PMA Monthly approvals from 10/1/2020 to 10/30/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190019	10/30/2020	PMAO - PMA Origi	RANGER¿ PACLITAXEL-COATED PTA BALLOON CATHETER	BOSTON SCIENTIFIC CORPORATION	Approval for the Ranger Paclitaxel-Coated PTA Balloon Catheter. This device is indicated for percutaneous transluminal angioplasty (PTA) of de novo or restenotic lesions up to 180 mm in length located in native superficial femoral and proximal popliteal arteries (SFA/ PPA) with reference vessel diameters of 4 -7 mm.
P200006	10/26/2020	PMAO - PMA Origi	FOUNDATIONONE LIQUID CDX (F1 LIQUID CDX)	FOUNDATION MEDICINE, INC.	Approval for FoundationOne® Liquid CDx is a qualitative next generation sequencing based in vitro diagnostic test that uses targeted high throughput hybridization-based capture technology to detect and report substitutions, insertions and deletions (indels) in 311 genes, including rearrangements in three (3) genes, and copy number alterations in three (3) genes. FoundationOne® Liquid CDx utilizes circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of cancer patients collected in FoundationOne® Liquid CDx cfDNA blood collection tubes included in the FoundationOne® Liquid CDx Blood Sample Collection Kit. The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in table 1 in accordance with the approved therapeutic product labeling. Table 1: Companion diagnostic indications Tumor Type Biomarker(s) Detected Therapy Non-small cell lung cancer (NSCLC) EGFR Exon 19 deletions and EGFR Exon 21 L858R alteration IRESSA® (gefitinib) TAGRISSO® (osimertinib) TARCEVA® (erlotinib) ALK Rearrangements ALECENSA® (alectinib) Prostate cancer BRCA1, BRCA2 alterations RUBRACA® (rucaparib) Ovarian Cancer BRCA1, BRCA2 alterations RUBRACA® (rucaparib) Breast Cancer PIK3CA mutations C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y PIQRAY® (alpelisib) Additionally, FoundationOne® Liquid CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. A negative result from a plasma specimen does not mean that the patient¿s tumor is negative for genomic findings. Patients who are negative for the mutations listed in Table 1 should be reflexed to routine biopsy and their tumor mutation status confirmed using an FDA-approved tumor tissue test, if feasible. Genomic findings other than those listed in Table 1 of the intended use statement are not prescriptive or conclusive for labeled use of any specific therapeutic product. FoundationOne® Liquid CDx is a single-site assay performed at Foundation Medicine, Inc. in Cambridge, MA.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P200023	10/09/2020	PMAO - PMA Origi	ZILVER VENA VENOUS SELF-EXPANDING STENT	COOK IRELAND LTD.	Approval for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic iliofemoral venous outflow obstruction.
P200026	10/21/2020	PMAO - PMA Origi	ABRE VENOUS SELF-EXPANDING STENT SYSTEM	MEDTRONIC VASCULAR, INC.	Approval for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S254	10/22/2020	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for software changes included in LATITUDE NXT Patient Management System Release 7.0.
N970003/S255	10/16/2020	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval to allow an additional mold release/de-nest agent to be applied to the polyethylene terephthalate glycol (PETG) sheets used to form sterile packaging trays.
P830055/S257	10/21/2020	O - Normal 180 Day	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a manufacturing site located at Johnson & Johnson Medical (DePuy Suzhou) Ltd., No. 299, Changyang Street, Suzhou Industrial Park, Suzhou Jiangsu, China, to manufacture Sigma PS Femur components of the LCS Total Knee System.
P850048/S054	10/07/2020	R - Real-Time Proc	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for modification to the Access 2 Immunoassay System Pipettor gantry.
P850048/S055	10/16/2020	R - Real-Time Proc	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a change to implement a new resin blend for the UniCel DxI Wash Buffer II Cubitainer.
P910023/S430	10/28/2020	R - Real-Time Proc	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Approval for minor design changes to the high voltage capacitors used in select families of ICD and CRT-D devices.
P910056/S042	10/28/2020	N - Normal 180 Day	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval for a new packaging configuration that consists of a Bausch + Lomb enVista IOL model MX60PL and SimplifEYE inserter.
P910077/S180	10/22/2020	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for software changes included in LATITUDE NXT Patient Management System Release 7.0.
P950022/S135	10/16/2020	R - Real-Time Proc	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Approval for the use of an optimized method for the calculation of the amount of DSP content identified on product labels for CRT and passive fixation cardiac lead.

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P960009/S383	10/28/2020	O - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P960030/S070	10/16/2020	R - Real-Time Proc	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ST. JUDE MEDICAL	Approval for the use of an optimized method for the calculation of the amount of DSP content identified on product labels for CRT and passive fixation cardiac lead.
P960040/S453	10/22/2020	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for software changes included in LATITUDE NXT Patient Management System Release 7.0.
P960043/S107	10/27/2020	N - Normal 180 Day	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for the Perclose ProStyle Suture-Mediated Closure and Repair System incorporating design changes to the deployment device and suture trimmer.
P970038/S042	10/07/2020	R - Real-Time Proc	TANDEM-R FREE PSA IMMUNORADIOMETRIC ASSAY/TANDEM-MP FREE PSA IMMUNOENZYMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for modification to the Access 2 Immunoassay System Pipettor gantry.
P970038/S043	10/16/2020	R - Real-Time Proc	TANDEM-R FREE PSA IMMUNORADIOMETRIC ASSAY/TANDEM-MP FREE PSA IMMUNOENZYMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a change to implement a new resin blend for the UniCel DxI Wash Buffer II Cubitainer.
P980035/S637	10/08/2020	O - Normal 180 Day	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for labeling updates for the Attesta and Sphera MRI SureScan Systems.
P980040/S115	10/14/2020	O - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for labeling modification to reflect the findings of the Post-Approval Study (PAS) for Models ZCT450, ZCT525, and ZCT600.
P980040/S120	10/26/2020	O - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for a manufacturing site located at AMO Puerto Rico Manufacturing Inc., Road 402 North, KM 4.2, Añasco, PR 00610; and, approval for a contract sterilization site located at Edwards Life Sciences Technology SARL, Hwy # 402 North, KM 1.4, Añasco, PR 00610.
P980041/S047	10/07/2020	R - Real-Time Proc	ACCESS AFP IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Approval for modification to the Access 2 Immunoassay System Pipettor gantry.
P980041/S048	10/16/2020	R - Real-Time Proc	ACCESS AFP IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Approval for a change to implement a new resin blend for the UniCel DxI Wash Buffer II Cubitainer.

