reduce moisture during battery manufacturing.
P110042/S075	02/14/2017	X - 30-Day Notice	EMBLEM SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Implementation of an optional process to reduce moisture during battery manufacturing.
P120016/S022	02/15/2017	X - 30-Day Notice	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Addition of a new test method, the Distal Outer Sleeve Joint Quality Check.
P120021/S003	02/22/2017	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ST. JUDE MEDICAL, INC.	Implementation of an automated environmental monitoring system.
P130023/S003	02/01/2017	X - 30-Day Notice	COHERA MEDICAL TISSUGLU SURGICAL ADHESIVE	COHERA MEDICAL, INC	Relocation of the lab equipment where quality control release testing of the TissuGlu Surgical Adhesive cartridge lots is conducted.
P140002/S007	02/27/2017	X - 30-Day Notice	MISAGO RX SELF-EXPANDING PERIPHERAL STENT SYSTEM	TERUMO MEDICAL CORPORATION	Changes to the final inspection sampling plan.
P140012/S008	02/21/2017	X - 30-Day Notice	RESHAPE INTEGRATED DUAL BALLOON SYSTEM	RESHAPE MEDICAL, INC.	Change of lot release testing of finished catheter-balloon assemblies.
P140015/S019	02/08/2017	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Combine lot release testing and in-process monitoring testing for the t:slim insulin cartridge component and to remove several redundant test procedures. The t:slim insulin cartridge is a component of the Tandem t:slim G4 Insulin Pump with Dexcom G4 Platinum CGM.
P140028/S024	02/13/2017	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	Changes to the stent laser cutting process.
P140028/S024	02/13/2017	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the stent laser cutting process.

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P140028/S024	02/13/2017	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the stent laser cutting process.
P140031/S031	02/27/2017	X - 30-Day Notice	QUALCRIMP CRIMPING ACCESSORY (LAMINATED)	EDWARDS LIFESCIENCES, LLC.	Change to the cutting process for the Qualcrimp crimping accessory.
P140033/S001	02/21/2017	X - 30-Day Notice	TENDRIL MRI	ST. JUDE MEDICAL, INC.	Changes to sample preparation for the HPLC test method.
P150011/S007	02/16/2017	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Introduction of a template tool to facilitate leaflet height inspection and revision of the steady flow test acceptance criteria.
P150011/S008	02/23/2017	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Implement a reprocessing step in the stent manufacturing process.
P150033/S014	02/07/2017	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	New supplier for material used in battery manufacturing.
P150033/S014	02/07/2017	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	New supplier for material used in battery manufacturing.
P150036/S004	02/16/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM (AORTIC VALVE MODEL 8300AB)	EDWARDS LIFESCIENCES, LLC.	Add another manufacturer for the loop yarn.
P150036/S005	02/28/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Implement a new ultrasonic welder to weld the polyester support band.
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