PMA Monthly approvals from 7/1/2017 to 7/31/2017

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160049	07/26/2017	PMAO - PMA Origi	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Approval of the Stellarex 0.035 OTW Drug-coated Angioplasty Balloon. This device is indicated for percutaneous transluminal angioplasty (PTA), after appropriate vessel preparation, of de novo or restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-6 mm.
P170006	07/31/2017	PMAO - PMA Origi	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC. HEART VALVE DIVISION	Approval for the Avalus Bioprosthesis, Model 400. This device is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S126	07/13/2017	Y - 135 Review Tra	AMBICOR INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Approval for changes in the molding and post-cure process parameters and work instructions of silicone molded components.
N970012/S127	07/28/2017	Y - 135 Review Tra	AMBICOR INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for changes in the molding process for the snap washer and two-piece poppet plastic components; removal of inner hole dimensional inspection of snap washer.
P800002/S022	07/05/2017	Y - 135 Review Tra	AVITENE® MICROFIBRILLAR COLLAGEN HEMOSTAT	C.R. BARD, INC.	Approval for the replacement of the automated blade cutting process with a die cutting machine.
P830055/S185	07/25/2017	S - Special CBE	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for updates to the cleaning instructions in IFU-0902-00-836.

Data as of 08/01/2017 03:05 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S344	07/11/2017	N - Normal 180 Day	INTELLIS(TM) IMPLANTABLE NEUROSTIMULATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for their new Implantable Neurostimulation System for Spinal Cord Stimulation (SCS) called Intellis(TM).
P860003/S090	07/21/2017	R - Real-Time Proc	THERAKOS CELLEX PHOTOPHERESIS SYSTEM	THERAKOS, INC.	Approval for a design change to replace the 24 V power supply in the device.
P900056/S157	07/05/2017	O - Normal 180 Day	ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a dual manufacturing site located at Boston Scientific Corporation, San Jose, 150 Baytech Drive, San Jose, California.
P910001/S091	07/07/2017	R - Real-Time Proc	SPECTRANETICS CVX-300 EXCLIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for changes to the Remote Interlock Connector.
P910001/S094	07/18/2017	S - Special CBE	ELCA	SPECTRANETICS CORP.	Approval for modifications to inspection practices for the primary packaging of the affected devices.
P910077/S155	07/06/2017	N - Normal 180 Day	MULTIPLE APPLICATION UTILITY MODEL 2909 (FROM V9.03 TO V9.04)	BOSTON SCIENTIFIC	Approval for the Automated Screening Tool software to aide in determining whether the S-ICD System is appropriate.
P920047/S098	07/24/2017	R - Real-Time Proc	BLAZER (II, II HTD, PRIMIE HTD)	BOSTON SCIENTIFIC CORP.	Approval for packaging changes to the carton, pouch, tray, and luer protector.
P930014/S102	07/18/2017	R - Real-Time Proc	ACRYSOF® IQ ASPHERIC IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM	ALCON RESEARCH, LTD.	Approval for expanding the range of lens powers and adding a new nozzle for larger lens powers.
P930016/S051	07/14/2017	R - Real-Time Proc	STAR S4 IR EXCIMER LASER SYSTEM	AMO MANUFACTURING USA, LLC	Approval for the replacement of the existing photo interrupter (3703-0124, manufactured by Hamamatsu) in the BSM Flex assembly (0030-1275) used in the Beam Shaping Module (BSM) assembly (0030-2162) of the STAR S4 IR, with a replacement photo interrupter (3703-0157-L, manufactured by Sharp Microelectronics).
P950005/S063	07/17/2017	Y - 135 Review Tra	WEBSTER CATHETER; CELSIUS THERMOCOOL CATHETER; CELSIUS CATHETER;; CELSIUS RMT CATHETER	CORDIS CORP.	Approval for transfer of the extrusion process for a subcomponent of the catheters from the Cordis Miami facility to the Webster Juarez manufacturing facility.
P950021/S014	07/27/2017	N - Normal 180 Day	ADVIA CENTAUR PSA ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur PSA assay to the ADVIA Centaur XPT system.
P960042/S058	07/18/2017	S - Special CBE	SLS / GLIDELIGHT	SPECTRANETICS CORP.	Approval for modifications to inspection practices for the primary packaging of the affected devices.
P970051/S161	07/17/2017	R - Real-Time Proc	NUCLEUS COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the CP802 Sound Processor.

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P980003/S074	07/24/2017	R - Real-Time Proc	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the packaging changes to the carton, pouch, tray, and luer protector.
P980016/S620	07/18/2017	N - Normal 180 Day	IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a change to a 11-pin feedthrough design and associated design and manufacturing changes for ICD and CRT-D devices.
P980049/S125	07/26/2017	R - Real-Time Proc	PARADYM AND PARADYM RF, UPDATE TO PLATINIUM EMBEDDED SOFTWARE	SORIN GROUP- CRM	Approval for updates to the embedded software and programmer module software.
P990025/S051	07/17/2017	Y - 135 Review Tra	NAVISTAR RMT; NAVISTAR RMT DS CATHETER	BIOSENSE WEBSTER, INC.	Approval for transfer of the extrusion process for a subcomponent of the catheters from the Cordis Miami facility to the Webster Juarez manufacturing facility.
