PMA Monthly approvals from 10/1/2018 to 10/31/2018

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180003	10/04/2018	PMAO - PMA Origi	BIOMIMICS 3D VASCULAR STENT SYSTEM	VERYAN MEDICAL LTD.	Approval for the BioMimics 3D Vascular Stent System. The device is indicated to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery and/or proximal popliteal arteries, with reference vessel diameters ranging from 4.0 - 6.0 mm and lesion lengths up to 140 mm.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S146	10/25/2018	Y - 135 Review Tra	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP) (WITH AND WITHOUT INHIBIZONE)	BOSTON SCIENTIFIC CORP.	Approval for use of a new PTFE-based coated reservoir mandrel with removal of soap dip step for manufacture of the reservoir.
P780007/S061	10/02/2018	Y - 135 Review Tra	POLYMACON SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION, INC.	Approval for the introduction and validation of a new laboratory sterilizer at CooperVision Caribbean Corporation manufacturing facility in Juana Diaz, Puerto Rico.
P830055/S209	10/22/2018	S - Special CBE	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for the addition of an independent inspection for visual and surface finish defects in the machining process.
P890003/S394	10/01/2018	R - Real-Time Proc	CARELINK NETWORK DDMA MODEL 2491	MEDTRONIC, INC.	Approval for Micra Programmer Application Software, Model SW022 version 8.1 for use on the 2090 CareLink Programmer and the 29901 Encore Programmer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S395	10/18/2018	R - Real-Time Proc	PULSE GENERATOR, PERMANENT IMPLANTABLE (DEVICE READER/INTERROGATOR)	MEDTRONIC, INC.	Approval for updates to the remote monitoring systems for Attesta and Sphera MRI SureScan IPG devices.
P890003/S398	10/05/2018	R - Real-Time Proc	MEDTRONIC CARELINK, CARELINK ENCORE	MEDTRONIC, INC.	Approval to implement a firewall-based restriction to block public access from the programmer to the software distribution network.
P890023/S031	10/02/2018	Y - 135 Review Tra	OCUFILCON D SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	THE COOPER COMPANIES	Approval for the introduction and validation of a new laboratory sterilizer at CooperVision Caribbean Corporation manufacturing facility in Juana Diaz, Puerto Rico.
P930036/S009	10/25/2018	R - Real-Time Proc	ATELLICA IM ALPHA FETOPROTEIN (AFP)	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for the placement of the PMA approved Siemens Atellica® IM Immunology assays on the Atellica Solution.
P950021/S016	10/25/2018	R - Real-Time Proc	ATELLICA IM PROSTATE-SPECIFIC ANTIGEN (PSA)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the placement of the PMA approved Siemens Atellica® IM Immunology assays on the Atellica Solution.
P950037/S195	10/22/2018	R - Real-Time Proc	PSW 1802.U, ACTROS, AXOS, BA03, CYLOS, DROMOS, KAIROS, PHILOS, PHILOS II, PROTOS, EVIA, ENTOVIS, ECURO, EFFECTA, ESTELLA, ENTOVIS, ETRINSA 8 AND 6, EPYRA 8 AND 6, ELUNA 8, EDORA 8, ENITRA 6 AND 8, ENTICOS 4 AND 8, AND EVITY 6 AND 8	BIOTRONIK, INC.	Approval for an updated version of Renamic and ICS 3000 programmer software, PSW 1802.U.
P960009/S318	10/12/2018	O - Normal 180 Day	MEDTRONIC DBS THERAPY FOR EPILEPSY	MEDTRONIC INC.	Approval for the Medtronic DBS Therapy for expanding the indications to include Epilepsy. Bilateral stimulation of the anterior nucleus of the thalamus (ANT) using the Medtronic DBS System for epilepsy is indicated as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial - onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications. The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness in patients who averaged six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.
P960043/S101	10/18/2018	R - Real-Time Proc	PERCLOSE PROGLIDE SUTURE-MEDIATED CLOSURE SYSTEM	ABBOTT VASCULAR INC.	Approval for changes to the design and materials of the device packaging.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S681	10/03/2018	O - Normal 180 Day	EVERA MRI DF-1 ICD, EVERA MRI ICD, MIRRO MRI DR ICD, MIRRO MRI VR ICD, PRIMO MRI DR ICVD, PRIMO MRI VR ID, VISIA AF MRI DF1 ICD, AND VISIA AF MRI VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling updates to the clinical study summary for the post approval study.
P980016/S685	10/18/2018	R - Real-Time Proc	EVERA MRI, EVERA, MARQUIS, SECURA, MAXIMO II, INTRINSIC, PROTECTA, PROTECTA XT, VIRTUOSO II, VISIA AF, PRIMO DR AND VR MRI, MIRRO VR MRI	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updates to the remote monitoring systems for Attesta and Sphera MRI SureScan IPG devices.
P980035/S558	10/03/2018	O - Normal 180 Day	ADVISA DR MRI IPG, ADVISA SR MRI IPG, ASTRA XT DR MRI IPG, ASTRA S DR MRI IPG, ASTRA S SR MRI IPG, ASTRA XT SR MRI IPG, AZURE S DR MRI IPG, AZURE S SR MRI IPG, AZURE XT DR MRI IPG AND AZURE XT SR MRI IPG	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post approval study.
P980035/S561	10/18/2018	R - Real-Time Proc	ATTESTA MRI, SPHERA MRI, ADAPTA, VERSA, SENSIA, ADVISA, ADVISA MRI, ENPULSE AND KAPPA	MEDTRONIC INC.	Approval for updates to the remote monitoring systems for Attesta and Sphera MRI SureScan IPG devices.
P990055/S017	10/25/2018	R - Real-Time Proc	ATELLICA IM COMPLEXED PSA (CPSA)	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the placement of the PMA approved Siemens Atellica® IM Immunology assays on the Atellica Solution.
P000009/S077	10/22/2018	R - Real-Time Proc	BELOS, LEXOS, LUMOS, AND XELOS	BIOTRONIK, INC.	Approval for an updated version of Renamic and ICS 3000 programmer software, PSW 1802.U..
P000037/S052	10/18/2018	S - Special CBE	ON-X PROSTHETIC HEART VALVE, MODEL ONXA	ON-X LIFE TECHNOLOGIES, INC.	Approval for the addition of an inspection to verify suture orientation marks.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S376	10/03/2018	O - Normal 180 Day	PERCEPTA BIPOLAR CRT-P, PERCEPTA QUADRIPOLAR CRT-P, SERENA BIPOLAR CRT-P, SERENA QUADRIPOLAR CRT-P, SOLARA BIPOLAR CRT-P, AND SOLARA QUADRIPOLAR CRT-P	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post approval study.
