PMA Monthly approvals from 3/1/2019 to 3/31/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180032	03/28/2019	PMAO - PMA Origi	CERENE® CRYOTHERAPY DEVICE	CHANNEL MEDSYSTEMS , INC.	Approval for the Cerene® Cryotherapy Device. This device is indicated for endometrial cryoablation in premenopausal women with heavy menstrual bleeding due to benign causes for whom child bearing is complete.
P180036	03/21/2019	PMAO - PMA Origi	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for the OPTIMIZER Smart System. The device which delivers Cardiac Contractility Modulation therapy, is indicated to improve 6-minute hall walk distance, quality of life, and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25% to 45%.
P180037	03/13/2019	PMAO - PMA Origi	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	Approval for the Venovo Venous Stent System. The device is indicated for the treatment of symptomatic iliofemoral venous outflow obstruction.
P180040	03/26/2019	PMAO - PMA Origi	TRILURON	FIDIA PHARMA USA S.P.A.	Approval for TRILURON. The device is indicated for use in the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S161	03/28/2019	O - Normal 180 Day	AMS AMBICOR INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for a sterilization site change for approval of BSC Coventry, Rhode Island as an additional sterilization site for ethylene oxide (EO) Cycle 101 due to the closure of the Sterigenics Willowbrook facility.

Data as of 04/03/2019 03:58 AM

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P830055/S210	03/27/2019	O - Normal 180 Day	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for the addition of new sterilization site approval for Shanghai JPY Ion-Tech Co., Ltd., No.1168, Huijin Road, Qingpu Industrial I one, Shanghai, China, 201707.
P840001/S406	03/13/2019	Y - 135 Review Tra	LGW- MASTER RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODU LATION	Approval for implementing a tolerance change and a tooling change in the battery cathode manufacturing process.
P840001/S419	03/08/2019	R - Real-Time Proc	MASTER RESTORE, ITREL, SYNERGY AND INTELLISM SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODU LATION	Approval for a change in material purity of niobium wire stock; second-tier raw material supplier change for niobium wire stock; lubricant change for wire drawing process; and process change to anneal wire prior to wire drawing process.
P840064/S070	03/20/2019	Y - 135 Review Tra	OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORI ES	Approval for use of the Bulk Syringe Line (BSL) as an additional alternate syringe processing and filling line to fill VISCOAT® and VISCOAT® as part of DUOVISC®
P850010/S082	03/13/2019	O - Normal 180 Day	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE/ORAFOAM ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	INTEGRA LIFESCIENCE S CORPORATIO N	Approval for an additional trade name, OraFOAM, for the Helistat® Absorbable Collagen Hemostatic Sponge.
P850079/S080	03/08/2019	O - Normal 180 Day	METHAFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISIO N, INC.	Approval for new packaging and labeling site to CooperVision Manufacturing, Ltd, Southampton, United Kingdom.
P860004/S324	03/08/2019	R - Real-Time Proc	SYNCHROMED INFUSION SYSTEM ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Approval for a change in material purity of niobium wire stock; second-tier raw material supplier change for niobium wire stock; lubricant change for wire drawing process; and process change to anneal wire prior to wire drawing process.
P880086/S304	03/13/2019	R - Real-Time Proc	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for software modification to the Merlin.net MN6000 HF Web Application v10.0 software.
P890003/S403	03/05/2019	O - Normal 180 Day	MEDTRONIC CARELINK MONITOR, CARDIOSIGHT READER	MEDTRONIC, INC.	Approval for labeling updates to the clinical study summary for the post approval study.

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P890023/S035	03/08/2019	O - Normal 180 Day	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Approval for new packaging and labeling site to CooperVision Manufacturing, Ltd, Southampton, United Kingdom.
P910001/S109	03/20/2019	Y - 135 Review Tra	CVX-300 EXCIMER LASER SYSTEM AND ELCA CORONARY ATHERECTOMY CATHETERS	SPECTRANETICS CORP.	Approval for a supplier change for the luer leg subcomponent, process change related to the luer leg, and an additional quality control inspection for the luer leg.
P910018/S023	03/28/2019	N - Normal 180 Day	LIPOSORBER LA-15 SYSTEM	KANEKA PHARMA AMERICA CORP.	Approval for modifying the indications for use statement.
P910023/S414	03/13/2019	R - Real-Time Proc	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC+, ATLAS/II/+ FAMILY OF ICDS	ST. JUDE MEDICAL	Approval for software modification to the Merlin.net MN6000 HF Web Application v10.0 software.
P920015/S225	03/05/2019	O - Normal 180 Day	SPRINT QUATTRO SECURE AND SPRINT QUATTRO SECURE S	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post approval study.
P930036/S010	03/07/2019	N - Normal 180 Day	ATELLICA IM ALPHA FETOPROTEIN (AFP)	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the migration of the ADVIA Centaur AFP Assay to the Atellica IM Analyzer.
P950037/S197	03/13/2019	N - Normal 180 Day	PSW 1803.U / HMSC 3.40.2 / CARDIOMESSENGER SMART	BIOTRONIK, INC.	Approval for the Acticor and Rivacor family (Cor devices) of ICD and CRT-D device models.
P960009/S324	03/13/2019	Y - 135 Review Tra	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval for implementing a tolerance change and a tooling change in the battery cathode manufacturing process.
P960009/S336	03/01/2019	R - Real-Time Proc	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval to add a Polyethylene terephthalate (PET) slip tube over proximal end of each cable conductor to prevent mechanical locking of the build epoxy to the Ethylene tetrafluoroethylene (ETFE) coated wire cables for DBS Extension models 37085 and 37086.
P960009/S337	03/08/2019	R - Real-Time Proc	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval to a change in material purity of niobium wire stock; second-tier raw material supplier change for niobium wire stock; lubricant change for wire drawing process; and process change to anneal wire prior to wire drawing process.