P000018/S048	07/13/2017	N - Normal 180 Day	NOVOSTE BETA-CATH SYSTEM	BEST VASCULAR, INC	Approval for a reduction in the existing minimum dose rate of the Jacketed Radiation Source Trains (JRST) of the Beta-Cath 3.5Fr System from 78.2mGy/s to 64.4mGy/s.
P010012/S443	07/24/2017	O - Normal 180 Day	ACTUITY X4 QUADRIPOLAR CORONARY VENOUS PACE/SENSE LEADS	BOSTON SCIENTIFIC CORP.	approval for creating a duplicate manufacturing line at the Boston Scientific Corporation, No.12, Road 698, Dorado, Puerto Rico facility for the ACTUITY X4 Quadripolar Coronary Venous Pace/Sense Leads.
P010014/S063	07/07/2017	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval to introduce additional inspection checks for cleaning, passivation and packaging processes, for the Oxford Partial Knee System components.
P010031/S579	07/18/2017	N - Normal 180 Day	IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an 11-pin feedthrough design and associated design and manufacturing changes for ICD and CRT-D devices.
P010032/S125	07/21/2017	N - Normal 180 Day	PROCLAIM FAMILY OF IMPLANTABLE PULSE GENERATORS; ST.JUDE MEDICAL EXTERNAL PULSE GENERATOR, CLINICAL PROGRAMMER AND PATIENT CONTROLLER APPS.	ST. JUDE MEDICAL	Approval for 1) Addition of a Proclaim IPG device models 3661 and 3663, each with a header that is compatible with Medtronic (MDT) leads; 2) Sustaining enhancements to the firmware (FW 1.1 new version of firmware; 3) Enabling the Burst stimulation feature (marketed as BurstDR stimulation) for Proclaim IPGs with MDT headers and 4) Inclusion of the Lead & Extension Insertion Tool (LEIT).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020025/S101	07/24/2017	R - Real-Time Proc	BLAZER (II XP, PRIME XP); INTELLATIP MIFI XP; INTELLANAV XP AND INTELLANAV MIFI XP	BOSTON SCIENTIFIC	Approval for packaging changes to the carton, pouch, tray, and luer protector.
P050023/S110	07/21/2017	O - Normal 180 Day	PROMRI ICD/CRT-D SYSTEM	BIOTRONIK, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P060027/S090	07/26/2017	R - Real-Time Proc	PARADYM AND PARADYM RF, UPDATE TO PLATINIUM EMBEDDED SOFTWARE	SORIN GROUP CRM USA, INC	Approval for updates to the embedded software and programmer module software.
P080012/S042	07/21/2017	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for electronic component changes occurring in the electronics module of the Flowonix Prometra Infusion Pump.
P100044/S022	07/25/2017	Y - 135 Review Tra	PROPEL AND PROPEL MINI SINUS IMPLANT	INTERSECT ENT	Approval for modification of the in-process drug coating weight specification from ± 5% to ± 7%.
P110042/S067	07/06/2017	N - Normal 180 Day	MODEL 2889 EMBLEM S-ICD AUTOMATED SCREENING TOOL, V1.01	BOSTON SCIENTIFIC CORPORATION	Approval for the Automated Screening Tool software to aide in determining whether the S-ICD System is appropriate.
P120023/S005	07/18/2017	O - Normal 180 Day	KAMRA INLAY	ACUFOCUS, INC.	Approval for revisions to the labeling to include the results of the post-approval study.
P130008/S023	07/28/2017	R - Real-Time Proc	SENSING LEAD	INSPIRE MEDICAL SYSTEMS	Approval for a change to the feedthrough component of the Model 4323 Sensing Lead.
P130021/S033	07/10/2017	P - Panel Track	COREVALVE SYSTEM; COREVALVE EVOLUT R SYSTEM; COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Approval for the Medtronic CoreValve System, CoreValve Evolut R System, and CoreValve Evolut PRO System. The devices are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality >= 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).
P130023/S005	07/27/2017	Y - 135 Review Tra	COHERA MEDICAL TISSUGLU SURGICAL ADHESIVE	COHERA MEDICAL, INC	Approval for a modification to the TissuGlu® synthesis process where a small percentage of the stability reagents (sulfuric acid and DMSO stock solution) that are normally added at the end of the product synthesis process is instead added at the beginning of synthesis ("borrowed acid process").
P140003/S021	07/14/2017	S - Special CBE	IMPELLA VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Approval for the inclusion of modified flow charts for the Impella 5.0 and Impella LD in the Instructions for Use.
P140010/S032	07/05/2017	R - Real-Time Proc	IN PACT ADMIRAL PACLITAREL-COATED BALLOON CATHETER	MEDTRONIC INC.	Approval for a shelf life extension to 36 months.

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P140016/S001	07/28/2017	S - Special CBE	ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT	COOK MEDICAL INCORPORATED	Approval to remove blunt thoracic aortic injury from the indications for use and remove references to the smaller diameter grafts that have been removed from the market.
P140018/S007	07/13/2017	S - Special CBE	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Approval for implementing bacterial endotoxin lot release testing for direct and indirect blood contacting components of the VenaSeal Delivery System.
P140026/S005	07/18/2017	N - Normal 180 Day	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval for labeling updates to incorporate the ROADSTER Study Continued Access data.
