PMA Monthly approvals from 5/1/2020 to 5/31/2020

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160028	05/11/2020	PMAO - PMA Origi	PHILIPS HEARTSTART FR3 DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS, INC.	Approval for the Philips HeartStart FR3 Defibrillator. The models 861388 and 861389 are indicated for use by trained responders to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA), and pulseless ventricular tachycardias (VTs). The models 861388 and 861389 are used with the SmartPads III or DP defibrillator pads applied to potential victims of SCA with the following symptoms: 1) Unresponsiveness; 2) Absence of normal breathing; and 3) Absence of pulse or signs of circulation The models 861388 and 861389 are intended for adults and children over 55 pounds (25 kg) or greater than 8 years old. The models 861388 and 861389 are also intended for children under 55 pounds (25 kg) or 0-8 years old when used with the optional Infant/Child Key. If the Infant/Child Key is not available, or you are uncertain of the child¿s age or weight, do not delay treatment.
P180028	05/11/2020	PMAO - PMA Origi	HEARTSTART FRX DEFIBRILLATOR	PHILIPS MEDICAL SYSTEMS	Approval for the HeartStart FRx Defibrillator (Model 861304). The device is indicated for use on potential victims of sudden cardiac arrest (SCA) with the following symptoms: 1) Unconsciousness; and 2) Absence of normal breathing The HeartStart FRx (Model 861304) is indicated for adults over 55 pounds (25 kg). The Model 861304 is also indicated for infants and children under 55 pounds (25 kg) or 0-8 years old when used with the optional Infant/Child Key (Model 989803139311). If the Infant/Child Key is not available, or you are uncertain of the child¿s age or weight, proceed using adult treatment without the infant/child key.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P190015	05/04/2020	PMAO - PMA Origi	TREO® ABDOMINAL STENT-GRAFT SYSTEM	BOLTON MEDICAL INC.	Approval for TREO® Abdominal Stent-Graft System. This device is indicated for use in the endovascular treatment of patients with infrarenal abdominal aortic and aorto-iliac aneurysms with the following characteristics: 1. Adequate iliac or femoral access compatible with the required delivery systems and accessories; 2. Proximal aortic landing zone with: 2a. Infrarenal landing neck length of >= 15mm; 2b. Aortic neck diameters >= 17 mm and <= 32 mm; 2c. Suprarenal neck angle of <= 45 degrees; 2d. Infrarenal neck angle of <= 60 degrees. 3. Distal iliac landing zone with: 3a. an inside diameter of 8 mm ¿ 13 mm and a length of >= 10 mm; or 3b. an inside diameter of > 13 mm ¿ 20 mm and a length of >= 15 mm. 4. Minimum overall AAA treatment length (proximal landing location to distal landing location) of 13 cm; and 5. Minimum overall length from the lowest renal artery to the aortic bifurcation of 9 cm.

Total: 3

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970012/S177	05/20/2020	O - Normal 180 Day	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Approval for a site change from the BSC Minnetonka, MN facility to the BSC St. Paul, Minnesota facility.
P810002/S108	05/18/2020	N - Normal 180 Day	BILEAFLET-CENTER OPENING CARDIAC VALVE	ST. JUDE MEDICAL, INC.	Approval for changes related to PET yarn supplier and PET yarn manufacturing.
P830063/S016	05/23/2020	R - Real-Time Proc	GAMBRO FIBER PLASMAFILTER	BAXTER INTERNATIONAL, INC.	Approval for a minor change to the raw material used for the header cap component, which is part of the plasmafilter subassembly of the PRISMAFLEX TPE2000 Set.
P860004/S345	05/15/2020	Y - 135 Review Tra	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval to change to a PFOA-free manufacturing process on a component of the non-implanted Anchor Dispenser Tool using an existing approved sub-tier supplier.
P880086/S306	05/13/2020	R - Real-Time Proc	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for a design and supplier change of the moisture getter.
P890003/S427	05/15/2020	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for a firmware update for MyCareLink Patient Monitor Models 24950 and 24952 to version M12.0 as well as CareLink Network updates to provide remote monitoring support for Micra AV.