P010015/S378	10/18/2018	R - Real-Time Proc	CONSULTA CRT-P, SYNCRA CRT-P AND VIVA CRT-P	MEDTRONIC INC.	Approval for updates to the remote monitoring systems for Attesta and Sphera MRI SureScan IPG devices.
P010031/S640	10/03/2018	O - Normal 180 Day	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D AND COMPIA MRI QUAD CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for labeling updates to the clinical study summary for the post approval study.
P010031/S644	10/18/2018	R - Real-Time Proc	VIVA, BRAVA, PROTECTA, PROTECTA XT, CONCERTO, CONCERTO II, CONSULTA, MAXIMO II, INSYNC II PROTECT, AMPLIA, COMPIA AND CLARIA	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updates to the remote monitoring systems for Attesta and Sphera MRI SureScan IPG devices.
P010033/S041	10/30/2018	R - Real-Time Proc	QUANTIFERON-TB GOLD TEST / QUANTIFERON TB GOLD PLUS TEST	QIAGEN	Approval for change in critical raw material of kit component.
P010047/S054	10/17/2018	Y - 135 Review Tra	PROGEL PLEURAL AIR LEAK SEALANT (PALS)	NEOMEND, INC.	Approval for packaging modification of the subject device. The changes being made include 1) modification of the materials and process for packaging Progel PALS for shipment in order to maintain its labeled environmental condition of two to eight (2-8) degrees Celsius, 2) release a manufacturing procedure regarding how the contract manufacturer AMP is required to package and ship HSA-filled and PEG-filled cartridges to Neomend, 3) replacement of a custom-made spray tip gauge with a spray tip reference aid to confirm set up of the Uson Sprint LC multi-leak air tester, and 4) modification of the Freeze Watch indicator."
P020018/S055	10/10/2018	R - Real-Time Proc	ZENITH FLEX AAA ENDOVASCULAR GRAFT	COOK, INC.	Approval for a change the hydrophilic coating of the introducer sheath.
P030054/S359	10/09/2018	O - Normal 180 Day	QUICKFLEX U 1258T LV LEAD	ST. JUDE MEDICAL	Approval for labeling updates to the clinical study summary for the post approval study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040020/S068	10/11/2018	O - Normal 180 Day	ACRYSOF IQ RESTOR APODIZED + 3.0D MULTIFOCAL TORIC INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Approval of the protocol for the post-approval protocol for the post-approval study (PAS) protocol.
P050023/S124	10/22/2018	R - Real-Time Proc	IFORIA 5/7, ILESTO 57/, INVENTRA 7, IPERIA 5/7, ITREVIA 5/7, ILIVIA 5/7, INTICA 5/7, INLEXA 5/7, LUMAX 300/340 AND 500/540, 600/640, 700/740, 640/740, AND KRONOS LV-T	BIOTRONIK, INC.	Approval for an updated version of Renamic and ICS 3000 programmer software, PSW 1802.U.
P050027/S013	10/23/2018	R - Real-Time Proc	KARL STORZ PHOTODYNAMIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Approval for the following alternate sterilization methods for the PDD Camera Heads: STERRAD NX Standard Cycle, STERRAD 100 NX Standard and Duo Cycles, V-Pro 60 Non-Lumen and Lumen Cycles.
P060002/S040	10/11/2018	Y - 135 Review Tra	FLAIR ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR	Approval for adding a sterilization line at the Bard Regional Sterilization, Madison Facility.
P070008/S097	10/22/2018	R - Real-Time Proc	STRATOS, EVIA, ENTOIVS, ELUNA 8, EPYRA 8, AND ETRINSA 8	BIOTRONIK, INC.	Approval for an updated version of Renamic and ICS 3000 programmer software, PSW 1802.U.
P070016/S009	10/10/2018	R - Real-Time Proc	ZENITH TX2 TAA ENDVASCULAR GRAFT	WILLIAM COOK EUROPE APS	Approval for a change the hydrophilic coating of the introducer sheath.
P080004/S019	10/11/2018	Y - 135 Review Tra	ISERT PRELOADED SYSTEM, ISYMM INTRAOCULAR LENS (AF-1), CLARISERT PRELOADED IOL SYSTEM	HOYA SURGICAL OPTICS, INC.	Approval for modifications to the coating of the stainless steel jigs used during the final washing process for the Hoya Medical Singapore Pte. Ltd. Manufacturing site located in Singapore.
P080011/S074	10/02/2018	Y - 135 Review Tra	COMFILCON A SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Approval for the introduction and validation of a new laboratory sterilizer at CooperVision Caribbean Corporation manufacturing facility in Juana Diaz, Puerto Rico.
P080032/S017	10/05/2018	Y - 135 Review Tra	ALAIR BRONCHIAL THERMOPLASTY CATHETER	BOSTON SCIENTIFIC CORP.	Approval for revising the manufacturing procedure for the Alair Bronchial Thermoplasty Catheter by allowing rework of the polyester heat shrink insulation placed over the electrodes if inspection criteria are not met.
P090013/S288	10/03/2018	O - Normal 180 Day	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Approval for labeling updates to the clinical study summary for the post approval study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090013/S289	10/18/2018	R - Real-Time Proc	REVO MRI	MEDTRONIC, INC	Approval for updates to the remote monitoring systems for Attesta and Sphera MRI SureScan IPG devices.
P100040/S036	10/19/2018	P - Panel Track	VALIANT NAVION THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval of the Valiant Navion Thoracic Stent Graft System, a modified device design from the Valiant Thoracic Stent Graft with Captivia Delivery System. This device is indicated for all lesions of the descending thoracic aorta (DTA) in patients having appropriate anatomy: 1) iliac or femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories; 2) nonaneurysmal aortic diameter in the range of: 16 mm to 42 mm for fusiform and saccular aneurysms/penetrating ulcers, 16 mm to 44 mm for blunt traumatic aortic injuries, 19 mm to 45 mm for dissections; 3) proximal landing zone (nonaneurysmal aortic proximal neck length for fusiform and saccular aneurysms/penetrating ulcers or nondissected length of aorta proximal to the primary tear for blunt traumatic aortic injuries and dissections) of: >= 20mm for FreeFlo configuration and ?>=25mm for CoveredSeal configuration; and 4) nonaneurysmal aortic distal neck length >= 20mm for FreeFlo and CoveredSeal configurations for fusiform and saccular aneurysms/penetrating ulcers.
P110013/S090	10/18/2018	Y - 135 Review Tra	RESOLUTE INTEGRITY ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for changes to methods used in API testing.
P120005/S077	10/11/2018	R - Real-Time Proc	G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for minor design changes to the firmware installed on the transmitter component of the Dexcom G5 Continuous Glucose Monitoring System.
P120016/S025	10/02/2018	R - Real-Time Proc	CARDIVA VASCADE VCS	CARDIVA MEDICAL, INC.	Approval to modify the key sub-assembly design for the 5F and 6/7F devices.