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P960009/S339	03/15/2019	R - Real-Time Proc	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Approval to correct the value for the electrode surface area used in the charge density calculation from 0.12 cm2 to 0.06 cm2. The erroneous value of 0.12 cm2 is currently used in the calculation to display the charge density warning notification when the Activa CPA is used with an ENS and twist lock cable.
P960016/S077	03/05/2019	O - Normal 180 Day	LIVEWIRE TC CABLES; SAFIRE ABLATION CATHETER; SAFIRE CABLE	ST. JUDE MEDICAL	Approval for an alternate sterilization site located at Sterigenics, 5725 Harold Gatty Drive, Salt Lake City, Utah.
P960058/S132	03/12/2019	N - Normal 180 Day	CHORUS SOUND PROCESSOR AND SOUNDWAVE PROFESSIONAL SUITE 3.2/ HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Approval for Chorus sound processor and accessories (battery, battery charger, protective case, programming cable) and SoundWave 3.2 fitting software.
P970003/S221	03/27/2019	R - Real-Time Proc	SENTIVA MODEL 1000 GENERATOR	LIVANOVA USA, INC.	Approval for firmware updates of the Model 1000 Generator.
P970004/S282	03/08/2019	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODU LATION	Approval for a change in material purity of niobium wire stock; second-tier raw material supplier change for niobium wire stock; lubricant change for wire drawing process; and process change to anneal wire prior to wire drawing process.
P980016/S698	03/05/2019	O - Normal 180 Day	SECURA DR ICD, MAXIMO II DR ICD, PROTECTA XT DR ICD, PROTECTA DR ICD, SECURA VR ICD, MAXIMO II VR ICD, PROTECTA XT VR ICD AND PROTECTA VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for labeling updates to the clinical study summary for the post approval study.
P980035/S576	03/27/2019	R - Real-Time Proc	ASTRA S DR MRI IPG, SR MRI IPG, ASTRA XT DR MRI IPG, SR MRI IPG, AZURE S DR MRI IPG, SR MRI IPG, AZURE XT DR MRI IPG, SR MRI IPG	MEDTRONIC INC.	Approval for a replacement Multi-Layer Ceramic Capacitor used in select Medtronic pacemakers and cardiac resynchronization therapy pacemakers.
P980049/S133	03/19/2019	R - Real-Time Proc	PLATINIUM VR 1210; PLATINIUM VR 1240; PLATINIUM DR 1510; PLATINIUM DR 1540; PLATINIUM CRT-D 1711; PLATINIUM CRT-D 1741; PLATINIUM 4LV CRT-D 1744	MICROPORT CRM USA INC.	Approval for updates to the embedded device software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P990009/S051	03/04/2019	R - Real-Time Proc	FLOSEAL HEMOSTATIC MATRIX	BAXTER HEALTHCARE CORP.	Approval for modifications to the 5ml and 10ml FLOSEAL Hemostatic Matrix (FLOSEAL) device kit configurations to reduce device preparation time. The modifications consist of minor changes to the device design, labeling, and packaging.
P990009/S052	03/22/2019	R - Real-Time Proc	FLOSEAL HEMOSTATIC MATRIX	BAXTER HEALTHCARE CORP.	Approval for the qualification of a second ethylene oxide sterilization cycle of the thrombin pouch assemblies.
P990040/S027	03/22/2019	O - Normal 180 Day	TRUFILL N-BUTYL CYANOACRYLATE (N-BCA) LIQUID EMBOLIC SYSTEM	CODMAN & SHURTLEFF, INC.	Approval for a manufacturing site located at Chemence Medical Products, Inc., 200 Technology Drive, Alpharetta, Georgia, for the manufacturing and sterilization of the n-butyl cyanoacrylate (n-BCA) component of the TRUFILL n-BCA Liquid Embolic System.
P000009/S078	03/13/2019	N - Normal 180 Day	PSW 1803.U / HMSC 3.40.2 / CARDIOMESSENGER SMART	BIOTRONIK, INC.	Approval for the Acticor and Rivacor family (Cor devices) of ICD and CRT-D device models.
P000039/S064	03/05/2019	O - Normal 180 Day	AMPLATZER SEPTAL OCCLUDER, AMPLATZER MULTI-FENESTRATED SEPTAL OCCLUDER	ABBOTT MEDICAL	Approval for an alternate sterilization site located at Sterigenics, 5725 Harold Gatty Drive, Salt Lake City, Utah.
P000053/S103	03/28/2019	O - Normal 180 Day	AMS 800 ARTIFICIAL URINARY SPHINCTER (WITH AND WITHOUT INHIBIZONE); AMS 700 INFLATABLE PENILE PROSTHESIS (WITH AND WITHOUT INHIBIZONE)	BOSTON SCIENTIFIC CORP.	Approval for a sterilization site change for approval of BSC Coventry, Rhode Island as an additional sterilization site for ethylene oxide (EO) Cycle 101 due to the closure of the Sterigenics Willowbrook facility.
P000057/S011	03/05/2019	O - Normal 180 Day	ASCENSION MCP	INTEGRA LIFESCIENCES CORPORATION	Approval for labeling changes to the package insert, surgical technique, patient information brochure, and post-operative therapy brochure.
P010015/S391	03/27/2019	R - Real-Time Proc	PERCEPTA BIPOLAR CRT-P, QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, QUADRIPOLAR CRT-P	MEDTRONIC INC.	Approval for a replacement Multi-Layer Ceramic Capacitor used in select Medtronic pacemakers and cardiac resynchronization therapy pacemakers.
P010031/S658	03/05/2019	O - Normal 180 Day	CONSULTA CRT-D, MAXIMO II CRT-D, PROTECTA XT CRT-D AND PROTECTA CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling updates to the clinical study summary for the post approval study.

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P010032/S147	03/26/2019	R - Real-Time Proc	SCS EPG HEADER	ABBOTT MEDICAL	Approval for design changes including increasing the thickness of the polyimide substrate and decreasing the thickness of the polyimide coverfilm on the Flex Printed Circuit Board (PCB) on the Spinal Cord Stimulation External Pulse Generator (SCS EPG) header, model 3032.
P020024/S055	03/05/2019	O - Normal 180 Day	AMPLATZER DUCT OCCLUDER, OCCLUDER II; AMPLATZER PICCOLO OCCLUDER	ABBOTT MEDICAL	Approval for an alternate sterilization site located at Sterigenics, 5725 Harold Gatty Drive, Salt Lake City, Utah.
P020050/S032	03/14/2019	S - Special CBE	ALLEGRO TOPOLYZER VARIO AND PATIENT BED SWIVEL	ALCON LABORATORIES, INC.	Approval for a change in labeling to align with the labeling recommendations of IEC 60601-1-2:2014 (4th edition).
P030008/S028	03/14/2019	S - Special CBE	WAVELIGHT ANALYZER II, ALLEGRO TOPOLYZER VARIO, PATIENT BED SWIVEL	ALCON LABORATORIES, INC.	Approval for a change in labeling to align with the labeling recommendations of IEC 60601-1-2:2014 (4th edition).
P030016/S034	03/07/2019	O - Normal 180 Day	VISIAN TORIC ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Approval of the revised protocol for the post-approval study (PAS) protocol.
P030031/S094	03/26/2019	R - Real-Time Proc	THERMOCOOL SMARTTOUCH BI-DIRECTIONAL NAVIGATION CATHETER; THERMOCOOL SMARTTOUCH UNI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for replacing the current puller wire assembly and modification to the method of affixing wires within the soft tip.
P030035/S175	03/13/2019	R - Real-Time Proc	ANTHEM, ALLURE/RF, ALLURE QUADRA/RF FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for software modification to the Merlin.net MN6000 HF Web Application v10.0 software.
P030054/S364	03/13/2019	R - Real-Time Proc	PROMOTE/+/RF/Q, PROMOTE ACCEL, PROMOTE QUADRA, UNIFY, UNIFY ASSURA, UNIFY QUADRA, QUADRA ASSURA, EPIC+/HF/HF+/II HF/II+ HF, ATLAS+HF/II HH/ II+ HF FAMILY OF CRT-DS	ST. JUDE MEDICAL	Approval for software modification to the Merlin.net MN6000 HF Web Application v10.0 software.

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P040036/S064	03/26/2019	R - Real-Time Proc	THERMOCOOL SMARTTOUCH SF BI-DIRECTIONAL NAVIGATION CATHETER; THERMOCOOL SMARTTOUCH SF UNI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Approval for replacing the current puller wire assembly and modification to the method of affixing wires within the soft tip.
P040037/S123	03/22/2019	N - Normal 180 Day	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Approval for design changes to the 9-13 mm stents and delivery systems.
P040040/S035	03/05/2019	O - Normal 180 Day	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Approval for an alternate sterilization site located at Sterigenics, 5725 Harold Gatty Drive, Salt Lake City, Utah.
P050023/S125	03/13/2019	N - Normal 180 Day	ACTICOR 7 VR-T / RIVACOR 7 VR-T /5VR-T /3 VR-T / ACTICOR 7 VR-T DX / RIVACOR 7 VR-T DX / RIVACOR 5 VR-T DX ; ACTICOR 7 DR-T /RIVACOR 7 /5 /3 / DR-T MRM'S ; ACTICOR 7 HF-T / RIVACOR 7/5/3 HT-T; ACTICOR 7 HF-T QP / RIVACOR 7/ 5 /3 HF-T QP CRT-D	BIOTRONIK, INC.	Approval for the Acticor and Rivacor family (Cor devices) of ICD and CRT-D device models.
P050034/S020	03/22/2019	O - Normal 180 Day	IMPLANTABLE MINIATURE TELESCOPE (IMT)	VISIONCARE, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P050047/S066	03/13/2019	R - Real-Time Proc	JUVEDERM INJECTABLE GEL IMPLANTS	ALLERGAN	Approval for the addition of a 0.55 mL-fill volume configuration in the same 1.0 mL COC syringe for Juvéderm Ultra, Juvéderm Ultra XC, and Juvéderm Ultra Plus XC.
P050051/S033	03/06/2019	N - Normal 180 Day	ALINITY I ANTI-HBS REGENT KIT, ALINITY I ANTI-HBS CALIBRATORS, AND ALINITY I ANTI-HBS CONTROLS	ABBOTT LABORATORIES INC	Approval for migration of the ARCHITECT AUSAB assay, ARCHITECT AUSAB Calibrators and ARCHITECT AUSAB Controls onto the Alinity i Analyzer. The manufacture of the Alinity i analyzer would be done at a new contract manufacturer, Sanmina, Singapore.
P060027/S098	03/19/2019	R - Real-Time Proc	PLATINIUM VR 1210; PLATINIUM VR 1240; PLATINIUM DR 1510; PLATINIUM DR 1540; PLATINIUM CRT-D 1711; PLATINIUM CRT-D 1741; PLATINIUM 4LV CRT-D 1744	MICROPORT CRM USA INC.	Approval for updates to the embedded device software.