P150004/S005	07/03/2017	O - Normal 180 Day	AXIUM LEADS AND OTHER ACCESSORIES	ST. JUDE MEDICAL	Approval for a manufacturing site located at St. Jude Medical, 6901 Preston Road, Plano, Texas, in which this site will manufacture components of the Axium Spinal Modulation Neurostimulator System.
P150005/S011	07/27/2017	Y - 135 Review Tra	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for changes to the catheter tip cleaning process.
P150005/S020	07/24/2017	R - Real-Time Proc	BLAZER OI, INTELLANAV OI, INTELLATIP MIFI OI	BOSTON SCIENTIFIC CORP.	Approval for packaging changes to the carton, pouch, tray, and luer protector.
P150012/S031	07/27/2017	N - Normal 180 Day	INGEVITY MRI MODELS: 7731, 7732, 7735, 7736, 7740, 7741, 7742	BOSTONSCIENTIFIC	Approval for a change in the raw material on the proximal electrode assembly of INGEVITY MRI lead models.
P150016/S005	07/06/2017	R - Real-Time Proc	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Approval to modify the storage conditions of Tridyne Vascular Sealant (Tridyne VS) from refrigerated conditions 2-8°C (36-46°F) to include a controlled ambient temperature storage excursion of 8-25°C (46-77°F) for a period of up to 35 days within the approved shelf life of 24 months.
P150021/S007	07/28/2017	R - Real-Time Proc	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for design changes to the sensor applicator and sensor pack used in the FreeStyle Libre Pro Flash Glucose Monitoring System.
P150024/S006	07/17/2017	R - Real-Time Proc	ASPIRE ASSIST	ASPIRE BARIATRICS INC	Approval for modifications to your product labeling.
P150039/S001	07/13/2017	O - Normal 180 Day	TRYTON SIDE BRANCH STENT	TRYTON MEDICAL, INC.	Approval of the protocol for the post-approval study (PAS) protocol.
P160001/S001	07/19/2017	O - Normal 180 Day	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 50

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S044	07/06/2017	X - 30-Day Notice	SURGICEL ABSORBABLE HEMOSTAT	ETHICON, INC.	Adding an automated label scanning system to verify the batch information and packaging components for product codes 435050 and 194350 at Ethicon SARL, Neuchâtel Switzerland.
N18033/S093	07/12/2017	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Change to the raw material storage conditions for VISTAKON® (senofilcon A) and VISTAKON® (etafilcon A) brand contact lenses.
P800036/S040	07/05/2017	X - 30-Day Notice	MODEL 400 IMPLANTABLE INFUSION PUMP	CODMAN & SHURTLEFF, INC.	Implementation of a new sterilization chamber control system at the sterilization facility to replace the current system.
P810031/S062	07/20/2017	X - 30-Day Notice	HEALON, HEALO GV, HEALON 5, HEALON ULRIMATE DUAL PACK, HEALON DUET DUAL PACK PRODUCTS	ABBOTT MEDICAL OPTICS INC	Change in the composition of the coating used inside the dissolution chambers.
P830061/S147	07/18/2017	X - 30-Day Notice	CAPSURE SENSE LEAD/ CAPSURE SP NOVUS LEAD/VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional in-process cleaning steps for stylet components.
P830061/S148	07/05/2017	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P840039/S062	07/11/2017	X - 30-Day Notice	PMMA POSTERIOR CHAMBER INTRAOCULAR LENSES	BAUSCH & LOMB, INC.	Additional supplier for the rotary lens case component.
P850048/S046	07/07/2017	X - 30-Day Notice	ACCESS HYBRITECH PSA REAGENTS ON THE ACCESS IMMUNOASSY SYSTEMS	BECKMAN COULTER, INC.	Manufacturing change to update a specification to allow for a limited amount of flash local to the gate location (where plastic material is injected into the reaction vessel) for the Access 2 Reaction Vessels, which are used during the processing of the assays.
P850064/S034	07/06/2017	X - 30-Day Notice	LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Change to the test equipment used for the testing during manufacturing and servicing of the finished Life Pulse High Frequency Ventilator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850089/S125	07/18/2017	X - 30-Day Notice	CAPSURE SP NOVUS LEAD/ CAPSURE SP Z LEAD/ CAPSURE Z NOVUS LEAD/ VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional in-process cleaning steps for stylet components.
P850089/S126	07/05/2017	X - 30-Day Notice	CAPSURE SP/Z NOVUS LEAD, VITATRON EXCELLENCE SS+/ IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P860004/S280	07/07/2017	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Implementation of a new helium leak test process at Medtronic Puerto Rico Operations Company (MPROC) in Juncos, Puerto Rico.
P860004/S282	07/26/2017	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of a process to monitor the electronic component humidity requirement of the Synchromed II infusion pump.
P860057/S164	07/18/2017	X - 30-Day Notice	CARPENTIER-EDWARDS® PERIMOUNT® PERICARDIAL/RSR/MAGNA/ MAGNA EASE AORTIC/ PLUS/ THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX¿ TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Addition of a staging station after the Final Bioburden Reduction Process for Edwards tissue valves.