P130005/S022	10/04/2018	N - Normal 180 Day	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Approval to add an alternative saline sheath, a travel limit clip, an alternative distal strain relief, and a manufacturing change for the crown.
P130022/S018	10/21/2018	R - Real-Time Proc	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for changing the length and shape of the handle, and the method of securing the cap and wire to the handle of the Stylets distributed with the Senza Spinal Cord Stimulation System
P130026/S034	10/15/2018	N - Normal 180 Day	TACTICATH QUARTZ EQUIPMENT	ST. JUDE MEDICAL	Approval for TactiSys Quartz motherboard and software changes.
P140002/S014	10/01/2018	Y - 135 Review Tra	MISAGO RX SELF-EXPANDING PERIPHERAL STENT	TERUMO MEDICAL CORPORATION	Approval for changes to release testing sampling and elimination of release testing for certain attributes.
P140017/S011	10/30/2018	R - Real-Time Proc	MELODY TPV SYSTEM	MEDTRONIC INC.	Approval for a dimensional change to the Platinum-Iridium marker bands on the Ensemble II Transcatheter Valve Delivery System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140020/S015	10/16/2018	N - Normal 180 Day	BRACANALYSIS CDX DEVICE	MYRIAD GENETIC LABORATORIES	Approval for extending the label claim of the BRACAnalysis CDx to include an indication for TALZENNA (talazoparib) in breast cancer patients.
P140020/S016	10/16/2018	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for extending the label claim of the BRACAnalysis CDx® to include treatment and maintenance indications for Rubraca® (rucaparib) in ovarian cancer patients.
P140020/S017	10/25/2018	R - Real-Time Proc	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval to reduce the number of samples for PQ for like-for-like instruments replacement.
P150003/S039	10/18/2018	N - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for 4.50 mm and 5.00 mm diameter device sizes.
P150024/S012	10/24/2018	S - Special CBE	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval for changes to the Physician Guide and Patient Guide.
P150033/S038	10/01/2018	R - Real-Time Proc	MICRA PROGRAMMER APPLICATION SOFTWARE MODEL SW022	MEDTRONIC INC.	Approval for Micra Programmer Application Software, Model SW022 version 8.1 for use on the 2090 CareLink Programmer and the 29901 Encore Programmer.
P150033/S039	10/03/2018	O - Normal 180 Day	MICRA TPS	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post approval study.
P150033/S041	10/18/2018	R - Real-Time Proc	MICRA	MEDTRONIC INC.	Approval for updates to the remote monitoring systems for Attesta and Sphera MRI SureScan IPG devices.
P150038/S008	10/24/2018	N - Normal 180 Day	EXABLATE (MODEL 4000) SYSTEM	INSIGHTEC	Approval to include the 2-year and 3-year post-market study outcomes in the device labeling.
P150040/S003	10/04/2018	P - Panel Track	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Approval for the VisuMax Femtosecond Laser. This device is indicated for use in small incision lenticule extraction (SMILE) for the reduction or elimination of myopia with or without astigmatism: 1) For spherical refractive error (in minus cylinder format) from -1.00 diopters through -10.00 diopters; 2) For cylinder from -0.75 diopters through -3.00 diopters; and 3) When refraction spherical equivalent is no greater in magnitude than 10.00 diopters, in patients 22 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in sphere and cylinder of less than or equal to 0.50 D in magnitude.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160001/S008	10/25/2018	Y - 135 Review Tra	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for adding an alternate adhesive supplier and adding an inflation gas supplier.
P160001/S011	10/05/2018	Y - 135 Review Tra	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval to modify the balloon film visual inspection acceptance criteria.
P160022/S004	10/26/2018	R - Real-Time Proc	ZOLL X SERIES DEVICE (ORIDION MICROMEDICO2)	ZOLL MEDICAL CORPORATION	Approval for minor changes made within the C02 module that is incorporated into ZOLL's X Series device.
P160022/S007	10/18/2018	R - Real-Time Proc	AED 3 BLS DEVICE	ZOLL MEDICAL CORPORATION	Approval for a minor design change of the AED 3 BLS device to support an alternate LCD display.
P160023/S004	10/16/2018	Y - 135 Review Tra	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Approval for the transfer of bulk reagent manufacturing to another facility.
P160024/S003	10/11/2018	Y - 135 Review Tra	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Adding a sterilization line at the Bard Regional Sterilization, Madison Facility.
P160030/S010	10/31/2018	N - Normal 180 Day	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM; FREESTYLE LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for the addition of the FreeStyle LibreLink App (iOS) as a compatible reading device and alternative primary display for the FreeStyle Libre and Freestyle Libre 14 Day Systems.
P160043/S016	10/18/2018	Y - 135 Review Tra	RESOLUTE ONYX ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for changes to methods used in API testing.
P160054/S008	10/18/2018	P - Panel Track	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for the HeartMate 3 Left Ventricular Assist System. The device is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.
P160054/S013	10/05/2018	N - Normal 180 Day	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORPORATION	Approval for the HeartMate 3 Outflow Graft Clip component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170013/S002	10/06/2018	S - Special CBE	LOW-PROFILE VISUALIZED INTRALUMINAL SUPPORT (LVIS) AND LVIS JR.	MICROVENTION, INC.	Approval for a revision to the Instructions for Use to add a Precaution related to the use of magnetic resonance angiography (MRA) for follow up assessment following treatment with the LVIS and LVIS Jr. devices and a revision to the symbols in the Instructions for Use and the package labeling to align these symbols with the current FDA recognized standard.
P170019/S003	10/11/2018	R - Real-Time Proc	FOUNDATIONONE CDX (F1CDX)	FOUNDATION MEDICINE, INC.	Approval to further delineate manufacturing steps for F1CDx.
P170025/S001	10/02/2018	N - Normal 180 Day	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Approval for the use of the Aptima HBV Quant Assay on the Panther System with the attachment of the Panther Fusion Module. The changes being approved include the addition of new hardware and updated software.
P170025/S004	10/16/2018	Y - 135 Review Tra	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Approval for the transfer of bulk reagent manufacturing to another facility.
P180002/S001	10/25/2018	R - Real-Time Proc	ZEPHYR ENDOBRONCHIAL VALVE (EBV) SYSTEM	PULMONX CORPORATION	Approval for the proposed design changes to the funnel of the Endobronchial Loader System that is included with the Zephyr 5.5 Endobronchial valve model.

Total: 72

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S048	10/17/2018	X - 30-Day Notice	SURGICEL FIBRILLAR ABSORBABLE HEMOSTATS	ETHICON, INC.	Increase the maximum dehumidification load up to 7,776 units for the SURGICEL® FIBRILLAR Absorbable Hemostat.