P890003/S428	05/17/2020	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for CareLink SmartSync Common Application version 3.2.01, CareLink SmartSync Azure Astra Application version 3.2.02, CareLink SmartSync Percepta Serena Solara Application version 3.2.02.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900056/S184	05/19/2020	O - Normal 180 Day	ROTABLATOR(R)	BOSTON SCIENTIFIC CORP.	Approval for an alternate Ethylene Oxide (EtO) sterilization facility.
P910007/S053	05/23/2020	O - Normal 180 Day	AXSYM TOTAL PSA & ARCHITECT TOTAL PSA	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.
P910056/S043	05/19/2020	N - Normal 180 Day	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval for an alternate packaging configuration for the IOL along with the designation as Model MX60PT.
P920047/S122	05/19/2020	O - Normal 180 Day	EPT-1000 CARDIAC ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P930021/S024	05/15/2020	N - Normal 180 Day	BIORA EMDOGAIN(R)	THE STRAUMANN COMPANY	Approval for adding two new packaging configurations branded as Emdogain® MI (design change), adding an alternate application needle (cannula) design for the two new packaging configurations (design change), and updating the name of the Supplier for the applicable needle (cannula) (Supplier name change).
P950020/S106	05/19/2020	O - Normal 180 Day	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P950022/S112	05/17/2020	R - Real-Time Proc	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Approval for single shock coil passive fixation lead models (Durata 7172Q and Optisure LDP210Q) and changes to the crimp subassemblies.
P950022/S131	05/15/2020	O - Normal 180 Day	TVL(TM) LEAD SYSTEM	ST. JUDE MEDICAL, INC.	Approval of the revised protocol for the post-approval study (PAS) and to discontinue the Externalization and Abrasion sub-study.
P950037/S207	05/11/2020	Y - 135 Review Tra	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for optimization changes of the MnO2 thermal treatment process and automation of ICD battery cathode manufacturing.
P950037/S211	05/29/2020	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for PSW 1904.U programmer software.
P970003/S231	05/13/2020	R - Real-Time Proc	VNS THERAPY SYSTEM	LIVANOVA USA, INC.	Approval for a new generator known as SenTiva Duo Model 1000-D Generator. The Model 1000-D Generator is identical to the Model 1000 SenTiva Generator with the exception of the header which will be compatible with dual pin leads.
P970051/S198	05/15/2020	O - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval of the protocol for the post-approval study (PAS) protocol.
P980003/S092	05/19/2020	O - Normal 180 Day	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P980007/S042	05/23/2020	O - Normal 180 Day	AXSYM FREE PSA	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S730	05/15/2020	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a firmware update for MyCareLink Patient Monitor Models 24950 and 24952 to version M12.0 as well as CareLink Network updates to provide remote monitoring support for Micra AV.
P980016/S731	05/08/2020	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for RAMware updates to ICD, CRT-D, CRT-P, and IPG devices and corresponding updates to Medtronic CareLink Programmer Model 2090 and Encore Programmer Model 29901 device applications SW034, SW035, SW030, and SW040.
P980023/S096	05/11/2020	Y - 135 Review Tra	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for optimization changes of the MnO2 thermal treatment process and automation of ICD battery cathode manufacturing.
P980023/S099	05/22/2020	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for additional MRI system configurations to include Plexa (ProMRI) S 60, Plexa (ProMRI) SD 60/16, Plexa (ProMRI) DF-1 S 60 and Plexa (ProMRI) DF-1 SD 60/16.
P980023/S100	05/29/2020	R - Real-Time Proc	PHYLAX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	BIOTRONIK, INC.	Approval for PSW 1904.U programmer software.
P980035/S616	05/15/2020	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for a firmware update for MyCareLink Patient Monitor Models 24950 and 24952 to version M12.0 as well as CareLink Network updates to provide remote monitoring support for Micra AV.
P980035/S618	05/08/2020	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for RAMware updates to ICD, CRT-D, CRT-P, and IPG devices and corresponding updates to Medtronic CareLink Programmer Model 2090 and Encore Programmer Model 29901 device applications SW034, SW035, SW030, and SW040.
P980035/S619	05/17/2020	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for CareLink SmartSync Common Application version 3.2.01, CareLink SmartSync Azure Astra Application version 3.2.02, CareLink SmartSync Percepta Serena Solara Application version 3.2.02.