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P000025/S115	10/07/2020	O - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for modification of the approved labeling for the MedEl EAS Cochlear Implant System to reflect the findings of the Post-Approval Study.
P000039/S071	10/06/2020	Y - 135 Review Tra	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Approval for a process change in the manufacture of the polyester used in the AMPLATZER device family.
P010012/S522	10/22/2020	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for software changes included in LATITUDE NXT Patient Management System Release 7.0.
P010030/S141	10/13/2020	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for the ZOLL ECG Classifier feature for use with the LifeVest Wearable Defibrillator, model 4000.
P010031/S711	10/19/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for software application model SW034 version 8.5.
P020018/S059	10/08/2020	S - Special CBE	ZENITH AAA ENDOVASCULAR GRAFT AND H&L-B ONE-SHOT INTRODUCTINO SYSTEM	COOK, INC.	Approval for the use of a Stent Orientation tool in the manufacturing of the Zenith AAA Endovascular Graft.
P020024/S061	10/06/2020	Y - 135 Review Tra	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for a process change in the manufacture of the polyester used in the AMPLATZER device family.
P030005/S200	10/22/2020	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for software changes included in LATITUDE NXT Patient Management System Release 7.0.
P030005/S201	10/16/2020	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval to allow an additional mold release/de-nest agent to be applied to the polyethylene terephthalate glycol (PETG) sheets used to form sterile packaging.

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P030009/S097	10/05/2020	O - Normal 180 Day	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Approval for a site change for packaging and labeling rework processes.
P030054/S382	10/28/2020	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Approval for minor design changes to the high voltage capacitors used in select families of ICD and CRT-D devices.
P030054/S384	10/16/2020	R - Real-Time Proc	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Approval for the use of an optimized method for the calculation of the amount of DSP content identified on product labels for CRT and passive fixation cardiac leads.
P040024/S117	10/01/2020	N - Normal 180 Day	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for the addition of an alternate qualified supplier for Lidocaine HCl.
P040040/S041	10/06/2020	Y - 135 Review Tra	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Approval for a process change in the manufacture of the polyester used in the AMPLATZER device family.
P040043/S118	10/05/2020	R - Real-Time Proc	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for the addition of a color additive to the secondary deployment line and sleeve attachment fibers of the GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System.
P040043/S120	10/15/2020	S - Special CBE	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval for implementation of updates to the Instructions for Use (IFU).
P040047/S056	10/02/2020	Y - 135 Review Tra	COAPTITE	MERZ NORTH AMERICA, INC	Approval for implementation of a cloud-based environmental monitoring software system in designated production areas at Site 100 and Site 125.
P050006/S085	10/23/2020	O - Normal 180 Day	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Approval of the revised protocol, and subsequent revised version of the protocol for the post-approval study (PAS) protocol.
P050037/S102	10/02/2020	Y - 135 Review Tra	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Approval for implementation of a cloud-based environmental monitoring software system in designated production areas at Site 100 and Site 125.
P050052/S120	10/02/2020	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for implementation of a cloud-based environmental monitoring software system in designated production areas at Site 100 and Site 125.
P060011/S023	10/16/2020	Y - 135 Review Tra	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Approval for the use of a new high-precision lathe and removal of the polishing step for the C-flex, C-flex aspheric, 6.0 mm aspheric and RayOne aspheric intraocular lenses.
P080011/S106	10/01/2020	Y - 135 Review Tra	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Approval for introduction of a new manufacturing line for Biofinity Sphere Minus and Biofinity Toric Minus and Plus (comfilcon A) contact lenses, and the use of alternative equipment for QC1 (in-process) measurement of sphere power, cylinder power, and axis of Biofinity Toric lenses.
P080012/S067	10/29/2020	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for change to implement a software update of the Clinician Programmer Application Software (2.01.6) to improve Bluetooth connection reliability in Clinician Programmer REF 13828.
P090016/S037	10/02/2020	Y - 135 Review Tra	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for implementation of a cloud-based environmental monitoring software system in designated production areas at Site 100 and Site 125.
P090026/S028	10/07/2020	R - Real-Time Proc	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for modification to the Access 2 Immunoassay System Pipettor gantry.