N18033/S100	10/03/2018	X - 30-Day Notice	VISTAKON (ETAFILCON A) BRAND CONTACT LENSES	VISTAKON, JOHNSON & JOHNSON VISION PRODUCTS, INC.	Addition of an alternate test method for use of measuring primary packages for VISTAKON® (senofilcon A) and (etafilcon A) brand contact lenses.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S149	10/24/2018	X - 30-Day Notice	AMS 700 SERIES INFLATABLE PENILE PROSTHESIS (IPP) WITH AND WITHOUT INHIBIZONE, AMBICOR IPP	BOSTON SCIENTIFIC CORP.	Use of a new traceability/tracking software in the incoming receiving inspection area.
P790007/S058	10/28/2018	X - 30-Day Notice	HANCOCK VALVED CONDUIT MODIFIED ORIFICE	MEDTRONIC HEART VALVES	Relocation of glass packaging jar manufacturing from New Jersey to Mexico.
P830055/S212	10/23/2018	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Introduction of additional mechanisms for part identification and traceability throughout the manufacturing process.
P830061/S162	10/18/2018	X - 30-Day Notice	CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD AND VITATRON CRYSTALLINE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P840001/S407	10/13/2018	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS; SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Removal of the silica application process from the TBC series Tantalum Capacitors assembly manufacturing process, manufactured and supplied by AVX Corporation (AVX).
P840001/S408	10/22/2018	X - 30-Day Notice	ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Manufacturing change to substrate material of the Stacked Chip Scale Package.
P840001/S409	10/16/2018	X - 30-Day Notice	SCS LEADS SPECFIY FAMILY	MEDTRONIC NEUROMODULATION	Removal of a redundant cleaning process for wire components used to manufacture Neuromodulation leads in the Specify® SureScan® MRI 5-6-5 and Specify® SureScan® MRI 2X8 Lead Kits for Spinal Cord Stimulation.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850064/S037	10/19/2018	X - 30-Day Notice	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	The LifePulse High Frequency Ventilator is indicated for use in ventilating critically ill infants with pulmonary interstitial emphysema (PIE). Infants studied ranged in birth weight from 750 to 3,529 grams and in gestational age from 24 to 41 weeks. The LifePulse High Frequency Ventilator is also indicated for use in ventilating critically ill infants with respiratory distress syndrome (RDS) complicated by pulmonary air leaks who are, in the opinion of their physicians, failing on conventional ventilation. The infants studied ranged in birth weight from 600 to 3,660 grams and in gestational age from 24 to 38 weeks.
P850089/S136	10/18/2018	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE Z NOVUS LEAD, AND VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P860004/S317	10/12/2018	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM, ASCENDA INTRATHECAL CATHETERS	MEDTRONIC INC.	Adding an additional inspection to the existing pump tubing incoming inspection procedures for the SynchroMed Infusion System, Ascenda Intrathecal Catheters.
P870078/S043	10/28/2018	X - 30-Day Notice	HANCOCK VALVED CONDUIT LOW POROSITY	MEDTRONIC, INC.	Relocation of glass packaging jar manufacturing from New Jersey to Mexico.
P880086/S302	10/01/2018	X - 30-Day Notice	ASSURITY / ASSURITY+ / ENDURITY	ST. JUDE MEDICAL, INC.	Use of an alternate transient surge suppressor for pacemaker and CRT-P devices.
P880086/S303	10/24/2018	X - 30-Day Notice	QUARTET, VICTORY, ZEPHYR, ACCENT, ASSURITY, ASSURITY +ENDURITY, IDENTITY XL, IDENTITY ADX XL, VERITY ADX XL, SUSTAIN XL DC. SUSTAIN,XL DR, SUSTAIN XL SC. SUSTAIN XL SR	ST. JUDE MEDICAL, INC.	Alternate supplier of 100% ethylene oxide gas for device sterilization.
P890003/S397	10/18/2018	X - 30-Day Notice	CAPSURE VDD 2 LEAD, PACKAGE ADAPTOR CABLE AND VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC, INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P910001/S107	10/15/2018	X - 30-Day Notice	CVX-300 EXCIMER LASER SYSTEM AND ELCA CORONARY ATHERECTOMY CATHETERS	SPECTRANETICS CORP.	New labeling software for printing product labels.
P910023/S412	10/24/2018	X - 30-Day Notice	FORTIFY, FORTIFY ASSURA, ELLIPSE	ST. JUDE MEDICAL	Alternate supplier of 100% ethylene oxide gas for device sterilization.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P910056/S034	10/31/2018	X - 30-Day Notice	ENVISTA ONE PIECE HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL)	BAUSCH & LOMB, INC.	Additional supplier for plastic vial components for the enVista® One Piece Hydrophobic Intraocular Lens (IOL).
P920015/S218	10/18/2018	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT, IS-1 CONNECTOR PORT PIN PLUG KIT, LEAD ADAPTOR, SPRINT QUATTRO LEAD, SUBCUTANEOUS LEAD, AND TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P930014/S113	10/04/2018	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Add an alternate supplier for a manufacturing material used to manufacture the AcrySof® Posterior Chamber Single Piece Intraocular Lenses and the AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lenses.
P930014/S114	10/04/2018	X - 30-Day Notice	ACRYSOF POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Introduce an alternate manufacturing tool to be used during the AcrySof monomer formulation process.
P930014/S115	10/11/2018	X - 30-Day Notice	ACRYSOF SINGLE PIECE INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Modifications to the control and monitoring program of the Environmental Controlled Areas for the AcrySof® IQ ReSTOR® Intraocular Lenses (Model Number, SN6AD1) and the AcrySof® Single Piece Intraocular Lenses (Models SN60AT, SA60AT, SN60WF, SA60WF, SN6AT3-T9) at the Alcon Cork, Ireland manufacturing facility.
P930039/S191	10/18/2018	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, AND VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC, INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P950020/S091	10/31/2018	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON MONORAIL OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Use of a new manufacturing aid and modifications to an inspection process.
P950022/S121	10/24/2018	X - 30-Day Notice	DURATA, OPTISURE	ST. JUDE MEDICAL, INC.	Alternate supplier of 100% ethylene oxide gas for device sterilization.
P950022/S123	10/31/2018	X - 30-Day Notice	DURATA AND OPTISURE HIGH VOLTAGE LEADS	ST. JUDE MEDICAL, INC.	Update to the cleaning process for incoming components.
P950024/S080	10/18/2018	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950037/S196	10/03/2018	X - 30-Day Notice	SIELLO S 45/53/60, SOLIA S 45/53/60, SIELLO T 53/60, SIELLO JT 45/53, SOLIA T 53/60, SOLIA JT 45/53, EFH-6F-W	BIOTRONIK, INC.	Updates to the white suture sleeve EFH-6F-W manufacturing process for full automation.
