PMA Monthly approvals from 2/1/2020 to 2/29/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P170022	02/18/2020	PMAO - PMA Origi	PYLOPLUS UBT SYSTEM	ARJ MEDICAL INC.	Approval of the PyloPlus UBT. The PyloPlus UBT system is intended for use in the qualitative detection of urease associated with H. pylori in the human stomach and is indicated as an aid in the initial diagnosis of H. pylori infection in adults 18 years old and older. The PyloPlus UBT system consists of the PyloPlus UBT Kit and the PyloPlus UBT analyzer. The analyzer is an infrared Spectrometer used for the measurement of the ratio of 13CO2 to 12CO2 in breath samples. The PyloPlus UBT system is for use by trained health care professionals as prescribed by a physician.
P180039	02/21/2020	PMAO - PMA Origi	LIAISON® XL MUREX ANTI-HBS, LIAISON® XL MUREX CONTROL ANTI-HBS AND LIAISON® XL MUREX ANTI-HBS VERIFIERS	DIASORIN INC.	Approval for the LIAISON XL MUREX Anti-HBs. The device is an in vitro chemiluminescent immunoassay (CLIA) for the qualitative and quantitative determination of antibody to hepatitis B surface antigen (anti-HBs) in human adult and pediatric (2 ¿ 21 years) serum and plasma (lithium and sodium heparin and K2 EDTA) including separator tubes, on the LIAISON XL Analyzer. Assay results in conjunction with other hepatitis B virus (HBV) serological markers and clinical information may be used as an aid in the diagnosis of HBV infection in patients with symptoms of hepatitis or who may be at risk for HBV infection. The assay results may be used as an aid in the determination of susceptibility to HBV infection in individuals prior to or following HBV vaccination or where vaccination status is unknown. The assay is not approved for use in screening blood, plasma or tissue donors. The LIAISON XL MUREX Control Anti-HBs (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON XL MUREX Anti-HBs assay. The performance characteristics of LIAISON XL MUREX Control Anti-HBs have not been established for any other assays or instrument platforms. The LIAISON XL MUREX Anti-HBs Verifiers (level 1, 2, 3, and level 4) are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON XL MUREX Anti-HBs assay. The performance characteristics of LIAISON XL MUREX Anti-HBs Verifiers have not been established in connection with any other assay or instrument platforms.

Total: 2

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S163	02/13/2020	R - Real-Time Proc	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Approval for the use of an improved UPLC method for release and stability, minor updates to microbial Zone of Inhibition method and other associated updates to the Sub System and System level Product Specifications for the AMS 700 Inflatable Penile Prosthesis with InhibiZone and AMS 800 Artificial Urinary Sphincter with InhibiZone Treatment to bring to current standards.
P800036/S041	02/07/2020	O - Normal 180 Day	INFUSAID IMPLANTABLE INFUSION PUMP MODEL-100,200,4	INTERA ONCOLOGY	Approval for a manufacturing site located at Intera Oncology, Inc., 65 William Street, Suite 200, Wellesley, Massachusetts, to conduct quality system activities.
P850064/S040	02/14/2020	Y - 135 Review Tra	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL, INC.	Approval for changes in servicing of the LifePulse HFV model 204 (HFV 204) and Patient Box model 314 (Patient Box 314).
P860004/S346	02/03/2020	R - Real-Time Proc	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for update to the Model A810 SynchroMed II Clinician Programmer handling of the corrupted CRC calculation for certain memory locations and additional minor software changes to bring the device back into specifications for known anomalies.
P890055/S073	02/07/2020	O - Normal 180 Day	MEDSTREAM PROGRAMMABLE INFUSION PUMP SYSTEM	INTERA ONCOLOGY	Approval for a manufacturing site located at Intera Oncology, Inc., 65 William Street, Suite 200, Wellesley, Massachusetts, to conduct quality system activities.