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P070008/S098	03/13/2019	N - Normal 180 Day	PSW 1803.U /HMSC 3.40.2 / CARDIOMESSENGER SMART	BIOTRONIK, INC.	Approval for the Acticor and Rivacor family (Cor devices) of ICD and CRT-D device models.
P080011/S079	03/08/2019	O - Normal 180 Day	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Approval for new packaging and labeling site to CooperVision Manufacturing, Ltd, Southampton, United Kingdom.
P080023/S028	03/06/2019	N - Normal 180 Day	ALINITY I ANTI-HBC REAGENT KIT, ALINITY I ANTI-HBC CALIBRATOR, ALINITY I ANTI-HBC CONTROLS	ABBOTT LABORATORIES	Approval for the migration of the ARCHITECT CORE Reagent Kit, ARCHITECT CORE Calibrator, ARCHITECT CORE Controls onto the Alinity i Analyzer.
P080025/S177	03/08/2019	R - Real-Time Proc	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM	MEDTRONIC NEUROMODULATION	Approval for a change in material purity of niobium wire stock; second-tier raw material supplier change for niobium wire stock; lubricant change for wire drawing process; and process change to anneal wire prior to wire drawing process.
P100009/S028	03/14/2019	P - Panel Track	MITRACLIP NT CLIP DELIVERY SYSTEM AND MITRACLIP NTR/XTR CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval for the MitraClip NT Clip Delivery System and MitraClip NTR/XTR Clip Delivery System for expanding the indication to include secondary mitral regurgitation. The devices, when used with maximally tolerated guideline-directed medical therapy (GDMT), are indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR >= Grade III per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) >= 20% and <= 50%, and a left ventricular end systolic dimension (LVESD) <= 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.
P100021/S072	03/08/2019	O - Normal 180 Day	ENDURANT STENT GRAFT SYSTEM, ENDURANT II STENT GRAFT SYSTEM, ENDURANT II AORTO-UNI-ILIAC (AUI) STENT GRAFT SYSTEM, ENDURANT IIS STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for labeling update to the Endurant Stent Graft IFU as well as the Endurant II/IIs Stent Graft IFU.
P100022/S032	03/26/2019	R - Real-Time Proc	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Approval to modify the 40-120 mm stent length delivery systems.
P100045/S035	03/13/2019	R - Real-Time Proc	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for software modification to the Merlin.net MN6000 HF Web Application v10.0 software.

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P100047/S135	03/13/2019	S - Special CBE	HEARTWARE VENTRICULAR ASSIST SYSTEM (HVAD)	MEDTRONIC	Approval for the addition of two 100% in process and incoming inspections at a tier two supplier of the HVAD Battery Charger PCB.
P110013/S094	03/08/2019	O - Normal 180 Day	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval of the protocol for the post-approval study (PAS) protocol.
P110016/S059	03/05/2019	O - Normal 180 Day	FLEXABILITY AND FLEXABILITY SE ABLATION CATHETER; FLEXABILITY CABLES, SENSOR ENABLED	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for an alternate sterilization site located at Sterigenics, 5725 Harold Gatty Drive, Salt Lake City, Utah.
P120005/S080	03/15/2019	O - Normal 180 Day	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for changes to the interim analysis.
P120021/S010	03/05/2019	O - Normal 180 Day	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Approval for an alternate sterilization site located at Sterigenics, 5725 Harold Gatty Drive, Salt Lake City, Utah.
P130006/S062	03/22/2019	N - Normal 180 Day	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES, INC	Approval for design changes to the 9-13 mm stents and delivery systems.
P130013/S025	03/01/2019	O - Normal 180 Day	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for approval for a manufacturing site, Synergy Health Ireland Ltd., (a STERIS Company), located at IDA Business and Technology Park, Srah, Tullamore, County Offaly, Ireland, as a new ethylene oxide (EO) sterilization site for the WATCHMAN Left Atrial Appendage Closure (LAAC) Device with Delivery System.
P130026/S042	03/05/2019	O - Normal 180 Day	TACTICATCH QUARTZ CONTACT FORCE ABLATION CATHETER	ST. JUDE MEDICAL	Approval for an alternate sterilization site located at Sterigenics, 5725 Harold Gatty Drive, Salt Lake City, Utah.
P140020/S014	03/06/2019	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for changes to the device labeling related to software/database and test report mockups
P140031/S084	03/13/2019	S - Special CBE	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a revision of the Instructions for Use for the Edwards SAPIEN 3 Transcatheter Heart Valve with the Edwards Commander Delivery System to add two warnings related to residual fluid left in the balloon and valve alignment.
P140032/S025	03/08/2019	R - Real-Time Proc	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for a change in material purity of niobium wire stock; second-tier raw material supplier change for niobium wire stock; lubricant change for wire drawing process; and process change to anneal wire prior to wire drawing process.

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P140033/S041	03/13/2019	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for software modification to the Merlin.net MN6000 HF Web Application v10.0 software.
P150002/S001	03/26/2019	O - Normal 180 Day	INCRAFT AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Approval of the protocol for the post-approval study (PAS) protocol.
P150003/S043	03/29/2019	O - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval of the post-approval study (PAS) protocol.
P150004/S023	03/26/2019	O - Normal 180 Day	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for Axium Neurostimulator System. The Axium Neurostimulator System is indicated for spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II*.
P150017/S012	03/22/2019	S - Special CBE	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Approval for adding a clarifying statement regarding the need for irrigation during drilling within the Instructions for Use and the Surgical Implantation Technique for the Cartiva Synthetic Cartilage Implant.
P150021/S038	03/19/2019	R - Real-Time Proc	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for design changes to improve drop, vibration, and shock resistance to the Freestyle Libre Pro Reader.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160002/S009	03/08/2019	P - Panel Track	VENTANA PD-L1(SP142) ASSAY.	VENTANA MEDICAL SYSTEMS, INC.	Approval for VENTANA PD L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD L1 clone SP142. The device is intended for use in the assessment of the programmed death-ligand 1 (PD-L1) protein in tumor cells and tumor-infiltrating immune cells in the formalin-fixed, paraffin-embedded (FFPE) tissues indicated below stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a VENTANA BenchMark ULTRA instrument. Determination of PD-L1 status is indication-specific, and evaluation is based on either the proportion of tumor area occupied by PD-L1 expressing tumor-infiltrating immune cells (% IC) of any intensity or the percentage of PD-L1 expressing tumor cells (% TC) of any intensity. VENTANA PD-L1 (SP142) Assay is indicated as an aid for identifying patients for treatment with the therapies for the respective cutoffs listed in Table 1 in accordance with the approved therapeutic product labeling. Table 1. Companion diagnostic indications for the VENTANA PD-L1 (SP142) Assay Indication for use Therapy Cutoff Urothelial Carcinoma TECENTRIQ >= 5% IC Triple-Negative Breast Carcinoma (TNBC) TECENTRIQ >= 1% IC PD-L1 expression in >= 50% TC or >= 10% IC determined by VENTANA PD-L1 (SP142) Assay in non-small cell lung cancer (NSCLC) patients may be associated with enhanced overall survival from TECENTRIQ (atezolizumab). This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.
P160014/S006	03/15/2019	Y - 135 Review Tra	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Approval for a new crimping/pillowing process.
P160015/S002	03/27/2019	Y - 135 Review Tra	CPR STAT-PADZ ELECTRODE AND CPR-D PADZ ELECTRODE	ZOLL MEDICAL CORPORATION	Approval for automation of a soldering process.
P160026/S004	03/24/2019	R - Real-Time Proc	LIFEPAK 15 MONITOR/ DEFIBRILLATOR	PHYSIO-CONTROL. INC.	Approval for a memory chip component replacement.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160037/S001	03/26/2019	Y - 135 Review Tra	BD ONCLARITY HPV ASSAY, BD VIPER LT SYSTEM	BECTON, DICKINSON AND COMPANY	Approval for a change to plastic resin used for reagent storage containers.
P160042/S004	03/15/2019	N - Normal 180 Day	REVANESSE VERSA, REVANESSE VERSA +	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for the increase in syringe volume from 1.0 mL to 1.2 mL of Revanesse Versa and Revanesse Versa+.
P160043/S018	03/14/2019	Y - 135 Review Tra	RESOLUTE ONYX RX ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM / RESOLUTE ONYX OTW ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval to utilize the Medtronic Ireland site as an alternate facility for the Parylene coating process.
P160043/S021	03/08/2019	O - Normal 180 Day	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval of the protocol for the post-approval study (PAS) protocol.
P160055/S002	03/04/2019	N - Normal 180 Day	RXSIGHT LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE	RXSIGHT, INC.	Approval for the post-approval study protocol, RxSight Light Adjustable Lens (LAL) and Light Delivery Device (LDD) New Enrollment Study, and modifications to the LAL posterior layer, the LAL haptic attachment manufacturing process, and the LDD light source, table configuration, infrared anterior segment illumination, and contact lens.
P160055/S003	03/06/2019	O - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for the addition of the following sterilization vendor for the Light Adjustable Lens (LAL) and Light Delivery Device (LDD): Steris Inc. 43425 Business Park Drive Temecula, California
P170012/S014	03/05/2019	S - Special CBE	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Approval for changes to the bacterial endotoxin testing including increased sample size and lowered limit of detection.
P170042/S002	03/01/2019	P - Panel Track	COVERA¿ VASCULAR COVERED STENT	C.R. BARD, INC	Approval of the COVERA Vascular Covered Stent. The device is indicated for use in hemodialysis patients for the treatment of stenoses in the venous outflow of an arterio-venous fistula and at the venous anastomosis of an ePTFE or other synthetic AV graft.
P180007/S002	03/01/2019	O - Normal 180 Day	SPIRATION VALVE SYSTEM	SPIRATION, INC.	Approval for the post-approval study (PAS) protocol on the extension of EMPROVE pivotal study for the Spiration Valve System

