PMA Monthly approvals from 9/1/2017 to 9/30/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150042	09/19/2017	PMAO - PMA Origi	ZEUS ELISA PARVOVIRUS B19 IGM TEST SYSTEM	ZEUS SCIENTIFIC, INC.	Approval for the ZEUS ELISA Parvovirus B19 IgM Test System is intended for the qualitative detection of IgM class antibodies to human parvovirus B19 in human serum including women of childbearing age where there is a suspicion of exposure to human parvovirus B19. The test is also for all symptomatic patients as an aid in the diagnosis of fifth disease (erythema infectiosum). This test is for in vitro diagnostic use only.
P150045	09/19/2017	PMAO - PMA Origi	ZEUS ELISA PARVOVIRUS B19 IGG TEST SYSTEM	ZEUS SCIENTIFIC, INC.	Approval for the ZEUS ELISA Parvovirus B19 IgG Test System is intended for the qualitative detection of IgG class antibodies to human parvovirus B19 in human serum including women of childbearing age where there is a suspicion of exposure to human parvovirus B19. The test is also for all symptomatic patients as an aid in the diagnosis of fifth disease (erythema infectiosum). This test is for in vitro diagnostic use only.
P160030	09/27/2017	PMAO - PMA Origi	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for the Freestyle Libre Flash Glucose Monitoring System. The FreeStyle Libre Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device indicated for the management of diabetes in persons age 18 and older. It is designed to replace blood glucose testing for diabetes treatment decisions. The System detects trends and tracks patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is intended for single patient use and requires a prescription.
P170011	09/20/2017	PMAO - PMA Origi	IMPELLA RP SYSTEM	ABIOMED, INC.	Approval for the Impella RP® System. This device is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area greater than or equal to 1.5 m2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Total: 4

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Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S204	09/11/2017	N - Normal 180 Day	ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT, ALTRUA 2 PACEMAKERS	BOSTON SCIENTIFIC CORP.	Approval for the Model 3300 LATITUDE Programming System.
N970003/S208	09/11/2017	R - Real-Time Proc	TORQUE WRENCH	BOSTON SCIENTIFIC CORP.	Approval for updates to the torque wrench tool.
N970003/S209	09/21/2017	R - Real-Time Proc	ALTRUA 2 /ESSENTIO/ PROPONENT/ ACCOLADE	BOSTON SCIENTIFIC CORP.	Approval for addition of a hydrogen getter component within the pulse generator.
N970012/S136	09/26/2017	R - Real-Time Proc	AMS 700 AND AMBICOR INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for changes to the cleaning and sterilization instructions labeling and packaging modification for the reusable AMS Tools.
P830055/S179	09/28/2017	O - Normal 180 Day	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a manufacturing site located at 3D Systems Inc., 5381 South Alkire Circle, Littleton, Colorado, 80127
P830055/S183	09/12/2017	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for the labeling update to the ATTUNE Knee System INTUITION SOLO Instruments Surgical Technique and the Sterile ATTUNE INTUTITION SOLO Single Use Surgical Instruments Instructions for Use.
P830055/S184	09/18/2017	R - Real-Time Proc	ATTUNE REVISION KNEE SYSTEM	DEPUY, INC.	Approval for the addition of ATTUNE Revision Rotating Platform (RP) Tibial Bases, ATTUNE Revision CRS RP Tibial Inserts, and ATTUNE Revision Tibial Sleeves to the ATTUNE Knee System.
P840001/S365	09/01/2017	R - Real-Time Proc	RESTORE, INTREL AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for a minor design change (lowering values of resistances R54 and R56 in the analog board of the INSR) to the Implantable Neurostimulator Recharger (INSR) used in the Restore Spinal Cord Stimulation and Activa Deep Brain Stimulation therapy systems.
P840001/S367	09/26/2017	R - Real-Time Proc	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for minor specification and material changes to the antenna wire and solder composition used in the model 37092 External Antenna, in addition to minor manufacturing changes and minor design changes to the exterior mold.
P860004/S284	09/26/2017	R - Real-Time Proc	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	minor specification and material changes to the antenna wire and solder composition used in the model 37092 External Antenna, as well as minor manufacturing changes and minor design changes to the exterior mold

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement P880086/S286 09/11/2017 R - Real-Time Proc
P890003/S372	09/01/2017	N - Normal 180 Day	SYNERGYST II PULSE GENERATOR	MEDTRONIC, INC.	Approval for the Heart Failure Risk Status feature for the CareLink Network.
P890003/S377	09/11/2017	R - Real-Time Proc	OUS VITATRON APPLICATION SOFTWARE	MEDTRONIC, INC.	Approval for release of non-US Vitatron device application software.
P900033/S063	09/08/2017	O - Normal 180 Day	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Approval for the Steris Applied Sterilization Technologies (AST) Electron Beam (E-Beam) processing facility located at 7225 North Noah Drive, Saxonburg, Pennsylvania, 16056, as an alternate E-Beam Sterilization facility for the Integra Regeneration Template (IDRT) product family.
P910023/S384	09/21/2017	N - Normal 180 Day	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Approval for MR Conditional labeling at 1.5T for the ICD systems consisting Ellipse ICDs, Durata, Optisure, and Tendril MRI leads.
P910023/S389	09/11/2017	R - Real-Time Proc	CURRENT+, FORTIFY, FORTIFY ASSURA, ELLIPSE	ST. JUDE MEDICAL	Approval of a change to the capacitance parameter of the Schottky diode.
P910023/S390	09/26/2017	R - Real-Time Proc	FORTIFY, FORTIFY ASSURA	ST. JUDE MEDICAL	Approval for a modification to an auxiliary coil Q-Factor parameter.
P910073/S142	09/20/2017	N - Normal 180 Day	ENDOTAK RELIANCE¿, (DEFIBRILLATION LEADS)	BOSTON SCIENTIFIC	Approval to label a subset of the market released devices as ImageReady MR Conditional Defibrillation System.
P910077/S159	09/11/2017	N - Normal 180 Day	LATITUDE ¿ PROGRAMMING SYSTEM	BOSTON SCIENTIFIC	Approval for the Model 3300 LATITUDE Programming System.