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P090026/S029	10/16/2020	R - Real-Time Proc	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a change to implement a new resin blend for the UniCel DxI Wash Buffer II Cubitainer.
P100014/S026	10/09/2020	O - Normal 180 Day	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Approval of labeling changes after the final report for the post-approval study (PAS) protocol.
P100018/S024	10/05/2020	O - Normal 180 Day	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS, INC. D/B/A EV3 NEUROVASCULAR	Approval for labeling changes to incorporate completed results from the post-approval study (PAS) titled Prospective Study on Embolization of Intracranial Aneurysms with Pipeline Embolization Device (PREMIER).
P100021/S077	10/21/2020	Y - 135 Review Tra	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for a modified wire forming process.
P100021/S082	10/21/2020	R - Real-Time Proc	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for the addition of a 146mm limb length configuration to the Endurant II/IIs product size matrix.
P100021/S083	10/05/2020	O - Normal 180 Day	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for site change for packaging and labeling rework processes.
P100040/S041	10/05/2020	O - Normal 180 Day	VALIANT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval for site change for packaging and labeling rework processes.
P110013/S103	10/05/2020	O - Normal 180 Day	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for site change for packaging and labeling rework processes.
P110019/S112	10/22/2020	R - Real-Time Proc	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Approval for extending the shelf-life for the XIENCE Sierra Everolimus-Eluting Coronary Stent System from 18 to 24 months and to revise the annual stability testing protocol to align with the other XIENCE stent family members.
P110042/S142	10/22/2020	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for software changes included in LATITUDE NXT Patient Management System Release 7.0.
P110042/S143	10/16/2020	R - Real-Time Proc	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval to allow an additional mold release/de-nest agent to be applied to the polyethylene terephthalate glycol (PETG) sheets used to form sterile packaging.
P120006/S037	10/09/2020	O - Normal 180 Day	OVATION ABDOMINAL STENT GRAFT SYSTEM	ENDOLOGIX, LLC	Approval for the Alto Randomized Post-Approval Study protocol.
P120019/S031	10/27/2020	N - Normal 180 Day	COBAS EGFR MUTATION TEST	ROCHE	Approval for cobas® EGFR Mutation Test v2 label expansion to obtain companion diagnostic group labeling claim for EGFR Tyrosine Kinase Inhibitors (TKI) for specific EGFR mutations detected by the test.

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P120021/S016	10/06/2020	Y - 135 Review Tra	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Approval for a process change in the manufacture of the polyester used in the AMPLATZER device family.
P130009/S109	10/27/2020	O - Normal 180 Day	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences Technology SARL, Hwy# 402 N Km 1.4, Añasco, Puerto Rico for ethylene oxide (EO) sterilization of the Edwards THV devices.
P130021/S080	10/05/2020	O - Normal 180 Day	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for a site change for packaging and labeling rework processes.
P140008/S021	10/16/2020	S - Special CBE	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Approval for implementation of a new retention force specification and corresponding quality control inspection.
P140010/S051	10/05/2020	O - Normal 180 Day	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for a site change for packaging and labeling rework processes.
P140031/S116	10/27/2020	O - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for a manufacturing site located at Edwards Lifesciences Technology SARL, Hwy# 402 N Km 1.4, Añasco, Puerto Rico for ethylene oxide (EO) sterilization of the Edwards THV devices.
P140032/S047	10/21/2020	N - Normal 180 Day	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for design and manufacturing changes for the remediated pump changes and labeling corrections for the Implantable System for Remodulin.
P150001/S088	10/09/2020	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for a design change to the keypad assembly of the Next Generation Pump (NGP), a component of the MiniMed 630G System with SmartGuard and the MiniMed 670G System.
P150005/S057	10/09/2020	R - Real-Time Proc	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval to modify the Loctite adhesive material used in the manufacture of the MetriQ Irrigation Tubing Set.
P150011/S013	10/16/2020	N - Normal 180 Day	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for a new Perceval device model, the Perceval PLUS Sutureless Heart Valve, including a modification to the bovine pericardial tissue chemical treatment process and a reduction of the inflow ring height for the size XL valve.
P150012/S099	10/22/2020	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for software changes included in LATITUDE NXT Patient Management System Release 7.0.
P150012/S100	10/16/2020	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval to allow an additional mold release/de-nest agent to be applied to the polyethylene terephthalate glycol (PETG) sheets used to form sterile packaging.
P150014/S039	10/07/2020	S - Special CBE	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for changes being effected to update hazard labeling.