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S159	03/27/2019	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE/ INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Add two new pump testing fixtures.
P790007/S060	03/03/2019	X - 30-Day Notice	HANCOCK VALVED CONDUIT LP	MEDTRONIC HEART VALVES	Use of a new compressed air system during heart valve manufacturing.
P810002/S109	03/25/2019	X - 30-Day Notice	ST. JUDE MEDICAL MASTERS MECHANICAL HEART VALVE, REGENT MECHANICAL HEART VALVE, MASTERS VALVES GRAFT	ST. JUDE MEDICAL, INC.	Modification to the air quality testing method and air microbe action and alert levels.
P810006/S084	03/15/2019	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE AND COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT-MICROFIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Replacement for the tendon slicer at the Collagen Manufacturing Center (CMC) Building.
P830055/S222	03/08/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Modification of the configuration of containers for gamma sterilization.
P830055/S223	03/13/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Changes to manufacturing processes for the subject device, including clarification of operations and improved efficiency of certain manufacturing operations.
P830055/S224	03/07/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Additional sterilization site for devices approved in P830055. The sponsor may sterilize the revision tibial baseplate components at their secondary sterilization site.
P830055/S225	03/13/2019	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Introduction of a new piece of equipment used for laser marking tibial baseplate components (i.e., Attune RP S+ Tray) from the LCS Total Knee System that are manufactured at the DePuy Ireland manufacturing facility.
P830061/S167	03/26/2019	X - 30-Day Notice	ADHESIVE, CAPSURE SENSE LEAD, CAPSURE SP NOVVUS LEAD STYLET KIT AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update for the use of a new process challenge device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S420	03/14/2019	X - 30-Day Notice	ITREL AND INTELLIS SPINAL CORD STIMULATION SYSTEMS	MEDTRONIC NEUROMODULATION	Several manufacturing process changes to the XTC008 surface mount tantalum capacitor manufactured by AVX Tantalum Corporation.
P840001/S421	03/22/2019	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of a Blood/Tissue and Cerebrospinal fluid Contact (BTCC) component endotoxin requirement and assessment/monitoring program.
P840062/S071	03/14/2019	X - 30-Day Notice	COLLACOTE, COLLATAPE, COLLAPLUG ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	INTEGRA LIFESCIENCES CORP.	Replacement for the tendon slicer at the Collagen Manufacturing Center (CMC) Building.
P850010/S084	03/15/2019	X - 30-Day Notice	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENT-FIBRILLAR FORM	INTEGRA LIFESCIENCES CORPORATION	Replacement for the tendon slicer at the Collagen Manufacturing Center (CMC) Building.
P850089/S140	03/26/2019	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD, STYLET KIT AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update for the use of a new process challenge device.
P860004/S326	03/29/2019	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Alternate location for testing peel strength for 8551 Catheter Access Port (CAP) Kits and 8540 refill kit for the Medtronic SynchroMed Infusion System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S187	03/03/2019	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS, THEON PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS, RSR PERICARDIAL AORTIC BIOPROSTHESIS, THEON RSR PERICARDIAL AORTIC BIOPROSTHEIS WITH THERMAFIX TISSUE PROCESS, MAGNA PERICARIDAL AORTIC BIOPROSTHESIS, MAGNA PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX PROCESS, MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX PROCESS, PLUS PERICARDIAL MITRAL BIOPROSTHESIS, THEON PERICARDIAL MITRAL BIOPROSTHESIS WITH THERMAFIX PROCESS AND PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCES, LLC.	Increased manning in Cleanroom #4 at the Changi, Singapore facility.
P870078/S045	03/03/2019	X - 30-Day Notice	HANCOCK VALVED CONDUIT MO	MEDTRONIC, INC.	Use of a new compressed air system during heart valve manufacturing.
P880047/S029	03/11/2019	X - 30-Day Notice	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Process change from manual to automated foiling and cartoning at the Ethicon SARL, Neuchatel Switzerland site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S405	03/26/2019	X - 30-Day Notice	CAPSURE VDD 2 LEAD, SERVICE KIT-PACEMAKER REPAIR KIT AND VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Update for the use of a new process challenge device.
P890023/S036	03/12/2019	X - 30-Day Notice	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Transfer of Biomedics 55 Asphere lens production from Juana Diaz, Puerto Rico to Scottsville, New York.
P890023/S037	03/26/2019	X - 30-Day Notice	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Manufacture of Biomedics Toric lenses in the plus power range at the CooperVision facility in Scottsville, New York.
P900033/S075	03/15/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Change to the Environmental Monitoring (EM) program for the cleanroom areas within the Collagen Manufacturing Center.
P900033/S076	03/15/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Replacement for the tendon slicer at the Collagen Manufacturing Center (CMC) Building.
P900061/S152	03/26/2019	X - 30-Day Notice	ACE HEADER, END CAP, EPICARDIAL PATCH LEAD AND UPSIZING SLEEVE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update for the use of a new process challenge device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S226	03/26/2019	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT, DF-1 CONNECTOR PORT PIN PLUG, IS-1 CONNECTOR PORT PIN PLUG, LEAD ADAPTOR, SPRINT QUATTRO LEAD, HV SPLITTER/ADAPTOR KIT, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD AND TUNNELING TOOL	MEDTRONIC INC.	Update for the use of a new process challenge device.
P920015/S227	03/08/2019	X - 30-Day Notice	SPRINT QUATTRO LEAD	MEDTRONIC INC.	New supplier for a silicone molded component.
P930014/S119	03/14/2019	X - 30-Day Notice	ACRYSOF INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Change an in-process quality control procedure associated with plasma treatments of the AcrySert and UltraSert Pre-loaded IOL Delivery Systems.
P930036/S011	03/08/2019	X - 30-Day Notice	ATELLICA IM ALPHA FETOPROTEIN (AFP) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Adding an additional manufacturing site for the instrument module.
P930038/S091	03/06/2019	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATION	Transfer the bypass tube coating process to the Terumo Caguas, Puerto Rico facility.
P930038/S092	03/21/2019	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATION	Transferring the procurement of, and receiving inspection activities for, certain components and raw materials used to manufacture ANGIO-SEAL VIP and STS Plus devices from Abbott to Terumo Puerto Rico.
P930038/S093	03/29/2019	X - 30-Day Notice	ANGIO SEAL VASCULAR CLOSURE DEVICES	TERUMO MEDICAL CORPORATION	Transfer the Angio-Seal Evolution product line manufacturing from Minnetonka to Caguas, Puerto Rico.
P930039/S196	03/26/2019	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD AND VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Update for the use of a new process challenge device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950005/S071	03/08/2019	X - 30-Day Notice	CELSIUS RMT CATHETER; NAVISTAR RMT THERMOCOOL CATHETER; CELSIUS RMT THERMOCOOL CATHETER; NAVISTAR RMT CATHETER	BIOSENSE WEBSTER, INC	Alternate qualified supplier of magnet components.
P950020/S096	03/19/2019	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Addition of a component manufacturing site.
P950021/S017	03/08/2019	X - 30-Day Notice	ATELLICA IM PROSTATE-SPECIFIC ANTIGEN (PSA) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Adding an additional manufacturing site for the instrument module.
P950024/S084	03/26/2019	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Update for the use of a new process challenge device.
P960009/S338	03/14/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Several manufacturing process changes to the XTC008 surface mount tantalum capacitor manufactured by AVX Tantalum Corporation.
P960009/S340	03/22/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of a Blood/Tissue and Cerebrospinal fluid Contact (BTCC) component endotoxin requirement and assessment/monitoring program.
P960040/S435	03/13/2019	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	BOSTON SCIENTIFIC	Updates to the pulse generator core assembly manufacturing process.
P960058/S136	03/08/2019	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Modification of the software controlling the sterilization chamber at Sterigenics, Salt Lake City, Utah.
P960058/S137	03/08/2019	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	New PCBA supplier for the Naida Sound Processor.
P960058/S138	03/22/2019	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Implementing Systems, Applications & Products (SAP) Software as the Enterprise Resource Planning (ERP) .
P970003/S223	03/12/2019	X - 30-Day Notice	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Removal of a redundant inspection step at receiving inspection for flange warpage from the inner and outer tray used to package VNS Therapy Generators, Leads, accessory Packs and Tunnelers.
P970004/S283	03/22/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Addition of a Blood/Tissue and Cerebrospinal fluid Contact (BTCC) component endotoxin requirement and assessment/monitoring program.
P970031/S065	03/03/2019	X - 30-Day Notice	FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Use of a new compressed air system during heart valve manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970051/S184	03/08/2019	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	New wash solution for cleaning of the electronic assembly after solder operations.
P980016/S699	03/26/2019	X - 30-Day Notice	EVERA: MRI DF-1 ICD, MRI ICD, S DR ICD, S VR ICD, XT DR ICD, XT VR ICD; MIRRO MRI DR ICD, MRI VR ICD; PRIMO MRI DR ICD, MRI VR ICD; PROTECTA ICD, VR ICD, XT ICD; SECURA DR ICD, ICD; VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	New external supplier for the dimer diamine for the Dadet epoxy.
P980016/S700	03/21/2019	X - 30-Day Notice	EVERA MRI DF-1 ICD, EVERA MRI ICD, EVERA S DR ICD, EVERA S VR ICD, EVERA XT DR ICD, EVERA XT VR ICD; MIRRO MRI DR ICD, MIRRO MRI VR ICD; PRIMO MRI DR ICD, PRIMO MRI VR ICD, PROTECTA, ICD, PROTECTA VR ICD, PROTECTA XT ICD; SECURA DR ICD, SECURA ICD; VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).
P980035/S577	03/26/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ADVISA DR IPG, DR MRI IPG, SR MRI IPG; ASTRA S DR MRI IPG, S SR MRI IPG, XT DR MRI IPG, XT SR MRI IPG; ATTESTA DR MRI IPG, SR MRI IPG; AZURE S DR MRI IPG, S SR MRI IPG, XT DR MRI IPG, XT SR MRI IPG; RELIA IPG, SPHERA DR MRI IPG, SR MRI IPG	MEDTRONIC INC.	New external supplier for the dimer diamine for the Dadet epoxy.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S578	03/06/2019	X - 30-Day Notice	ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG; AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG	MEDTRONIC INC.	Tightening the capacitance test limits at an external supplier.
P980035/S579	03/21/2019	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG; ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA XT SR MRI IPG, ATTESTA DR MRI IPG, ATTESTA SR MRI IPG; AZURE S DR MRI IPG; AZURE S SR MRI IPG, AZURE XT DR MRI IPG, AZURE XT SR MRI IPG, RELIA IPG; SPHERA DR MRI IPG; SPHERA SR MRI IPG	MEDTRONIC INC.	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).
P980040/S101	03/14/2019	X - 30-Day Notice	SENSAR AND TECNIS 1-PIECE IOL, TECNIS OPTICBLUE IOL, TECNIS MULTIFOCAL 1-PIECE IOL, TECNIS SYMFONY EXTENDED RANGE OF VISION IOL, TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOL, TECNIS TORIC 1-PIECE IOL, TECNIS ITEC PRELOADED DELIVERY SYSTEM AND SENSAR 3-PIECE MULTIFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Modification of the incoming specification for a raw material used to produce the soft acrylic intraocular lenses produced by Johnson & Johnson Surgical Vision.
P980043/S070	03/03/2019	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Use of a new compressed air system during heart valve manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980049/S134	03/05/2019	X - 30-Day Notice	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR ICDS	MICROPORT CRM USA INC.	Addition of a pre-conditioning step prior to the Electrical Wafer Sorting test.
P980050/S121	03/26/2019	X - 30-Day Notice	TRANSVENE CS/SVS LEAD	MEDTRONIC INC.	Update for the use of a new process challenge device.
P990025/S057	03/08/2019	X - 30-Day Notice	NAVISTAR RMT CATHETER	BIOSENSE WEBSTER, INC.	Alternate qualified supplier of magnet components.
P990055/S018	03/08/2019	X - 30-Day Notice	ATELLICA IM COMPLEXED PSA (CPSA) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Adding an additional manufacturing site for the instrument module.
P990064/S078	03/03/2019	X - 30-Day Notice	MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Use of a new compressed air system during heart valve manufacturing.
P990080/S049	03/14/2019	X - 30-Day Notice	TECNIS 3-PIECE ACRYLIC MONOFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Modification of the incoming specification for a raw material used to produce the soft acrylic intraocular lenses produced by Johnson & Johnson Surgical Vision.
P000015/S035	03/08/2019	X - 30-Day Notice	NUCLEUS AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	New wash solution for cleaning of the electronic assembly after solder operations.
P000039/S065	03/25/2019	X - 30-Day Notice	AMPLATZER SEPTAL OCCLUDER AND AMPLATZER CRIBRIFORM OCCLUDER	ABBOTT MEDICAL	Modification to the air quality testing method and air microbe action and alert levels.
P000053/S102	03/29/2019	X - 30-Day Notice	AMS 800 ARTIFICIAL URINARY SPHINCTER WITH AND WITHOUT INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Addition of two new alternate pressure regulating balloon testers.
P010001/S019	03/06/2019	X - 30-Day Notice	TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Addition of a new grinding machine for the TRANSCEND Hip Articulation System.
P010012/S499	03/13/2019	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR	BOSTON SCIENTIFIC CORP.	Updates to the pulse generator core assembly manufacturing process.
P010013/S073	03/01/2019	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Addition of an automated fixture to cut the suction line and the RF cable assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S392	03/26/2019	X - 30-Day Notice	CONSULTA CRT-P; PERCEPTA BIPOLAR CRT-P; PERCEPTA QUADRIPOLAR CRT-P; SERENA BIPOLAR CRT-P; SERENA QUADRIPOLAR CRT-P; SOLARA BIPOLAR CRT-P; SOLARA QUADRIPOLAR CRT-P; SYNCRA CRT-P; VIVA CRT-P	MEDTRONIC INC.	New external supplier for the dimer diamine for the Dadet epoxy.
P010015/S393	03/06/2019	X - 30-Day Notice	PERCEPTA BIPOLAR CRT-P; PERCEPTA QUADRIPOLAR CRT-P; SERENA BIPOLAR CRT-P; SERENA QUADRIPOLAR CRT-P; SOLARA BIPOLAR CRT-P; SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Tightening the capacitance test limits at an external supplier.
P010015/S394	03/26/2019	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD AND ATTAIN OTW LV LEAD	MEDTRONIC INC.	Update for the use of a new process challenge device.
P010015/S395	03/21/2019	X - 30-Day Notice	CONSULTA CRT-P; PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P; SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P; SOLARA BIPOLAR CRT-P, SOLARA QUADRIPOLAR CRT-P; SYNCRA CRT-P; VIVA CRT-P	MEDTRONIC INC.	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).
P010019/S071	03/22/2019	X - 30-Day Notice	(LOTRAFILCON A) SOFT CONTACT LENSES FOR DAILY AND EXTENDED WEAR	ALCON LABORATORIES, INC.	Qualification of additional plasma coating equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S114	03/13/2019	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	New solder paste printer and solder paste inspection system on the Surface Mount Line used during the PCA manufacturing process.
P010030/S115	03/01/2019	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Additional supplier for the electrode belt therapy electrode punched lidding layer.
P010030/S116	03/27/2019	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	New solder paste printer, solder paste inspection system, and glue dispenser equipment on the Surface Mount Line used during the PCA manufacturing process.
P010031/S659	03/26/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, MRI QUAD CRT-D; BRAVA CRT-D, QUAD CRT-D; CLARIA MRI CRT-D, MRI QUAD CRT-D; COMPIA MRI CRT-D, MRI QUAD CRT-D; CONSULTA CRT-D; PROTECTA CRT-D, XT CRT-D; VIVA QUAD S CRT-D, XT CRT-D, VIVA S CRT-D, XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	New external supplier for the dimer diamine for the Dadet epoxy.
P010031/S660	03/21/2019	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA QUAD CRT-D; BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D; CONSULTA CRT-D; PROTECTA CRT-D, PROTECTA XT CRT-D; VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the biocontamination sample monitoring for devices that are processed outside the Controlled Environment Area (CEA).