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P930014/S126	02/26/2020	P - Panel Track	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	The AcrySof IQ Vivity Extended Vision IOL Model DFT015 is indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof IQ Vivity IOL is intended for capsular bag placement only. The AcrySof IQ Vivity Toric Extended Vision IOL Models DFT315, DFT415, and DFT515 are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lenses provide improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof IQ Vivity Toric IOLs are intended for capsular bag placement only. The AcrySof IQ Vivity Extended Vision UV Absorbing IOL Model DAT015 is indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof IQ Vivity UV Absorbing IOL is intended for capsular bag placement only. The AcrySof IQ Vivity Toric Extended Vision UV Absorbing IOL Models DAT315, DAT415, and DAT515 are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof IQ Vivity Toric UV Absorbing IOLs are intended for capsular bag placement only.
P930016/S061	02/14/2020	R - Real-Time Proc	VISX EXCIMER LASER SYSTEM MODELS "B" AND "C"	AMO MANUFACTURING USA, LLC	Approval for a replacement of a Super Luminescent Diode (SLD) used in the iDESIGN Refractive Studio as a replacement for an SLD that is now obsolete.
P970004/S292	02/19/2020	N - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for the implementation of new components and kit configurations.
P970051/S191	02/14/2020	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new implant of Nucleus Cochlear CI600 Series Implants, the CI624 Implant.
P970051/S195	02/21/2020	S - Special CBE	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for changes to MR Conditional labeling for CI24REH, CI24RE and CI500 Series Cochlear Implants.
P980040/S107	02/28/2020	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval of the TECNIS Multifocal Toric II IOLs, Models ZKU150, ZKU225, ZKU300, ZKU375 and ZLU150, ZLU225, ZLU300, ZLU375.

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P000053/S104	02/13/2020	R - Real-Time Proc	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the use of an improved UPLC method for release and stability, minor updates to microbial Zone of Inhibition method and other associated updates to the Sub System and System level Product Specifications for the AMS 700 Inflatable Penile Prosthesis with InhibiZone and AMS 800 Artificial Urinary Sphincter with InhibiZone Treatment to bring to current standards.
P000054/S054	02/04/2020	Y - 135 Review Tra	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for introduction of additional cell lines and the use of related raw materials into Pfizers Andover, Massachusetts facility.
P000058/S073	02/04/2020	Y - 135 Review Tra	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for introduction of additional cell lines and the use of related raw materials into Pfizers Andover, Massachusetts facility.
P020004/S166	02/05/2020	N - Normal 180 Day	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for use of an alternate deployment fiber with the Gore EXCLUDER Low-Profile Aortic Extender device component.
P040027/S074	02/28/2020	O - Normal 180 Day	GORE VIATORR TIPS	W. L. GORE & ASSOCIATES, INC.	Approval of a new ethylene oxide sterilization cycle to pe performed at a new sterilization site (Sterigenics US, LLC located at 4900 Gifford Ave. Los Angeles, CA).
P040037/S134	02/28/2020	O - Normal 180 Day	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval of a new ethylene oxide sterilization cycle to pe performed at a new sterilization site (Sterigenics US, LLC located at 4900 Gifford Ave. Los Angeles, CA).
P050053/S045	02/05/2020	Y - 135 Review Tra	INFUSE BONE GRAFT	MEDTRONIC INC.	Approval for introduction of additional cell lines and the use of related raw materials into Pfizers Andover, Massachusetts facility.
P080025/S187	02/13/2020	N - Normal 180 Day	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for the implementation of new components and kit configurations.
P080028/S001	02/05/2020	N - Normal 180 Day	STORZ MEDICAL DUOLITH SD1 SHOCK WAVE THERAPY	STORZ MEDICAL AG	Approval for upgrading the power supply, controller, and Graphical User Interface software revision to accommodate new hardware, as well as the addition of an optional control module and ultrasound imaging unit/monitor.
P090016/S035	02/06/2020	Y - 135 Review Tra	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for qualification of an alternative supplier of needles (27G x 1/2", 30G x 1/2") and modification of associated secondary packaging components to accommodate the new needles.
P090016/S036	02/04/2020	R - Real-Time Proc	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for labeling updates to the package inserts and patient information guides for the Belotero Balance Dermal Filler and Belotero Balance (+) Lidocaine Dermal Filler.
P090018/S039	02/24/2020	O - Normal 180 Day	ESTEEM TOTALLY IMPLANTABLE HEARING SYSTEM	ENVOY MEDICAL CORPORATION	Approval of the following changes to the post-approval study (i.e., the New Enrollment 2 study, approved under P090018/S030) for the device: (a) use the evaluable bone conduction data at 1 month as a safety endpoint to measure cochlear stability collected from the 45 subjects used for the efficacy endpoints (SRT and WRS), and (b) supplement the AE safety endpoints (SAEs including facial paresis/paralysis at 1 month) with data from a retrospective review of charts from patients not participating in the post-approval study.
P100026/S069	02/20/2020	N - Normal 180 Day	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for the MRI Conditional labeling for the RNS system products.
P100044/S043	02/28/2020	O - Normal 180 Day	PROPEL	INTERSECT ENT	Approval for a manufacturing site located at Steri-Tek, Smart World LLC, dba Steri-Tek, 48225 Lakeview Blvd., Fremont, CA 94538, which performs sterilization.