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P150015/S041	10/07/2020	S - Special CBE	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for changes being effected to update hazard labeling.
P150039/S005	10/04/2020	O - Normal 180 Day	TRYTON SIDE BRANCH STENT	POSEIDON MEDICAL INC.	Approval for early termination of enrollment for the post-approval study (PAS) protocol.
P160017/S087	10/09/2020	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for a design change to the keypad assembly of the Next Generation Pump (NGP), a component of the MiniMed 630G System with SmartGuard and the MiniMed 670G System.
P160019/S011	10/19/2020	N - Normal 180 Day	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for 1) the Elecsys HBsAg II Auto Confirm: Immunoassay for in vitro qualitative confirmation of the presence of hepatitis B surface antigen in human serum and plasma (sodium heparin, lithium heparin, K2-EDTA, sodium citrate) samples repeatedly reactive when tested with the Elecsys HBsAg II assay. The electrochemiluminescence immunoassay ECLIA is intended for use on cobas e immunoassay analyzers; 2) the PreciControl HBsAg Auto Confirm: PreciControl HBsAg Auto Confirm is used for quality control of the Elecsys HBsAg II Auto Confirm Immunoassay on the cobas e 801 immunoassay analyzer; and 3) the PreciControl HBsAg II: PreciControl HBsAg II is used for quality control of the Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm immunoassays on the cobas e immunoassay analyzers. The performance of PreciControl HBsAg II has not been established with any other HBsAg assay.
P160032/S008	10/16/2020	R - Real-Time Proc	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Approval for circuit board design changes necessary to replace obsolete flash components in Defibtech DDU-100 series Automated External Defibrillator (AED) Systems
P160032/S009	10/23/2020	R - Real-Time Proc	LIFELINE/REVIVER DDU-100, LIFELINE/ REVIVER AUTO DDU-120, LIFELINE/REVIVER VIEW DDU-2300, LIFELINE/ REVIVER VIEW AUTO DDU-2200, LIFELINE/ REVIVER ECG DDU-2450, AND LIFELINE/REVIVER ECG+ DDU-2475 AUTOMATED EXTERNAL DEFIBRILLATORS	DEFIBTECH, LLC	Approval for software updates to the self-test features for the DDU-100 series AEDs.
P160041/S031	10/07/2020	S - Special CBE	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Approval for changes being effected to update hazard labeling.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160042/S012	10/13/2020	R - Real-Time Proc	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval to change the shelf-life from 18 months to 24 months for Revanesse Versa+
P160043/S037	10/05/2020	O - Normal 180 Day	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for a site change for packaging and labeling rework processes.
P160045/S021	10/23/2020	R - Real-Time Proc	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Approval for the expansion of shelf-life claim of the Oncomine Dx Target Test (ODxT Test) from 9 to 23 months.
P160054/S032	10/20/2020	R - Real-Time Proc	HEARTMATE 3¿ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for the Controller Main Application software upgrade from version 1.6 to version 1.7.
P170006/S018	10/22/2020	R - Real-Time Proc	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Approval for an updated protocol and additional testing performed for shelf-life extension.
P170007/S006	10/08/2020	R - Real-Time Proc	DUROLANE	BIOVENTUS LLC	Approval for the removal of testing of heavy metals in raw materials for DUROLANE as per USP<231> and replacing it by a risk analysis on the final product based on ICH Q3D Guideline for Elemental Impurities.
P170019/S017	10/23/2020	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order to expand the intended use of FoundationOne®CDx (F1CDx) to include NTRK1/2/3 fusions in patients with solid tumors who may benefit from treatment with VITRAKVI® (larotrectinib).
P170019/S020	10/15/2020	R - Real-Time Proc	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for the deployment of an updated version of the F1CDx analysis pipeline (v. 3.4.5).
P170023/S003	10/22/2020	R - Real-Time Proc	BULKAMID URETHRAL BULKING SYSTEM	CONTURA INTERNATIONAL A/S	Approval for changes in the primary packaging of Bulkamid Urethral Bulking System (Bulkamid Rotatable Sheath), upgrade to the corresponding process equipment, and replacement of the pouch sealing machine
P170030/S011	10/30/2020	O - Normal 180 Day	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170036/S006	10/08/2020	O - Normal 180 Day	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Approval of the revised protocol for the post-approval study (PAS) protocol.
P170042/S005	10/07/2020	O - Normal 180 Day	COVERA¿ VASCULAR COVERED STENT	C.R. BARD, INC	Approval for an update to the labeling to include the 24-month data on patients enrolled in the AVeVA clinical study.
P180002/S015	10/06/2020	Y - 135 Review Tra	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval for a manufacturing change with the existing approved supplier Confluent Medical (Fremont, CA) for the nitinol retainer component of the Zephyr 4.0 EBV.
P180014/S005	10/23/2020	O - Normal 180 Day	XPS¿ WITH STEEN SOLUTION¿ PERFUSATE	XVIVO PERFUSION, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180046/S020	10/09/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to extent the current shelf life from 27 months to 36 months
P180047/S001	10/26/2020	Y - 135 Review Tra	LIAISON QUANTIFERON - TB GOLD PLUS, LIAISON CONTROL QUANTIFERON - TB GOLD PLUS AND LIAISON QUANTIFERON SOFTWARE	DIASORIN, INC.	Approval for change in supplier of reagent components.
P190006/S020	10/09/2020	R - Real-Time Proc	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Approval to extent the current shelf life from 27 months to 36 months
P190015/S003	10/30/2020	O - Normal 180 Day	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Approval of the statistical analysis plan for the post-approval study (PAS) protocol.
P190028/S003	10/07/2020	S - Special CBE	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Approval for changes being effected to update hazard labeling.