P980037/S078	05/05/2020	O - Normal 180 Day	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the addition of a manufacturing site located at Synergy Health AST, SRL, in Alajuela, Costa Rica to perform contract sterilization.
P980037/S079	05/19/2020	O - Normal 180 Day	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Approval for an alternate Ethylene Oxide (EtO) sterilization facility.
P980040/S109	05/01/2020	N - Normal 180 Day	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for the modification of the optics to elongate the depth of focus further than the optical parent lens, the TECNIS Symfony Extended Range of Vision IOL, Model ZXR00.

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P980040/S112	05/28/2020	R - Real-Time Proc	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for an addition to the TECNIS Symfony family of Extended Range of Vision one-piece IOLs manufactured from OptiBlue lens material.
P980041/S043	05/28/2020	Y - 135 Review Tra	ACCESS AFP IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Approval to optimize the metal ion ratios in order to support stable alkaline phosphatase activity in the conjugate diluent used in the Access AFP Reagents.
P990056/S037	05/12/2020	N - Normal 180 Day	ELECSYS TOTAL PSA IMMUNOASSAY AND TOTAL PSA CALSET	ROCHE DIAGNOSTICS CORP.	Approval for the update of the Elecsys total PSA immunoassay to improve the tolerance to biotin interference.
P000009/S082	05/11/2020	Y - 135 Review Tra	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for optimization changes of the MnO2 thermal treatment process and automation of ICD battery cathode manufacturing.
P000009/S084	05/29/2020	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for PSW 1904.U programmer software.
P000027/S035	05/12/2020	N - Normal 180 Day	ELECSYS FREE PSA IMMUNOASSAY/CALSET/ CALCHECK	ROCHE DIAGNOSTICS CORP.	Approval for the update of the Elecsys free PSA immunoassay to improve the tolerance to biotin interference.
P000040/S038	05/19/2020	O - Normal 180 Day	HYDRO THERMABLATOR ENDOMETRIAL ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P000053/S112	05/20/2020	O - Normal 180 Day	AMS SPHINCTER 800 URINARY CONTROL SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a site change from the BSC Minnetonka, Minnesota facility to the BSC St. Paul, Minnesota facility.
P010015/S428	05/15/2020	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for a firmware update for MyCareLink Patient Monitor Models 24950 and 24952 to version M12.0 as well as CareLink Network updates to provide remote monitoring support for Micra AV.
P010015/S429	05/08/2020	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for RAMware updates to ICD, CRT-D, CRT-P, and IPG devices and corresponding updates to Medtronic CareLink Programmer Model 2090 and Encore Programmer Model 29901 device applications SW034, SW035, SW030, and SW040.
P010015/S430	05/17/2020	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for CareLink SmartSync Common Application version 3.2.01, CareLink SmartSync Azure Astra Application version 3.2.02, CareLink SmartSync Percepta Serena Solara Application version 3.2.02.
P010031/S691	05/15/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for a firmware update for MyCareLink Patient Monitor Models 24950 and 24952 to version M12.0 as well as CareLink Network updates to provide remote monitoring support for Micra AV.
P010031/S692	05/08/2020	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for RAMware updates to ICD, CRT-D, CRT-P, and IPG devices and corresponding updates to Medtronic CareLink Programmer Model 2090 and Encore Programmer Model 29901 device applications SW034, SW035, SW030, and SW040.

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P020025/S126	05/19/2020	O - Normal 180 Day	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P030011/S077	05/01/2020	R - Real-Time Proc	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for making minor design changes to the resistors on the Companion 2 Main Printed Circuit Board Assembly (PCBA).
P050010/S021	05/08/2020	O - Normal 180 Day	PRODISC -L TOTAL DISC REPLACEMENT DEVICE	CENTINEL SPINE, LLC	Approval for additional cleaning, passivation and thermal rinse steps, and the following four (4) manufacturing sites, at the following addresses, and for the following purposes: Centinel Spine (Manufacturer) 900 Airport Road Suite 3B West Chester, PA 19380 Hammill Medical (Contract Manufacturer) 360 Tomahawk Drive Maumee, OH 43537 Fruh Verpackungstechnik AG (Contract Manufacturer) Allmendstrasse 47 Fehraltoff Switzerland 8320 Synergy Health Daniken AG (Contract Sterilizer) Hogenweidstrasse 6 Daniken Solothurn Switzerland 4658
P050023/S139	05/11/2020	Y - 135 Review Tra	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for optimization changes of the MnO2 thermal treatment process and automation of ICD battery cathode manufacturing.