P910077/S161	09/20/2017	N - Normal 180 Day	MULTI-APPLICATION UTILITY MODEL, (NON-IMPLANTABLE ACCESSORIES)	BOSTON SCIENTIFIC	Approval to label a subset of the market released devices as ImageReady MR Conditional Defibrillation System.
P930014/S103	09/21/2017	R - Real-Time Proc	ACRYSOF IQ TONIC LENSES	ALCON RESEARCH, LTD.	Approval for the use of the Enhanced Dry NIMO Wavefront Measurement System for quality control inspection of optical performance for in situ spherical equivalent and cylindrical powers, image quality, spherical aberration and labeled axis of AcrySof® Toric Intraocular Lenses (IOLs), and spherical aberration and labeled axis of AcrySof® Multifocal and Multifocal-Toric Intraocular Lenses.
P950022/S105	09/21/2017	N - Normal 180 Day	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Approval for MR Conditional labeling at 1.5T for the ICD systems consisting Ellipse ICDs, Durata, Optisure, and Tendril MRI leads.
P960004/S081	09/20/2017	N - Normal 180 Day	FINELINE¿ II STEROX LEADS, SUTURE SLEEVE ACCESSORY FOR FINELINE II LEADS, (PACING LEADS AND ACCESSORIES)	BOSTON SCIENTIFIC	Approval to label a subset of the market released devices as ImageReady MR Conditional Defibrillation System.
P960009/S284	09/01/2017	R - Real-Time Proc	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for a minor design change (lowering values of resistances R54 and R56 in the analog board of the INSR) to the Implantable Neurostimulator Recharger (INSR) used in the Restore Spinal Cord Stimulation and Activa Deep Brain Stimulation therapy systems.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960009/S286	09/26/2017	R - Real-Time Proc	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for minor specification and material changes to the antenna wire and solder composition used in the model 37092 External Antenna, in addition to minor manufacturing changes and minor design changes to the exterior mold.
P960040/S391	09/11/2017	N - Normal 180 Day	TELIGEN, ENERGEN, PUNTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN	BOSTON SCIENTIFIC	Approval for the Model 3300 LATITUDE Programming System.
P960040/S395	09/20/2017	N - Normal 180 Day	RESONATE, VIGILANT, PERCIVA NG4 ICDS AUTOGEN, DYNAGEN, INOGEN, ORIGEN NG3 ICDS	BOSTON SCIENTIFIC	Approval to label a subset of the market released devices as ImageReady MR Conditional Defibrillation System.
P960040/S398	09/11/2017	R - Real-Time Proc	TORQUE WRENCH	BOSTON SCIENTIFIC	Approval for updates to the torque wrench tool.
P970004/S247	09/25/2017	N - Normal 180 Day	MASTER INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY PROGRAMMING SYSTEMS)	MEDTRONIC NEUROMODULATION	Approval of new Model A511 clinician programmer application and Model A521 patient programmer application; labeling change; and packaging change.
P970004/S249	09/26/2017	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Approval for minor specification and material changes to the antenna wire and solder composition used in the model 37092 External Antenna, in addition to minor manufacturing changes and minor design changes to the exterior mold.
P970051/S166	09/20/2017	R - Real-Time Proc	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for an update to the Cochlear Integrity Test System version 1.4 to version 1.5. The update to version 1.5 from 1.4 is a minor software change that includes 1) the addition of a dropdown box for Cochlear employees to select the CI532 with Slim Modiolar Electrode from the suite of compatible implants and 2) a revision to the stimulation safety limits.
P980016/S616	09/01/2017	N - Normal 180 Day	EVERA MRI DF-1/ DF-1 ICD/ MRI ICD/ EVERA XT DR ICD/ VR ICD; PROTECTA XT ICD; SECURA ICD; VIRTUOSO II DR/VR ICD; VISIA AF MRI DFI ICD; MRI VR ICD & VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Heart Failure Risk Status feature for the CareLink Network.
P980016/S638	09/21/2017	R - Real-Time Proc	MAXIMO II ICD, PROTECTA ICD, PROTECTA VR ICD, PROTECTA XT ICD, SECURA DR ICD, SECURA ICD, VIRTUOSO II DR/VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a minor design change and related manufacturing process changes to the resistor array network component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000006/S047	09/08/2017	R - Real-Time Proc	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Approval for addition of 16 cm and 18 cm narrow base zero degree cylinder models.
P000015/S023	09/20/2017	R - Real-Time Proc	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for an update to the Cochlear Integrity Test System version 1.4 to version 1.5. The update to version 1.5 from 1.4 is a minor software change that includes 1) the addition of a dropdown box for Cochlear employees to select the CI532 with Slim Modiolar Electrode from the suite of compatible implants; and 2) a revision to the stimulation safety limits.
P000053/S080	09/26/2017	R - Real-Time Proc	AMS 800 ARTIFICIAL URINARY SPHINCTER	BOSTON SCIENTIFIC CORP.	Approval for changes to the cleaning and sterilization instructions labeling and packaging modification for the reusable AMS Tools.
P000053/S083	09/18/2017	S - Special CBE	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Approval to update the Instructions for Use to enhance the safety of the AMS 800 device.
P000058/S065	09/21/2017	N - Normal 180 Day	INFUSE (R) BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for expansion of the approved indications for use of Infuse Bone Graft to include implantation with two additional interbody fusion devices, the Divergence-L Anterior/ Oblique Lumbar Fusion System or the Pivox Oblique Lateral Spinal System, utilizing select open surgical procedures in conjunction with supplemental spinal fixation hardware, as well as modifying the surgical technique manual to allow surgeons to optionally wrap a resorbable suture around the fusion cage component to maintain the position of the Infuse Bone Graft within the central cavity of the fusion cage component.
P010012/S448	09/11/2017	N - Normal 180 Day	COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN CRT-DS	BOSTON SCIENTIFIC CORP.	Approval for the Model 3300 LATITUDE Programming System.
P010012/S453	09/20/2017	N - Normal 180 Day	RESONATE, VIGILANT NG4 CRT-DS, AUTOGEN, DYNAGEN, INOGEN, ORIGEN NG3 CRT-DS, ACUITY¿ X4 LEADS, SLIT SUTURE SLEEVE ACCESSORY FOR ACUITY X4, (CORONARY PACING LEADS AND ACCESSORY	BOSTON SCIENTIFIC CORP.	Approval to label a subset of the market released devices as ImageReady MR Conditional Defibrillation System.