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P100045/S041	02/05/2020	R - Real-Time Proc	CARDIOMEMS HF SYSTEM	ST. JUDE MEDICAL	Approval for software fixes and enhancements in the CardioMEMS Heart Failure System.
P110038/S021	02/13/2020	Y - 135 Review Tra	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval for added inspections and manufacturing process clarifications for the delivery system tip sub-assembly.
P130006/S073	02/28/2020	O - Normal 180 Day	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Approval of a new ethylene oxide sterilization cycle to pe performed at a new sterilization site (Sterigenics US, LLC located at 4900 Gifford Ave. Los Angeles, CA).
P130016/S043	02/21/2020	S - Special CBE	NUCLEUS HYBRID L24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for changes to MR Conditional labeling for CI24REH, CI24RE and CI500 Series Cochlear Implants.
P130028/S028	02/12/2020	Y - 135 Review Tra	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Approval for implementation of a modified reflow process to bond the polyurethane tip plug to the molded component of the distal end of the Algovita leads.
P140003/S059	02/18/2020	Y - 135 Review Tra	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Approval for the addition of a second supplier for the contamination sleeve component.
P140008/S016	02/13/2020	N - Normal 180 Day	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Approval for changes to the material of the sheath and fill tube device components, change in the suppliers of the fill tube device component, design changes to the sheath component of the device, removal of the guidewire component of the fill tube, change in the manufacturing process of the sheath component of the device, packaging changes, and labeling changes.
P140013/S011	02/12/2020	O - Normal 180 Day	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for a manufacturing site change to the new facility located at Minerva Surgical, 4255 Burton Drive, Santa Clara, California. The facility operations at this site involve the manufacturing of the Minerva Endometrial Ablation System Disposable Handpiece.
P150013/S018	02/27/2020	O - Normal 180 Day	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for labeling changes to include results from additional non-clinical studies. The device will be marketed under the trade name PD-L1 IHC 22C3 pharmDx and is indicated for the following: PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using monoclonal mouse anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), gastric or gastroesophageal junction (GEJ) adenocarcinoma, esophageal squamous cell carcinoma (ESCC), cervical cancer, urothelial carcinoma and head and neck squamous cell carcinoma (HNSCC) tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity. PD-L1 protein expression in gastric or GEJ adenocarcinoma, ESCC, cervical cancer, urothelial carcinoma and HNSCC is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100.