Total: 97

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Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S256	10/01/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Relocate several manufacturing steps for Tachy, Brady, and S-ICD's.
N970003/S257	10/22/2020	X - 30-Day Notice	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Change the inspection criteria, cycle duration, brush life, and gowning requirements for the automated de-burring process of pulse generator case halves.
N970012/S183	10/30/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Modification to the manufacturing process for the outer and inner Tyvek packaging pre-printed tray lids components.
P810025/S040	10/01/2020	X - 30-Day Notice	AMVISC(R)	BAUSCH & LOMB, INC.	Removal of an in-process raw material quality control test affecting the sodium hyaluronate (NaHy) raw material for the Amvisc and Amvisc Plus Ophthalmic Viscosurgical Devices (OVDs) and change the release specification criteria for Amvisc and Amvisc Plus OVDs.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P820033/S013	10/22/2020	X - 30-Day Notice	PLASMAFLO OP-05 W(A) ASAHI PLASMA SEPARATOR	ASAHI KASEI MEDICAL CO., LTD.	Change in the sterilization bag supplier for the Plasmaflo OP-05W(A).
P830061/S185	10/15/2020	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer chemical and mechanical testing activities to the MPROC Juncos facility.
P840001/S470	10/01/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Relocation of Innovizes sheet-converting manufacturing area from 500 Oak Grove Parkway to 450 Oak Grove Parkway.
P840064/S073	10/23/2020	X - 30-Day Notice	VISCOAT(TM)/DVOVISC/ DISCOVISC OPHTHALMIC VISCOSURGICAL DEVICES	ALCON LABORATORIES	Alternate release testing site for raw materials and primary packaging components in the production of VISCOAT, PROVISC, DUOVISC, and DISCOVISC.
P880086/S314	10/29/2020	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Alternate supplier of the ceramic capacitor component.
P880086/S315	10/26/2020	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P890003/S435	10/15/2020	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Transfer chemical and mechanical testing activities to the MPROC Juncos facility.
P890023/S047	10/16/2020	X - 30-Day Notice	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	Addition of Biomedics Toric lens capability to the LVA3 manufacturing cell.
P890047/S056	10/23/2020	X - 30-Day Notice	PROVISC(TM) VISCOELASTIC PREPARATION	ALCON RESEARCH, LTD.	Alternate release testing site for raw materials and primary packaging components in the production of VISCOAT, PROVISC, DUOVISC, and DISCOVISC.
P900033/S090	10/13/2020	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Modification of steam sterilization load patterns for the Getinge Autoclave at the Integra Life Sciences facility in Plainsboro, New Jersey.
P910023/S433	10/26/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P920015/S246	10/15/2020	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Transfer chemical and mechanical testing activities to the MPROC Juncos facility.
P920048/S018	10/02/2020	X - 30-Day Notice	FETAL FIBRONECTIN ENZYME IMMUNOASSAY KIT (EIK)	HOLOGIC, INC.	Addition of a manufacturing site at 10210 Genetic Center Dr., San Diego, CA 92121 (GCD) for the manufacture of critical components, proteins and protein conjugates, of the Rapid fFN cassette for theTLiIQ System.
P930014/S133	10/02/2020	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Adding an alternate supplier for the blue tinted fiber strands which the Alcon Huntington (Alcon HWV) manufacturing site will further process into individual haptics for AcrySof® and AcrySof® ReSTOR® multi-piece intraocular lenses (IOLs).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930039/S215	10/15/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Transfer chemical and mechanical testing activities to the MPROC Juncos facility.
P930039/S216	10/26/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Updates to the cell operating system transformation of screw-in distal assembly manufacturing process.
P950021/S023	10/27/2020	X - 30-Day Notice	ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Implementation of medical decision pools for use in the control system.
P950022/S136	10/26/2020	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P950029/S128	10/20/2020	X - 30-Day Notice	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Alternate equipment to be used for microelectronic and Surface Mount Technology assembly.
P960009/S384	10/01/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Relocation of Innovizes sheet-converting manufacturing area from 500 Oak Grove Parkway to 450 Oak Grove Parkway.
P960013/S115	10/26/2020	X - 30-Day Notice	TENDRIL DX MODEL 1388T & 1388K ENDOCARDIAL PACING LEADS	ST JUDE MEDICAL	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P960016/S085	10/16/2020	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Alternative batch sampling for bacterial endotoxin testing.
P960030/S071	10/26/2020	X - 30-Day Notice	PASSIVE PLUS DX ENDOCARDIAL STEROID ELUTING, PASSIVE-FIXATION PACING LEADS	ST. JUDE MEDICAL	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P960040/S454	10/01/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Relocate several manufacturing steps for Tachy, Brady, and S-ICD's.
P960040/S455	10/22/2020	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Change the inspection criteria, cycle duration, brush life, and gowning requirements for the automated de-burring process of pulse generator case halves.
P960043/S109	10/01/2020	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Automation of an existing manual inspection process through the introduction of alternate automated test equipment for the subject device.
P970004/S316	10/01/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Relocation of Innovizes sheet-converting manufacturing area from 500 Oak Grove Parkway to 450 Oak Grove Parkway.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970013/S084	10/26/2020	X - 30-Day Notice	MICRONY PACEMAKERS	ST. JUDE MEDICAL, INC.	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P980016/S756	10/22/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Replace the cleaning agent used at Medtronic Swiss Manufacturing Operations.
P980035/S643	10/06/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of manufacturing changes to the parylene coating process associated with the backfill hole weld process.
P980035/S644	10/09/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of a dadet minimum height visual inspection.
P980035/S645	10/13/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement a battery height weld inspection.
P980035/S646	10/13/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement modifications of controls in the process of wire routing in the connector channels.
P980035/S647	10/07/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Manufacturing changes regarding the resistive spot welding process used for the backfill hole weld process.
P980035/S648	10/15/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implement a press tool for the medical adhesive application process.
P980035/S649	10/22/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Replace the cleaning agent used at Medtronic Swiss Manufacturing Operations.
P980035/S650	10/26/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Updates to the distribution control sorter tool for select implantable devices.
P980035/S651	10/28/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Add an alternate supplier for the cathode current collector component used in the manufacture of batteries and establish associated incoming inspection procedures.