P010012/S458	09/11/2017	R - Real-Time Proc	TORQUE WRENCH	BOSTON SCIENTIFIC CORP.	Approval for updates to the torque wrench tool.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010014/S065	09/08/2017	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM - FEMORAL COMPONENTS, TIBIAL TRAY COMPONENTS, MENISCAL BEARINGS	BIOMET MANUFACTURING CORP.	Approval to update the surgical technique provided on the placement of the femoral drill hole, within the approved surgical technique for the Oxford Partial Knee System.
P010015/S318	09/01/2017	N - Normal 180 Day	CONSULTA CRT-P & VIVA CRT-P	MEDTRONIC INC.	Approval for the Heart Failure Risk Status feature for the CareLink Network.
P010031/S575	09/01/2017	N - Normal 180 Day	AMPLIA MRI CRT-D /QUAD CRT-D; CLARIA MRI CRT-D/ QUAD CRT-D; COMPIA MRI CRT-D /QUAD CRT-D; CONCERTO ICD & II CRT-D; CONSULTA CRT-D; PROTECTA XT CRT-D; VIVA QUAD XT CRT-D/XT CRT-D; VIVA XT CRT-D.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Heart Failure Risk Status feature for the CareLink Network.
P010031/S599	09/21/2017	R - Real-Time Proc	CONCERTO II CRT-D, CONSULTA CRT-D, MAXIMO II CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a minor design change and related manufacturing process changes to the resistor array network component.
P020024/S048	09/21/2017	O - Normal 180 Day	AMPLATZER DUCT OCCLUDER II	AGA MEDICAL CORP.	Approval for the AMPLATZER Duct Occluder II Instructions for Use, which has been updated to include the results of the completed post approval study.
P030005/S152	09/11/2017	N - Normal 180 Day	INVIVE, INTUA, VISIONIST, VALITUDE	GUIDANT CORP.	Approval for the Model 3300 LATITUDE Programming System.
P030005/S156	09/11/2017	R - Real-Time Proc	TORQUE WRENCH	GUIDANT CORP.	Approval for updates to the torque wrench tool.
P030017/S277	09/08/2017	O - Normal 180 Day	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Cardiac Pacemakers, Inc. (CPI), A wholly owned subsidiary of Guidant Corporation, A wholly owned subsidiary of Boston Scientific Corporation, 4100 Hamline Avenue North, St. Paul, Minnesota 55112.
P030035/S158	09/11/2017	R - Real-Time Proc	ALLURE. ALLURE QUADRA	ST. JUDE MEDICAL, INC.	Approval of a change to the capacitance parameter of the Schottky diode.
P030054/S326	09/21/2017	N - Normal 180 Day	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Approval for MR Conditional labeling at 1.5T for the ICD systems consisting Ellipse ICDs, Durata, Optisure, and Tendril MRI leads.
P030054/S333	09/11/2017	R - Real-Time Proc	PROMOTE+, UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, AND QUADRA ASSURA MP	ST. JUDE MEDICAL	Approval of a change to the capacitance parameter of the Schottky diode.

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P030054/S334	09/26/2017	R - Real-Time Proc	UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, QUADRA ASSURA MP	ST. JUDE MEDICAL	Approval for a modification to an auxiliary coil Q-Factor parameter.
P040020/S070	09/21/2017	R - Real-Time Proc	ACRYSOF RESTOR +2.5 D MULTIFOCAL INTRAOCULAR LENS / TORIC INTRAOCULAR LENS/3.0 D MULTIFOCAL TORIC INTRAOCULAR LENSES/ TORIC INTRAOCULAR LENSES, ACRYSOL RESTOR 4 D MULTIFOCAL INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Approved for use of the Enhanced Dry NIMO Wavefront Measurement System for quality control inspection of optical performance for in situ spherical equivalent and cylindrical powers, image quality, spherical aberration and labeled axis of AcrySof® Toric Intraocular Lenses (IOLs), and spherical aberration and labeled axis of AcrySof® Multifocal and Multifocal-Toric Intraocular Lenses.
P040044/S077	09/28/2017	R - Real-Time Proc	MYNXGRIP VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Approval to implement minor modifications to the MynxGrip Vascular Closure Device desiccant canister and desiccant canister cavity within the device packaging tray.
P050052/S096	09/18/2017	O - Normal 180 Day	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P060028/S025	09/01/2017	R - Real-Time Proc	MENTOR MEMORYSHAPE SILICONE GEL-FILLED BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval of a product line extension to the currently marketed MemoryShape Silicone Gel-Filled Breast Implants product line involving additional breast implant options with volume and dimensional values that are bracketed within the currently approved ranges for the commercially available MemoryShape implants.
P080012/S046	09/11/2017	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for changes to the Power and Prescription buttons of the Flowonix Prometra Patient Therapy Controller.
P080025/S142	09/25/2017	N - Normal 180 Day	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL PROGRAMMING SYSTEMS)	MEDTRONIC NEUROMODULATION	Approval of new Model A511 clinician programmer application and Model A521 patient programmer application; labeling change; and packaging change.
P080025/S144	09/26/2017	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for minor specification and material changes to the antenna wire and solder composition used in the model 37092 External Antenna, in addition to minor manufacturing changes and minor design changes to the exterior mold.
P080026/S021	09/01/2017	Y - 135 Review Tra	ABBOTT REAL TIME HBV AMPLIFICATION REAGENT KIT / HBV CONTROL KIT / HBV CALIBRATOR KIT	ABBOTT MOLECULAR, INC.	Approval for changes to the polypropylene resin, cap colorant and inside diameter of the tubes and screw-caps used for storage and transport of the finished calibrators and controls, and for the master mix assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090028/S010	09/12/2017	N - Normal 180 Day	VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG REAGENT PACK/ PRODUCTS HBEAG CALIBRATOR/PRODUCTS HBE CONTROLS	ORTHO-CLINICAL DIAGNOSTICS, INC.	Approval for the migration of the VITROS Immunodiagnostic Products HBeAg Reagent Pack, Calibrator, and Controls to two additional systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System.