P960009/S325	10/13/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Removal of the silica application process from the TBC series Tantalum Capacitors assembly manufacturing process, manufactured and supplied by AVX Corporation (AVX).
P960009/S326	10/22/2018	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Manufacturing change to substrate material of the Stacked Chip Scale Package.
P960013/S101	10/24/2018	X - 30-Day Notice	TENDRIL SDX LEAD, TENDRIL ST LEAD, OPTISENSE, TENDRIL STS LEAD	ST JUDE MEDICAL	Alternate supplier of 100% ethylene oxide gas for device sterilization.
P960013/S103	10/31/2018	X - 30-Day Notice	TENDRIL AND OPTISENSE LOW VOLTAGE LEADS	ST JUDE MEDICAL	Update to the cleaning process for incoming components.
P960030/S060	10/24/2018	X - 30-Day Notice	ISOFLEX OPTIM	ST. JUDE MEDICAL	Alternate supplier of 100% ethylene oxide gas for device sterilization.
P960030/S062	10/31/2018	X - 30-Day Notice	ISOFLEX LOW VOLTAGE LEADS	ST. JUDE MEDICAL	Update to the cleaning process for incoming components.
P960040/S429	10/10/2018	X - 30-Day Notice	ICDS AUTOGEN, INOGEN, DYNAGEN, ORIGEN, RESONATE, MOMENTUM, VIGILANT, PERCIVA, PUNCTUA, ENERGEN, AND INCEPTA	BOSTON SCIENTIFIC	Changes to the battery assembly process sequence and parylene coating process.
P960042/S064	10/15/2018	X - 30-Day Notice	SPECTRANETICS LASER SHEATHS SLS	SPECTRANETICS CORP.	New labeling software for printing product labels.
P970004/S278	10/09/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS BOWEL NEUROSTIMULATOR)	MEDTRONIC NEUROMODULATION	Manufacturing process changes at a supplier for the 3 um Complementary Metal Oxide Semiconductor components.
P970013/S079	10/24/2018	X - 30-Day Notice	MICRONY	ST. JUDE MEDICAL, INC.	Alternate supplier of 100% ethylene oxide gas for device sterilization.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S688	10/18/2018	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, VISIA AF MRI DF1 ICD, VISIA AF MRI VR ICD, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P980016/S689	10/31/2018	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 MANAGEMENT	Removal of the silica application process by the TBC capacitor supplier.
P980016/S690	10/26/2018	X - 30-Day Notice	EVERA MRI, ICD, DF-1 ICD, S DR ICD, XT DR ICD, XT VR ICD; MIRRO MRI DR ICD, VR ICD; PRIMO MRI DR ICD, VR ICD; VISIA AF MRI DF1 ICD, MRI VR ICD, VR ICD,.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates at the supplier to the Semi-Automate Feedthrough Inspection.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S691	10/24/2018	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, AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change the stacked chip scale to convert from halogenated to halogen-free.
P980035/S564	10/18/2018	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, AND SPHERA DR MRI IPG	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P980035/S565	10/31/2018	X - 30-Day Notice	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; AZURE S DR MRI IPG; AZURE S SR MRI IPG; AZURE XT DR MRI IPG; AZURE XT SR MRI IPG	MEDTRONIC INC.	Removal of the silica application process by the TBC capacitor supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S566	10/24/2018	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, 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 AND SPHERA SR MRI IPG	MEDTRONIC INC.	Change the stacked chip scale to convert from halogenated to halogen-free.
P980037/S070	10/02/2018	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY SYSTEM, ANGIOJET ULTRA XMI/ ANGIOJET ULTRA SPIROFLEX/ANGIOJET ULTRA DISTAFLEX THROMBECTOMY SET, ANGIOJET SPIROFLEX VG THROMBECTOMY	BOSTON SCIENTIFIC CORP.	Changes to the incoming inspection process for the pump body component.
P980043/S068	10/22/2018	X - 30-Day Notice	MOSAIC BIOPROSTHESIS AND HANCOCK II BIOPROSTHESIS	MEDTRONIC, INC.	Implementation of a new RODI water system at Covidien Medical Products (Shanghai) Manufacturing L.L.C.
P990056/S034	10/25/2018	X - 30-Day Notice	ELECSYS TOTAL PSA	ROCHE DIAGNOSTICS CORP.	Addition of a raw material supplier.
P990064/S076	10/22/2018	X - 30-Day Notice	MOSAIC BIOPROSTHESIS AND HANCOCK II BIOPROSTHESIS	MEDTRONIC, INC.	Implementation of a new RODI water system at Covidien Medical Products (Shanghai) Manufacturing L.L.C.
P000013/S015	10/18/2018	X - 30-Day Notice	TRIDENT ALUMINA INSERT	HOWMEDICA OSTEONICS CORP.	Change in corrosion protection oil used during the vendor's proof test.
P000027/S032	10/25/2018	X - 30-Day Notice	ELECSYS FREE PSA TEST SYSTEM	ROCHE DIAGNOSTICS CORP.	Addition of a raw material supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000053/S093	10/18/2018	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to the molding parameters of the silicone pump shell component.
P000053/S097	10/24/2018	X - 30-Day Notice	AMS 800 URINARY CONTROL SYSTEM WITH AND WITHOUT INHIBIZONE	BOSTON SCIENTIFIC CORP.	Use of a new traceability/tracking software in the incoming receiving inspection area.
P010012/S490	10/10/2018	X - 30-Day Notice	CRT-DS AUTOGEN, INOGEN, DYNAGEN, ORIGEN, RESONATE, MOMENTUM, VIGILANT, PERCIVA, PUNCTUA, ENERGEN, AND INCEPTA	BOSTON SCIENTIFIC CORP.	Changes to the battery assembly process sequence and parylene coating process.
P010014/S082	10/24/2018	X - 30-Day Notice	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Remove the percent crystallinity testing for the Oxford Partial Knee tibial meniscal bearing components.
P010015/S380	10/18/2018	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, 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 AND VIVA CRT-P	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P010015/S381	10/31/2018	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.	Removal of the silica application process by the TBC capacitor supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010015/S382	10/24/2018	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, AND VIVA CRT-P	MEDTRONIC INC.	Change the stacked chip scale to convert from halogenated to halogen-free.
P010031/S646	10/18/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P010031/S647	10/26/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, QUAD CRT -D; BRAVA CRT-D, QUAD CRT-D; CLARIA MRI CRT-D, QUAD CRT-D; COMPIA MRI CRT-D, MRI QUAD CRT-D; VIVA QUAD S CRT-D; VIVA QUAD XT CRT-D, S CRT-D, XT CRT-D.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates at the supplier to the Semi-Automate Feedthrough Inspection.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S648	10/31/2018	X - 30-Day Notice	AMPLIA MRI CRT-D; AMPLIA MRI QUAD CRT-D; BRAVA CRT-D; BRAVA QUAD CRT-D; CLARIA MRI CRT-D; CLARIA MRI QUAD CRT-D; COMPIA MRI CRT-D; COMPIA MRI QUAD CRT-D; CONSULTA CRT-D; 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	Removal of the silica application process by the TBC capacitor supplier.