P050023/S144	05/22/2020	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for additional MRI system configurations.
P050023/S145	05/29/2020	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for PSW 1904.U programmer software.
P050042/S041	05/23/2020	O - Normal 180 Day	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the Alinity i System.
P050042/S042	05/23/2020	O - Normal 180 Day	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.
P050047/S076	05/28/2020	S - Special CBE	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for reducing the bacterial endotoxin specification to enhance the safety of the device.

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P050051/S038	05/23/2020	O - Normal 180 Day	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the Alinity i System.
P050051/S039	05/23/2020	O - Normal 180 Day	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.
P060006/S100	05/19/2020	O - Normal 180 Day	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P060035/S029	05/23/2020	O - Normal 180 Day	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the Alinity i System.
P060035/S030	05/23/2020	O - Normal 180 Day	ARCHITECT CORE-M REAGENT KIT/ CALIBRATORS/CONTROLS	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.
P070001/S018	05/08/2020	O - Normal 180 Day	PRODISC TM-C TOTAL DISC REPLACEMENT	CENTINEL SPINE, LLC	Approval for additional cleaning, passivation and thermal rinse steps, and the following four (4) manufacturing sites, at the following addresses, and for the following purposes: Centinel Spine (Manufacturer) 900 Airport Road Suite 3B West Chester, PA 19380 Hammill Medical (Contract Manufacturer) 360 Tomahawk Drive Maumee, OH 43537 Fruh Verpackungstechnik AG (Contract Manufacturer) Allmendstrasse 47 Fehraltoff Switzerland 8320 Synergy Health Daniken AG (Contract Sterilizer) Hogenweidstrasse 6 Daniken Solothurn Switzerland 4658
P070008/S110	05/11/2020	Y - 135 Review Tra	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for optimization changes of the MnO2 thermal treatment process and automation of ICD battery cathode manufacturing.
P070008/S114	05/22/2020	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for additional MRI system configurations.
P070008/S115	05/29/2020	R - Real-Time Proc	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Approval for PSW 1904.U programmer software.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P080023/S032	05/23/2020	O - Normal 180 Day	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the Alinity i System.
P080023/S033	05/23/2020	O - Normal 180 Day	ARCHITECT CORE REAGENT KIT, ARCHITECT CORE CALIBRATOR AND ARCHITECT CORE CONTROLS	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.
P100025/S014	05/26/2020	O - Normal 180 Day	BREATHTEK UBT FOR H. PYLORI KIT AND PEDIATRIC UREA HYDROLYSIS RATE CALCULATION APPLICATION (PUHR-CA), VERSION 1.0	OTSUKA AMERICA PHARMACEUTICAL, INC.	Approval of new manufacturing facility.
P100047/S142	05/07/2020	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the design modifications to the monitor AC adapter and labeling modifications to the HVAD Physician IFU and Patient Manual.
P100047/S154	05/05/2020	R - Real-Time Proc	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the addition of a new leak test requirement (IPX8 Per IEC60529) to the driveline connector and a 100% in process verification of this requirement.
P110010/S176	05/19/2020	O - Normal 180 Day	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P110012/S020	05/22/2020	N - Normal 180 Day	VYSIS ALK BREAK APART FISH PROBE KIT, VYSIS PARAFFIN PRETREATMENT IV & POST HYBRIDIZATION WASH BUFFER KIT PROBECHEK ALK	ABBOTT MOLECULAR, INC.	Approval of the expansion of the Indications for Use for the Vysis ALK Break Apart FISH Probe Kit to include an indication for ALUNBRIG® (brigatinib). The device, as modified, will be marketed under the trade name Vysis ALK Break Apart FISH Probe Kit and is indicated for: INTENDED USE The Vysis ALK Break Apart FISH Probe Kit is a qualitative test to detect rearrangements involving the ALK gene via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) tissue specimens from non-small cell lung cancer (NSCLC) patients. INDICATION FOR USE The Vysis ALK Break Apart FISH Probe Kit is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib) and ALUNBRIG® (brigatinib) in accordance with the approved therapeutic product labeling.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110029/S031	05/23/2020	O - Normal 180 Day	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the Alinity i System.