P100001/S010	09/12/2017	N - Normal 180 Day	VITROS ANTI-HBE REAGENT PACK/ANTI-HBE CALIBRATOR/ANTI HBE CONTROLS	ORTHO-CLINICAL DIAGNOSTICS	Approval for the migration of the VITROS Immunodiagnostic Products Anti-HBe Reagent Pack, Calibrator, and Controls to two additional systems, the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System.
P100017/S020	09/01/2017	Y - 135 Review Tra	ABBOTT REAL TIME HCV AMPLIFICATION REAGENT KIT /HCV CONTROL KIT / HCV CALIBRATOR KIT	ABBOTT MOLECULAR, INC.	Approval for changes to the polypropylene resin, cap colorant and inside diameter of the tubes and screw-caps used for storage and transport of the finished calibrators and controls, and for the master mix assembly.
P100021/S063	09/29/2017	P - Panel Track	EDURANT II/IIS STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for the expansion of the indications for use of the Endurant II/Endurant IIs Stent Graft System to include the treatment of infrarenal abdominal aortic aneurysms having neck lengths >= 4 mm and < 10 mm (short necks), when used in conjunction with the Heli-FX EndoAnchor System. The Endurant II/Endurant IIs bifurcated stent grafts are indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms. They may be utilized in conjunction with the Heli-FX EndoAnchor System when augmented radial fixation and/or sealing is required; in particular, in the treatment of abdominal aortic aneurysms with short (>= 4 mm and < 10 mm) infrarenal necks. The Endurant II aorto-uni-iliac (AUI) stent graft is indicated for the endovascular treatment of infrarenal abdominal aortic or aortoiliac aneurysms in patients whose anatomy does not allow the use of a bifurcated stent graft. The Endurant II/Endurant IIs Stent Graft System is indicated for use in patients with the following characteristics: 1) Adequate iliac or femoral access that is compatible with vascular access techniques, devices, or accessories; 2) Proximal neck length of: >= 10 mm or >= 4 and < 10 mm, when used in conjunction with the Heli-FX EndoAnchor System (bifurcated stent graft only) (Note: Neck length is defined as the length over which the aortic diameter remains within 10% of the infrarenal diameter); 3) Infrarenal neck angulation of <= 60°; 4) Aortic neck diameters with a range of 19 to 32 mm; 5) Distal fixation length(s) of >= 15 mm; 6) Iliac diameters with a range of 8 to 25 mm; and 7) Morphology suitable for aneurysm repair.
P100047/S090	09/27/2017	P - Panel Track	HEARTWARE HVAD SYSTEM	MEDTRONIC	Approval for the HeartWare HVAD System. This device is indicated for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a bridge to cardiac transplantation (BTT), myocardial recovery, or as destination therapy (DT) in patients for whom subsequent transplantation is not planned.
P110006/S008	09/07/2017	O - Normal 180 Day	INVENIA ABUS AUTOATED BREAST ULTRASOUND SYSTEM	U-SYSTEMS, INC.	Approval for a manufacturing site change to GE Parallel Design Inc., 4313 E Cotton Center Blvd., Suite 100, Phoenix, Arizona.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110016/S034	09/29/2017	Y - 135 Review Tra	FLEXABILITY ABLATION CATHETERS (BI & UNI DIRECTIONAL)	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for changes to the tip-to-shaft adhesive bond assembly process utilized in the distal shaft of the FlexAbility Ablation Catheters (Bi-Directional and Uni-Directional).
P110029/S026	09/27/2017	R - Real-Time Proc	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Approval for changes in conditions for specimen centrifugation.
P110032/S013	09/20/2017	O - Normal 180 Day	AORFIX AAA FLEXIBLE STENT GRAFT SYSTEM WITH AORFLEX DELIVERY DEVICE	LOMBARD MEDICAL TECHNOLOGIES INC	Approval to the post-approval study (PAS) protocol.
P110042/S077	09/29/2017	N - Normal 180 Day	MODEL 3501 EMBLEM S-ICD SUBCUTANEOUS ELECTRODE	BOSTON SCIENTIFIC CORPORATION	Approval for the EMBLEM S-ICD Electrode Model 3501 and labeling changes to the components of the EMBLEM S-ICD System.
P110042/S083	09/11/2017	N - Normal 180 Day	S-ICD (SUBCUTANEOUS-ICD) TELEMETRY WAND	BOSTON SCIENTIFIC CORPORATION	Approval for the Model 3300 LATITUDE Programming System.
P110042/S088	09/11/2017	R - Real-Time Proc	TORQUE WRENCH	BOSTON SCIENTIFIC CORPORATION	Approval for updates to the torque wrench tool.
P120005/S065	09/21/2017	R - Real-Time Proc	DEXCON G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for firmware modifications to the touchscreen receiver in the Dexcom G5 Mobile Glucose Monitoring System.
P120012/S016	09/01/2017	Y - 135 Review Tra	ABBOTT REAL TIME HCV GENOTYPE II AMPLIFICATION REAGENT KIT / HCV GENOTYPE II CONTROL KIT	ABBOTT MOLECULAR	Approval for changes to the polypropylene resin, cap colorant and inside diameter of the tubes and screw-caps used for storage and transport of the finished calibrators and controls, and for the master mix assembly.
P120021/S002	09/22/2017	O - Normal 180 Day	AMPLATZER PFO OCCLUDER	ST. JUDE MEDICAL, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P130008/S022	09/11/2017	O - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval of the revised protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130016/S021	09/22/2017	O - Normal 180 Day	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval of the revised protocol for the post-approval study (PAS) protocol.
P130016/S030	09/20/2017	R - Real-Time Proc	NUCLEUS HYBRID IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for an update to the Cochlear Integrity Test System version 1.4 to version 1.5. The update to version 1.5 from 1.4 is a minor software change that includes 1) the addition of a dropdown box for Cochlear employees to select the CI532 with Slim Modiolar Electrode from the suite of compatible implants; and 2) a revision to the stimulation safety limits.
P140003/S023	09/21/2017	R - Real-Time Proc	IMPELLA 2.5 SYSTEM AND IMPELLA VENTRICULAR SUPPORT SUSTEMS	ABIOMED, INC.	Implementation of the Automated Impella Controller (AIC) software version 6.0.1.