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					NSCLC TPS >= 1% PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with KEYTRUDA® (pembrolizumab).** Gastric or GEJ Adenocarcinoma CPS >= 1 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying gastric or GEJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab). ESCC CPS >= 10 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying ESCC patients for treatment with KEYTRUDA® (pembrolizumab). Cervical Cancer CPS >= 1 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying cervical cancer patients for treatment with KEYTRUDA® (pembrolizumab). Urothelial Carcinoma CPS >= 10 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying urothelial carcinoma patients for treatment with KEYTRUDA® (pembrolizumab). ** HNSCC CPS >= 1 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying HNSCC patients
P150017/S013	02/09/2020	O - Normal 180 Day	CARTIVA SYNTHETIC CARTILAGE IMPLANT (CARTIVA SCI)	CARTIVA, INC	Approval for a manufacturing site located at Steris (Synergy Health AST, LLC), 7225 North Noah Drive, Saxonburg, Pennsylvania, 16056-9704 for device sterilization.
P160001/S044	02/11/2020	R - Real-Time Proc	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for a modification to the software of the Obalon Navigation Console.
P160015/S001	02/28/2020	N - Normal 180 Day	AED PLUS AND FULLY AUTOMATIC AED PLUS	ZOLL MEDICAL CORPORATION	Approval for the AED 3 Defibrillator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160019/S010	02/27/2020	N - Normal 180 Day	ELECSYS HBSAG II/ ELECSYS HBSAG CONFIRMATORY TEST/ PRECICONTROL HBSAG II	ROCHE DIAGNOSTICS , INC.	Approval for (1) the inclusion of a biotin scavenger antibody in Reagent 2 of the test kit to increase the biotin tolerance of the assay and (2) the proposed labeling changes for Elecsys HBsAg II and Elecsys HBsAg Confirmatory Test.
P160021/S024	02/28/2020	O - Normal 180 Day	GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Approval of a new ethylene oxide sterilization cycle to pe performed at a new sterilization site (Sterigenics US, LLC located at 4900 Gifford Ave. Los Angeles, CA).
P160026/S012	02/21/2020	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for minor design changes associated with the LIFEPAK 15 monitor/defibrillator. The design changes to the Retaining Nut component and the Battery Pin component were made in order to prevent conditions of device shut down, and as part of Physio-Control¿s CAPA.
P160026/S014	02/13/2020	R - Real-Time Proc	LIFEPAK 1000 DEFIBRILLATOR, LIFEPAK 20 DEFIBRILLATOR/ MONITOR, LIFEPAK 20E DEFIBRILLATOR/ MONITOR, LIFEPAK 15 MONITOR/DEFIBRILLATOR, LIFEPAK 12 DEFIBRILLATOR/ MONITOR	PHYSIO-CONTROL. INC.	Approval for a minor design change for the keypad assembly associated with the LIFEPAK 15 monitor/defibrillator
P160035/S008	02/20/2020	Y - 135 Review Tra	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for a change to implement and qualify a new supplier for the batteries in the IKUS Driving Unit.
P160043/S027	02/14/2020	O - Normal 180 Day	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for revisions to the labeling that incorporate the results of the RESOLUTE ONYX Core (2.25 mm - 4.0 mm) and REOSLUTE ONYX 2.00 mm Clinical Studies.
P170032/S003	02/07/2020	N - Normal 180 Day	WOVEN ENDOBRIDGE (WEB) ANEURYSM EMBOLIZATION SYSTEM	MICROVENTION, INC.	Approval for a new WEB Detachment Controller (WDC-2).
P180035/S001	02/05/2020	O - Normal 180 Day	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Approval for a repackaging/relabeling site located at CooperVision Manufacturing, Ltd., Mountpark, Unit 1, Wide Lane, Southampton, United Kingdom SO18 2NQ.
P180036/S004	02/28/2020	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for shelf life extension to 2 years.