P110029/S032	05/23/2020	O - Normal 180 Day	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.
P110035/S056	05/05/2020	O - Normal 180 Day	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of a manufacturing site located at Synergy Health AST, SRL, in Alajuela, Costa Rica to perform contract sterilization.
P110035/S057	05/19/2020	O - Normal 180 Day	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P120008/S014	05/23/2020	O - Normal 180 Day	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the Alinity i System.
P120008/S015	05/23/2020	O - Normal 180 Day	ABBOTT ARCHITECT AFP ASSAY	ABBOTT LABORATORIES	Approval for a manufacturing site located at Abbott Laboratories, 1915 Hurd Drive, Irving, Texas 75038, USA for the production of the ARCHITECT i1000SR System.
P130004/S008	05/05/2020	O - Normal 180 Day	RESURE SEALANT	OCULAR THERAPEUTIX, INC.	Approval of the revised protocol for the post-approval study (PAS), Device Exposure Registry Study.
P130008/S047	05/03/2020	Y - 135 Review Tra	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval to update soldermask application process for the PCB component of Model 3028 Implantable Pulse Generator (IPG)
P130021/S072	05/28/2020	R - Real-Time Proc	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for design changes to the actuator component of the delivery catheter system
P130022/S033	05/26/2020	S - Special CBE	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for adding B1+RMS scanner limits to support 1.5T Full Body MRI conditional labeling for IPG1000/1500/2000/2500 with Surpass surgical and Percutaneous leads to enhance the safety of the Senza SCS system. Also, you requested approval for some other minor additional administration clarifications added in the manual based on customer feedback on the readability of the manual.
P130024/S034	05/14/2020	R - Real-Time Proc	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Approval for a new tie-layer material in the inner catheter shaft.
P130028/S031	05/05/2020	N - Normal 180 Day	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Approval use for the Algovita Clinician Programmer application and Nuvectra Bridge Communicator as per the letter dated May 5, 2020.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130030/S067	05/19/2020	O - Normal 180 Day	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P140020/S020	05/19/2020	N - Normal 180 Day	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval to expand the intended use of BRACAnalysis® CDx to include a companion diagnostic indication for BRCA1/2 mutations in patients with metastatic castration resistant prostate cancer who may benefit from treatment with Lynparza® (olaparib).
P140023/S022	05/18/2020	R - Real-Time Proc	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for a formulation change to the cobas DNA Sample Preparation Kit used with the cobas KRAS Mutation Test (P140023).
P140028/S055	05/05/2020	O - Normal 180 Day	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for the addition of a manufacturing site located at Synergy Health AST, SRL, in Alajuela, Costa Rica to perform contract sterilization.
P140028/S056	05/19/2020	O - Normal 180 Day	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P140029/S025	05/21/2020	S - Special CBE	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for revisions to the clinician and patient labeling of Restylane Defyne and Restylane Refyne to include updated safety information based upon post marketing surveillance data.
P140033/S048	05/13/2020	R - Real-Time Proc	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval for a design and supplier change of the moisture getter.
P140033/S057	05/22/2020	O - Normal 180 Day	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P150003/S055	05/28/2020	N - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for 48 mm device lengths for the 2.50 to 4.00 mm devices along with modifications to the delivery catheter design and changes to the packaging design. The device, as modified, will be marketed under the trade name SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System and is indicated for improving luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation MI or documented silent ischemia due to atherosclerotic lesions in native coronary arteries >= 2.25 mm to <= 5.0 mm in diameter in lesions <= 44 mm in length.
P150003/S059	05/19/2020	O - Normal 180 Day	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150005/S053	05/19/2020	O - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P150005/S054	05/29/2020	O - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval of the final protocol and analysis plan for the post-approval study (PAS) protocol.