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P980035/S652	10/08/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of battery height weld inspection.
P980035/S654	10/20/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of modifications of select manufacturing processes.
P980035/S656	10/21/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Change in the inner seal concentricity inspection.
P980035/S657	10/28/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes in the resistance spot weld inspection.
P980037/S082	10/29/2020	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Change in endotoxin sampling plan.
P980049/S140	10/20/2020	X - 30-Day Notice	DEFENDER II MODEL 9201 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	MICROPORT CRM USA INC.	Alternate equipment to be used for microelectronic and Surface Mount Technology assembly.
P990071/S045	10/01/2020	X - 30-Day Notice	STOCKERT 70 RADIOFREQUENCY ABLATION GENERATOR	BIOSENSE WEBSTER, INC.	Update the parameters of an in-process quality control leak test.
P990075/S047	10/27/2020	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Automate the reject system in the secondary packaging process.
P990075/S048	10/30/2020	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Change in manufacturing equipment and supplier location for molding components of the Dome Pack accessories that are provided with the Spectrum® Saline-Filled Breast Implants.
P000006/S057	10/01/2020	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Adding an additional Rotate and Dip (RAD) machine.
P000014/S036	10/22/2020	X - 30-Day Notice	VITROS IMMUNODIAGNOSTIC PRODUCTS:ANTI-HBS REAGENT PACK/ANTI-HBS CALIBRATORS	ORTHO-CLINICAL DIAGNOSTICS , INC.	Amendment of the assay specific release for sale limits and customer calibration limits used with Immunodiagnostic Products, VITROS Anti-HBs reagent pack and calibrators.
P000021/S043	10/13/2020	X - 30-Day Notice	DIMENSION(R) RXL PSA FLEX(R) REAGENT CARTRIDGE	SIEMENS HEALTHCARE DIAGNOSTICS	Qualification of a new supplier for the luminescent oxygen channeling immunoassay reaction vessel used on the Dimension Vista instrument
P000025/S119	10/21/2020	X - 30-Day Notice	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Introduction of two additional new sterilization chambers at the contract sterilizer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000053/S117	10/30/2020	X - 30-Day Notice	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Modification to the manufacturing process for the outer and inner Tyvek packaging pre-printed tray lids components.
P010012/S523	10/01/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Relocate several manufacturing steps for Tachy, Brady, and S-ICD's.
P010012/S524	10/22/2020	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Change the inspection criteria, cycle duration, brush life, and gowning requirements for the automated de-burring process of pulse generator case halves.
P010013/S079	10/19/2020	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Add an additional supplier of deionized water used in the manufacture of the Novosure device.
P010013/S080	10/27/2020	X - 30-Day Notice	NOVASURE IMPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM	HOLOGIC, INC.	Change in supplier of the cervical seal components of the Novosure Gen 3 disposable device.
P010015/S451	10/09/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of a dadet minimum height visual inspection.
P010015/S452	10/22/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Replace the cleaning agent used at Medtronic Swiss Manufacturing Operations.
P010015/S453	10/28/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Add an alternate supplier for the cathode current collector component used in the manufacture of batteries and establish associated incoming inspection procedures.
P010023/S014	10/28/2020	X - 30-Day Notice	SOUNDTEC DIRECT SYSTEM	OTOTRONIX, LLC	Ethylene oxide (EO) sterilization process change for the implantable Magnet Canister Assembly.
P010031/S717	10/22/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Replace the cleaning agent used at Medtronic Swiss Manufacturing Operations.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020027/S038	10/13/2020	X - 30-Day Notice	DIMENSION FPSA FLEX REAGENT CARTRIDGE AND DIMENSION T/F PSA CALIBRATOR FOR DIMENSION RXL AND XPAND SYSTEMS	SIEMENS HEALTHCARE DIAGNOSTICS	Qualification of a new supplier for the luminescent oxygen channeling immunoassay reaction vessel used on the Dimension Vista instrument
P020036/S043	10/23/2020	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Replace a supplier's winding equipment used to manufacture a component of the delivery system.
P030005/S202	10/01/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Relocate several manufacturing steps for Tachy, Brady, and S-ICD's.
P030005/S203	10/22/2020	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Change the inspection criteria, cycle duration, brush life, and gowning requirements for the automated de-burring process of pulse generator case halves.
P030009/S098	10/30/2020	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Changes to the acceptance criteria for the temperature probes during product parameter profile studies conducted during requalification of the sterilization cycle.
P030011/S079	10/28/2020	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Supplier change of Freedom Driver injection molded parts.
P030035/S182	10/26/2020	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P030036/S123	10/15/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Transfer chemical and mechanical testing activities to the MPROC Juncos facility.
P030053/S055	10/27/2020	X - 30-Day Notice	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Automate the reject system in the secondary packaging process.
P030054/S386	10/26/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P040012/S060	10/06/2020	X - 30-Day Notice	ACCULINK CAROTID STENT SYSTEM AND RX ACCULINK CAROTID STENT SYSTEM	ABBOTT VASCULAR	New suppliers of injection molded components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040014/S041	10/16/2020	X - 30-Day Notice	IBI THERAPY CARDIAC ABLATION SYSTEM ERS/ 1500T RF GENERATOR	IRVINE BIOMEDICAL, INC.	Alternative batch sampling for bacterial endotoxin testing.
P040020/S096	10/02/2020	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Adding an alternate supplier for the blue tinted fiber strands which the Alcon Huntington (Alcon HWV) manufacturing site will further process into individual haptics for AcrySof® and AcrySof® ReSTOR® multi-piece intraocular lenses (IOLs).
P040021/S044	10/14/2020	X - 30-Day Notice	SJM BIOCOR VALVE / SJM BIOCOR SUPRA VALVE	ST. JUDE MEDICAL, INC.	Addition of a new tissue supplier.
P040024/S120	10/14/2020	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Changes to the distribution systems for water for injection (WFI) and compressed air distribution systems at the Uppsala, Sweden manufacturing facility for Restylane, Perlane, Restylane L, Restylane Lyft with Lidocaine and Restylane Silk.
P040037/S140	10/13/2020	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Change to heparin activity lot release acceptance criteria.
P040042/S047	10/16/2020	X - 30-Day Notice	THERAPY DUAL 8 CARDIAC ABLATION SYSTEM,THERAM 8MM THERMISTER ABLATION CATHETER SAFIRE TX ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Alternative batch sampling for bacterial endotoxin testing.
P040047/S061	10/15/2020	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Adding Merz North America as an alternate facility to perform microbial analysis of water in the microbiology laboratory at manufacturing sites of COAPTITE, RADIESSE, and RADIESSE (+) Lidocaine.
P040047/S062	10/14/2020	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Qualify the Keyence Image Dimension Measurement System for inspection of up to thirty-six (36) syringe plunger end caps simultaneously.
P040047/S063	10/23/2020	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Permission for Merz NA to inspect incoming Glycerin raw material in-house in alignment with the USP-NF Glycerin Monograph used in COAPTITE, RADIESSE, and RADIESSE (+) products.
P050037/S107	10/15/2020	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Adding Merz North America as an alternate facility to perform microbial analysis of water in the microbiology laboratory at manufacturing sites of COAPTITE, RADIESSE, and RADIESSE (+) Lidocaine.
P050037/S108	10/14/2020	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Qualify the Keyence Image Dimension Measurement System for inspection of up to thirty-six (36) syringe plunger end caps simultaneously.
P050037/S109	10/23/2020	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Permission for Merz NA to inspect incoming Glycerin raw material in-house in alignment with the USP-NF Glycerin Monograph used in COAPTITE, RADIESSE, and RADIESSE (+) products.
P050047/S078	10/28/2020	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Change to the cleaning method of process equipment used during the manufacturing of Juvéderm injectable gel products.
P050052/S125	10/15/2020	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Adding Merz North America as an alternate facility to perform microbial analysis of water in the microbiology laboratory at manufacturing sites of COAPTITE, RADIESSE, and RADIESSE (+) Lidocaine.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050052/S126	10/14/2020	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Qualify the Keyence Image Dimension Measurement System for inspection of up to thirty-six (36) syringe plunger end caps simultaneously.
P050052/S127	10/23/2020	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Permission for Merz NA to inspect incoming Glycerin raw material in-house in alignment with the USP-NF Glycerin Monograph used in COAPTITE, RADIESSE, and RADIESSE (+) products.
P060019/S049	10/16/2020	X - 30-Day Notice	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Alternative batch sampling for bacterial endotoxin testing.
P060027/S104	10/20/2020	X - 30-Day Notice	OVATIO CRT SYSTEM	MICROPORT CRM USA INC.	Alternate equipment to be used for microelectronic and Surface Mount Technology assembly.
P060028/S036	10/27/2020	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Automate the reject system in the secondary packaging process.
P060040/S078	10/27/2020	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Add an alternative second tier supplier of a component used to manufacture the Sealed Inflow Graft of the HeartMate II Left Ventricular Assist Device.
P070026/S076	10/05/2020	X - 30-Day Notice	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Updates to the chemical monitoring requirements of their porous coating vacuum furnace heat treatment for the Pinnacle Acetabular Shell and Summit Porous Femoral Stems.
P080004/S037	10/13/2020	X - 30-Day Notice	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Manufacturing process change to the buttons used for Hoya's AF-1 family of intraocular lenses.
P080011/S117	10/05/2020	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION, INC.	Manufacture of Biofinity Toric Lenses on Biofinity Line 16.
P080025/S211	10/01/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Relocation of Innovize¿s sheet-converting manufacturing area from 500 Oak Grove Parkway to 450 Oak Grove Parkway.
P080027/S037	10/16/2020	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Implementation of two incoming inspection test methods.
P090013/S309	10/15/2020	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Transfer chemical and mechanical testing activities to the MPROC Juncos facility.
P090015/S012	10/20/2020	X - 30-Day Notice	BOND ORACLE HER2 IHC SYSTEM	LEICA BIOSYSTEMS	Addition of a reagent supplier.
P090016/S043	10/29/2020	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Addition of a camera system to the carton packaging line and the change to the tamper evident seal of the carton packaging.
P090022/S036	10/15/2020	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Different source of polypropylene for HEMA IOLs delivery system.
P090022/S037	10/23/2020	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Qualifying the addition of a prewash step to the manufacturing process for vials used to package its intraocular lenses (IOLs).

