PMA Monthly approvals from 6/1/2017 to 6/30/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150046	06/28/2017	PMAO - PMA Origi	NEVISENSE	SCIBASE AB	Approval for the Nevisense. This device is indicated for use on cutaneous lesions with one or more clinical or historical characteristics of melanoma, when a dermatologist chooses to obtain additional information when considering biopsy. Nevisense should not be used on clinically obvious melanoma. The Nevisense result is one element of the overall clinical assessment. The output of Nevisense should be used in combination with clinical and historical signs of melanoma to obtain additional information prior to a decision to biopsy. Nevisense is indicated only for use on: primary skin lesions with a diameter between 2 mm and 20 mm; lesions that are accessible by the Nevisense probe; lesions where the skin is intact (i.e., non-ulcerated or non-bleeding lesions); lesions that do not contain a scar or fibrosis consistent with previous trauma; lesions not located in areas of psoriasis, eczema, acute sunburn, or similar skin conditions; lesions not in hair-covered areas; lesions which do not contain foreign matter; lesions not on special anatomic sites (i.e., not for use on acral skin, genitalia, eyes, mucosal areas).
P150048	06/29/2017	PMAO - PMA Origi	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Approval of the Edwards Pericardial Aortic Bioprosthesis and Edwards INSPIRIS RESILIA Aortic Valve. The Edwards Pericardial Aortic Bioprosthesis, Model 11000A, is indicated for the replacement of native or prosthetic aortic heart valves. The Edwards INSPIRIS RESILIA Aortic Valve, Model 11500A, is indicated for the replacement of native or prosthetic aortic heart valves.
P160035	06/06/2017	PMAO - PMA Origi	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for the EXCOR® Pediatric Ventricular Assist Device (referred to as EXCOR Pediatric) is intended to provide mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients. Pediatric candidates with severe isolated left ventricular or biventricular dysfunction who are candidates for cardiac transplant and require circulatory support may be treated using the EXCOR Pediatric.
P160038	06/29/2017	PMAO - PMA Origi	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Approval for the Praxis Extended RAS Panel is a qualitative in vitro diagnostic test using targeted high throughput parallel sequencing for the detection of 56 specific mutations in RAS genes [KRAS (exons 2, 3, and 4) and NRAS (exons 2, 3, and 4)] in DNA extracted from formalin-fixed, paraffin-embedded (FFPE) colorectal cancer (CRC) tissue samples. The Praxis¿ Extended RAS Panel is indicated to aid in the identification of patients with colorectal cancer for treatment with Vectibix® (panitumumab) based on a no mutation detected test result. The test is intended to be used on the Illumina MiSeqDx® instrument.

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P160041	06/01/2017	PMAO - PMA Origi	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Approval of the cobas CMV test - This device is indicated for: cobas® CMV is an in vitro nucleic acid amplification test for the quantitation of cytomegalovirus (CMV) DNA in human EDTA plasma. cobas® CMV is intended for use as an aid in the management of CMV in solid organ transplant patients and in hematopoietic stem cell transplant patients. In patients receiving anti-CMV therapy, serial DNA measurements can be used to assess viral response to treatment. The results from cobas® CMV must be interpreted within the context of all relevant clinical and laboratory findings. cobas® CMV is not intended for use as a screening test for blood or blood products.
P160045	06/22/2017	PMAO - PMA Origi	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval for the The Oncomine Dx Target Test is a qualitative in vitro diagnostic test that uses targeted high throughput, parallel-sequencing technology to detect single nucleotide variants (SNVs) and deletions in 23 genes from DNA and fusions in ROS1 from RNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue samples from patients with non-small cell lung cancer (NSCLC) using the Ion PGM Dx System. The test is indicated to aid in selecting NSCLC patients for treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. Table 1. List of variants for therapeutic use Gene Variant Targeted therapy BRAF BRAF V600E TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib) ROS1 ROS1 fusions XALKORI® (crizotinib) EGFR L858R, Exon 19 deletions IRESSA® (gefitinib) Safe and effective use has not been established for selecting therapies using this device for the variants in Table 1 in tissue types other than NSCLC. Results other than those listed in Table 1 are indicated for use only in patients who have already been considered for all appropriate therapies (including those listed in Table 1). Analytical performance using NSCLC specimens has been established for the variants listed in Table 2. Table 2. List of variants with established analytical performance only Gene Variant ID Nucleotide change KRAS COSM512 c.34_35delGGinsTT KRAS COSM516 c.34G>T MET COSM707 c.3029C>T PIK3CA COSM754 c.1035T>A The test is not indicated to be used for standalone diagnostic purposes, screening, monitoring, risk assessment, or prognosis.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160047	06/14/2017	PMAO - PMA Origi	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Approval for the AEGEA Vapor System (including the AEGEA Vapor Probe Procedure Kit, AEGEA Vapor Generator, and AEGEA Vapor Generator Accessory Kit). This device is indicated to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes in whom childbearing is complete.

Total: 7

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S114	06/15/2017	Y - 135 Review Tra	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for the use of a new source of purified water in the controlled manufacturing environment.
N970012/S135	06/16/2017	S - Special CBE	AMBICOR IMPLANTABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for an addition of a manufacturing inspection step.
P850007/S036	06/22/2017	R - Real-Time Proc	SPINALSTIM	ORTHOFIX, INC.	Approval for software and firmware updates to the SpinalStim and CervicalStim devices. The updates made are identical to both devices, and include modifications to the user display and mobile medical phone application
P850048/S045	06/16/2017	R - Real-Time Proc	ACCESS HYBRITECH PSA REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl Clinical System's sample probe to improve the manufacturability of the component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S156	06/20/2017	Y - 135 Review Tra	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESES/ THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMALFIX TISSUE PROCESS/ RSR PERICARDIAL AORTIC BIOPROSTHESIS & THEO RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMANFIX TISSUE PROCESS / MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS / MEGNA EASE PERICARDINAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/ PLUS PERICARDIAL MITRAL & THEON WITH THERMAFIX TISSUE PROCESS/ MEGNA MITRAL PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/ MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Approval of an additional site for manufacturing components used in the Edwards surgical heart valves.
P890003/S368	06/09/2017	N - Normal 180 Day	MYCARELINK PATIENT MONITOR MODEL	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for hardware, firmware, labeling, and manufacturing changes to support replacing the Bluetooth (BT) Classic module with a BT Low Energy module in the monitor base station.

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P890003/S373	06/23/2017	R - Real-Time Proc	MYCARELINK AND MYCARELINK SMART PATIENT MONITOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for changes to the MyCareLink Model 24950 and MyCareLink Smart Model 25000 Patient Monitor clinician manuals.
P930016/S048	06/30/2017	P - Panel Track	STAR S4 IR EXCIMER LASER SYSTEM AND IDESIGN ADVANCED WAVESCAN STUDIO SYSTEM	AMO MANUFACTURING USA, LLC	Approval for the STAR S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio System. The STAR S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio System is indicated for Wavefront-guided laser assisted in situ keratomileusis (LASIK) in patients: 1) with hyperopia with and without astigmatism as measured by iDesign® Advanced WaveScan Studio System up to +4.00 D spherical equivalent, with up to 2.00 D cylinder; 2) with agreement between manifest refraction (adjusted for optical infinity) and iDesign® Advanced WaveScan Studio System refraction as follows: - Spherical Equivalent: Magnitude of the difference is less than 0.625 D. - Cylinder: Magnitude of the difference is less than or equal to 0.5 D; 3) 18 years of age or older; and 4) with refractive stability (a change of less than or equal to 1.0 D in sphere or cylinder for a minimum of 12 months prior to surgery).
P950034/S047	06/29/2017	S - Special CBE	SEPRAFILM ADHESION BARRIER	GENZYME CORP.	Approval for revisions that include contraindication statements regarding use of Seprafilm® in patients with a history of hypersensitivity to Seprafilm® and against use of Seprafilm® being wrapped directly around a fresh anastomotic suture or staple line. In addition, new warnings regarding the use of Seprafilm® in patients with infections in the abdominopelvic cavity, patients with abdominopelvic malignancies, the placement of Seprafilm® in locations other than directly associated with the surgical incision lines, use in patients with ongoing local and/or systemic inflammatory cell responses, Seprafilm® use in the presence of other implants, and use in patients requiring re-operation within a 4 week, post-operative period, were added to the product label. Furthermore, a new warning regarding careful examination of the bowel for inadvertent enterotomies following adhesiolysis procedures prior to application of Seprafilm®, and the change of a current precaution to a warning regarding potential foreign body reactions to Seprafilm® were identified. Finally, the current precaution noting that safety and effectiveness information for use of Seprafilm® in pregnant women has been revised to specifically include pregnant patients undergoing Cesarean section surgical procedures.