P860057/S165	07/20/2017	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT RSR THEON/ MAGNA/PLUS PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMALFIX TISSUE PROCESS,	EDWARDS LIFESCIENCES, LLC.	Implement a new water system and two new pouch sealers.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S166	07/28/2017	X - 30-Day Notice	CARPENTIER-EDWARS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS/ THERMAFIX TISSUE PROCESS; CARPENTIER-EDWARDS PERIMOUNT RSR PERICARDIAL AORTIC BIOPROSTHESIS/ THERMAFIX TISSUE PROCESS/ MAGNA PERICARDIAL AORTIC BIOPROSTHESIS/ MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/ MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/PLUS PERICARDIAL MITRAL BIOPROSTHESIS/ THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS/MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCE S, LLC.	Change to static fixation of pericardial tissue.
P880047/S027	07/06/2017	X - 30-Day Notice	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Adding an automated label scanning system verify the batch information and packaging components for product codes 435050 and 194350 at Ethicon SARL, Neuchâtel Switzerland.
P890003/S375	07/18/2017	X - 30-Day Notice	CAPSURE VDD 2 LEAD/ VITRON BRILLIANT S+VDD LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Additional in-process cleaning steps for stylet components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S376	07/05/2017	X - 30-Day Notice	CAPSURE VDD 2 LEAD, VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P890055/S068	07/05/2017	X - 30-Day Notice	CODMAN 3000 AND MEDSTREAM IMPLANTABLE INFUSION PUMPS	CODMAN	Implementation of a new sterilization chamber control system at the sterilization facility to replace the current system.
P890064/S034	07/25/2017	X - 30-Day Notice	DIGENE HC2 HIGH RISK HPV DNA TEST	QIAGEN GAITHERSBURG, INC	Change a current quality control functional testing procedure.
P900033/S062	07/11/2017	X - 30-Day Notice	INTEGRE DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Installation, operation and performance qualification of a cold storage room.
P900056/S162	07/24/2017	X - 30-Day Notice	ROTABLATOR® ROTATIONAL ATHERECTOMY SYSTEM	BOSTON SCIENTIFIC CORP.	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P910023/S387	07/26/2017	X - 30-Day Notice	CURRENT, FORTIFY, FORTIFY ASSURA	ST. JUDE MEDICAL	Reduction in time for the burn-in environmental screen used during the processing of high voltage RF Module assemblies.
P920015/S199	07/18/2017	X - 30-Day Notice	SPRINT QUATTRO LEAD/ SUBCUTANIOUS LEAD/ TRANSVENE CS.SVC LEAD	MEDTRONIC INC.	Additional in-process cleaning steps for stylet components.
P920015/S200	07/05/2017	X - 30-Day Notice	SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P920047/S099	07/24/2017	X - 30-Day Notice	BLAZER IITM CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P930031/S060	07/03/2017	X - 30-Day Notice	WALLSTENT (TIPS) ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate vendor for stainless steel tubing for use in the delivery system.
P930039/S173	07/18/2017	X - 30-Day Notice	CAPSUREFIX LEAD/ CAPSUREFIX NOVUS LEAD/ VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional in-process cleaning steps for stylet components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930039/S174	07/05/2017	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION/PIROUET LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P940016/S023	07/06/2017	X - 30-Day Notice	HEPARIN_INDUCED EXTRACORPOREAL LDL PRECIPITATION (H.E.L.P.) FUTURA APHERESIS SYSTEM	B. BRAUN AVITUM AG	Qualification of an additional clean room area for the B. Braun Avitum Italy Plant for the manufacturing of the H.E.L.P Futura Set.
P940019/S051	07/03/2017	X - 30-Day Notice	WALLSTENT ILLIAC ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC SCIMED, INC.	Alternate vendor for stainless steel tubing for use in the delivery system.
P950005/S065	07/27/2017	X - 30-Day Notice	THERAPEUTIC CATHETERS	CORDIS CORP.	Addition of an alternate supplier for tip electrode components.
P950005/S066	07/27/2017	X - 30-Day Notice	EZ STEER NON-NAVIGATIONAL 8MM (DS) ; EZ STEER DS ; EZ STEER NON-NAVIGATIONAL 4MM (TC) & (THR) ; CELSIUS 4MM BI-DIR T ; CELSIUS FLTR BI-DIR	CORDIS CORP.	Implementation of the 6-Up Reflow Machine with Recipe Control for Reflow process on all Biosense Webster quad lumen catheter tips at Irwindale
P950022/S108	07/26/2017	X - 30-Day Notice	QUARTET CRT LEADS	ST. JUDE MEDICAL, INC.	Addition of a curing oven during the connector assembly solvent bond process.
P950024/S074	07/05/2017	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P950029/S115	07/27/2017	X - 30-Day Notice	SMARTVIEW HOTSPOT	SORIN GROUP- CRM	Addition of a rework process for components used in the SMARTVIEW hotspot and the Orchestra Plus Link peripheral devices.
P960042/S059	07/31/2017	X - 30-Day Notice	SPECTRANETICS LASER SHEATH II (SLS II) GLIDELIGHT CATHETERS	SPECTRANETI CS CORP.	Implementation of a replacement fusing machine and a reduction in the epoxy cure time.
P970004/S246	07/07/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (URINARY)	MEDTRONIC NEUROMODU LATION	Additional site to receive packaging materials and to perform the cleaning, non-sterile final pack, labeling, final QA inspection, and shipping activities.