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P100021/S084	10/15/2020	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Restart commercial sterilization activities at an existing alternate sterilization site, to add an alternate packaging supplier, and to update the E-Beam sterilization process dose range.
P100021/S085	10/30/2020	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Changes to the acceptance criteria for the temperature probes during product parameter profile studies conducted during requalification of the sterilization cycle.
P100029/S043	10/14/2020	X - 30-Day Notice	ST JUDE MEDICAL TRIFECTA VALVE	ST. JUDE MEDICAL, INC.	Addition of a new tissue supplier.
P100047/S172	10/06/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Implement component changes for obsolete components of the HeartWare Ventricular Assist Device (HVAD) Power Adapters.
P110005/S005	10/08/2020	X - 30-Day Notice	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Change to the bacterial endotoxins (BE) test method used for the device components.
P110005/S006	10/08/2020	X - 30-Day Notice	SINOVIAL (SODIUM HYALURONATE 0.8%)	IBSA INSTITUT BIOCHIMIQUE SA	Change to the bacterial endotoxins (BE) acceptance limit for the glass syringe associated with change in BE test method.
P110010/S182	10/13/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Additional of two UV Bonders to the catheter manufacturing lines.
P110016/S071	10/16/2020	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Alternative batch sampling for bacterial endotoxin testing.
P110033/S056	10/28/2020	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Change to the cleaning method of process equipment used during the manufacturing of Juvéderm injectable gel products.
P110042/S146	10/01/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Relocate several manufacturing steps for Tachy, Brady, and S-ICD's.
P120002/S018	10/23/2020	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS CORP.	Replace a supplier's winding equipment used to manufacture a component of the delivery system.
P130006/S079	10/13/2020	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Change to heparin activity lot release acceptance criteria.

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P130008/S062	10/14/2020	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Changes to the insulation tape application process in the coil of the Model 2500 Patient Sleep Remote
P130017/S043	10/07/2020	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Manufacturing Changes to Tube Assembly
P130017/S044	10/20/2020	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Transfer of Test Methods to new manufacturing site.
P130021/S081	10/30/2020	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Changes to the acceptance criteria for the temperature probes during product parameter profile studies conducted during requalification of the sterilization cycle.
P130026/S065	10/16/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Alternative batch sampling for bacterial endotoxin testing.
P140010/S052	10/14/2020	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Cleanroom area reduction at the manufacturing site.
P140029/S030	10/14/2020	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Changes to the distribution systems for water for injection (WFI) and compressed air distribution systems at the Uppsala, Sweden manufacturing facility for Restylane Refyne, Restylane Defyne and Restylane Kysse.
P140031/S120	10/05/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Implementation of a new inspection and a new cutting fixture related to the Commander Delivery System valve crimp section.
P140033/S061	10/29/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Alternate supplier of the ceramic capacitor component.
P140033/S063	10/26/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Adjust the minimum relative humidity from 40% to 35% in the product packaging area.
P150003/S065	10/13/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Additional of two UV Bonders to the catheter manufacturing lines.