P970003/S205	06/06/2017	N - Normal 180 Day	VNS THERAPY SYSTEM	CYBERONICS, INC.	Approval for updates that are being made to the MRI chapter of VNS Therapy® System Physician's Manual.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970003/S207	06/23/2017	P - Panel Track	VNS THERAPY SYSTEM	CYBERONICS, INC.	Approval for the VNS Therapy System. The device is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.
P970038/S033	06/16/2017	R - Real-Time Proc	ACCESS HYBRITECH FREE PSA REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl Clinical System's sample probe to improve the manufacturability of the component.
P970051/S151	06/13/2017	N - Normal 180 Day	NUCLEUS COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new CochlearTM CP1000 Nucleus N7 Sound Processor, which is an external component of the Nucleus 24 Cochlear Implant System, the Nucleus Hybrid L24 Implant System, and the Nucleus Auditory Brainstem Implant System.
P970053/S016	06/08/2017	R - Real-Time Proc	EC-5000 EXCIMER LASER SYSTEM	NIDEK CO., LTD.	Approval for changes to the Final Fit V1.11 and V1.12 Custom Ablation Treatment Planning Software for Nidek EC-5000 Excimer Laser System. The updated Final Fit software is V1.13.
P980016/S612	06/09/2017	N - Normal 180 Day	EVERA MRI, EVERA XT DR ICD, INTRINSIC 30 ICD, MARQUIS VR ICD, MAXIMO II ICD, PROTECTA ICD, PROTECTA XT ICD, VIRTUOSO II ICD, VISIA AF MRI	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for hardware, firmware, labeling, and manufacturing changes to support replacing the Bluetooth (BT) Classic module with a BT Low Energy module in the monitor base station.
P980035/S483	06/09/2017	N - Normal 180 Day	ADAPTA, VERSA, SENSIA IPGENPULSE E1 IPG KAPPA DR (KAPPA 700/600)	MEDTRONIC INC.	Approval for hardware, firmware, labeling, and manufacturing changes to support replacing the Bluetooth (BT) Classic module with a BT Low Energy module in the monitor base station.
P980037/S065	06/02/2017	O - Normal 180 Day	ANGIOJET RHEOLYTIC THROMBECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at BSC Maple Grove, Two Scimed Place Maple Grove, Minnesota for final sterilization packaging and labeling.
P980040/S080	06/02/2017	O - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	ABBOTT MEDICAL OPTICS INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P980041/S036	06/16/2017	R - Real-Time Proc	ACCESS AFP REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl Clinical System's sample probe to improve the manufacturability of the component.
P980043/S059	06/30/2017	Y - 135 Review Tra	HANOCK II BIOPROSTHESIS, MODELS T505 AND T510	MEDTRONIC HEART VALVES	Approval for the use of Covidien Medical Products (Shanghai) Manufacturing LLC located in Shanghai, China as an alternate manufacturing facility for the receiving and processing of raw tissue valve components used in the manufacture of Medtronic bioprosthetic valves.
P990064/S068	06/30/2017	Y - 135 Review Tra	MOSAIC BIOPROSTHESIS, MODELS 305 AND 310	MEDTRONIC HEART VALVES	Approval for the use of Covidien Medical Products (Shanghai) Manufacturing LLC located in Shanghai, China as an alternate manufacturing facility for the receiving and processing of raw tissue valve components used in the manufacture of Medtronic bioprosthetic valves.

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P990071/S035	06/21/2017	S - Special CBE	STOCKERT 70 RF GENERATOR FOOT PEDAL	BIOSENSE WEBSTER, INC.	Approval for Stockert 70 RF Generator Foot Pedal updated instruction for use.
P000015/S016	06/13/2017	N - Normal 180 Day	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new CochlearTM CP1000 Nucleus N7 Sound Processor, which is an external component of the Nucleus 24 Cochlear Implant System, the Nucleus Hybrid L24 Implant System, and the Nucleus Auditory Brainstem Implant System.
P000040/S035	06/29/2017	O - Normal 180 Day	GENESYS HTA 115V CONTROL UNIT, GENESYS HTA 115V CONTROL UNIT (DEMO), GENESYS HTA 115V CONTROL UNIT (REFURB), GENESYS HTA 115V CONTROL UNIT (ZERO COST)	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corporation, 150 Baytech Drive, San Jose, California.
P000053/S062	06/15/2017	Y - 135 Review Tra	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the use of a new source of purified water in the controlled manufacturing environment.
P010015/S314	06/09/2017	N - Normal 180 Day	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for hardware, firmware, labeling, and manufacturing changes to support replacing the Bluetooth (BT) Classic module with a BT Low Energy module in the monitor base station.
P010031/S572	06/09/2017	N - Normal 180 Day	AMPLIA, BRAVA, CLARIA ,	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for hardware, firmware, labeling, and manufacturing changes to support replacing the Bluetooth (BT) Classic module with a BT Low Energy module in the monitor base station.
P010033/S031	06/07/2017	N - Normal 180 Day	QUANTTFERON-TB GOLD PLUS	QIAGEN	Approval for a design change to the device TB Antigen blood collection tubes.
P020016/S008	06/08/2017	O - Normal 180 Day	TOTAL TEMPOROMANDIBULAR JOINT (TMJ) REPLACEMENT SYSTEM	BIOMET MICROFIXATION, INC.	Approval for proposed labeling changes following the conclusion of the postmarket surveillance study for the total temporomandibular joint replacement system..
P020025/S095	06/23/2017	O - Normal 180 Day	RF FILTER MODULE	BOSTON SCIENTIFIC	Approval for a manufacturing site located at Boston Scientific Corporation, 150 Baytech Drive, San Jose, California.
P020025/S098	06/01/2017	R - Real-Time Proc	INTELLA TIP MIFI XP CARDIAC ABLATION CATHETERS	BOSTON SCIENTIFIC	Approval for design and associated manufacturing changes to the distal tip of IntellaTip MiFi XP ablation catheters.
P030011/S055	06/09/2017	R - Real-Time Proc	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Approval for a minor change to the Companion 2 Driveline packaging configuration.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S287	06/06/2017	R - Real-Time Proc	PRECISION NOVI SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for modification of Precision NoviTM header for improved manufacturability.
P030017/S288	06/01/2017	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for minor updates to the Printed Circuit Board Assembly (PCBA) of the Freelink Remote Control (Model SC-5250). Specifically, the update is to use a microcontroller from the same supplier with more flash memory and Random Access Memory (RAM). Because of the microcontroller memory size change, the device firmware is also updated.
P030034/S010	06/22/2017	R - Real-Time Proc	CERVICALSTIM	ORTHOFIX, INC.	Approval for software and firmware updates to the SpinalStim and CervicalStim devices. The updates made are identical to both devices, and include modifications to the user display and mobile medical phone application
P030050/S026	06/09/2017	Y - 135 Review Tra	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for the installation of a restricted access barrier system for aseptic filling.
P040002/S058	06/02/2017	Y - 135 Review Tra	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, INC.	Approval for the removal of an on-going sampling plan for the AFX2 Endovascular AAA System.
P040044/S075	06/28/2017	Y - 135 Review Tra	MYNXGRIP VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Approval to implement process improvements for the balloon to catheter bonds.
P040047/S044	06/13/2017	Y - 135 Review Tra	COAPTITE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the implementation of an additional heat sealer with optimized parameters.
P050037/S076	06/13/2017	Y - 135 Review Tra	RADIESSE 1.5CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for the implementation of an additional heat sealer with optimized parameters.
P050052/S088	06/13/2017	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for the implementation of an additional heat sealer with optimized parameters.
P060040/S059	06/23/2017	N - Normal 180 Day	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for the addition of an Intensive Care Unit (ICU) Cover accessory.
P060040/S065	06/30/2017	N - Normal 180 Day	HEARTMATE II LVAS	THORATEC CORP.	Approval to revise the Instruction for Use (IFU) for the HeartMate II LVAS to include a summary of results from the PREVENT post-market study, post-approval rates of pump thrombosis, and changes to the clinical management guidelines.