P970029/S035	07/28/2017	X - 30-Day Notice	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Change to specify an upper specification limit (USL) of 4.0 lbs/in for packaging with a chevron or peel able area for aseptic presentation.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970038/S034	07/07/2017	X - 30-Day Notice	ACCESS HYBRITECH FREE PSA REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Manufacturing change to update a specification to allow for a limited amount of flash local to the gate location (where plastic material is injected into the reaction vessel) for the Access 2 Reaction Vessels, which are used during the processing of the assays.
P970051/S165	07/06/2017	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	External supplier, Jabil Circuit in China, to be added as an alternate supplier of the CP800 Series Tamper resistant Battery Cover, CP800 Series Battery Holder and Nucleus Battery Holder components. A change was also requested to the solder material used in the battery holder printed circuit board assembly (PCBA).
P980003/S076	07/24/2017	X - 30-Day Notice	CHILLI II TM COOLED ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC CORP.	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P980016/S637	07/18/2017	X - 30-Day Notice	EVERA/MRI/DF, ICD, S DR, XT DR, S VR, XT VR, MAXIMO II ICD, SECURA DR ICD/ DR, VISIA AF MRI DFI ICD/VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.3 at Medtronic Swiss Manufacturing Operations.
P980033/S049	07/03/2017	X - 30-Day Notice	WALLSTENT (VENOUS) ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Alternate vendor for stainless steel tubing for use in the delivery system.
P980035/S510	07/12/2017	X - 30-Day Notice	ADAPTA, VERSA SENSIA IPG RELIA IPG	MEDTRONIC INC.	Changes to the integrated circuit tests used for pacemaker devices.
P980035/S511	07/18/2017	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR,MRI,SR IPG, ASTRA S DR, S SR, XT DR, XT SR IPG, RELIA IPG	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.3 at Medtronic Swiss Manufacturing Operations.
P980035/S512	07/26/2017	X - 30-Day Notice	ASTRA S DR/ XT DR /SR MRI IPG	MEDTRONIC INC.	Manufacturing process change for a Cell Operating System for the feedthrough component.
P980041/S037	07/07/2017	X - 30-Day Notice	ACCESS AFP REAGENTS ON THE ACCESS IMMUNOASSY SYSTEMS	BECKMAN COULTER, INC.	Manufacturing change to update a specification to allow for a limited amount of flash local to the gate location (where plastic material is injected into the reaction vessel) for the Access 2 Reaction Vessels, which are used during the processing of the assays.
P980044/S040	07/28/2017	X - 30-Day Notice	SUPARTZ FX AND VISCO-3	SEIKAGAKU CORP.	Change to the final device back-up storage facility for SUPARTZ FX and VISCO-3.
P980049/S126	07/27/2017	X - 30-Day Notice	SMARTVIEW HOTSPOT; ORCHESTRA PLUS LINK	SORIN GROUP- CRM	Addition of a rework process for components used in the SMARTVIEW hotspot and the Orchestra Plus Link peripheral devices.
P980050/S111	07/18/2017	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Additional in-process cleaning steps for stylet components.

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P980050/S112	07/05/2017	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P990025/S053	07/27/2017	X - 30-Day Notice	EZ STEER NAVIGATIONAL 4MM (TC)	BIOSENSE WEBSTER, INC.	Implementation of the 6-Up Reflow Machine with Recipe Control for Reflow process on all Biosense Webster quad lumen catheter tips at Irwindale
P990040/S025	07/05/2017	X - 30-Day Notice	CODMAN TRUFILL N-BUTYL CYANOACRYLATE LIQUID EMBOLIC SYSTEM	CODMAN & SHURTLEFF, INC.	Implementation of a new sterilization chamber control system at the STERIS, Northborough MA sterilization facility to replace the current system.
P990074/S039	07/05/2017	X - 30-Day Notice	NATRELLE-SALINE-FILLED BREAST IMPLANTS	ALLERGAN	Implement an Electronic Data Acquisition (EDA) System for the shell assembly vulcanization process to collect and store temperature, pressure, and time data. The above change is located 900 Parkway Global Park, La Aurora, Heredia, Costa Rica.
P000015/S022	07/06/2017	X - 30-Day Notice	AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	External supplier, Jabil Circuit in China, to be added as an alternate supplier of the CP800 Series Tamper resistant Battery Cover, CP800 Series Battery Holder and Nucleus Battery Holder components. A change was also requested to the solder material used in the battery holder printed circuit board assembly (PCBA).
P000021/S032	07/17/2017	X - 30-Day Notice	DIMENSION TPSA FLEX REAGENT CARTRIDGE (RF451)	SIEMENS HEALTHCARE DIAGNOSTICS	Add the Siemens facility located in Flanders, NJ as an internal supplier for the tested subassembly components for Dimension® EXL system.
P000025/S096	07/12/2017	X - 30-Day Notice	MI1200 HYBRID BY SUPPLIER MICRODUL	MED-EL CORP.	Addition of a second source supplier for the hybrid assembly of the Mi1200 SYNCHRONY Cochlear Implant.
P010013/S068	07/18/2017	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Changes to the RF Cable assembly process for the NovaSure disposable device.
P010015/S335	07/18/2017	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD; ATTAIN OTW LV LEAD	MEDTRONIC INC.	Additional in-process cleaning steps for stylet components.