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P150012/S101	10/01/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Relocate several manufacturing steps for Tachy, Brady, and S-ICD's.
P150012/S102	10/22/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Change the inspection criteria, cycle duration, brush life, and gowning requirements for the automated de-burring process of pulse generator case halves.
P150033/S086	10/22/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Replace the cleaning agent used at Medtronic Swiss Manufacturing Operations.
P150040/S006	10/07/2020	X - 30-Day Notice	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Additional supplier for the Treatment Pack contact glass lens.
P150048/S049	10/28/2020	X - 30-Day Notice	EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (MODEL 11000A) AND EDWARDS INSPIRIS RESILIA AORTIC VALVE (MODEL 11500)	EDWARDS LIFESCIENCES, LLC.	Implementation of a sampling plan in place of 100% dimensional inspection of the INSPIRIS wireform cover cloth.
P160008/S014	10/22/2020	X - 30-Day Notice	HEARTSINE TECHNOLOGIES LLC'S SAMARITAN PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATORS (SAM 350P, SAM 360P AND SAM 450P) AND ACCESSORIES	HEARTSINE TECHNOLOGIES, LTD.	Modifications to the soldering method used for seven (7) specific plated through-hole (PTH) components from selective soldering to manual soldering and adding manual cleaning of the test point pads of the printed circuit board assembly (PCBA).
P160015/S006	10/07/2020	X - 30-Day Notice	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Auto Configuration Software Tool to automate a manual configuration process for the ZOLL AED Plus.
P160024/S010	10/28/2020	X - 30-Day Notice	LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT	BARD PERIPHERAL VASCULAR, INC.	Changes to lot release destructive testing.
P160035/S017	10/23/2020	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Extension of EXCOR blood pumps manufacturing area.
P160035/S018	10/27/2020	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Change the end of life and maintenance schedule of the manual air pump provided with each Ikus driving unit.
P160037/S009	10/13/2020	X - 30-Day Notice	BD ONCLARITY HPV ASSAY	BECTON, DICKINSON AND COMPANY	Manufacturing process scale-up.

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P160045/S022	10/08/2020	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Removal of the Quality Control specification for an unreported variant.
P160047/S014	10/20/2020	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Changes in manufacturing to reduce the amount of copper on the printed circuit board assembly (PCBA). These include a reduction in the amount of copper around the solder hole for the ground pin of the PCBA-mounted pressure sensor and around non-plater thru holes (NPTH).
P160047/S015	10/20/2020	X - 30-Day Notice	AEGEA VAPOR SYSTEM, AEGEA VAPOR PROBE PROCEDURE KIT, AEGEA VAPOR GENERATOR AND AEGEA VAPOR GENERATOR ACCESSORY KIT	AEGEA MEDICAL , INC	Use of a new coil bender tool during manufacturing to standardize the bend radius of the coil inlet tube for connection to the saline supply tube.
P170007/S008	10/21/2020	X - 30-Day Notice	DUROLANE	BIOVENTUS LLC	Changes to the Water for Injection (WFI) and compressed air systems used in manufacture of DUROLANE.
P170018/S009	10/07/2020	X - 30-Day Notice	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Changes to the Initial Software Load (ISL) and Final Configuration (FC) manufacturing test system software used in the manufacture of the LIFEPAK CR2 Automated External Defibrillator.
P170018/S010	10/04/2020	X - 30-Day Notice	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Replace machine vision equipment used in manufacturing the LIFEPAK CR2 Automated External Defibrillator.
P170018/S011	10/22/2020	X - 30-Day Notice	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Change in the LIFEPAK CR2 lid supplier's injection molding equipment in order to manufacture lids that meet a tightened dimensional tolerance.
P170030/S010	10/21/2020	X - 30-Day Notice	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Changes to the sirolimus impurities and chloroform residual testing methods.
P170035/S010	10/19/2020	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Implementation of a new power measurement method on the Spin-Blot System for Bausch + Lomb Ultra (samfilcon A) Visibility Tinted Soft Contact Lenses for astigmatism vision correction.
P170036/S007	10/14/2020	X - 30-Day Notice	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Add a new Cervical Flexural Resistance (CER-FR) tester.
P170042/S008	10/01/2020	X - 30-Day Notice	COVERA¿ VASCULAR COVERED STENT	C.R. BARD, INC	Implementation of a reduction in the inner diameter of a distal cap of a delivery system joint of the Covera Vascular Covered Stent.
P180002/S016	10/30/2020	X - 30-Day Notice	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Modify the manufacturing process of laminating the inner shaft for Endobronchial Delivery Catheters (EDCs).

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P180029/S027	10/07/2020	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modifications to acceptance criteria for visual inspection of the Multi-Lumen Extrusion (MLE) component of the LOTUS Edge delivery system.
P180037/S004	10/01/2020	X - 30-Day Notice	VENOVO VENOUS STENT SYSTEM	BARD PERIPHERAL VASCULAR, INC.	New equipment for the stent sheath stretching process.
P190008/S006	10/14/2020	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Cleanroom area reduction at the manufacturing site.
P190015/S005	10/16/2020	X - 30-Day Notice	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Implementation of updates to the manufacturing process for the TREO delivery system.
P190015/S006	10/30/2020	X - 30-Day Notice	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Use an alternative sterilization load configuration for the TREO Abdominal Stent-Graft System.

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