P080002/S002	06/23/2017	N - Normal 180 Day	FC2 FEMALE CONDOM	THE FEMALE HEALTH CO.	Approval for your proposed change in the formulation of the FC2 Female Condom.
P080012/S044	06/29/2017	S - Special CBE	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval of updated labeling to the Flowonix Prometra Programmable Infusion Pump System Instructions for Use.
P090013/S242	06/09/2017	N - Normal 180 Day	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Approval for hardware, firmware, labeling, and manufacturing changes to support replacing the Bluetooth (BT) Classic module with a BT Low Energy module in the monitor base station.

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P090026/S018	06/16/2017	R - Real-Time Proc	ACCESS HYBRITECH P2PSA REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl Clinical System's sample probe to improve the manufacturability of the component.
P100022/S025	06/15/2017	R - Real-Time Proc	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Approval for minor modifications to the female luer lock adapter component.
P100045/S017	06/15/2017	Y - 135 Review Tra	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for adjusting the temperature setpoints of the equipment used for the CardioMEMS delivery catheter tipping process.
P110004/S022	06/07/2017	S - Special CBE	NIRXCELL COCR CORONARY STENT ON RX	MEDINOL LTD.	Approval to introduce a microbiological test to the incoming inspection of the hydrophilic coating solution.
P120005/S057	06/06/2017	N - Normal 180 Day	DEXCOM G5 MOBILE CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for the addition of the G5 Mobile Android App as an additional display device for use with a compatible smart device.
P120011/S006	06/27/2017	O - Normal 180 Day	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for updated patient and physician labeling that includes 5 year follow-up clinical data
P120024/S004	06/20/2017	N - Normal 180 Day	ACTIVL ARTIFICIAL DISC	AESCULAP IMPLANT SYSTEMS, LLC	Approval for labeling changes to the surgical technique and for the addition of the Class III activL® Slim Trial Instruments and the activL® Artificial Disc Ancillary Trialing & Confirmation instrument tray to the system
P130008/S021	06/23/2017	N - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval to expand the Apnea Hypopnea Index (AHI) range from 20 to 65, to 15 to 65 events per hour.
P130012/S003	06/08/2017	S - Special CBE	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Approval for the addition of a 100% in-line inspection for gel lumps in the body tubing of the Myopore lead.
P130016/S022	06/13/2017	N - Normal 180 Day	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval order should be issued for the new CP1000 N7 cochlear implant sound processor.
P130023/S002	06/23/2017	O - Normal 180 Day	COHERA MEDICAL TISSUEGLU SURGICAL ADHESIVE	COHERA MEDICAL, INC	Approval for a manufacturing site located at Ximedica LLC, 55 Dupont Drive, Providence, Rhode Island, as a facility for cartridge filling, device assembly, packaging, management of sterilization, and final product release.
P130027/S002	06/02/2017	N - Normal 180 Day	ARTUS CMV RGQ MDX KIT	QIAGEN, INC.	Approval to expand the use of the artus CMV RGQ MDx assay system to include the QIAsymphony RGQ MDx system. The new assay system includes the QIAsymphony SP instrument and QIAsymphony DSP Virus/Pathogen Kit for automated sample preparation, automated assay setup on the QIAsymphony AS, artus CMV QS- RGQ MDx Kit, and Rotor-Gene Q MDx instrument with Rotor-Gene AssayManager v1.0 software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140004/S008	06/07/2017	O - Normal 180 Day	SUPERION INDIRECT DECOMPRESSION SYSTEM	VERTIFLEX (R), INCORPORATED	Approval for a manufacturing site located at Turner Medical, Inc., 130 Durham Drive, Athens, Alabama for the production of the Superion InterSpinous Decompression System.
P140008/S006	06/06/2017	S - Special CBE	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGERY INC	Approval for labeling changes have been requested by the Office of Surveillance and Biometrics, Signal Management Program as a result of a safety signal with fluid filled gastric balloons.
P140012/S010	06/27/2017	O - Normal 180 Day	RESHAPE INTEGRATED DUAL BALLON SYSTEM	RESHAPE MEDICAL, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P140013/S007	06/26/2017	R - Real-Time Proc	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for software changes to the Minerva Endometrial Ablation System (i.e., software modifications to 1) correct an error code during device start; 2) to redefine existing error codes to better align them with the observed device conditions; and 3) to add five software checks to the device).
P140031/S028	06/05/2017	P - Panel Track	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the SAPIEN 3 Transcatheter Heart Valve and accessories. The device is indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality greater than or equal to 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).
P140031/S034	06/06/2017	R - Real-Time Proc	EDWARDS SAPIEN 3 TRANSCATHETER HEART VLAVE	EDWARDS LIFESCIENCES, LLC.	Approval for extending the shelf life of the SAPIEN 3 Transcatheter Heart Valve to 2 years.
P140031/S035	06/07/2017	R - Real-Time Proc	EDWARDS CRIMPER	EDWARDS LIFESCIENCES, LLC.	Approval for a new packaging configuration for the Edwards Crimper, model 9600CR.
P150001/S008	06/02/2017	N - Normal 180 Day	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for adding the Guardian Sensor (3) and Guardian Link (3) Transmitter to the MiniMed 630G System with SmartGuard, as well as lowering the approved age limit from 16 years old to 14 years old.
P150001/S017	06/29/2017	S - Special CBE	MINIMED 630G SYSTEM WITH SMARTGUARD	MEDTRONIC MINIMED	Approval for a test method change for the keypad assembly used in the MiniMed 630G and 670G Insulin Pumps.
P150006/S001	06/27/2017	N - Normal 180 Day	CELT ACD VASCULAR CLOSURE DEVICE	VASORUM LTD	Approval for the addition of a 7F size CELT ACD Vascular Closure Device and minor manufacturing and design changes to the 5F, 6F, and 7F CELT ACD Vascular Closure Devices.
P150021/S001	06/02/2017	N - Normal 180 Day	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for changing the adhesive tie layer and the sensor mount components in the Freestyle Libre Pro Flash Glucose Monitoring System Sensor.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150021/S006	06/23/2017	N - Normal 180 Day	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for hardware modifications to the Reader button architecture and for an update to the back label of the Reader.
P150033/S012	06/09/2017	N - Normal 180 Day	MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for hardware, firmware, labeling, and manufacturing changes to support replacing the Bluetooth (BT) Classic module with a BT Low Energy module in the monitor base station.
P150036/S002	06/20/2017	Y - 135 Review Tra	EDWARDS INTUITY VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Approval of an additional site for manufacturing components used in the Edwards surgical heart valves.
P150038/S003	06/26/2017	N - Normal 180 Day	EXABLATE	INSIGHTEC	Approval for a software maintenance upgrade from Software Version 6.6 to Version 7.0 for the unilateral Thalamotomy treatment of idiopathic Essential Tremor (ET) patients with medication ¿refractory tremor.
P160002/S002	06/06/2017	O - Normal 180 Day	VENTANA PD-L1 (SP142) ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for updated product labeling with additional non-clinical data.
P160017/S014	06/29/2017	S - Special CBE	MINIMED 670G SYSTEM	MEDTRONIC MINIMED	Approval for a test method change for the keypad assembly used in the MiniMed 630G and 670G Insulin Pumps.

Total: 75

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18033/S092	06/16/2017	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Reduce the process limit for the maximum allowable cumulative sterilization exposure from 3 to 2 full sterilization runs.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P790005/S056	06/02/2017	X - 30-Day Notice	EBI OSTEOGEN IMPLANTABLE BONE GROWTH STIMULATORS	EBI, LLC	Addition of a new capacity discharge resistance welder and helium mass spectrometer leak detector.
P830055/S182	06/08/2017	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Introduce a Rofin Easymark IV E10 laser (Laser 15) as an additional alternative to Laser 7 for laser marking tibial baseplate components.
P830061/S146	06/22/2017	X - 30-Day Notice	CAPSURE SENSE/ CAPSURE SP/CAPSURE SP NOVUS/CAPSURESENSE/ VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to heavy metal testing for silicone.
P840001/S363	06/15/2017	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS (SCS)	MEDTRONIC NEUROMODU LATION	Implementation of an additional vision system.
P840001/S364	06/21/2017	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODU LATION	Several changes to the stacked chip scale package (SCSP) process flow and modified visual inspection requirements.