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P010033/S043	03/15/2019	X - 30-Day Notice	TB GOLD AND QUANTIFERON - TB GOLD PLUS	QIAGEN	Modification of in process manufacturing processes and lyophilization of a critical component.
P020004/S163	03/18/2019	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Implement the use of new cleanrooms.
P020011/S012	03/21/2019	X - 30-Day Notice	APTIMA HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Transfer Quality Control testing services for components and raw materials to a separate contractor facility.
P020024/S056	03/25/2019	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER, AMPLATZER DUCT OCCLUDER II AND AMPLATZER PICCOLO OCCLUDER	ABBOTT MEDICAL	Modification to the air quality testing method and air microbe action and alert levels.
P030017/S322	03/11/2019	X - 30-Day Notice	PRECISION SPECTRA SPINAL CORD STIMULATORY (SCS) SYTEM; SPECTRA WAVEWRITER SPINAL CORD STIMULATOR (SCS) SYSTEM; PRECISION NOVI SPINAL CORD STIMULATOR SYSTEM (SCS); PRECISION MONTAGE AND PRECISION MONTAGE MRI SPINAL CORD STIMULATOR SYSTEMS (SCS)	BOSTON SCIENTIFIC CORP.	Addition of an automated tool used in the manufacturing of a subassembly component inside the header of implantable pulse generators (IPGs).
P030023/S007	03/27/2019	X - 30-Day Notice	CAPSULAR TENSION RING (CTR)	OPHTEC USA, INC.	Ethylene oxide sterilization cycle improvements for 1 full sterilization cycle for the Artisan Myopia Intraocular Lenses sterilized at AT Sterigenics in Belgium.
P030031/S096	03/08/2019	X - 30-Day Notice	NAVISTAR RMT THERMOCOOL CATHETER; CELSIUS THERMOCOOL CATHETER; CELSIUS RMT THERMOCOOL CATHETER	BIOSENSE WEBSTER, INC.	Alternate qualified supplier of magnet components.
P030036/S108	03/26/2019	X - 30-Day Notice	ANCHORING SLEEVE KIT AND SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update for the use of a new process challenge device.