P140011/S005	09/29/2017	R - Real-Time Proc	MAMMOMAT INSPIRATION WITH TOMOSYNTHESIS OPTION / MAMMOMAT REVELATION WITH TOMOSYNTHESIS OPTION	SIEMENS MEDICAL SOLUTIONS USA, INC.	Approval for a change to the detector, updated detector (LMAM2V2) with new electronic circuits for read-out.
P140031/S052	09/28/2017	N - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Approval for updates to the labeling to include instructions for implantation using the subclavian and axillary access approaches.
P140033/S006	09/21/2017	N - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for MR Conditional labeling at 1.5T for ICD systems consisting of Ellipse ICDs, Durata, Optisure, and Tendril MRI leads.
P150004/S008	09/29/2017	N - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ST. JUDE MEDICAL	Approval for the Axium Dorsal Root Ganglion (DRG) External Pulse Generator (EPG) Neurostimulator System.
P150012/S032	09/20/2017	N - Normal 180 Day	INGEVITY¿ MRI LEADS, SLIT SUTURE SLEEVE ACCESSORY FOR INGEVITY LEADS (PACING LEADS AND ACCESSORIES)	BOSTONSCIENTIFIC	Approval to label a subset of the market released devices as ImageReady MR Conditional Defibrillation System.
P150012/S033	09/11/2017	R - Real-Time Proc	TORQUE WRENCH	BOSTONSCIENTIFIC	Approval for updates to the torque wrench tool.
P150012/S039	09/11/2017	N - Normal 180 Day	INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, ACCOLADE MRI, PROPONENT MRI	BOSTONSCIENTIFIC	Approval for the Model 3300 LATITUDE Programming System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150013/S006	09/22/2017	P - Panel Track	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for the PD-L1 IHC 22C3 pharmDx for expanding the indications to include gastric cancer patients. This device is indicated for the followingPD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and gastric or gastroesophageal junction (GEJ) adenocarcinoma tissues using EnVision FLEX visualization system on Autostainer Link 48. Non-Small Cell Lung Cancer (NSCLC) PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. The specimen should be considered to have PD-L1 expression if TPS ?1% and high PD-L1 expression if TPS ?50%. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab). See the KEYTRUDA® product label for expression cutoff values guiding therapy in specific clinical circumstances. Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma PD-L1 protein expression in gastric or GEJ adenocarcinoma is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100 . The specimen should be considered to have PD-L1 expression if CPS ? 1. PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150025/S003	09/15/2017	P - Panel Track	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for the PD-L1 IHC 28-8 pharmDx for expanding the indications to squamous cell carcinoma of the head and neck, and urothelial cancer patients. This device is indicated for the following: For in vitro diagnostic use. PD-L1 IHC 28-8 pharmDx is a qualitative immunohistochemical assay using Monoclonal Rabbit Anti-PD-L1, Clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-squamous non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), urothelial carcinoma (UC), and melanoma tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is defined as the percentage of evaluable tumor cells exhibiting partial or complete membrane staining at any intensity. Tumor PD-L1 status is defined by indication specific staining interpretation. Tumor Indication* Intended Use PD-L1 Expression Clinical Cut off nsNSCLC PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx in non-squamous NSCLC and SCCHN may be associated with enhanced survival from OPDIVO® (nivolumab). >=1%, >=5%, >=10% SCCHN >=1% UC PD-L1 expression as detected by PD-L1 IHC 28-8 pharmDx in UC may be associated with enhanced response rate from OPDIVO®. >=1% Melanoma Positive PD-L1 status as determined by PD-L1 IHC 28-8 pharmDx in melanoma is correlated with the magnitude of the treatment effect on progression-free survival from OPDIVO®. >=1% *For details on staining interpretation, refer to section 13 of the product insert and indication specific PD-L1 IHC 28-8 pharmDx Interpretation Manuals.
P150048/S001	09/21/2017	O - Normal 180 Day	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Approval for revisions to the protocol for the ODE lead post-approval study (PAS).
P160044/S001	09/01/2017	Y - 135 Review Tra	ABBOTT REAL TIME CMV AMPLIFICATION REAGENT KIT / CMV CONTROL KIT / CMV CALIBRATOR KIT.	ABBOTT MOLECULAR	Approval for changes to the polypropylene resin, cap colorant and inside diameter of the tubes and screw-caps used for storage and transport of the finished calibrators and controls, and for the master mix assembly.

Total: 91

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16837/S022	09/15/2017	X - 30-Day Notice	ARTEGRAFT COLLAGEN VASCULAR GRAFT	ARTEGRAFT, INC.	Add an additional supplier and material for a component of the Artegraft Collagen Vascular Graft primary packaging.
N970003/S212	09/25/2017	X - 30-Day Notice	PACEMAKERS: ADVANTIO, INGENIO, VITALIO, FORMIO, ESSENTIO, PROPONENT, ACCOLADE, AND ALTRUA 2	BOSTON SCIENTIFIC CORP.	Modify the quartz crystal component manufacturing process.
P830055/S186	09/18/2017	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change in manufacturing location for the augment and wedge screws.
P830055/S187	09/20/2017	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Reducing the inspection procedures for the grinding manufacturing process.
P840001/S375	09/22/2017	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Make a sub-tier supplier change to source a hypotube that will be coated with PTFE without the presence of PFOA as a manufacturing aid; 2) mask the flared portion of the hypotube during manufacturing to eliminate PTFE coating during forming operations; and 3) update the product specification to the correct referenced standard for EN 45502. i.e. The Change in particulate matter standard EN45502-1.
P840001/S378	09/19/2017	X - 30-Day Notice	MASTER RESTORE, INTREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of new laser workstation equipment.
P860003/S095	09/14/2017	X - 30-Day Notice	CELLEX PHOTOPHERESIS SYSTEM	THERAKOS, INC.	Manufacturing site change for the pressure dome assembly component of the Therakos CELLEX Photopheresis Procedural Kit used in the Therakos CELLEX Photopheresis System.