P850035/S045	06/02/2017	X - 30-Day Notice	SPF IMPLANTABLE SPINAL FUSION STIMULATORS	EBI, LLC	Addition of a new capacity discharge resistance welder and helium mass spectrometer leak detector.
P850089/S124	06/22/2017	X - 30-Day Notice	CAPSURE SP NOVUS/ CAPSURE SP Z/CAPSURE Z NOVUS/VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to heavy metal testing for silicone.
P860004/S279	06/12/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	New DLC coating supplier for the DLC coating process for the shaft components for the SynchroMed II Programmable Pump (Model 8637, 20 ml and 40 ml).
P860008/S023	06/19/2017	X - 30-Day Notice	TAPSCOPE 550 - 200-0010, 200-0025, 250-0010, 250-0025	CARDIO COMMAND	New supplier for the molding of the pacing wire connector.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S162	06/09/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS/ THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/ RSP PERICARDIAL AORTIC BIOPROSTHESIS/ THEON RSP PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/MAGNA PERICARDIAL AORTIC BIOPROSTHESIS/ MAGNA PERICARDINAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/ MAGNA EASE PERCARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/PLUS PERICARDINAL MITRAL BIOPROSTHESIS/ THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/ MAGNA MITRAL EASE PERICARDIAL BIOPRESTHESIS WITH THERMAFIX TISSUE PROCESS.	EDWARDS LIFESCIENCES, LLC.	Cobalt chromium band forming and welding operations be completed by the vendor.
P860057/S163	06/20/2017	X - 30-Day Notice	PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Implement upgrades to the TagAlert sensor.
P900061/S146	06/22/2017	X - 30-Day Notice	EPICARDIAL PATCH LEAD/ UPSIZING SLEEVE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to heavy metal testing for silicone.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910001/S093	06/20/2017	X - 30-Day Notice	CVX-300 AND CVX-300P EXCIMER LASER SYSTEMS	SPECTRANETICS CORP.	Extend the final test cycle on laser calibration.
P910073/S143	06/30/2017	X - 30-Day Notice	ENDOTAK RELIANCE IS-1 LEAD	BOSTON SCIENTIFIC	Implementation of serial number reading stations with optical character recognition equipment and software for use in lead manufacturing.
P920015/S197	06/05/2017	X - 30-Day Notice	SPRINT QUATTRO LEAD	MEDTRONIC INC.	Modification to the sealing process during manufacturing of Sprint Quattro lead models.
P920015/S198	06/22/2017	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT/DF-1 CONNECTOR PORT PIN PLUG/HV SPLITTER/ADAPTOR KIT/ LEAD ADAPTOR/SPRINT QUATTRO LEAD/ SUBCUTANEOUS LEAD/ TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P930016/S052	06/23/2017	X - 30-Day Notice	STAR S4 IR EXCIMER LASER SYSTEM	AMO MANUFACTURING USA, LLC	Changes to the acceptance criteria and the supplier of the beam splitter used in the STAR S4 IR Excimer Laser System.
P930031/S059	06/28/2017	X - 30-Day Notice	WALLSTENT (TIPS) ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Use of updated equipment for a subassembly process.
P930039/S171	06/28/2017	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD 4076, 5076 - VITATRON CRYSTALLINE ACTIVE FIXATION LEAD ICF09, ICF09B, ICFQ09B	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the helix tip grinding process.
P930039/S172	06/22/2017	X - 30-Day Notice	CAPSUREFIX/CAPSUREFIX NOVUS/VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to heavy metal testing for silicone.
P940019/S050	06/28/2017	X - 30-Day Notice	WALLSTENT LILAC ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC SCIMED, INC.	Use of updated equipment for a subassembly process.
P950022/S106	06/13/2017	X - 30-Day Notice	DURATA / OPTISURE (PASSIVE); / DURATA / OPTISURE (ACTIVE)	ST. JUDE MEDICAL, INC.	Implementation of batch release analytical testing of the drug component characteristics on high voltage leads.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950024/S073	06/22/2017	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P950037/S178	06/23/2017	X - 30-Day Notice	SIELLO S 45, S53, S60 / SOLIA S 45, S53, S 60	BIOTRONIK, INC.	Changes to the lead connector assembly process.
P960009/S282	06/15/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMUALTION THERAPY SYSTEM (DBS)	MEDTRONIC INC.	Implementation of an additional vision system.
P960009/S283	06/21/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Several changes to the stacked chip scale package (SCSP) process flow and modified visual inspection requirements.
P960040/S392	06/06/2017	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) ORIGEN, INOGEN, DYNAGEN, AUTOGEN, PUNCTUA, ENERGEN, INCEPTA, MOMENTUM, VIGILANT, PERCIVA, RESONATE	BOSTON SCIENTIFIC	Alternate supplier for Titanium ribbon.
P960040/S394	06/21/2017	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) - ORIGEN: D000, D001, D002, D003, D050, D051, D052, D053 - INOGEN: D010, D011, D012, D013, D140, D141, D142, D143 - DYNAGEN: D020, D021, D022, D023, D150, D151, D152, D153 - AUTOGEN: D160, D161, D162, D163 - MOMENTUR: D120, D121 - VIGILANT: D220, D221, D232, D233 - RESONATE: D420, D421, D432, D433, D520, D521, D532, D533 - PERCIVA: D400, D401, D412, D413, D500, D501, D512, D513	BOSTON SCIENTIFIC	Updates to the torque and final pack electrical test software.
P960040/S397	06/30/2017	X - 30-Day Notice	FINELINE II LEAD	BOSTON SCIENTIFIC	Implementation of serial number reading stations with optical character recognition equipment and software for use in lead manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S245	06/15/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Implementation of an additional vision system.
P970037/S010	06/07/2017	X - 30-Day Notice	AUTODELFIA HAFP TEST SYSTEM	PERKINELMER, INC.	Changes being made in the hAFP antibody production: 1) use of additional L-glutamine supplement during the production of the coating antibody to the medium that contains nutrients (glucose and glutamine), and setting a recommended minimum concentration of glutamine during the production of the hAFP antibodies; and 2) addition of glutamine and glutamate testing of the routine anti-hAFP antibody production samples to the presently performed glucose and lactate testing.
P970051/S163	06/13/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Introduction of the new CBO Sprint Cleanroom at the Cochlear Brisbane Operations (CBO) manufacturing site.
P980003/S075	06/13/2017	X - 30-Day Notice	CHILLI II COOLED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Alternate component vendors for Chill II, Blazer OI, IntellaNav OI, and IntellaTip MiFi OI catheters.
P980016/S632	06/08/2017	X - 30-Day Notice	EVERA, MAXIMO, PROTECTA, SECURA, SOLARA QUADRIPOLAR,SYNCRA, VIVA MRI DF XT ICD CRT-P	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the chemical used for the etch process for integrated circuit components.
P980016/S633	06/08/2017	X - 30-Day Notice	EVERA MRI DF-1 ICD DVMB1D1, DDMB1D1, DDMC3D1, DVMC3D1; EVERA MRI ICD DDMC3D4, DVMB1D4, DVMC3D4, DDMB1D4; EVERA S DR ICD DDBC3D1, DDBC3D4; EVERA S VR ICD DVBC3D1, DVBC3D4; EVERA XT DR ICD DDBB1D1, DDBB1D4; EVERA XT VR ICD DVBB1D1, DVBB1D4; VISIA AF MRI DF1 ICD DVFB1D1, DVFC3D1; VISIA AF MRI VR ICD DVFB1D4, DVFC3D4; VISIA AF VR ICD DVAB1D4, DVAC3D1, DVAC3D4, DVAB1D1	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional vision system for inspection of final packaged devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S634	06/20/2017	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI DF-1 ICD; EVERA MRI ICD; EVERA S DR/ S VR/ XT DR/ XT VR ICD'S ; MAXIMO II ICD; PRITECTAI ICD/ VR/ XT ICD'S ; SECURA ICD; VISIA AF MRI DF 1 ICD; VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update (release 10.2) to the Next Generation Hybrid Tester (NGHT) for currently marketed devices.
P980016/S635	06/30/2017	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Software and hardware changes to the Titan Device Tester which is used during final functional device testing
P980016/S636	06/22/2017	X - 30-Day Notice	EVERA MRI DF-1/EVERA MRI/EVERA S DR/EVERA S VR/EVERA XT DR/EVERA XT VR/MAXIMO II/ PROTECTA/PROTECTA VR/ PROTECTA XT/SECURA DR/SECURA/VISIA AF MRI DF1/VISIA AF MRI VR/VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to heavy metal testing for silicone.