P010031/S649	10/24/2018	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, BRAVA CRT-D, BRAVA QUAD CRT-D, CLARIA MRI CRT-D, CLARIA MRI QUAD CRT-D, COMPIA MRI CRT-D, COMPIA MRI QUAD CRT-D, CONSULTA CRT-D, PROTECTA CRT-D, PROTECTA XT CRT-D, VIVA QUAD S CRT-D, VIVA QUAD XT CRT-D, VIVA S CRT-D AND VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Change the stacked chip scale to convert from halogenated to halogen-free.
P010032/S143	10/03/2018	X - 30-Day Notice	SPINAL CORD STIMULATION (SCS) LEADS, EXTENSIONS AND ADAPTERS	ST. JUDE MEDICAL	Manufacturing process change that incorporates an automatic test method to measure the inner and outer SCS and DBS tubing.
P010033/S040	10/04/2018	X - 30-Day Notice	QUANTIFERON TB GOLD TEST, QUANTIFERON TB GOLD TEST (REFERENCE LAB PACK), QUANTIFERON TB GOLD PLUS TEST, QUANTIFERON TB GOLD PLUS TEST (REFERENCE PACK)	QIAGEN	Change in sub-bulk component manufacturing.
P020004/S157	10/11/2018	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Manufacturing facility move for a supplier of the GORE EXCLUDER AAA Endoprosthesis packaging mandrel.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020004/S158	10/11/2018	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an additional resin blend pelletizer that is used in the manufacturing process of base tube device components.
P020004/S159	10/24/2018	X - 30-Day Notice	EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of a new film wrapping machine for use in the manufacturing of the GORE EXCLUDER AAA Endoprosthesis and GORE EXCLUDER AAA Endoprosthesis
P020011/S011	10/31/2018	X - 30-Day Notice	APTIMA HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Removal of raw material QC testing not relevant to the product.
P020047/S070	10/04/2018	X - 30-Day Notice	MULTI-LINK 8 CORONARY STENT SYSTEM, MULTI-LINK 8 SV/ 8 LL CORONARY STENT SYSTEM	ABBOTT VASCULAR	Increase the sterilization load density with a modified configuration.
P020050/S031	10/26/2018	X - 30-Day Notice	WAVELIGHT EX500 EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Internally source component assembly and testing services for the Model 1125 bed, in addition to externally sourcing this service from the external supplier.
P030008/S027	10/26/2018	X - 30-Day Notice	WAVELIGHT EX500 EXCIMER LASER SYSTEM	ALCON LABORATORIES, INC.	Internally source component assembly and testing services for the Model 1125 bed, in addition to externally sourcing this service from the external supplier.
P030009/S094	10/05/2018	X - 30-Day Notice	INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Implement a new labeling system at the Galway facility.
P030024/S027	10/16/2018	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC REAGENT PACK AND CALIBRATOR	ORTHO-CLINICAL DIAGNOSTICS	Add an additional supplier, and implement an in-house processing step for a critical raw material.
P030028/S006	10/23/2018	X - 30-Day Notice	ARTISAN MYOPIA	OPHTEC BV	Ethylene oxide sterilization cycle improvements for 1 full sterilization cycle for the Artisan Myopia Intraocular Lenses sterilized at AT Sterigenics in Belgium.
P030035/S173	10/01/2018	X - 30-Day Notice	ALLURA, ALLURE QUADRA/ QUADRA ALLURE MP	ST. JUDE MEDICAL, INC.	Use of an alternate transient surge suppressor for pacemaker and CRT-P devices.
P030035/S174	10/24/2018	X - 30-Day Notice	ALLURE, ALLURE QUADRA, QUADRA ALLURE MP	ST. JUDE MEDICAL, INC.	Alternate supplier of 100% ethylene oxide gas for device sterilization.
P030036/S103	10/18/2018	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030054/S360	10/24/2018	X - 30-Day Notice	UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, QUADRA ASSURA MP, QUICKFLEX U, QUARTET, QUARTET CRT LEADS	ST. JUDE MEDICAL	Alternate supplier of 100% ethylene oxide gas for device sterilization.
P030054/S362	10/31/2018	X - 30-Day Notice	LEFT HEART LEADS (QUICKFLEX U AND QUARTET)	ST. JUDE MEDICAL	Update to the cleaning process for incoming components.
P040020/S081	10/04/2018	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Add an alternate supplier for a manufacturing material used to manufacture the AcrySof® Posterior Chamber Single Piece Intraocular Lenses and the AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lenses.
P040020/S082	10/04/2018	X - 30-Day Notice	ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON RESEARCH, LTD.	Introduce an alternate manufacturing tool to be used during the AcrySof monomer formulation process.
P040020/S083	10/11/2018	X - 30-Day Notice	ACRYSOF IQ RESTOR INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Modifications to the control and monitoring program of the Environmental Controlled Areas for the AcrySof® IQ ReSTOR® Intraocular Lenses (Model Number, SN6AD1) and the AcrySof® Single Piece Intraocular Lenses (Models SN60AT, SA60AT, SN60WF, SA60WF, SN6AT3-T9) at the Alcon Cork, Ireland manufacturing facility.
P040027/S067	10/11/2018	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an additional resin blend pelletizer that is used in the manufacturing process of base tube device components.
P040037/S122	10/11/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of an additional resin blend pelletizer that is used in the manufacturing process of base tube device components.
P040038/S033	10/04/2018	X - 30-Day Notice	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Increase the sterilization load density with a modified configuration.
P040043/S104	10/11/2018	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an additional resin blend pelletizer that is used in the manufacturing process of base tube device components.
P040043/S105	10/17/2018	X - 30-Day Notice	GORE CONFORMABLE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implement an additional film attach machine to be used during the manufacture of the GORE Conformable TAG Thoracic Endoprosthesis.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040045/S101	10/03/2018	X - 30-Day Notice	VISTAKON (SENOFILCON A) BRAND CONTACT LENSES	VISTAKON, DIVISION OF JOHNSON & JOHNSON VISION CAR	Addition of an alternate test method for use of measuring primary packages for VISTAKON® (senofilcon A) and (etafilcon A) brand contact lenses.
P050018/S025	10/15/2018	X - 30-Day Notice	ANGIOSCULPT PTCA SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Change in the location of a qualified supplier.
P050042/S035	10/19/2018	X - 30-Day Notice	ARCHITECT ANTI-HCV	ABBOTT LABORATORIES INC	Modifications to the manufacturing processing for a blocking reagent.