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P860057/S168	09/07/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS/ THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/PERIMOUNT RSR PERICARDIAL AORTIC BIOPROSTHESIS/ PERIMOUNT THEON RSR PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMA FIX TISSUE PROCESS/PERIMOUNT MAGNA PERICARDIAL AORTIC BIOPROSTHESIS/ WITH THERMA FIX TISSUE PROCESS/PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMA FIX TISSUE PROCESS/PERIMOUNT PLUS PERICARDIAL MITRAL BIOPROSTHESIS/ PERIMOUNT THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMA FIX TISSUE PROCESS	EDWARDS LIFESCIENCE S, LLC.	Transfer of stent sub-assembly operations from an existing approved cleanroom to a new cleanroom.
P880086/S287	09/11/2017	X - 30-Day Notice	ENDURITY CORE, ENDURITY, ASSURITY+, ASSURITY, SISTAIN, ACCENT, ZEPHYR, VICTORY, VERIFY ADX XL, IDENTITY ADX, IDENTITY PACEMAKERS	ST. JUDE MEDICAL, INC.	Change in the header manufacturing process.
P900009/S042	09/11/2017	X - 30-Day Notice	EXOGEN ULTRASOUND BONE HEALING SYSTEM	BIOVENTUS LLC	Addition of an alternative supplier for the rechargeable battery pack.
P910001/S098	09/01/2017	X - 30-Day Notice	ELCA CORONARY LASER ATHERECTOMY CATHETERS	SPECTRANETI CS CORP.	Changes to the Distal Tip manufacturing and inspection process.

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P910001/S099	09/21/2017	X - 30-Day Notice	ELCA CORONARY LASER ATHERECTOMY CATHETERS	SPECTRANETICS CORP.	Manufacturing process changes to the fuse joints of the ELCA Laser Catheters.
P910023/S392	09/11/2017	X - 30-Day Notice	ELLIPSE. FORTIFY ASSURA, FORTIFY, CURRENT ACCEL, CURRENT+, CURRENT ICDS	ST. JUDE MEDICAL	Change in the header manufacturing process.
P920015/S202	09/05/2017	X - 30-Day Notice	HV SPLITTER/ADAPTOR KIT 5019	MEDTRONIC INC.	Change from manual to robotic automation of the application of adhesive to adaptor housing halves.
P920047/S102	09/26/2017	X - 30-Day Notice	BLAZER II HTD, BLAZER PRIME HTD	BOSTON SCIENTIFIC CORP.	Add an alternate vendor for Tyvek Pouch utilized with the BSC Ablation Catheters.
P950020/S083	09/07/2017	X - 30-Day Notice	FLEXTOME CUTTING BALLOON MICROSURGICAL DILATION DEVICE	BOSTON SCIENTIFIC CORP.	Relocation of sub-assembly processes from Cleanroom Environment 8 (CE8) to Cleanroom Environment 10 (CE10).
P950029/S116	09/07/2017	X - 30-Day Notice	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR	LIVANOVA USA, INC.	Alternate method for the laser welding process.
P950037/S180	09/11/2017	X - 30-Day Notice	PK-222 AND PK-ELECTRODE CLIP (ACCESSORY TO RENAMIC)	BIOTRONIK, INC.	Supplier change for Renamic programmer accessories and corresponding material changes.
P960009/S289	09/01/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of a new supplier of polysulfone resin.
P960009/S295	09/19/2017	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implementation of two new additional laser equipment at Medtronic Puerto Rico Operations Company (MPROC) in Villalba, Puerto Rico.
P960040/S402	09/28/2017	X - 30-Day Notice	ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, PERCIVA, RESONATE; IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(ICD)	BOSTON SCIENTIFIC	Addition of an alternate supplier of the titanium raw material.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960040/S403	09/25/2017	X - 30-Day Notice	ICDS: ORIGEN, INOGEN, DYNAGEN, MOMENTUM EL ICD, AUTOGEN, VIGILIANT EL ICD, PERCIVA ICD, RESONATE EL ICD, PERCIVA HF ICD, RESONATE HF ICD, PUNCTUA ICD, ENERGEN ICD, AND INCEPTA ICD	BOSTON SCIENTIFIC	Modify the quartz crystal component manufacturing process.
P970004/S255	09/27/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (URINARY SCREENING)	MEDTRONIC NEUROMODULATION	Additional site to assemble and sterilize the test lead assembly.
P970013/S072	09/11/2017	X - 30-Day Notice	MICRONY PACEMAKERS	ST. JUDE MEDICAL, INC.	Change in the header manufacturing process.
P970029/S036	09/08/2017	X - 30-Day Notice	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Removal of the EO gas weight parameter from CryoLife Procedures.
P970051/S169	09/05/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Introduction of an additional quality control step after the coil and hardball welding operation of the CI500 series implants.
P980003/S079	09/26/2017	X - 30-Day Notice	CHILL II	BOSTON SCIENTIFIC CORP.	Add an alternate vendor for Tyvek Pouch utilized with the BSC Ablation Catheters.
P980037/S067	09/28/2017	X - 30-Day Notice	ANGIOJET ULTRA THROMBECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of alternate external process challenge device options used during sterilization for routine product release.
P980040/S083	09/26/2017	X - 30-Day Notice	TECNIS SYMFONY AND SYMFONY TORIC INTRAOCULAR LENSES	ABBOTT MEDICAL OPTICS INC	Utilization of an alternate manufacturing site.
P990004/S032	09/21/2017	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE, U.S.P.	FERROSAN MEDICAL DEVICES A/S	Addition of a new secondary packaging site: Ferrosan Medical Devices Sp. z.o.o.
P000015/S025	09/05/2017	X - 30-Day Notice	NECLEUS AUDITORY BRAINSTEM IMPANT SYSTEM	COCHLEAR AMERICAS	Introduction of an additional quality control step after the coil and hardball welding operation of the CI500 series implants.
P000053/S082	09/14/2017	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Implementation of Manufacturing Execution System software to electronically capture the device history record.
P010003/S028	09/12/2017	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Removal of the EO gas weight parameter from CryoLife procedures.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S461	09/28/2017	X - 30-Day Notice	ORIGEN, INOGEN, DYNAGEN, AUTOGEN, MOMENTUM, VIGILANT, RESONATE; IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D)	BOSTON SCIENTIFIC CORP.	Addition of an alternate supplier of the titanium raw material.