P980033/S048	06/28/2017	X - 30-Day Notice	WALLSTENT (VENOUS) ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Use of updated equipment for a subassembly process.
P980035/S499	06/04/2017	X - 30-Day Notice	ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG	MEDTRONIC INC.	1) New supplier for material used in battery manufacturing; implementation of an update to FACTORYworks (FW) Release 9.3.; 2) updated test equipment for use in battery manufacturing; 3) changes to the acceptance parameter specification limits for certain wafers and associated process changes; 4) the addition of mixing equipment used in battery manufacturing; 5) an additional laser welder for use in battery manufacturing; and 6) changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.
P980035/S500	06/06/2017	X - 30-Day Notice	ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG	MEDTRONIC INC.	Update to hybrid final function testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S501	06/08/2017	X - 30-Day Notice	ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG	MEDTRONIC INC.	Implementation of process monitoring for the electronic module assembly and final assembly steps.
P980035/S502	06/08/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR/SR MRI IPG, ASTRA S DR MRI IPG, RELIA IPG	MEDTRONIC INC.	Change to the chemical used for the etch process for integrated circuit components.
P980035/S503	06/04/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG ADDRS1, ADSR01, ADDR03, SESR01, ADSR06, VEDR01, ADD01, SEDRL1, SED01, SES01, ADDR01, ADDRL1, ADDR06, ADSR03, ADVDD01, SEDR01; RELIA IPG RED01, REDR01, RES01, RESR01, REVDD01	MEDTRONIC INC.	Update to the hybrid testing process.
P980035/S504	06/05/2017	X - 30-Day Notice	TITAN DEVICE TESTER	MEDTRONIC INC.	Software, hardware, self-test, and application software changes to the Titan Device Tester used during final functional device testing.
P980035/S505	06/13/2017	X - 30-Day Notice	ASTRA S DR MIR IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI, ASTRA XT SR MRI IPG	MEDTRONIC INC.	Align manufacturing of the Percepta, Solara, Serena and Astra IPGs with existing manufacturing of market approved devices by implementing a change to the monitoring frequency for the battery header laser weld inspection.
P980035/S507	06/08/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG ADDR01, ADSR01, ADDR03, ADVDD01, ADDRS1, ADSR03, SEDR01, ADDR06, ADDRL1, ADSR06, SESR01, VEDR01, ADD01, SEDRL1, SED01, SES01; ADVISA DR IPG A4DR01; ADVISA DR MRI IPG A2DR01; ADVISA SR MRI IPG A3SR01; ASTRA S DR MRI IPG X3DR01; ASTRA S SR MRI IPG X3SR01; ASTRA XT DR MRI IPG X1DR01; ASTRA XT SR MRI IPG X1SR01; RELIA IPG RED01, REDR01, RES01, RESR01, REVDD01	MEDTRONIC INC.	Additional vision system for inspection of final packaged devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S508	06/22/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA/ ADVISA DR/ADVISA DR MRI/ADVISA SR MRI/ASTRA S DR MRI/ASTRA S SR MRI/ ASTRA XT DR MRI/ASTRA XT SR MRI/RELIA IPG	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P980035/S509	06/28/2017	X - 30-Day Notice	ASTRA S DR MRI IPG X3DR01, ASTRA S SR MRI IPG X3SR01, ASTRA XT DR MRI IPG X1DR01, ASTRA XT SR MRI IPG X1SR01	MEDTRONIC INC.	Update to the Distribution Center Sorter Tool.
P980040/S082	06/05/2017	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 TORIC 1-PIECE IOLS, TECNIS MULTIFOCAL 1-PIECE IOL MODEL ZLB00, TECNIS MULTIFOCAL 1-PIECE IOL MODEL ZKB00, SYMFONY EXTENDED RANGE OF VISION IOL, TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOL, TECNIS ITEC PRELOADED DELIVERY SYSTEM, TECNIS ITEC PRELOADED DELIVERY SYSTEM MODEL	ABBOTT MEDICAL OPTICS INC	Change in sampling plan for a quality release test for one-piece, soft acrylic intraocular lenses (IOLs).
P980050/S110	06/22/2017	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P990013/S035	06/16/2017	X - 30-Day Notice	COLLAMER, UV-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	STARR SURGICAL CO.	Adding an alternative water purification system to the STARR Surgical Monrovia, CA manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990056/S026	06/23/2017	X - 30-Day Notice	ELECSYS TOTAL PSA (100/200 TESTS) IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P000015/S021	06/13/2017	X - 30-Day Notice	NUCLEUS AB1541 AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Introduction of the new CBO Sprint Cleanroom at the Cochlear Brisbane Operations (CBO) manufacturing site.
P000025/S095	06/01/2017	X - 30-Day Notice	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Addition of a second laser welding process in the manufacture of SONATA cochlear implants.
P000027/S025	06/23/2017	X - 30-Day Notice	ELECSYS FREE PSA IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P000044/S035	06/27/2017	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG REAGENT PACK; VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS, INC.	Change in the process for negative plasma.
P000053/S079	06/09/2017	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Use of new molding equipment; relocation of and changes to the milling and molding process of the silicone pump shell component.
P000054/S048	06/21/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Source manufacturing change to the absorbable collagen sponge component of Infuse Bone Graft.
P000058/S067	06/21/2017	X - 30-Day Notice	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Source manufacturing change to the absorbable collagen sponge component of Infuse Bone Graft.
P010012/S449	06/06/2017	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) ORIGEN, INOGEN, DYNAGEN, AUTOGEN, PUNCTUA, ENERGEN, INCEPTA, MOMENTUM, VIGILANT, RESONATE	BOSTON SCIENTIFIC CORP.	Alternate supplier for Titanium ribbon.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S451	06/21/2017	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) - ORIGNE: G050, G051, G056, G058 - INOGEN: G140, G141, G146, G148 - DYNAGEN: G150, G151, G154, G156, G158 - AUTOGEN: G160, G161, G164, G166, G168 - MOMENTUM: G124, G125, G126, G128, G138 - VIGILANT: G224, G225, G228, G237, G247, G248 - RESPMATE: G424, G425, G426, G428, G437, G447, G448, G524, G525, G526, G528, G537, G547, G548	BOSTON SCIENTIFIC CORP.	Updates to the torque and final pack electrical test software.
P010012/S455	06/26/2017	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILL	BOSTON SCIENTIFIC CORP.	Reduction in the liquid silicone rubber minimum cure time used to mold the distal end of the ACUITY X4 lead body.
P010012/S456	06/30/2017	X - 30-Day Notice	EASYTRACK 2 LEAD, ACUITY SPIRAL LEAD	BOSTON SCIENTIFIC CORP.	Implementation of serial number reading stations with optical character recognition equipment and software for use in lead manufacturing.
P010015/S327	06/04/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P,SOLAR BIPOLAR CRT-P, SOLAR QUADRIPOLAR CRT-P	MEDTRONIC INC.	1) New supplier for material used in battery manufacturing; implementation of an update to FACTORYworks (FW) Release 9.3.; 2) updated test equipment for use in battery manufacturing; 3) changes to the acceptance parameter specification limits for certain wafers and associated process changes; 4) the addition of mixing equipment used in battery manufacturing; 5) an additional laser welder for use in battery manufacturing; and 6) changes to the manufacturing process flow at an integrated circuit component supplier as well as the addition of visual inspection requirements.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S328	06/06/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P,SOLAR BIPOLAR CRT-P, SOLAR QUADRIPOLAR CRT-P	MEDTRONIC INC.	Update to hybrid final function testing.
P010015/S329	06/08/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P,SOLAR BIPOLAR CRT-P, SOLAR QUADRIPOLAR CRT-P	MEDTRONIC INC.	Implementation of process monitoring for the electronic module assembly and final assembly steps.
P010015/S330	06/08/2017	X - 30-Day Notice	CONSULTA, PERCEPTA, SERENA, SOLARA BIPOLAR CRT-P, QUADRIPOLAR CRT-P	MEDTRONIC INC.	Change to the chemical used for the etch process for integrated circuit components.
P010015/S331	06/13/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Align manufacturing of the Percepta, Solara, Serena and Astra IPGs with existing manufacturing of market approved devices by implementing a change to the monitoring frequency for the battery header laser weld inspection.