P010015/S336	07/18/2017	X - 30-Day Notice	CONSULTA, PERCEPT BIPOLAR, PERCEPTA QUADRIPOLAR, SERENA BIPOLAR/QUADRIPOLAR, SYNCRA, VIVA CRT-P	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.3 at Medtronic Swiss Manufacturing Operations.
P010015/S337	07/26/2017	X - 30-Day Notice	PERCEPTA/ SERENA / SOLARA BIPOLAR, QUADRIPOLAR CRT-P	MEDTRONIC INC.	Manufacturing process change for a Cell Operating System for the feedthrough component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S598	07/18/2017	X - 30-Day Notice	AMPLIA MRI/QUAD, BRAVA/ QUAD CRT-D, CLARIA MRI/ QUAD CRT-D, COMPIA MRI/ QUAD CRT-D, CONSULTA CRT-D, MAXIMO II CRT-D, VIVAD S/QUAD XT CRT-D, VIVA S/XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.3 at Medtronic Swiss Manufacturing Operations.
P010032/S130	07/21/2017	X - 30-Day Notice	TRIPOLE, TRIPOLE 16C, TRIPOLE 16, EXCLAIM, LAMITRODE 4, 44, S-4, S-8, 88, WINGED, PENTA, QUATTRODE, OCTRODE, DUAL 4, SINGLE 8 EXTENSION, A127, 8 CHANNEL ADAPTERS, COMPUSTIM ADAPTER	ST. JUDE MEDICAL	1) Add a St. Jude Medical Facility located in Plymouth, MN as an alternate supplier for the extrusion and manufacture of the outer tubing and spacer components of the leads, extensions, and adapters; 2) adjust tolerances due to tighter process controls; and 3) implement the use of a visual measurement system for inspection.
P010068/S054	07/27/2017	X - 30-Day Notice	EZ STEER NAVIGATIONAL 8MM (DS) ; CELSIUS FLTR UNI-DIR.	BIOSENSE WEBSTER, INC.	Implementation of the 6-Up Reflow Machine with Recipe Control for Reflow process on all Biosense Webster quad lumen catheter tips at Irwindale
P020004/S145	07/11/2017	X - 30-Day Notice	EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,I NC	Remove an in-process tensile test of the GORE EXCLUDER AAA Endoprosthesis and GORE EXCLUDER Iliac Branch Endoprosthesis graft material.
P020025/S103	07/24/2017	X - 30-Day Notice	BLAZER II ¿ XP CARDIAC ABLATION CATHETER AND CABLE	BOSTON SCIENTIFIC	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P020027/S027	07/17/2017	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTRIDGE (RF451)	SIEMENS HEALTHCARE DIAGNOSTICS	Add the Siemens facility located in Flanders, NJ as an internal supplier for the tested subassembly components for Dimension® EXL system.
P020056/S042	07/05/2017	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Implement an Electronic Data Acquisition (EDA) System for the shell assembly vulcanization process to collect and store temperature, pressure, and time data. The above change is located 900 Parkway Global Park, La Aurora, Heredia, Costa Rica.
P030016/S032	07/20/2017	X - 30-Day Notice	VISIAN IMPLANTABLE COLLAMER LENS FOR MYOPIA	STAAR SURGICAL CO.	Addition of an alternate manufacturing process at the Monrovia facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S298	07/12/2017	X - 30-Day Notice	PRECISION SPECTRA / NOVI / WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEM, PRECISION MONTAGE SPINAL CORD STIMULATOR (SCS) SYSTEM, PRECISION MONTAGE MRI SPINAL CORD STIMULATORS (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Adding an alternate qualified supplier and post-curing process for the core seals used in the assembly to the Precision Spectra WaveWriter Implantable Pulse Generator (IPG).
P030017/S299	07/19/2017	X - 30-Day Notice	PRECISION MONTAGE (MRI) SPINAL CORD STIMULATION (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Adding an alternate qualified supplier for the ceramic chip capacitors used in the Printed Circuit Board Assembly (PCBA) of the Precision Montage and Precision Montage MRI Implantable Pulse Generators (IPGs).
P030031/S081	07/27/2017	X - 30-Day Notice	EZ STEER NAVIGATIONAL 4MM; C3 EZ STEER THERMOCOOL NAV; EZ STEER THERMOCOOL NON-NAVIGATIONAL 4MM (TC); EZ STEER THERMOCOOL NON-NAVIGATIONAL 4MM(THR); C3 EZ STEER THERMOCOOL SF NAV ; C3 EZ STEER THERMOCOOL SF NON-NAV; C3 NAVISTAR THERMOCOOL SF; EZ STEER THERMOCOOL SF NAV	BIOSENSE WEBSTER, INC.	Implementation of the 6-Up Reflow Machine with Recipe Control for Reflow process on all Biosense Webster quad lumen catheter tips at Irwindale
P030054/S330	07/26/2017	X - 30-Day Notice	DURATA AND OPTISURE HV LEADS	ST. JUDE MEDICAL	Addition of a curing oven during the connector assembly solvent bond process.
P030054/S331	07/26/2017	X - 30-Day Notice	PROMOTE, UNIFY QUADRA, ASSURA, QUADRA ASSURA	ST. JUDE MEDICAL	Reduction in time for the burn-in environmental screen used during the processing of high voltage RF Module assemblies.