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P030040/S015	03/08/2019	X - 30-Day Notice	ATELLICA IM HEPATITIS B ORFE IGM (AHBCM) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Adding an additional manufacturing site for the instrument module.
P030044/S007	03/13/2019	X - 30-Day Notice	EGFR PHARMDX	DAKO NORTH AMERICA, INC.	Addition of a distribution site.
P030056/S014	03/08/2019	X - 30-Day Notice	ATELLICA IM HEPATITIS C (AHCV) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Adding an additional manufacturing site for the instrument module.
P040004/S015	03/08/2019	X - 30-Day Notice	ATELLICA IM ANTI-HEPATITIS B CORE TOTAL (HBCT) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Adding an additional manufacturing site for the instrument module.
P040021/S039	03/04/2019	X - 30-Day Notice	BIOCOR/EPIC VALVES	ST. JUDE MEDICAL, INC.	Expansion of a controlled access environment room for the manufacture of tissue heart valves and the installation of two new biological safety cabinets at the Abbott Belo Horizonte, Brazil manufacturing site.
P040021/S040	03/25/2019	X - 30-Day Notice	BIOCOR AND EPIC VALVES	ST. JUDE MEDICAL, INC.	Modification to the air quality testing method and air microbe action and alert levels.
P040024/S107	03/07/2019	X - 30-Day Notice	RESTYLANE INJECTABLE GELS	Q-MED AB	Replacement of a wall panel with an emergency exit door.
P040027/S070	03/21/2019	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS AND GORE VIATORR TIPS ENDOPROSTHESIS WITH CONTROLLED EXPANSION	W. L. GORE & ASSOCIATES, INC.	Relocate the manufacturing equipment for a delivery system component.
P040027/S071	03/18/2019	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implement the use of new cleanrooms.
P040036/S066	03/08/2019	X - 30-Day Notice	NAVISTAR RMT THERMOCOOL CATHETER	BIOSENSE WEBSTER, INC.	Alternate qualified supplier of magnet components.
P040037/S127	03/06/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES, INC	Update raw material specifications and non-compendial test methods.
P040037/S128	03/21/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Relocate the manufacturing equipment for a delivery system component.

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P040037/S129	03/18/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES, INC	Implement the use of new cleanrooms.
P040038/S035	03/14/2019	X - 30-Day Notice	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Modification to the ethylene oxide sterilization dunnage configuration layers and pallet dimensions.
P040040/S036	03/25/2019	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Modification to the air quality testing method and air microbe action and alert levels.
P040043/S109	03/18/2019	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implement the use of new cleanrooms.
P040044/S083	03/14/2019	X - 30-Day Notice	MYNXGRIP, MYNX ACE AND MYNX CONTROL VASCULAR CLOSURE DEVICE (VCD)	ACCESS CLOSURE, INC.	Implement an automated rolling process for the hydrogel component.
P050006/S073	03/25/2019	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCULUDER	W.L. GORE & ASSOCIATES, INC	Installation of alternative equipment for powder coating.
P050006/S074	03/18/2019	X - 30-Day Notice	GORE CARDIOFORM SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES, INC	Implement the use of new cleanrooms.
P050017/S017	03/21/2019	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK INCORPORATED	Modification for an incoming raw material specification.
P060011/S016	03/28/2019	X - 30-Day Notice	C-FLEX INTRAOCULAR LENS, C-FLEX ASPHERIC INTRAOCULAR LENS, 6.0MM ASPHERIC INTRAOCULAR LENS ADN RAYONE ASPHERIC	RAYNER INTRAOCULAR LENSES LTD.	Additional alternate testing laboratory for endotoxin and bioburden testing for the Rayner intraocular lenses.
P060027/S099	03/05/2019	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR	MICROPORT CRM USA INC.	Addition of a pre-conditioning step prior to the Electrical Wafer Sorting test.
P060039/S093	03/26/2019	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Update for the use of a new process challenge device.

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P080006/S131	03/26/2019	X - 30-Day Notice	ATTAIN ABILITY LEAD AND ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Update for the use of a new process challenge device.
P080010/S018	03/14/2019	X - 30-Day Notice	TECNIS 3-PIECE MULTIFOCAL	JOHNSON & JOHNSON SURGICAL VISION, INC.	Modification of the incoming specification for a raw material used to produce the soft acrylic intraocular lenses produced by Johnson & Johnson Surgical Vision.
P080012/S055	03/07/2019	X - 30-Day Notice	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Adding a laser welding operation at the pump contract manufacturer for the Prometra Programmable Infusion Pump System.
P080020/S032	03/13/2019	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Sharing of the current facility and equipment used to manufacture Gel-One for the purpose of manufacturing another product in development.
P080020/S033	03/13/2019	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Change to a solvent and processing aid used in the manufacture of Gel-One.
P080025/S178	03/22/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Addition of a Blood/Tissue and Cerebrospinal fluid Contact (BTCC) component endotoxin requirement and assessment/monitoring program.
P090013/S296	03/26/2019	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Update for the use of a new process challenge device.
P090024/S006	03/08/2019	X - 30-Day Notice	ATELLICA IM HEPATITIS B E ANTIGEN (HBEAG) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Adding an additional manufacturing site for the instrument module.
P100010/S088	03/05/2019	X - 30-Day Notice	ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER	MEDTRONIC CRYOCATH LP	Addition of a manufacturing line (duplicating existing manufacturing line A7 using an identical manufacturing process) at your firm¿s Montreal Manufacturing Facility (MMO).
P100013/S018	03/26/2019	X - 30-Day Notice	EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS CORPORATION	Relocate the manufacturing facility for the bioabsorbable component.
P100020/S043	03/11/2019	X - 30-Day Notice	COBAS 4800 HPV MASTER MIX	ROCHE MOLECULAR SYSTEMS, INC.	Change the manufacturing and filling process for a critical component.
P100029/S038	03/04/2019	X - 30-Day Notice	TRIFECTA/TRIFECTA GT VALVES	ST. JUDE MEDICAL, INC.	Expansion of a controlled access environment room for the manufacture of tissue heart valves and the installation of two new biological safety cabinets at the Abbott Belo Horizonte, Brazil manufacturing site.
P100029/S039	03/25/2019	X - 30-Day Notice	TRIFECTA AND TRIFECTA GT SURGICAL HEART VALVE	ST. JUDE MEDICAL, INC.	Modification to the air quality testing method and air microbe action and alert levels.