P010015/S332	06/08/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P W1TR01; PERCEPTA QUADRIPOLAR CRTP W4TR01; SERENA BIPOLAR CRT-P W1TR02, W4TR02; SOLARA BIPOLAR CRT-P W1TR03; SOLARA QUADRIPOLAR CRT-P W4TR03	MEDTRONIC INC.	Additional vision system for inspection of final packaged devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S333	06/22/2017	X - 30-Day Notice	ATTAIN BIPOLAR OTW/ ATTAIN OTW LV LEAD; CONSULTA/PERCEPTA BIPOLAR/PERCEPTA QUADRIPOLAR/SERENA BIPOLAR/SERENA QUADRIPOLAR/SOLARA BIPOLAR/SOLARA QUADRIPOLAR/SYNCRA/ VIVA CRT-P	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P010015/S334	06/28/2017	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P W1TR01, PERCEPTA QUADRIPOLAR CRT-P W4TR01, SERENA BIPOLAR CRT-P W1TR02, SERENA QUADRIPOLAR CRT-P W4TR02, SOLARA BIPOLAR CRT-P W1TR03, SOLARA QUADRIPOLAR CRT-P W4TR03	MEDTRONIC INC.	Update to the Distribution Center Sorter Tool.
P010019/S055	06/30/2017	X - 30-Day Notice	AIR OPTIX NIGHT & DAY AQUA	ALCON LABORATORIES, INC.	Implementation of an improvement of the operation procedure for the plasma coating process for lotrafilcon A and B soft contact lenses.
P010031/S593	06/08/2017	X - 30-Day Notice	AMPLIA, BRAVA, CLARIA, COMPIA, CONSULTA, MAXIMO, PROTECTA XT MRI/CRT-D, VIVA QUAD S AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change to the chemical used for the etch process for integrated circuit components.

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P010031/S594	06/08/2017	X - 30-Day Notice	AMPLIA MRI CRTD DTMB1D1, DTMB1D4; AMPLIA MRI QUAD CRT-D DTMB1Q1, DTMB1QQ; BRAVA CRT-D DTBC1D4; DTBC1D1; BRAVA QUAD CRTD DTBC1QQ, DTBC1Q1; CLARIA MRI CRT-D DTMA1D1, DTMA1D4; CLARIA MRI QUAD CRT-D DTMA1Q1, DTMA1QQ; COMPIA MRI CRTD DTMC1D1, DTMC1D4; COMPIA MRI QUAD CRT-D DTMC1QQ; 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 vision system for inspection of final packaged devices.
P010031/S595	06/20/2017	X - 30-Day Notice	AMPLIA MRI CRT-D; AMPLIA MRI QUAD CRT-D; BRAVA CRT-D; BRAVA QUAD CRT-D; CLARIA MRI CRT-D; CLARIA MRI QUAD CRT-D; COMPIA MRI CRT-D; COMPIA MRI QUAD CRT-D; CONSULTA CRT-D; MAXIMO II CRT-D; PROTECTA CRT-D; PROTECTA XT CRT-D; VIVA QUAD S CRT-D; VIVA QUAD XT CRT-D; VIVA S CRT-D; VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update (release 10.2) to the Next Generation Hybrid Tester (NGHT) for currently marketed devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S596	06/30/2017	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Software and hardware changes to the Titan Device Tester which is used during final functional device testing.
P010031/S597	06/22/2017	X - 30-Day Notice	AMPLIA MRI/AMPLIA MRI QUAD;BRAVA/BRAVA QUAD; CLARIA MRI/CLARIA MRI QUAD; COMPIA MRI/ COMPIA MRI QUAD; CONSULTA; MAXIMO II; PROTECTA/PROTECTA XT; DAXIMO II; VIVA QUAD S/ VIVA QUAD XT/VIVA S/VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to heavy metal testing for silicone.
P010032/S128	06/21/2017	X - 30-Day Notice	SPINAL CORD STIMULATOR EXTERNAL PULSE GENERATOR	ST. JUDE MEDICAL	Update to SCS EPG Header Assembly Process.
P010032/S129	06/28/2017	X - 30-Day Notice	TRIM CHANGE	ST. JUDE MEDICAL	Software update to the Automated Test Equipment (ATE) that will set the value of Open Threshold and Switch Threshold for all Proclaim, Infinity, and Proclaim DRG devices to a constant value of 253 during manufacturing instead of calculating the trim value using a formula.
P010033/S034	06/20/2017	X - 30-Day Notice	QUANTIFERON TB GOLD	QIAGEN	Add an in-house facility as an additional site for Quality Control testing for components.
P010054/S030	06/23/2017	X - 30-Day Notice	ELECSYS ANTI-HBS IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P020004/S143	06/16/2017	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Updates to bioburden action/alert limits for the Gore Cardioform Septal Occluder, Gore TAG Thoracic Endoprosthesis, and Gore Excluder AAA Endoprosthesis, as well as approval to reassess alert limits periodically according to the given protocol and report updated alert limits in future PMA annual reports.
P020004/S144	06/19/2017	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Modifications to an in-process dimensional inspection method, associated specifications, and sampling plan for a sub-component.
P020025/S102	06/27/2017	X - 30-Day Notice	INTELLANAV XP AND INTELLANAV MIFI XP TEMPERATURE ABLATION CATHETERS	BOSTON SCIENTIFIC	Alternate vendor to manufacture the tube braid component used for the IntellaNav XP and IntellaNav MiFI XP Temperature Ablation Catheters.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030016/S031	06/16/2017	X - 30-Day Notice	VISIAN IMPLANTABLE COLLAMER LENS FOR MYOPIA	STAAR SURGICAL CO.	Adding an alternative water purification system to the STARR Surgical Monrovia, CA manufacturing site.
P030017/S292	06/19/2017	X - 30-Day Notice	PRECISION SPECTRA AND SPECTRA WAVEWRITER SPINAL CORD STIMULATOR	BOSTON SCIENTIFIC CORP.	Adding a maximum of five (5) minute transfer time at ambient conditions from a vacuum bake oven to a laser welder for the Precision Spectra and the Spectra Wave Writer Implantable Pulse Generators (IPGs).
P030017/S293	06/21/2017	X - 30-Day Notice	PRECISION MONTAGE AND PRECISION MONTAGE MRI SPINAL CORD STIMULATOR SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the Montage and Montage MRI IPG Automated Test Equipment (ATE) device level test software to address elevated noise levels during stimulation timing testing which may affect communication between the test computer and device being tested.
P030017/S294	06/21/2017	X - 30-Day Notice	PRECISION SPECTRA SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add 40 seconds delay between the Bootloader and application firmware download tests to the Precision® Spectra Implantable Pulse Generator (IPG) Packaging Automated Test Equipment (ATE) Test System.
P030022/S043	06/02/2017	X - 30-Day Notice	REFLECTION CERAMIC ACETABULAR HIP SYSTEM (RCHS)	SMITH & NEPHEW, INC.	Separation of the water treatment system and replacement of some water treatment machinery.
P040027/S056	06/06/2017	X - 30-Day Notice	GORE, VIATORR TIPS ENDOPROSTHESIS - WITH CONTROLLED EXPANSION	W. L. GORE & ASSOCIATES, INC.	Alternate supplier and the elimination of a redundant inspection for a component of the GORE® VIATORR® TIPS Endoprosthesis and GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion.
P040027/S057	06/19/2017	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Modifications to an in-process dimensional inspection method, associated specifications, and sampling plan for a sub-component.
P040037/S099	06/19/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS/GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Modifications to an in-process dimensional inspection method, associated specifications, and sampling plan for a sub-component.
P040043/S092	06/16/2017	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Updates to bioburden action/alert limits for the Gore Cardioform Septal Occluder, Gore TAG Thoracic Endoprosthesis, and Gore Excluder AAA Endoprosthesis, as well as approval to reassess alert limits periodically according to the given protocol and report updated alert limits in future PMA annual reports.
P040043/S093	06/19/2017	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Modifications to an in-process dimensional inspection method, associated specifications, and sampling plan for a sub-component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040045/S072	06/14/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Qualification of a flexible recartoning line used to repackage Vistakon (senofilcon A) Brand Contact Lenses.
P040045/S073	06/16/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Reduce the process limit for the maximum allowable cumulative sterilization exposure from 3 to 2 full sterilization runs.