P040036/S059	07/27/2017	X - 30-Day Notice	EZ STEER SMART TOUCH; THERMOCOOLL ST UNI	BIOSENSE WEBSTER, INC.	Implementation of the 6-Up Reflow Machine with Recipe Control for Reflow process on all Biosense Webster quad lumen catheter tips at Irwindale

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040045/S077	07/12/2017	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Change to the raw material storage conditions for VISTAKON® (senofilcon A) and VISTAKON® (etafilcon A) brand contact lenses.
P040046/S023	07/05/2017	X - 30-Day Notice	NATRELLE HIGHLY COHESIVE ANATOMICALLY SHAPED SILICONE-FILLED	ALLERGAN	Implement an Electronic Data Acquisition (EDA) System for the shell assembly vulcanization process to collect and store temperature, pressure, and time data. The above change is located 900 Parkway Global Park, La Aurora, Heredia, Costa Rica.
P050019/S028	07/03/2017	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROTHESIS PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Alternate vendor for stainless steel tubing for use in the delivery system.
P060002/S039	07/19/2017	X - 30-Day Notice	FLAIR ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR	Upgrade the sterilization control system for sterilization line #1 at Bard Regional Sterilization, Covington Facility.
P060006/S083	07/24/2017	X - 30-Day Notice	EXPRESS® SD MONORAIL® PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P060027/S091	07/27/2017	X - 30-Day Notice	SMARTVIEW HOTSPOT ; ORCHESTRA PLUS LINK	SORIN GROUP CRM USA, INC	Addition of a rework process for components used in the SMARTVIEW hotspot and the Orchestra Plus Link peripheral devices.
P060037/S049	07/06/2017	X - 30-Day Notice	ZIMMER NEXGEN LPS-FLEX MOBILE AND LPS MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Addition of a second test method for performing Bacterial Endotoxin Testing (BET).
P060039/S079	07/18/2017	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Additional in-process cleaning steps for stylet components.
P060039/S080	07/26/2017	X - 30-Day Notice	ATTAIN STARFIX LEAD 4195	MEDTRONIC INC.	Automation of the documentation process of the data results from electrical resistance functional testing.
P070001/S015	07/27/2017	X - 30-Day Notice	PRODISC-C TOTAL DISC REPLACEMENT	SYNTHES SPINE	Change to the holding fixture and coordinate measuring machine (CMM) software programs used to dimensionally inspect the ProDisc-C Total Disc Replacement inferior and superior plates.
P070008/S086	07/27/2017	X - 30-Day Notice	SENTUS PROMRI OTW QP S-75, S-85, S-95, L-75, L-95, S-75/49, S-85/49, S-95/49, L-75/49, L-85/49 AND SENTUS PROMRI OTW QP L-95/49	BIOTRONIK, INC.	Shelf life extension of the steroid collar component from 9 to 12 months.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P070026/S048	07/13/2017	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Two changes to the SUMMIT and TRI-LOCK BPS hip stems: automation of the turn taper and laser etch operations, and an increase in degrease process capacity from 2 units/cycle to 5 units/cycle. A third change is proposed to the TRI-LOCK BPS hip stems, which will be to implement a new protective guard to be used during the polishing process.
P070026/S049	07/24/2017	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change to the inspection method for S-ROM Stem components.
P080006/S110	07/18/2017	X - 30-Day Notice	ATTAIN ABILITY LEAD; ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Additional in-process cleaning steps for stylet components.
P080006/S111	07/26/2017	X - 30-Day Notice	ATTAIN ABILITY LEADS 4196, 4296, 4396	MEDTRONIC INC.	Automation of the documentation process of the data results from electrical resistance functional testing.
P080006/S112	07/05/2017	X - 30-Day Notice	ATTAIN ABILITY/ PERFORMA LEAD	MEDTRONIC INC.	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P080025/S141	07/07/2017	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Additional site to receive packaging materials and to perform the cleaning, non-sterile final pack, labeling, final QA inspection, and shipping activities.
P090013/S260	07/18/2017	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Additional in-process cleaning steps for stylet components.
P090013/S261	07/18/2017	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.3 at Medtronic Swiss Manufacturing Operations.
P090015/S005	07/25/2017	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	New reagent supplier for a device component.
P090026/S019	07/07/2017	X - 30-Day Notice	ACCESS HYBRITECH P2PSA REAGENTS ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Manufacturing change to update a specification to allow for a limited amount of flash local to the gate location (where plastic material is injected into the reaction vessel) for the Access 2 Reaction Vessels, which are used during the processing of the assays.
P110010/S142	07/24/2017	X - 30-Day Notice	PROMUS ELEMENT¿ PLUS EVEROLIMUS-EIUTING STENT SYSTEM I, PROMUS PREMIER EVEROLIMUS-EIUTING PLATINUM CHROMIUM CORONARY	BOSTON SCIENTIFIC CORP.	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P110016/S047	07/27/2017	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC.	Alternative laser cutting machine for the Flex Tip component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120017/S009	07/05/2017	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Removal of the use of clean benches from the Heart Failure and Low Voltage manufacturing areas at Medtronic Puerto Rico Operations Company in Villalba, Puerto Rico.
P120020/S016	07/14/2017	X - 30-Day Notice	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Change the dilution used for routine lot release pyrogenic testing for the Supera Peripheral Stent System from 1:5 to 1:100.