P010012/S462	09/25/2017	X - 30-Day Notice	CRT-DS: ORIGEN, MOMENTUM, INOGEN, DYNAGEN, AUTOGEN, VIGILANT, RESONATE, PUNCTUA, ENERGEN AND INCEPTA	BOSTON SCIENTIFIC CORP.	Modify the quartz crystal component manufacturing process.
P010019/S056	09/05/2017	X - 30-Day Notice	AIR, OPTIX, AQUA, MULTIFOCAL (LOTRAFILCON B) SOFT CONTACT LENSES FOR DAILY AND EXTENDED WEAR	ALCON LABORATORIES, INC.	Update to the device quality control testing by changing the in-process inspection of lens power, lens optical quality and lens diameter for AIR OPTIX AQUA MULTIFOCAL (lotrafilcon B) soft contact lenses.
P010019/S058	09/21/2017	X - 30-Day Notice	LOTRAFILCON A AND B SOFT CONTACT LENSES FOR DAILY AND EXTENDED WEAR	ALCON LABORATORIES, INC.	Replacement of the manual (human) foil lidding part number verification by an electronic (automated) system.
P010019/S059	09/25/2017	X - 30-Day Notice	LOTRAFILCON A SOFT CONTACT LENSES FOR DAILY AND EXTENDED WEAR	ALCON LABORATORIES, INC.	Update to the Manufacturing Execution System for manufacture of lotrafilcon A contact lenses.
P010030/S099	09/21/2017	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Implementation of version 3.0 of the Monitor Automated Detect and Treat Test manufacturing software.
P010032/S133	09/06/2017	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ST. JUDE MEDICAL	Updates to the sterilization equipment and bioburden test site.
P020004/S147	09/27/2017	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Additional supplier of films used in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE CARDIOFORM Septal Occluder, and GORE VIABHAN Endoprosthesis with and without Heparin Bioactive Surface.

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P020012/S015	09/28/2017	X - 30-Day Notice	BELLAFILL DERMAL FILLER	SUNEVA MEDICAL, INC.	Removal of redundant quality control tests for SAN 8250 In-Process Tests with respect to PMMA.
P020025/S106	09/26/2017	X - 30-Day Notice	BLAZER II XP, BLAZER PRIME XP, INTELLATIP MIFI XP, INTELLANAV XP, INTELLANAV MIFI XP	BOSTON SCIENTIFIC	Add an alternate vendor for Tyvek Pouch utilized with the BSC Ablation Catheters.
P030005/S160	09/25/2017	X - 30-Day Notice	CRT-PS: INVIVE, VALITUDE, AND VISIONIST	GUIDANT CORP.	Modify the quartz crystal component manufacturing process.
P030011/S056	09/29/2017	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, LLC	Change supplier and connectors of the Freedom Driver speaker PCBA.
P030024/S024	09/01/2017	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS	Process improvements to increase to maximum batch size for manufacturing of anti-HBc coated wells from 2500 to 5000 plates.
P030035/S159	09/11/2017	X - 30-Day Notice	QUADRA ALLURA MP RF CRT-P. QUADRA ALLURE MP CRT-P, ALLURA QUADRA CRT-P, ANTHEM RF CRT-P, FRONTIER II CRT-P PACEMAKERS	ST. JUDE MEDICAL, INC.	Change in the header manufacturing process.
P030054/S336	09/11/2017	X - 30-Day Notice	QUADRA ASSURA MP CRT-D, QUADRA ASSURA CRT-D, UNIFY ASSURA CRT-D, UNIFY QUADRA CRT-D, PROMOTE QUADRA CRT-D, PROMOTE Q CRT-D, PROMOTE ACCEL CRT-D ICDS	ST. JUDE MEDICAL	Change in the header manufacturing process.
P040021/S032	09/22/2017	X - 30-Day Notice	BIOCOR AND EPIC HEART VALVES	ST. JUDE MEDICAL, INC.	Addition of a new supplier of polyester woven fabric to be used for the construction of heart valves.
P040027/S058	09/27/2017	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Additional supplier of films used in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE CARDIOFORM Septal Occluder, and GORE VIABHAN Endoprosthesis with and without Heparin Bioactive Surface.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040029/S005	09/05/2017	X - 30-Day Notice	EUCLID SYSTEMS ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATIO N	Addition of an alternate lens blank supplier.
P040037/S101	09/08/2017	X - 30-Day Notice	VIABHAN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Changes to your stent oven monitoring process.
P040037/S102	09/21/2017	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,I NC	Change to the design of the split die thermal bonder.
P040037/S103	09/27/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Additional supplier of films used in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE CARDIOFORM Septal Occluder, and GORE VIABHAN Endoprosthesis with and without Heparin Bioactive Surface.
P040043/S095	09/27/2017	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Additional supplier of films used in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE CARDIOFORM Septal Occluder, and GORE VIABHAN Endoprosthesis with and without Heparin Bioactive Surface.
P040045/S079	09/15/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Tightened specification for a raw material.
P040045/S081	09/05/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Introduction of a new formulation room for the production of solutions used in VISTAKON (senofilcon A) Brand Contact Lenses.
P040045/S082	09/13/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Implementation of an alternate raw material supplier source for the VISTAKON (senofilcon A) ACUVUE OASYS Brand Contact Lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050006/S061	09/27/2017	X - 30-Day Notice	GORE CADIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Additional supplier of films used in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE CARDIOFORM Septal Occluder, and GORE VIABHAN Endoprosthesis with and without Heparin Bioactive Surface.
P060006/S086	09/13/2017	X - 30-Day Notice	EXPRESS SD RENAL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of a redundant inspection step.
P060030/S059	09/01/2017	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST, V 2.0	ROCHE MOLECULAR SYSTEMS, INC.	Modification of the in-process and release testing specifications for a critical component.
P060037/S050	09/29/2017	X - 30-Day Notice	ZIMMER NEXGEN LPS-FLEX MOBILE AND LPS MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	New and modified heat seal parameters, which define the process parameters for the heat sealing of sterile package lidding to thermoformed polymer trays as part of the packaging configuration for NexGen LPS-Flex/LPS-Mobile Bearing Knee System tibial bearing components.
P080006/S115	09/22/2017	X - 30-Day Notice	ATTAIN PERFORMA LEAD MODELS 4298, 4398, 4598	MEDTRONIC INC.	Process update for silicone seals used in quadripolar left ventricular lead models.