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P100033/S010	03/15/2019	X - 30-Day Notice	PROGENSA PCA3 ASSAY	GEN-PROBE INCORPORATED	Transfer of quality control (QC) testing from one facility to another.
P100039/S007	03/08/2019	X - 30-Day Notice	ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2) ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Adding an additional manufacturing site for the instrument module.
P100042/S021	03/21/2019	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Transfer Quality Control testing services for components and raw materials to a separate contractor facility.
P100045/S037	03/07/2019	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	New heat sealer for sealing device pouches.
P100045/S038	03/20/2019	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Change to the supplier of the power supply component.
P100045/S039	03/26/2019	X - 30-Day Notice	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Change the air sampling method of the Controlled Access Environment located at the Atlanta facility.
P100047/S136	03/26/2019	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Add additional battery testers for in-process inspection.
P100047/S137	03/26/2019	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST DEVICE SYSTEM	MEDTRONIC	Change in delivery system that is used to dispense epoxy for HVAD assemblies.
P110023/S025	03/21/2019	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEM	MEDTRONIC VASCULAR INC	Alternate piece of manufacturing equipment to perform the delivery system tip shaping process.
P110041/S007	03/08/2019	X - 30-Day Notice	ATELLICA IM HEPATITIS B SURFACE ANTIGEN II (HBSII(AND ATELLICA IM HEPATITIS B SURFACE ANTIGEN 1 1 COMFIRMATORY *HBS11 CONF)	SIEMENS CORP.	Adding an additional manufacturing site for the instrument module.
P110042/S122	03/27/2019	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD) PLUS GENERATOR (PG) DEVICES	BOSTON SCIENTIFIC CORPORATION	Alternate 4A Fuse Surface Mount component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120010/S128	03/13/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Additional injection molding equipment at a contract manufacturer in order to increase production capacity for the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P120010/S129	03/11/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Additional equipment for the production of Tyvek lid and thermoformed tray used for the packaging of Guardian (3) and Enlite sensors. The Guardian Sensor (3) is a component of of the Medtronic MiniMed 670G, MiniMed 630G with SmartGuard and Guardian Connect Systems and the Enlite Sensor is a component of the Medtronic MiniMed 530G, MiniMed 630G with SmartGuard, iPro2 and Paradigm REAL-Time Revel Systems.
P120017/S017	03/26/2019	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Update for the use of a new process challenge device.
P120020/S022	03/14/2019	X - 30-Day Notice	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGI ES INC)	Modification to the ethylene oxide sterilization dunnage configuration layers and pallet dimensions.
P120021/S011	03/25/2019	X - 30-Day Notice	AMPLATZER PATENT FORAMEN OVALE OCCLUDER	ABBOTT MEDICAL	Modification to the air quality testing method and air microbe action and alert levels.
P130006/S066	03/06/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATESI INC	Update raw material specifications and non-compendial test methods.
P130006/S067	03/21/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES, INC	Relocate the manufacturing equipment for a delivery system component.
P130006/S068	03/18/2019	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES, INC	Implement the use of new cleanrooms.
P130008/S040	03/06/2019	X - 30-Day Notice	INSPIRE UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Move manufacturing activities for the Model 2740 Physician Programmer to Nortech Systems.

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P130009/S096	03/03/2019	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Increased manning in Cleanroom #4 at the Changi, Singapore facility.
P130009/S097	03/19/2019	X - 30-Day Notice	EDWARDS SAPIEN 3 (XT) TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCES, LLC.	Modifications to the bioburden monitoring plan for the Edwards SAPIEN 3 and SAPIEN XT THVs manufactured at the Singapore facility.
P130011/S007	03/20/2019	X - 30-Day Notice	SOLO SMART HEART VALVE	LIVANOVA CANADA CORP.	Modifications to the manufacturing process for primary packaging.
P130013/S027	03/12/2019	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE DEVICE AND DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate ethylene oxide sterilization chamber using an updated cycle as well as to use this updated cycle in the chamber already in use.
P130016/S037	03/08/2019	X - 30-Day Notice	NUCLEUS HYBRID IMPLANT SYSTEM	COCHLEAR AMERICAS	New wash solution for cleaning of the electronic assembly after solder operations.
P130017/S026	03/11/2019	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Scale-up of components in the Cologuard sDNA based colorectal cancer screening test.
P130017/S028	03/19/2019	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Fill-volume reduction of a reagent.
P130026/S040	03/14/2019	X - 30-Day Notice	TACTICATH QUARTZ CONTRACT FORCE ABLATION CATHETER	ST. JUDE MEDICAL	Addition of a manufacturing aide for the distal tip adhesive application process of the TactiCath Quartz Contact Force Ablation Catheter.
P140003/S046	03/03/2019	X - 30-Day Notice	IMPELLA CP WITH SMARTASSIST	ABIOMED, INC.	Addition of a second supplier for two subcomponents used in the Impella CP with SmartAssist.
P140003/S048	03/20/2019	X - 30-Day Notice	IMPELLA 2.5	ABIOMED, INC.	Alternative manufacturing method for the Impella 2.5 cannula.
P140009/S045	03/13/2019	X - 30-Day Notice	MULTILEAD TRIAL CABLE (MLTC)	ABBOTT MEDICAL	Updates to the Deep Brain Stimulation (DBS) Multilead Trial Cable (MLTC) printed circuit board (PCB) manufacturing process.
P140015/S028	03/01/2019	X - 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH DEXCOM G5 MOBILE CGM SYSTEM	TANDEM DIABETES CARE, INC.	Introduce alternate suppliers for PCB and PCBA parts for the t:slim X2 Insulin Pump. The t:slim X2 Insulin Pump is a component of the Dexcom G5 Mobile CGM System.
P140028/S037	03/04/2019	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modification to the resin changeover cleaning process.

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P140028/S038	03/04/2019	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change a mold used to manufacture the delivery system.
P140029/S016	03/15/2019	X - 30-Day Notice	RESTYLANE REFYNE AND RESTYLANE DEFYNE	Q-MED AB	Change to the frequency for performing the In-Process Control of the syringe fill weights for Restylane Refyne and Restylane Defyne.
P140031/S080	03/03/2019	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE AND SAPIEN 3 ULTRA TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Increased manning in Cleanroom #4 at the Changi, Singapore facility.
P140031/S082	03/19/2019	X - 30-Day Notice	EDWARDS SAPIEN 3, SAPIEN 3 ULTRA TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCES, LLC.	Implementation of an automated measurement system for thread count inspections.
P140031/S083	03/19/2019	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVES	EDWARDS LIFESCIENCES, LLC.	Modifications to the bioburden monitoring plan for the Edwards SAPIEN 3 and SAPIEN XT THVs manufactured at the Singapore facility.
P140032/S027	03/20/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Minor manufacturing changes at the needle vendor for the 8540PAH catheter patency kit and 201106 refill kit for the Medtronic Implantable System for Remodulin.
P140032/S028	03/29/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN (ISR)	MEDTRONIC, INC.	Alternate location for testing peel strength for 201106 Catheter Access Port (CAP) Kits and refill kit for the Medtronic Implantable System for Remodulin.
P140032/S029	03/26/2019	X - 30-Day Notice	DRUG DELIVERY CATHETER	MEDTRONIC, INC.	Update for the use of a new process challenge device.
P150001/S059	03/13/2019	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Additional injection molding equipment at a contract manufacturer in order to increase production capacity for the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150001/S061	03/11/2019	X - 30-Day Notice	MINIMED 630G SYSTEM	MEDTRONIC MINIMED	Additional equipment for the production of Tyvek lid and thermoformed tray used for the packaging of Guardian (3) and Enlite sensors. The Guardian Sensor (3) is a component of of the Medtronic MiniMed 670G, MiniMed 630G with SmartGuard and Guardian Connect Systems and the Enlite Sensor is a component of the Medtronic MiniMed 530G, MiniMed 630G with SmartGuard, iPro2 and Paradigm REAL-Time Revel Systems.
P150001/S062	03/21/2019	X - 30-Day Notice	GUARDIAN LINK (3) TRANSMITTER (MINIMED 630G SYSTEM WITH SMARTGUARD)	MEDTRONIC MINIMED	New manufacturing site for the transmitter components of the Guardian Connect System, the MiniMed 630G System, and the MiniMed 670G System.