P060006/S094	10/10/2018	X - 30-Day Notice	EXPRESS SD RENAL MONORAIL PREMOUNTED SYSTEM	BOSTON SCIENTIFIC CORP.	Removal of an in-process wall thickness inspection.
P060039/S090	10/18/2018	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P070015/S143	10/04/2018	X - 30-Day Notice	XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM, XIENCE NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR INC.	Increase the sterilization load density with a modified configuration.
P080006/S126	10/18/2018	X - 30-Day Notice	ATTAIN ABILITY LEAD AND ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P080011/S081	10/15/2018	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION MANUFACTURING, LTD.	Introduction of Biofinity line 18.
P080014/S023	10/09/2018	X - 30-Day Notice	CERVISTA® HPV HR ASSAY	HOLOGIC, INC.	Transfer the purification and dilution operations for specified reagents within an existing manufacturing facility.
P080015/S015	10/09/2018	X - 30-Day Notice	CERVISTA HPV 16/18 ASSAY	HOLOGIC, INC.	Transfer the purification and dilution operations for specified reagents within an existing manufacturing facility.
P080025/S173	10/09/2018	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM, VERIFY EVALUATION SYSTEM (SNS URINARY NEUROSTIMULATOR)	MEDTRONIC NEUROMODULATION	Manufacturing process changes at a supplier for the 3 um Complementary Metal Oxide Semiconductor components.

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P090003/S044	10/10/2018	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED SYSTEM	BOSTON SCIENTIFIC CORPORATION	Removal of an in-process wall thickness inspection.
P090013/S290	10/18/2018	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P090016/S031	10/23/2018	X - 30-Day Notice	BELOTERO BALANCE DERMAL FILLER	MERZ NORTH AMERICA, INC	Replacement of the daily biocide disinfectant, addition of a weekly and monthly sporicide disinfectant, and removal of quarterly sporicide cleaning requirement
P100018/S018	10/15/2018	X - 30-Day Notice	PIPELINE FLEX EMBOLIZATION DEVICE	MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR	Changing HDPE and LDPE suppliers for introducer and temporary sheaths.
P100021/S073	10/05/2018	X - 30-Day Notice	ENDURANT, ENDURANT II AND ENDUREANT IIS STENT GRAFT SYSTEMS	MEDTRONIC VASCULAR	Implement a new labeling system at the Galway facility.
P100026/S060	10/05/2018	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	NeuroPace's battery supplier, Integer, to use an alternate supplier (second tier) to procure electrolyte used in batteries for RNS Neurostimulator model RNS-300M and model RNS-320.
P100029/S036	10/01/2018	X - 30-Day Notice	TRIFECTA VALVE WITH GLIDE TECHNOLOGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Additional manufacturing site for the assembly of Trifecta GT welded fabric tube sub-assemblies.
P100033/S009	10/18/2018	X - 30-Day Notice	PROGENSA PCA3 ASSAY	GEN-PROBE INCORPORATED	Remove an in-process performance test that is no longer applicable to currently marketed products.
P100034/S020	10/19/2018	X - 30-Day Notice	OPTUNE SYSTEM	NOVOCURE, LTD.	Change to lead-free solder.
P100040/S037	10/05/2018	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM	MEDTRONIC VASCULAR	Implement a new labeling system at the Galway facility.
P100045/S032	10/24/2018	X - 30-Day Notice	CARDIOMEMS HF PRESSURE MEASUREMENT SYSTEM	ST. JUDE MEDICAL	Change to receiving inspection procedures for the hydrophilic coating solutions used to coat the CardioMEMS Delivery System catheter.
P100047/S130	10/23/2018	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implementation of a new internal Final Packaging and Product Labeling Management System and process.

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P100049/S024	10/16/2018	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Implementation of changes to a manufacturing equipment.
P110010/S160	10/31/2018	X - 30-Day Notice	PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Extend the shelf life of the drug coating solution for the Promus ELITE product.
P110013/S092	10/05/2018	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Implement a new labeling system at the Galway facility.
P110019/S102	10/04/2018	X - 30-Day Notice	XIENCE PRIME EVEROLIMUS ELUTING CORONARY STENT SYSTEM, XIENCE PRIME SV/LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM, XIENCE XPEDITION EVEROLIMUS ELUTING CORONARY STENT SYSTEM, XIENCE XPEDITION SV/LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM , XIENCE ALPINE/ SIERRA EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Increase the sterilization load density with a modified configuration.
P110035/S047	10/18/2018	X - 30-Day Notice	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modified procedure for loading and processing stents during the electropolishing process.
P110042/S114	10/24/2018	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (S-ICD) ELECTRODE	BOSTON SCIENTIFIC CORPORATION	Add the "first-half" of the EMBLEM S-ICD lead manufacturing line at the Dorado Site.
P110042/S115	10/10/2018	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the battery assembly process sequence and parylene coating process.

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P120005/S078	10/04/2018	X - 30-Day Notice	G4 PLATINUM CONTINUOUS GLUCOSE MONITORING SYSTEM AND G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Extending the relative humidity excursion period for the Dexcom G4 PLATINUM/G5 Mobile Sensor. The proposed change seeks to extend the allowable relative humidity excursion period for the sensor component in its primary packaging. The Dexcom G4 PLATINUM/G5 Mobile Sensor is a component of the Dexcom G4 Platinum and Dexcom G5 Mobile Continuous Glucose Monitoring System, respectively.
P120017/S014	10/18/2018	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P120020/S020	10/04/2018	X - 30-Day Notice	SUPERA PERIPHERAL STENT SYSTEM, SUPERA PRO INTERWOVEN PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Increase the sterilization load density with a modified configuration.
P130006/S061	10/11/2018	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of an additional resin blend pelletizer that is used in the manufacturing process of base tube device components.
P130017/S024	10/29/2018	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Implementation of manufacturing changes to a wash component of the Cologuard sDNA based colorectal cancer screening test.
P130021/S053	10/05/2018	X - 30-Day Notice	MEDTRONIC CORE VALVE EVOLUT R AND PRO R SYSTEM	MEDTRONIC COREVALVE LLC	Implement a new labeling system at the Galway facility.
P130021/S054	10/21/2018	X - 30-Day Notice	ENVEO R AND ENVEO PRO DELIVERY CATHETER SYSTEM (DCS)	MEDTRONIC COREVALVE LLC	Add a new visual inspection method to the assembly process for the EnVeo R/EnVeo PRO Delivery Catheter System.
P130030/S056	10/31/2018	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Use of a new manufacturing aid and modifications to an inspection process.
P140009/S040	10/03/2018	X - 30-Day Notice	INFINITY DEEP BRAIN STIMULATION (DBS) LEADS, EXTENSIONS AND ADAPTERS	ST. JUDE MEDICAL NEUROMODULATION	Manufacturing process change that incorporates an automatic test method to measure the inner and outer SCS and DBS tubing.