P040045/S074	06/20/2017	X - 30-Day Notice	SENOFILCON A REACTIVE MONOMER MIX (RMM) BATCHES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of a preliminary visual inspection screening of incoming reactive monomer mixture (RMM) batches.
P040045/S075	06/16/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Change to the expiry date of a diluent.
P040045/S076	06/20/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) ACUVUE OASYS® BRAND CONTACT LENSES.	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Conversion of an existing production line to produce VISTAKON (senofilcon A) ACUVUE OASYS® Brand Contact Lenses.
P040047/S045	06/27/2017	X - 30-Day Notice	COAPTITE INJECTABL IMPLANT	MERZ NORTH AMERICA, INC	Installation of an alternate X-Ray Diffraction unit at Merz North America Quality Lab.
P050006/S059	06/16/2017	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Updates to bioburden action/alert limits for the Gore Cardioform Septal Occluder, Gore TAG Thoracic Endoprosthesis, and Gore Excluder AAA Endoprosthesis; and reassess alert limits periodically according to the given protocol and report updated alert limits in future PMA annual reports.
P050037/S080	06/27/2017	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Installation of an alternate X-Ray Diffraction unit at Merz North America Quality Lab.
P050037/S081	06/26/2017	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Upgrade to manufacturing steam system equipment.
P050052/S094	06/27/2017	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMA FILLER	MERZ NORTH AMERICA, INC	Installation of an alternate X-Ray Diffraction unit at Merz North America Quality Lab.
P050052/S095	06/26/2017	X - 30-Day Notice	RADIESSE (+) LIDOCAINE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Upgrade to manufacturing steam system equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050053/S039	06/14/2017	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Source manufacturing change to the absorbable collagen sponge component of Infuse Bone Graft.
P060039/S078	06/22/2017	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P070015/S137	06/23/2017	X - 30-Day Notice	XIENCE V/NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Extend the retest period from 60 months to 96 months for everolimus repackaged in Configuration I.
P080006/S109	06/22/2017	X - 30-Day Notice	ATTAIN ABILITY/ PERFORMA LEAD	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P080011/S059	06/09/2017	X - 30-Day Notice	BIOFINITY SPHERE AND BIOFINITY XR SPHERE ; BIOFINITY TORIC AND BIOFINITY XR TORIC ; BIOFINITY MULTIFOCAL ; BIOFINITY ENERGYS	COOPERVISION MANUFACTURING, LTD.	Change in the denatured alcohol used in the extraction process for comfilcon A soft contact lenses.
P080011/S060	06/22/2017	X - 30-Day Notice	BIOFINITY XR TORIC	COOPERVISION MANUFACTURING, LTD.	Modification to the surface finish of the male plug used in the manufacturing of Biofinity MTO (Made to Order) XR Toric lenses.
P080012/S043	06/07/2017	X - 30-Day Notice	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Alternate supplier (Hudson Technologies Company, One Blue Hill Plaza, Pearl River, New York) of R-21(dichlorofluoromethane) for the Prometra Programmable Infusion Pump System.
P080025/S140	06/15/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS) BOWEL	MEDTRONIC NEUROMODULATION	Implementation of an additional vision system.
P080027/S028	06/30/2017	X - 30-Day Notice	ORAQUICK HCV ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Production scale-up of a critical component used for pouched test devices.
P090013/S257	06/08/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG RVDR01	MEDTRONIC, INC	Additional vision system for inspection of final packaged devices.
P090013/S258	06/28/2017	X - 30-Day Notice	CAPSUREFIX MRI LEAD 5086MRI	MEDTRONIC, INC	Modifications to the helix tip grinding process.
P090013/S259	06/22/2017	X - 30-Day Notice	CAPSUREFIX MRI LEAD/ REVO MRI SURESCAN IPG	MEDTRONIC, INC	Changes to heavy metal testing for silicone.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090018/S036	06/09/2017	X - 30-Day Notice	ESTEEM	ENVOY MEDICAL CORPORATION	New component supplier for the polyether ether ketone (PEEK) overmold component of the Esteem Model 7004/7010 Sensor assemblies and Model 7504/7510 Driver assemblies.
P090022/S034	06/05/2017	X - 30-Day Notice	LENSTEC SOFTEC HD ASPHERIC POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Supplier change for the glass vials and lids used to package the Softec Intraocular Lenses.
P100009/S024	06/22/2017	X - 30-Day Notice	MITRACLIP AND MITRACLIP NT CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Increase the capacity and number of personnel in the Menlo Park cleanroom.
P100031/S018	06/23/2017	X - 30-Day Notice	ELECSYS ANTI-HBC IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P100032/S015	06/23/2017	X - 30-Day Notice	ELECSYS ANTI-HBC IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P100044/S029	06/28/2017	X - 30-Day Notice	PROPEL CONTOUR SINUS IMPLANT DELIVERY SYSTEM	INTERSECT ENT	Changes to the tip molding and the applicator forming manufacturing processes for the Propel Contour Sinus Implant Delivery System.
P100045/S020	06/15/2017	X - 30-Day Notice	CARDIOMEMS PA SENSOR AND DELIVERY CATHETER	ST. JUDE MEDICAL	Adding an additional supplier for a component of the CardioMEMS PA sensor and adding additional alignment marks.
P100047/S092	06/13/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of new laser welding parameters for the HeartWare Ventricular Assist Device pump.
P100047/S093	06/20/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Replacement of an existing inspection method for the outer inflow tube O-ring channel width.
P100047/S094	06/21/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change to a quality control inspection activity for the HVAD Pump.
P100047/S095	06/27/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of new visual criteria and inspection for particulates in the packaging trays of HVAD components.
P100047/S096	06/08/2017	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Modify the inspection procedure for the impeller used in the HeartWare Ventricular Assist Device (HVAD) pump component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100047/S097	06/27/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST DEVICE SYSTEM	MEDTRONIC	Implementation of a new Pouch Sealer and a modification to the peel strength test.
P100047/S098	06/27/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Modification to the manufacturing and quality inspection procedures and process record for the inner bearing assembly component in the HeartWare Ventricular Assist Device Pump.
P100047/S099	06/13/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Change to the inspection method for the inner Inflow Tube in the Cannula on the HeartWare Ventricular Assist Device (HVAD) Pump.
P100047/S100	06/29/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST DEVICE SYSTEM	MEDTRONIC	Modification to an existing inspection method for the HVAD Center Post component and addition of a new inspection for the HVAD Center Post component.
P110002/S019	06/02/2017	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS	LDR SPINE USA	Manufacturing changes that include the addition of a new plasma spray coating supplier and raw titanium material supplier
P110009/S019	06/02/2017	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS	LDR SPINE USA INC.	Manufacturing changes that include the addition of a new plasma spray coating supplier and raw titanium material supplier
P110013/S079	06/21/2017	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Add an alternate vendor for rapamycin, the zotarolimus starting material.
P110019/S093	06/23/2017	X - 30-Day Notice	XIENCE PRIME SV/LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Extend the retest period from 60 months to 96 months for everolimus repackaged in Configuration I.
P110022/S021	06/23/2017	X - 30-Day Notice	ELECSYS ANTI-HBC IGM IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P110025/S019	06/23/2017	X - 30-Day Notice	ELECSYS ANTI-HBC IGM IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P110031/S018	06/23/2017	X - 30-Day Notice	ELECSYS ANTI-HBC IGM IMMUNOASSAY	ROCHE DIAGNOSTICS CORP.	Change to the manufacture of microparticles.
P110035/S041	06/16/2017	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Minor modifications to the electropolishing process.

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P110042/S085	06/06/2017	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) EMBLEM MRI, S-ICD GEN 2.	BOSTON SCIENTIFIC CORPORATION	Alternate supplier for Titanium ribbon.
P120010/S104	06/23/2017	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Qualification of a second injection molding machine to produce the "Hub Body" component of the Enlite Sensor (MMT-7008). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 Continuous Glucose Monitoring System.
P120017/S008	06/22/2017	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Changes to heavy metal testing for silicone.
P130006/S038	06/19/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS/GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Modifications to an in-process dimensional inspection method, associated specifications, and sampling plan for a sub-component.
P130007/S026	06/09/2017	X - 30-Day Notice	ANIMAS, VIBE SYSTEM	ANIMAS CORP.	New injection molding equipment and tooling used for injection molding processes during manufacture of three components of the Animas 2.0 mL Insulin Cartridge. The Insulin Cartridge is a component of the Animas Vibe System.