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P150011/S016	03/20/2019	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE AND PERCEVAL PLUS SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Modifications to the manufacturing process for primary packaging.
P150012/S072	03/14/2019	X - 30-Day Notice	INGEVITY DISTAL TIP LASER WELD PROCESS	BOSTONSCIENTIFIC	Modifications of the distal tip laser weld, laser weld fixtures, processes, and software used for the helix to coupler weld.
P150013/S015	03/13/2019	X - 30-Day Notice	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Addition of a distribution site.
P150019/S053	03/13/2019	X - 30-Day Notice	REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Additional injection molding equipment at a contract manufacturer in order to increase production capacity for the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150019/S054	03/11/2019	X - 30-Day Notice	PARADIGM REAL-TIME RVEL SYSTEM	MEDTRONIC MINIMED	Additional equipment for the production of Tyvek lid and thermoformed tray used for the packaging of Guardian (3) and Enlite sensors. The Guardian Sensor (3) is a component of of the Medtronic MiniMed 670G, MiniMed 630G with SmartGuard and Guardian Connect Systems and the Enlite Sensor is a component of the Medtronic MiniMed 530G, MiniMed 630G with SmartGuard, iPro2 and Paradigm REAL-Time Revel Systems.
P150021/S040	03/04/2019	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Additional manufacturing and assembly line for a component of the FreeStyle Libre sensor pack. The sensor pack is a component of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P150025/S011	03/13/2019	X - 30-Day Notice	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Addition of a distribution site.
P150029/S026	03/13/2019	X - 30-Day Notice	IPRO2 SYSTEM	MEDTRONIC MINIMED	Additional injection molding equipment at a contract manufacturer in order to increase production capacity for the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150029/S027	03/11/2019	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Additional equipment for the production of Tyvek lid and thermoformed tray used for the packaging of Guardian (3) and Enlite sensors. The Guardian Sensor (3) is a component of of the Medtronic MiniMed 670G, MiniMed 630G with SmartGuard and Guardian Connect Systems and the Enlite Sensor is a component of the Medtronic MiniMed 530G, MiniMed 630G with SmartGuard, iPro2 and Paradigm REAL-Time Revel Systems.
P150031/S012	03/07/2019	X - 30-Day Notice	VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Add an alternate supplier for the raw material (Grade-23 ELI Titanium) that is used by Heraeus Medical when manufacturing the Case Half and Back-up Band for the Vercise Gevia implantable pulse generator that is manufactured by Boston Scientific Neuromodulation in Clonmel.

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P150031/S013	03/13/2019	X - 30-Day Notice	VERCISE PC DEEP AND VERCISE GEVIARN DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Automated tool used in the manufacturing of the Stack Assembly, a subassembly component inside the header of Implantable Pulse Generators (IPGs) of the Vercise PC and Vercise Gevia DBS systems.
P150031/S014	03/14/2019	X - 30-Day Notice	VERCISE PC AND VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Removing the weekly Printed Circuit Board Assembly (PCBA) Ionic Contamination (IC) Testing for the Implantable Pulse Generators (IPGs) used in the following Systems: Vercise PC and Vercise Gevia Deep Brain Stimulation (DBS) Systems.
P150031/S015	03/19/2019	X - 30-Day Notice	VERCISE, VERCISE PC AND VERCISE GEVIA DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Adding an alternate qualified supplier (Heraeus) for the cables used in the Deep Brain Stimulation (DBS) Leads, which include the standard DBS Leads and the Vercise Cartesia DBS Directional Leads.
P150033/S049	03/06/2019	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Tightening the capacitance test limits at an external supplier.
P150036/S037	03/03/2019	X - 30-Day Notice	EDWARDS INTUITY ELITE VALVE SYSTEM	EDWARDS LIFESCIENCES, LLC.	Increased manning in Cleanroom #4 at the Changi, Singapore facility.
P150048/S031	03/03/2019	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Increased manning in Cleanroom #4 at the Changi, Singapore facility.
P160001/S032	03/01/2019	X - 30-Day Notice	OBALON BALLOON SYSTEM WITH NAVIGATION AND TOUCH	OBALON THERAPEUTICS, INC.	Implementation of a cybersecurity update for a manufacturing process.
P160004/S025	03/06/2019	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Update raw material specifications and non-compendial test methods.
P160004/S026	03/18/2019	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Implement the use of new cleanrooms.
P160007/S013	03/13/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Additional injection molding equipment at a contract manufacturer in order to increase production capacity for the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P160007/S015	03/11/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Additional equipment for the production of Tyvek lid and thermoformed tray used for the packaging of Guardian (3) and Enlite sensors. The Guardian Sensor (3) is a component of of the Medtronic MiniMed 670G, MiniMed 630G with SmartGuard and Guardian Connect Systems and the Enlite Sensor is a component of the Medtronic MiniMed 530G, MiniMed 630G with SmartGuard, iPro2 and Paradigm REAL-Time Revel Systems.

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P160007/S016	03/21/2019	X - 30-Day Notice	GUARDIAN CONNECT TRANSMITTER	MEDTRONIC MINIMED	New manufacturing site for the transmitter components of the Guardian Connect System, the MiniMed 630G System, and the MiniMed 670G System.
P160008/S005	03/04/2019	X - 30-Day Notice	SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS AND ACCESSORIES	HEARTSINE TECHNOLOGIES LLC	Use of an additional pick and place machine at a PCBA supplier.
P160014/S008	03/21/2019	X - 30-Day Notice	COBRA PZF NANOCOATED CORONARY STENT SYSTEM	CELONOVA BIOSCIENCES, INC.	Change to an in-process inspection.
P160017/S055	03/13/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Additional injection molding equipment at a contract manufacturer in order to increase production capacity for the Guardian Sensor (3) and Enlite Sensor. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P160017/S057	03/11/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Additional equipment for the production of Tyvek lid and thermoformed tray used for the packaging of Guardian (3) and Enlite sensors. The Guardian Sensor (3) is a component of of the Medtronic MiniMed 670G, MiniMed 630G with SmartGuard and Guardian Connect Systems and the Enlite Sensor is a component of the Medtronic MiniMed 530G, MiniMed 630G with SmartGuard, iPro2 and Paradigm REAL-Time Revel Systems.
P160017/S058	03/21/2019	X - 30-Day Notice	GUARDIAN LINK (3) TRANSMITTER (MINIMED 670G SYSTEM)	MEDTRONIC MINIMED, INC.	New manufacturing site for the transmitter components of the Guardian Connect System, the MiniMed 630G System, and the MiniMed 670G System.
P160021/S017	03/06/2019	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Update raw material specifications and non-compendial test methods.
P160021/S018	03/18/2019	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS MANUFACTURING EXPANSION	W. L. GORE & ASSOCIATES, INC.	Expand the manufacturing operations for a cleanroom.
P160021/S019	03/18/2019	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implement the use of new cleanrooms.
P160022/S009	03/21/2019	X - 30-Day Notice	X SERIES/PROPAQ MD	ZOLL MEDICAL CORPORATION	Automation of the power supply measurement test for the system board.
P160023/S010	03/21/2019	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Transfer Quality Control testing services for components and raw materials to a separate contractor facility.

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P160030/S032	03/04/2019	X - 30-Day Notice	FREESTYLE LIBRE 14DAY FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Additional manufacturing and assembly line for a component of the FreeStyle Libre sensor pack. The sensor pack is a component of the FreeStyle Libre and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P160038/S009	03/05/2019	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Remove redundant testing and to update a manufacturing process for a saturated solution.
P160038/S010	03/25/2019	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Update an enzymes purification processing steps.
P160043/S022	03/07/2019	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Automate the coordination of in-process stents at the drying work step.
P160045/S014	03/05/2019	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Manufacturing Site Change for certain steps of the panel manufacturing process
P170002/S002	03/22/2019	X - 30-Day Notice	RHA 2, RHA 3, AND RHA 4 DERMAL FILLERS	TEOXANE S.A.	Automation of the degassing process.
P170006/S010	03/03/2019	X - 30-Day Notice	AVALUS BIOPROSTHESIS	MEDTRONIC INC.	Use of a new compressed air system during heart valve manufacturing.
P170007/S002	03/13/2019	X - 30-Day Notice	DUROLANE	BIOVENTUS LLC	Modification to a cleanroom utilized in the manufacture of DUROLANE.
P170012/S015	03/13/2019	X - 30-Day Notice	HEMOBLAST BELLOWS	BIOM'UP SA	Changes to the Porcine Collagen Powder (POW04) production process in order to increase the manufacturing capacity of the component. Changes include duplicating existing equipment and optimizing the production process in order to decrease the overall time needed to manufacture a batch of POW04.
P170025/S008	03/08/2019	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Implementation of additional in-process testing and associated specifications for lyophilized kit reagents.
P170025/S009	03/21/2019	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Transfer Quality Control testing services for components and raw materials to a separate contractor facility.
P180010/S003	03/06/2019	X - 30-Day Notice	GORE CAROTID STENT	W. L GORE & ASSOCIATES, INC	Update raw material specifications and non-compendial test methods.
P180010/S004	03/18/2019	X - 30-Day Notice	GORE CAROTID STENT	W. L GORE & ASSOCIATES, INC	Implement the use of new cleanrooms.
P180011/S005	03/18/2019	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of an alternate nitinol tubing supplier.

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