P080025/S150	09/27/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (BOWL SCREENING)	MEDTRONIC NEUROMODULATION	Additional site to assemble and sterilize the test lead assembly.
P080027/S029	09/07/2017	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Replace the current raw material Protein A with a Protein A using an animal-free medium process supplied from the same vendor.
P080027/S030	09/27/2017	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Scale-up production of an intermediate component used to produce a conjugate.
P090003/S043	09/13/2017	X - 30-Day Notice	EXPRESS LD LLIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Removal of a redundant inspection step.
P100001/S011	09/15/2017	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS	Replace the current size exclusion chromatography system with a Crossflow Tangential Flow Purification System for the preparation of the Biotin Conjugate Concentrate.
P100044/S030	09/27/2017	X - 30-Day Notice	MOMETASONE FUROATE CONTAINER CLOSURE SYSTEM	INTERSECT ENT	Addition of automated sealing equipment to add aluminum seals to the mometasone furoate (MF) container closure system utilized to store drug in the manufacturing area.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100045/S024	09/06/2017	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Updates to the sterilization equipment and bioburden test site.
P100047/S107	09/13/2017	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Relocation of a facility for manufacturing of the HeartWare Ventricular Assist Device (HVAD) AC and DC adapters.
P100047/S108	09/11/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of process changes at a Tier 2 supplier and a new visual inspection at the contract manufacturer for the AC and DC adapter components used within the HeartWare Ventricular Assist Device.
P100047/S109	09/27/2017	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implement changes to the inspection method of the 16mm and 19mm HVAD Reverse Core Cutter.
P110004/S025	09/19/2017	X - 30-Day Notice	NIRXCELL COCR CORONARY STENT ON RX SYSTEM	MEDINOL LTD.	Removal of the redundant supplier seal peel test for the sterilization pouch.
P110010/S145	09/13/2017	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of a redundant inspection step.
P110010/S146	09/22/2017	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE/ PROMUS PREMIER EVEROLIMUS ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Change the hanger clamp used for the balloon manufacturing process.
P110013/S081	09/01/2017	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Modify the HPLC method for Zotarolimus active pharmaceutical ingredient (API) testing.
P110016/S049	09/18/2017	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER & FLEXABILITY ABLATION CATHETER, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Change in routine bioburden sampling frequency for the Flex and Flex SE catheters.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120005/S066	09/09/2017	X - 30-Day Notice	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Modification to transmitter machining and polishing processes for transmitters that are components of the Dexcom G5 Mobile/G4 PLATINUM Continuous Glucose Monitoring Systems.
P120006/S029	09/05/2017	X - 30-Day Notice	OVATION IX ABDOMINAL STENT GRAFT SYSTEM	TRIVASCULAR INC	Add a qualified alternate supplier for Ethylene Oxide (EO) sterilization for the Ovation iX Abdominal Stent Graft System.
P130006/S040	09/08/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Changes to your stent oven monitoring process.
P130006/S041	09/21/2017	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Change to the design of the split die thermal bonder.
P130006/S042	09/27/2017	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Additional supplier of films used in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis, GORE VIATORR TIPS Endoprosthesis, GORE TAG Thoracic Endoprosthesis, GORE CARDIOFORM Septal Occluder, and GORE VIABHAN Endoprosthesis with and without Heparin Bioactive Surface.
P130013/S015	09/28/2017	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Implement a new electropolishing system.
P130030/S044	09/13/2017	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of a redundant inspection step.
P140002/S008	09/29/2017	X - 30-Day Notice	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Modifications to cleanroom procedures.
P140009/S028	09/06/2017	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ST. JUDE MEDICAL NEUROMODULATION	Updates to the sterilization equipment and bioburden test site.
P140033/S013	09/11/2017	X - 30-Day Notice	ENDURITY MRI ,ASSURITY MRI PACEMAKER	ST. JUDE MEDICAL, INC.	Change in the header manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150003/S033	09/13/2017	X - 30-Day Notice	SYNERG EVEROLIMUS ELUTING CONRONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Removal of a redundant inspection step.
P150003/S034	09/22/2017	X - 30-Day Notice	SYNERGY EVEROLIMUS ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORPORATION	Change the hanger clamp used for the balloon manufacturing process.
P150004/S012	09/06/2017	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ST. JUDE MEDICAL	Updates to the sterilization equipment and bioburden test site.
P150005/S025	09/06/2017	X - 30-Day Notice	OPEN-IRRIGATED ABLATION CATHETERS: BLAZER OI, INTELLATIP MIFI OI, AND INTELLANAV OI	BOSTON SCIENTIFIC CORP.	Changes to the main body tip bond process.
P150005/S026	09/15/2017	X - 30-Day Notice	BLAZER OI AND INTELLANAV OI	BOSTON SCIENTIFIC CORP.	New adhesive placement fixture for bonding the proximal shaft to the distal tube.
P150005/S027	09/26/2017	X - 30-Day Notice	BLAZER OI, INTELLANAV OI, INTELLATIP MIFI OI	BOSTON SCIENTIFIC CORP.	Add an alternate vendor for Tyvek Pouch utilized with the BSC Ablation Catheters.
P150012/S037	09/25/2017	X - 30-Day Notice	PACEMAKERS: INGENIO MRI, VITALIO MRI, FORMIO MRI, ESSENTIO MRI, PROPONENT MRI, AND ACCOLADE MRI	BOSTONSCIENTIFIC	Modify the quartz crystal component manufacturing process.
P150036/S018	09/07/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Transfer of stent sub-assembly operations from an existing approved cleanroom to a new cleanroom.
P150048/S004	09/07/2017	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS/ INSPIRIS RESILIA AORTIC VALVE	EDWARDS LIFESCIENCES, LLC.	Transfer of stent sub-assembly operations from an existing approved cleanroom to a new cleanroom.
P160043/S005	09/01/2017	X - 30-Day Notice	RESOLUTE ONYX CORONARY STENT SYSTEMS	MEDTRONIC INC.	Modify the HPLC method for Zotarolimus active pharmaceutical ingredient (API) testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160043/S006	09/13/2017	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC INC.	Implement a new piece of equipment used to apply the hydrophilic coating to the Resolute Onyx catheter shaft.

Total: 99