Total: 46

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S034	02/27/2020	X - 30-Day Notice	GELFOAM	PFIZER, INC.	Implementation of the alternate bulk sterilization procedure for GEL-FLOW NT that is further processed into GEL-FLOW Kits and the addition of the protective laminate coating and update to the ribbon stock for the GEL-FLOW NT outer pouch label.
N970012/S174	02/21/2020	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Automated removal of reservoir shells from the mold in the liquid injection molding (LIM) manufacturing process and to update the process parameter settings for the reservoir component of the AMS 700 Inflatable Penile Prosthesis (IPP) with and without InhibiZone treatment.
P840001/S453	02/05/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Change in the destructive testing pull test sampling, sampling frequency, and tightening of the control limits established for the pull test monitoring.
P840001/S454	02/20/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Supplier manufacturing change that will move the laser ablation and marking equipment and process for lead wire components of Spinal Cord Stimulation leads, trialing leads, and extensions from the suppliers Montevideo, MN facility to the suppliers Reynosa, Mexico facility.
P870076/S024	02/12/2020	X - 30-Day Notice	FALOPE RING BAND AND APPLICATOR SYSTEMS	GYRUS ACMI, INC.	Qualification of a new supplier of the Trocar Knife (part number 004556-503) to assure that it will continue to meet the previously approved specifications for this component. The Trocar Knife is currently supplied by XL Precision and was proposed to be supplied by the new supplier RMS Surgical.
P880086/S312	02/28/2020	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Adopt sterilization recipe Cycle PG 600 for the Abbott Penang Malaysia manufacturing facility.
P890023/S042	02/14/2020	X - 30-Day Notice	H55 HYDROPHILIC CONTACT LENS	THE COOPER COMPANIES	Implementation of the manufacture of Biomedics 55 Asphere extended wear contact lenses with a base curve of 8.8 mm at the CooperVision facility located in Scottsville, New York.
P910023/S425	02/28/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Adopt sterilization recipe Cycle PG 600 for the Abbott Penang Malaysia manufacturing facility.
P920047/S120	02/07/2020	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of BSC Heredia as an alternate supplier for the steering control wire sub-assembly.
P920047/S121	02/19/2020	X - 30-Day Notice	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Updating weld process parameters to harmonize across multiple ablation catheter families.
P930039/S209	02/04/2020	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Modify the anchoring sleeve installation and verification process.
P950005/S073	02/26/2020	X - 30-Day Notice	WEBSTER DIAG./ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC	Line 13 transfer and addition of new Slim Line Dryer
P950020/S101	02/20/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Addition of a component manufacturing site.
P950020/S102	02/24/2020	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Addition of a component manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950022/S129	02/24/2020	X - 30-Day Notice	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Manufacturing process improvements for MCRD components in HV Active leads.
P960009/S368	02/05/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change in the destructive testing pull test sampling, sampling frequency, and tightening of the control limits established for the pull test monitoring.
P970004/S307	02/05/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change in the destructive testing pull test sampling, sampling frequency, and tightening of the control limits established for the pull test monitoring.
P970013/S083	02/28/2020	X - 30-Day Notice	MICRONY PACEMAKERS	ST. JUDE MEDICAL, INC.	Adopt sterilization recipe Cycle PG 600 for the Abbott Penang Malaysia manufacturing facility.
P990025/S058	02/26/2020	X - 30-Day Notice	NAVI-STAR DIAGNOSTIC/ ABLATION DEFLECTABLE TIP CATHETER	BIOSENSE WEBSTER, INC.	Line 13 transfer and addition of new Slim Line Dryer
P990064/S081	02/02/2020	X - 30-Day Notice	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Alternate manufacturing bioburden reduction process flow for the Mosaic Bioprosthesis.
P000029/S088	02/27/2020	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Use a resistometer in the D-value determination for Biological Indicators.
P010001/S021	02/04/2020	X - 30-Day Notice	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Updates to the drying and rinsing stations prior to visual inspection of parts for cracks.
P010068/S058	02/26/2020	X - 30-Day Notice	NAVISTAR/CELSIUS DS DIAGNOSTIC/ABLATION DEFLECTABLE 8MM TIP CATHETER	BIOSENSE WEBSTER, INC.	Line 13 transfer and addition of new Slim Line Dryer
P020011/S015	02/14/2020	X - 30-Day Notice	VERSANT HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Change the shipping container used to ship frozen product.
P020025/S124	02/07/2020	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Addition of BSC Heredia as an alternate supplier for the steering control wire sub-assembly.
P020025/S125	02/19/2020	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Updating weld process parameters to harmonize across multiple ablation catheter families.
P020045/S093	02/03/2020	X - 30-Day Notice	7F FREEZOR CARDIAC CRYOABLATION CATHETER AND CCT.2 CRYOCONSOLE SYSTEM	MEDTRONIC CRYOCATH LP	Use of Windows 10 operator system driver software.
P030004/S023	02/28/2020	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Add manufacturing equipment at a supplier site that provides a component for the proximal sub-assembly of the Apollo Onyx Delivery Micro Catheter.
P030031/S101	02/26/2020	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Line 13 transfer and addition of new Slim Line Dryer