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P140010/S041	10/05/2018	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATEDE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Implement a new labeling system at the Galway facility.
P140015/S026	10/11/2018	X - 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH DEXCOM G5 MOBILE CGM	TANDEM DIABETES CARE, INC.	Removal of plasma treatment on the patient line, modification to the final packing verification process, and the addition of additional testing/acceptance criteria for the pumps. The Tandem cartridges and pumps are part of the Tandem t:slim X2 Insulin Pump system.
P140015/S027	10/26/2018	X - 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH DEXCOM G5 MOBILE CGM	TANDEM DIABETES CARE, INC.	Change the procedure for wake button replacement during PCBA refurbishment by discontinuing replacement of the wake button if it meets specific criteria and by transferring various reprogramming steps in-house. The wake button switch assemblies are components of the t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM and the t:slim Insulin Pump with Basal-IQ Technology.
P140017/S012	10/28/2018	X - 30-Day Notice	MELODY	MEDTRONIC INC.	Relocation of glass packaging jar manufacturing from New Jersey to Mexico.
P140018/S013	10/05/2018	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implement a new labeling system at the Galway facility.
P140028/S033	10/18/2018	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Modified procedure for loading and processing stents during the electropolishing process.
P140029/S014	10/17/2018	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Change to replace pumps and pipes for Water For Injection used in the buffer mixing system for the manufacture of Restylane Refyne and Restylane Defyne.
P140030/S008	10/15/2018	X - 30-Day Notice	ASTRON STENT SYSTEM	BIOTRONIK, INC.	Changing a stent component laser cutting process parameter.
P140031/S075	10/19/2018	X - 30-Day Notice	9600CR CRIMPER	EDWARDS LIFESCIENCE S, LLC.	Implement a change in the inspection method for the jaw during the line assembly of the Crimper Model number 9600CR.
P140031/S076	10/25/2018	X - 30-Day Notice	EDWARDS COMMANDER DELIVERY SYSTEM	EDWARDS LIFESCIENCE S, LLC.	Addition of an inspection for Spring Coil orientation at final inspection for all sizes of Commander Delivery System products.
P140033/S037	10/01/2018	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI	ST. JUDE MEDICAL, INC.	Use of an alternate transient surge suppressor for pacemaker and CRT-P devices.
P140033/S038	10/24/2018	X - 30-Day Notice	ASSURITY MRI, ENDURITY MRI, TENDRIL MRI, MRI ACTIVATOR,	ST. JUDE MEDICAL, INC.	Alternate supplier of 100% ethylene oxide gas for device sterilization.

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P140033/S040	10/31/2018	X - 30-Day Notice	TENDRIL MRI LEAD	ST. JUDE MEDICAL, INC.	Update to the cleaning process for incoming components.
P150022/S007	10/01/2018	X - 30-Day Notice	CLOSER VASCULAR SEALING SYSTEM (VSS)	REX MEDICAL, L.P.	Addition of an alternate vendor for the tipping process.
P150033/S042	10/18/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Transfer receiving and incoming inspection activities for device components from Medtronic Rice Creek to Medtronic Puerto Rico Operations Company (MPROC) Villalba/ Juncos sites and the FedEx/3PL (Third Party Logistics) facility in Guaynabo, Puerto Rico.
P150033/S043	10/31/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Removal of the silica application process by the TBC capacitor supplier.
P150033/S044	10/24/2018	X - 30-Day Notice	MICRA TPS	MEDTRONIC INC.	Change the stacked chip scale to convert from halogenated to halogen-free.
P160001/S022	10/01/2018	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Addition of a cleaning step for a component manufacturing process.
P160001/S023	10/05/2018	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Addition of a component inspection step in the manufacturing process.
P160004/S021	10/11/2018	X - 30-Day Notice	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Implementation of an additional resin blend pelletizer that is used in the manufacturing process of base tube device components.
P160008/S001	10/09/2018	X - 30-Day Notice	SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS AND ACCESSORIES	HEARTSINE TECHNOLOGIES LLC	Implementation of an alternative manufacturing process (selective soldering) for soldering through-hole components on the printed circuit board assemblies used in the SAM 350P and SAM 360P public access defibrillators.
P160008/S002	10/22/2018	X - 30-Day Notice	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS AND ACCESSORIES	HEARTSINE TECHNOLOGIES LLC	Use of an alternate PCBA functional tester at the component supplier sites.
P160021/S014	10/11/2018	X - 30-Day Notice	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHEIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an additional resin blend pelletizer that is used in the manufacturing process of base tube device components.
P160023/S007	10/31/2018	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Removal of raw material QC testing not relevant to the product.

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P160026/S002	10/31/2018	X - 30-Day Notice	LIFEPAK AUTOMATED EXTERNAL DEFIBRILLATORTS (AEDS)	PHYSIO-CONTROL. INC.	Change in manufacturing location of a critical component.
P160035/S004	10/26/2018	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Changes to the quality control testing of titanium connectors.
P160043/S017	10/01/2018	X - 30-Day Notice	RESOLUTE ONYX RX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM, RESOLUTE ONYX OTW ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Modify the sampling scheme for lot release testing.
P160043/S019	10/05/2018	X - 30-Day Notice	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Implement a new labeling system at the Galway facility.
P160045/S010	10/30/2018	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Supplier change of critical raw material used in Ion OneTouch Dx Template kits.
P170012/S011	10/10/2018	X - 30-Day Notice	HEMOBLAST¿ BELLOWS	BIOM'UP SA	Increase batch production size during drying, implement the use of stainless steel drying trays, increase storage time of in-process device, and increase the sampling plan throughout the manufacturing process.
P170024/S001	10/05/2018	X - 30-Day Notice	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Reduction of the frequency of in-process inspection for the pouch sealing process to once daily.
P170025/S005	10/31/2018	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Removal of raw material QC testing not relevant to the product.
P180008/S005	10/11/2018	X - 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	TANDEM DIABETES CARE, INC.	Removal of plasma treatment on the patient line, modification to the final packing verification process, and the addition of additional testing/acceptance criteria for the pumps. The Tandem cartridges and pumps are part of the Tandem t:slim X2 Insulin Pump system.
P180008/S006	10/26/2018	X - 30-Day Notice	T:SLIM X2 INSULIN PUMP WITH BASAL-IQ TECHNOLOGY	TANDEM DIABETES CARE, INC.	Change the procedure for wake button replacement during PCBA refurbishment by discontinuing replacement of the wake button if it meets specific criteria and by transferring various reprogramming steps in-house. The wake button switch assemblies are components of the t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM and the t:slim Insulin Pump with Basal-IQ Technology.

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