P130008/S024	06/07/2017	X - 30-Day Notice	INSPIRE MEDICAL SYSTEMS MODEL 3028 IMPLANTABLE PULSE GENERATOR	INSPIRE MEDICAL SYSTEMS	Changes to the final functional testing of the Model 3028 IPG.
P130008/S025	06/07/2017	X - 30-Day Notice	MODEL 3028 IPG	INSPIRE MEDICAL SYSTEMS	Changes to the serial number test system.
P130008/S026	06/09/2017	X - 30-Day Notice	INSPIRE MEDICAL SYSTEM MODEL 3028 HYBRID PROCESS	INSPIRE MEDICAL SYSTEMS	Changes to the weld blocks/solder paste used in the manufacture of the Model 3028 IPG.
P130009/S076	06/20/2017	X - 30-Day Notice	SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement upgrades to the TagAlert sensor.
P130009/S077	06/22/2017	X - 30-Day Notice	SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implementation of changes to the frame tensile specimen geometry, surface treatment and test method.
P130014/S004	06/02/2017	X - 30-Day Notice	ADHERUS AUTOSPRAY DURAL SEALANT	HYPERBRANCH MEDICAL TECHNOLOGY, INC.	Addition of a secondary supplier for polyolefin elastomer spike caps.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130015/S010	06/23/2017	X - 30-Day Notice	ELECSYS HBEAG IMMUNOASSAY	ROCHE DIAGNOSTICS OPERATIONS INC	Change to the manufacture of microparticles.
P130016/S027	06/13/2017	X - 30-Day Notice	NUCLEUS HYBRID COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Introduction of the new CBO Sprint Cleanroom at the Cochlear Brisbane Operations (CBO) manufacturing site.
P130017/S018	06/30/2017	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Use of a method of evaluating and diluting incoming lots of an enzyme.
P130017/S019	06/23/2017	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Secondary supplier of a raw material.
P130021/S038	06/28/2017	X - 30-Day Notice	ENVEO R DELIVERY CATHETER SYSTEM	MEDTRONIC COREVALVE LLC	Changes to the inspections of the outer shaft subassembly of the EnVeo R Delivery Catheter System.
P140003/S019	06/20/2017	X - 30-Day Notice	IMPELLA CP VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC.	Add a second supplier for the internal motor coil component of the Impella CP catheters.
P140009/S024	06/28/2017	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ST. JUDE MEDICAL NEUROMODULATION	Software update to the Automated Test Equipment (ATE) that will set the value of Open Threshold and Switch Threshold for all Proclaim, Infinity, and Proclaim DRG devices to a constant value of 253 during manufacturing instead of calculating the trim value using a formula.
P140010/S034	06/23/2017	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED BALLON CATHETER	MEDTRONIC INC.	Use of a new fixture for proximal connector tube flaring.
P140015/S022	06/15/2017	X - 30-Day Notice	G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM SYSTEM	TANDEM DIABETES CARE, INC.	Modification to add a QC Manufacturing Aid to complement Quality Control acceptance review during the manufacturing of the t:slim G4 insulin pump, intended to be used with Dexcom G4 Continuous Glucose Monitoring (CGM) sensor and transmitter.
P140021/S009	06/23/2017	X - 30-Day Notice	ELECSYS ANTI-HCV II (100/200 TESTS) IMMUNOASSAY	ROCHE DIAGNOSTICS OPERATIONS INC	Change to the manufacture of microparticles.
P140028/S026	06/14/2017	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Laser software update for the stent laser cutting process.

Number	Decision	Review Track	Trade Name	Name	Approval Order Statement
P140028/S027	06/16/2017	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Minor modifications to the electropolishing process.
P140031/S042	06/20/2017	X - 30-Day Notice	SAPIEN S3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement upgrades to the TagAlert sensor.
P140031/S043	06/22/2017	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implementation of changes to the frame tensile specimen geometry, surface treatment and test method.
P140031/S044	06/16/2017	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCES, LLC.	Changes to the receiving inspection and dimensional tolerance for the flex shaft component of the Commander Delivery System.
P150001/S015	06/06/2017	X - 30-Day Notice	MEDTRONIC MINIMED 630G INSULIN PUMP	MEDTRONIC MINIMED	Changes to update tester software that performs a series of tasks during final acceptance activities, after 630G and 670G insulin pumps have been fully assembled. The 630G insulin pump is part of the MiniMed 630G system and the 670G insulin pump is part of the MiniMed 670G system.
P150001/S016	06/23/2017	X - 30-Day Notice	MEDTRONIC MINIMED 630G SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Qualification of a second injection molding machine to produce the "Hub Body" component of the Enlite Sensor (MMT-7008). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 Continuous Glucose Monitoring System.
P150003/S031	06/14/2017	X - 30-Day Notice	SYNERGY EVEROLIMUS ELUTING CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Laser software update for the stent laser cutting process.
P150004/S010	06/28/2017	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	SPINAL MODULATION, INC	Software update to the Automated Test Equipment (ATE) that will set the value of Open Threshold and Switch Threshold for all Proclaim, Infinity, and Proclaim DRG devices to a constant value of 253 during manufacturing instead of calculating the trim value using a formula.
P150005/S021	06/13/2017	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER, INTELLANAV OPEN-IRRIGATED ABLATION CATHETER, INTELLA TIP MIFI OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Alternate component vendors for Chill II, Blazer OI, IntellaNav OI, and IntellaTip MiFi OI catheters.
P150014/S007	06/07/2017	X - 30-Day Notice	ROCHE COBAS HBV	ROCHE MOLECULAR SYSTEMS, INC.	Increase the manufacturing batch size range for a bulk kit reagent.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150015/S006	06/07/2017	X - 30-Day Notice	ROCHE COBAS HCV	ROCHE MOLECULAR SYSTEMS, INC.	Increase the manufacturing batch size range for a bulk kit reagent.
P150019/S030	06/23/2017	X - 30-Day Notice	PARADIGM REAL TIME REVEL SYSTEM	MEDTRONIC MINIMED	Qualification of a second injection molding machine to produce the "Hub Body" component of the Enlite Sensor (MMT-7008). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 Continuous Glucose Monitoring System.
P150023/S009	06/23/2017	X - 30-Day Notice	ABSORB GTI BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM	ABBOTT VASCULAR INC.	Extend the retest period from 60 months to 96 months for everolimus repackaged in Configuration I.
P150029/S009	06/23/2017	X - 30-Day Notice	IPRO2 CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM WITH ENLITE SYSTEM	MEDTRONIC MINIMED	Qualification of a second injection molding machine to produce the "Hub Body" component of the Enlite Sensor (MMT-7008). The Enlite Sensor is a component of the MiniMed 530G System, the MiniMed 630G System, the Paradigm Real-Time Revel System, and the iPro2 Continuous Glucose Monitoring System.
P150030/S002	06/02/2017	X - 30-Day Notice	R3 DELTA CERAMIC HIP SYSTEM	SMITH & NEPHEW, INC.	Separation of the water treatment system and replacement of some water treatment machinery.
P150033/S023	06/08/2017	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Change to the chemical used for the etch process for integrated circuit components.
P150036/S011	06/09/2017	X - 30-Day Notice	EDWARDS INTUITY VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Cobalt chromium band forming and welding operations be completed by the vendor.
P150036/S012	06/20/2017	X - 30-Day Notice	INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Implement upgrades to the TagAlert sensor.
P160004/S004	06/19/2017	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Modifications to an in-process dimensional inspection method, associated specifications, and sampling plan for a sub-component.
P160017/S013	06/06/2017	X - 30-Day Notice	MINIMED 670G INSULIN PUMP	MEDTRONIC MINIMED	Changes to update tester software that performs a series of tasks during final acceptance activities, after 630G and 670G insulin pumps have been fully assembled. The 630G insulin pump is part of the MiniMed 630G system and the 670G insulin pump is part of the MiniMed 670G system.
P160019/S002	06/23/2017	X - 30-Day Notice	ELECSYS HBSAG II (100/200 TESTS) IMMUNOASSAY	ROCHE DIAGNOSTICS, INC.	Change to the manufacture of microparticles.
P160021/S002	06/19/2017	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Modifications to an in-process dimensional inspection method, associated specifications, and sampling plan for a sub-component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160043/S002	06/21/2017	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC INC.	Add an alternate vendor for rapamycin, the zotarolimus starting material.

Total: 188