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030035/S180	02/28/2020	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Adopt sterilization recipe Cycle PG 600 for the Abbott Penang Malaysia manufacturing facility.
P030036/S117	02/03/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the dispensing volume of Beclomethasone Dipropionate solution used in SelectSecure 3830 leads.
P030050/S030	02/27/2020	X - 30-Day Notice	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Change in the connection of the temperature probes with the electrical cabinets recording the temperature.
P030050/S031	02/28/2020	X - 30-Day Notice	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Change in the master protocol for requalification of the Cobalt-60 irradiation source used for gamma sterilization of PLLA and replacement of Cobalt-60 source and subsequent requalification performed in accordance with the revised protocol for Sculptra and Sculptra Aesthetic.
P030054/S376	02/28/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Adopt sterilization recipe Cycle PG 600 for the Abbott Penang Malaysia manufacturing facility.
P040024/S118	02/27/2020	X - 30-Day Notice	RESTYLANE INJECTABLE GEL	Q-MED AB	Replacement of a window/wall section with a new door in Q-Med's Facility Line 1 (L1) located in Building 3 at Seminariegatan 21, SE-752 28 Uppsala, Sweden.
P040029/S012	02/28/2020	X - 30-Day Notice	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	Changes in the software that generates the code for lathing Euclid Systems Orthokeratology Contact Lenses for Overnight Wear.
P040036/S069	02/26/2020	X - 30-Day Notice	NAVISTAR THERMOCOOL DEFLECTABLE DIAGNOSTIC/ABLATION CATHETER	BIOSENSE WEBSTER, INC.	Line 13 transfer and addition of new Slim Line Dryer
P050017/S018	02/07/2020	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK INCORPORATED	Change to the delivery system tip manufacturing process.
P050028/S081	02/20/2020	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for critical instrument sub-components.
P060011/S019	02/21/2020	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Upgrades to optical measuring equipment.
P060030/S082	02/20/2020	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for critical instrument sub-components.
P080025/S202	02/05/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change in the destructive testing pull test sampling, sampling frequency, and tightening of the control limits established for the pull test monitoring.

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P090016/S038	02/07/2020	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Changes to the NaHA assay for Belotero Balance Dermal Filler and Belotero Balance (+) Lidocaine Dermal Filler, including the introduction of 125 mL HDPE bottles, the use of two series of 40 samples from each series, and the use of an alternate water source for testing.
P100009/S037	02/26/2020	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Modification to the bonding process of the radiopaque ring and Delivery Catheter shaft of the MitraClip NTR/XTR and G4 Clip Delivery Systems.
P100010/S101	02/03/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Use of Windows 10 operator system driver software.
P100010/S103	02/24/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Manufacturing changes associated with the luer component at the Medtronic Villalba site.
P100014/S025	02/27/2020	X - 30-Day Notice	SOLESTA INJECTABLE GEL	PALETTE LIFE SCIENCES	Use a resistometer in the D-value determination for Biological Indicators.
P100042/S029	02/10/2020	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Change specifications for a critical raw material used to manufacture a critical assay reagent.
P100047/S152	02/18/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Changes to the supplier assembly process rework for the HeartWare Ventricular Assist Device (HVAD), Battery Charger Pack.
P110002/S023	02/18/2020	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (ONE-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Change in process flow order and addition of temporary storage location.
P110009/S023	02/18/2020	X - 30-Day Notice	MOBI-C CERVICAL DISC PROSTHESIS (TWO-LEVEL INDICATION)	ZIMMER BIOMET SPINE, INC.	Change in process flow order and addition of temporary storage location.
P110010/S174	02/06/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modification of incoming raw material testing and specifications for PVDF-HFP.
P110019/S110	02/13/2020	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Modification to the Stent Press process for the XIENCE 4.0 mm diameter stent.
P110035/S055	02/20/2020	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Duplicate manufacturing line and equipment updates for a component of the device delivery system.
P110037/S052	02/20/2020	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for critical instrument sub-components.
P120014/S010	02/26/2020	X - 30-Day Notice	BIOMERIEUX THXID BRAF ASSAY KIT	BIOMERIEUX, INC.	Change of manufacturing material and manufacturer of the manufacturing material