P120022/S015	07/24/2017	X - 30-Day Notice	THERASCREEN EGFR, RGQ, PCR KIT	QIAGEN MANCHESTER LTD	Improvement to the therascreen EFGR Kit stock Internal Control (IC) Mix manufacturing process.
P130009/S078	07/18/2017	X - 30-Day Notice	EDWARDS SAPIEN XT ¿ TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Addition of a staging station after the Final Bioburden Reduction Process for Edwards tissue valves.
P130009/S079	07/20/2017	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement a new water system and two new pouch sealers.
P130009/S080	07/27/2017	X - 30-Day Notice	ASCENDRA+ DELIVERY SYSTEM; BALLOON AORTIC VALVULOPLASTY CATHETER; NOVAFLEX+ DELIVERY SYSTEM; CRIMPER; EDWARDS BALLON CATHETER; EDWARDS EXPANDABLE INTRODUCER SHEATH SET; QUALCRIMP CRIMPING ACCESSORY (INCLUDED WITH NOVAFLEX+ DELIVERY SYSTEM PACKAGING)	EDWARDS LIFESCIENCES, LLC.	Implement a new minimum load configuration for the EO sterilization cycle at Sterigenics, Salt Lake City, Utah.
P130009/S081	07/28/2017	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Change to static fixation of pericardial tissue.
P130013/S014	07/27/2017	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE DEVICE AND DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Modify the process settings for the fabric cutting equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130016/S029	07/06/2017	X - 30-Day Notice	NUCLEUS 24 HYBRID SYSTEM	COCHLEAR AMERICAS	External supplier, Jabil Circuit in China, to be added as an alternate supplier of the CP800 Series Tamper resistant Battery Cover, CP800 Series Battery Holder and Nucleus Battery Holder components. A change was also requested to the solder material used in the battery holder printed circuit board assembly (PCBA).
P130021/S039	07/17/2017	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM/ EVOLUT R SYSTEM/ EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Implementation of additional tissue laser cutters at the Medtronic Tijuana, Mexico facility.
P130030/S041	07/24/2017	X - 30-Day Notice	REBEL TM PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P140009/S025	07/24/2017	X - 30-Day Notice	DBS EXTENSIONS	ST. JUDE MEDICAL NEUROMODULATION	1) Add a St. Jude Medical Facility located in Plymouth, MN as an alternate supplier for the extrusion and manufacture of the outer tubing and spacer components of the leads, extensions, and adapters; 2) adjust tolerances due to tighter process controls; and (3) implement the use of a visual measurement system for inspection
P140010/S035	07/28/2017	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED BALLOON CATHETER	MEDTRONIC INC.	Modification to the sampling plan for lot release testing.
P140029/S003	07/06/2017	X - 30-Day Notice	RESTYLANE REFYNE AND RESTYLANE DEFYNE	Q-MED AB	Change in the colorant raw material used in the plastic plunger rod for Restylane Refyne and Restylane Defyne.
P140031/S045	07/18/2017	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Addition of a staging station after the Final Bioburden Reduction Process for Edwards tissue valves.
P140031/S046	07/20/2017	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement a new water system and two new pouch sealers.
P140031/S049	07/27/2017	X - 30-Day Notice	COMMANDER DELIVERY SYSTEM; CERTITUDE DELIVERY SYSTEM; CERTITUDE INTRODUCER SHEATH; CRIMPER	EDWARDS LIFESCIENCES, LLC.	Implement a new minimum load configuration for the EO sterilization cycle at Sterigenics, Salt Lake City, Utah.
P140031/S050	07/28/2017	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Change to static fixation of pericardial tissue.
P140033/S009	07/27/2017	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	In-process changes to the monolithic controlled release device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150005/S022	07/24/2017	X - 30-Day Notice	BLAZER¿ OPEN IRRIGATED TEMPERATURE ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Optimized BSC2000-2 EO sterilization cycle in Chambers 8 and 9 at Synergy Health Tullamore.
P150011/S010	07/26/2017	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Implement a new laser cutter for the Perceval stent.
P150021/S010	07/12/2017	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Changes to the molding process parameters and molding equipment used for the plastic component which houses the sensor introducer needle in the sensor applicator for the Freestyle Libre Pro Flash Glucose Monitoring System.
P150033/S024	07/05/2017	X - 30-Day Notice	MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Component inspection changes for the tether lock insert housing.
P150033/S025	07/18/2017	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Update the manufacturing execution system (MES) to FACTORYworks (FW) Release 9.3 at Medtronic Swiss Manufacturing Operations.
P150036/S013	07/18/2017	X - 30-Day Notice	EDWARDS INTUITY VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Addition of a staging station after the Final Bioburden Reduction Process for Edwards tissue valves.
P150036/S014	07/20/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Implement a new water system and two new pouch sealers.
P150036/S015	07/28/2017	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Change to static fixation of pericardial tissue.
P160024/S001	07/19/2017	X - 30-Day Notice	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Upgrade the sterilization control system for sterilization line #1 at Bard Regional Sterilization, Covington Facility.
P160043/S003	07/19/2017	X - 30-Day Notice	RESOLUTE ONYX RX AND OTW CORONARY STENT SYSTEMS	MEDTRONIC INC.	Introduce changes to the work steps used in the manufacture of the bare metal stent, collectively titled the "Lean Cell (LC) manufacturing process".

Total: 129