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P130005/S028	02/24/2020	X - 30-Day Notice	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Upgrades to the process controls at the sterilization site.
P130011/S008	02/10/2020	X - 30-Day Notice	FREEDOM SOLO STENTLESS HEART VALVE	LIVANOVA CANADA CORP.	Modification to the sealing ring of the primary packaging.
P130013/S036	02/27/2020	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Reduce ethylene oxide sterilization concentrations and increase maximum density for a sterilization load at specified cycles/chambers in Steris Tullamore and Steris Minnesota.
P130021/S071	02/28/2020	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Upgrade the supplier manufacturing equipment used to manufacture the suture component of the 23mm TAV in the CoreValve Evolut R System, CoreValve Evolut PRO System and Evolut PRO+ System.
P140003/S069	02/28/2020	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Adding a second supplier of a component for the Impella CP with SmartAssist.
P140010/S049	02/20/2020	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Addition of in process controls.
P140028/S054	02/20/2020	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Duplicate manufacturing line and equipment updates for a component of the device delivery system.
P140029/S023	02/20/2020	X - 30-Day Notice	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Change from single batch dialysis to dual-batch dialysis in manufacturing.
P140033/S055	02/28/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Adopt sterilization recipe Cycle PG 600 for the Abbott Penang Malaysia manufacturing facility.
P150005/S052	02/19/2020	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Updating weld process parameters to harmonize across multiple ablation catheter families.
P150011/S018	02/10/2020	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Modification to the sealing ring of the primary packaging.
P150014/S035	02/06/2020	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for a critical component.

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P150015/S037	02/06/2020	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for a critical component.
P150026/S010	02/20/2020	X - 30-Day Notice	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Implementation of a revised Nosecone Forming Fixture used in manufacturing of the HeartLight® family of Catheters.
P160023/S017	02/14/2020	X - 30-Day Notice	APTIMA HCV QUANT DX ASSAY	HOLOGIC, INC.	Change the shipping container used to ship frozen product.
P160041/S028	02/06/2020	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for a critical component.
P160049/S008	02/11/2020	X - 30-Day Notice	STELLAREX 0.035 OTW DRUG-COATED ANGIOPLASTY BALLOON	THE SPECTRANETICS CORP.	Modified incoming inspection steps.
P170025/S015	02/14/2020	X - 30-Day Notice	APTIMA HBV QUANT ASSAY	HOLOGIC, INC	Change the shipping container used to ship frozen product.
P180011/S022	02/06/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Modification of incoming raw material testing and specifications for PVDF-HFP.
P180011/S023	02/12/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Addition of a sterilization cycle to a sterilization chamber.
P180011/S026	02/20/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Duplicate manufacturing line and equipment updates for a component of the device delivery system.
P180011/S027	02/27/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change the stent coating filtration process.
P180035/S002	02/04/2020	X - 30-Day Notice	MISIGHT 1 DAY (OMAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR	COOPERVISION, INC.	Manufacture of MiSight I Day lenses on Dry Line HC at the CooperVision Manufacturing, Ltd. facility in Chandlers Ford, United Kingdom.
P180046/S005	02/28/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Add a second supplier for machining the ceramic casing.
P190006/S005	02/28/2020	X - 30-Day Notice	AXONICS SACRAL NEUROMODULATION SYSTEM	AXONICS MODULATION TECHNOLOGIES, INC.	Add a second supplier for machining the ceramic casing.

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P190008/S002	02/20/2020	X - 30-Day Notice	IN.PACT AV PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC VASCULAR INC.	Addition of in process controls.

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