P150021/S046	05/12/2020	N - Normal 180 Day	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for 1) introducing an alternate adhesive used in the assembly of the sensor puck; 2) introducing an additional sensor puck assembly manufacturing line at an existing manufacturing site; and 3) introducing a new ISO 8 cleanroom in which the additional assembly line will be located. The sensor puck is a component of the FreeStyle Libre 14-day and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P150025/S013	05/15/2020	P - Panel Track	PD-L1 IHC 28-8 PHARMDX	DAKO NORTH AMERICA, INC.	Approval application (PMA) supplement submitted to expand the indication for the PD-L1 IHC 28-8 pharmDx to include detection of PD-L1 protein in NSCLC patients for treatment with OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab). The device, as modified, will be marketed under the trade name PD-L1 IHC 28-8 pharmDx and is indicated for in vitro diagnostic use. PD-L1 IHC 28-8 pharmDx is a qualitative immunohistochemical assay using Monoclonal Rabbit Anti-PD-L1, Clone 28-8 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), and urothelial carcinoma (UC) tissues using EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is defined as the percentage of evaluable tumor cells exhibiting partial or complete membrane staining at any intensity. Companion Diagnostic Indication Tumor Indication PD-L1 Expression Clinical Cut Off Intended Use NSCLC >=1% tumor cell expression PD-L1 IHC 28-8 pharmDx is indicated as an aid in identifying NSCLC patients for treatment with OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab). PD-L1 expression (>=1% or ?5% or >=10% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in non-squamous NSCLC may be associated with enhanced survival from OPDIVO®. PD-L1 expression (>=1% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in SCCHN may be associated with enhanced survival from OPDIVO®. PD-L1 expression (>=1% tumor cell expression), as detected by PD-L1 IHC 28-8 pharmDx in UC may be associated with enhanced response rate from OPDIVO®. See the OPDIVO® and YERYOV® product labels for specific clinical circumstances guiding PD-L1 testing.
P150026/S008	05/08/2020	N - Normal 180 Day	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	Approval for the HeartLight X3 Endoscopic Ablation System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150033/S067	05/15/2020	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for a firmware update for MyCareLink Patient Monitor Models 24950 and 24952 to version M12.0 as well as CareLink Network updates to provide remote monitoring support for Micra AV.
P160002/S012	05/18/2020	N - Normal 180 Day	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval of the VENTANA PD-L1 (SP142) Assay as a companion diagnostic for identifying patients with non-small cell lung carcinoma (NSCLC) with PD-L1 expression in TC >= 50% or IC >= 10% for treatment with TECENTRIQ based upon the IMpower110 clinical study.
P160007/S029	05/20/2020	N - Normal 180 Day	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for introduction of the Guardian Connect Android Application and software changes to the Guardian Connect iOS Application.
P160030/S039	05/12/2020	N - Normal 180 Day	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for 1) introducing an alternate adhesive used in the assembly of the sensor puck; 2) introducing an additional sensor puck assembly manufacturing line at an existing manufacturing site; and 3) introducing a new ISO 8 cleanroom in which the additional assembly line will be located. The sensor puck is a component of the FreeStyle Libre 14-day and FreeStyle Libre Pro Flash Glucose Monitoring Systems.
P160030/S042	05/21/2020	O - Normal 180 Day	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Approval for a manufacturing site located at Tech Group Europe Limited t/a West, Damastown Close, Damastown Industrial Park, Mulhuddart, Dublin 15, D15 K009 Ireland for sensor kit assembly. The sensor kit is a component of the Freestyle Libre 14 day Flash Glucose Monitoring System.
P160040/S006	05/14/2020	N - Normal 180 Day	LEUKOSTRAT CDX FLT3 MUTATION ASSAY	INVIVOSCRIBE TECHNOLOGIES, INC	Approval for distribution of the Leukostrat® CDx FLT3 Mutation Assay on the 3500xL Dx Genetic Analyzer Instrument. The device, as modified, will be marketed under the trade name LeukoStrat CDx FLT3 Mutation Assay and is indicated for: The LeukoStrat CDx FLT3 Mutation Assay is a PCR-based in vitro diagnostic test designed to detect internal tandem duplication (ITD) and tyrosine kinase domain (TKD) mutations D835 and I836 in the FLT3 gene in genomic DNA extracted from mononuclear cells obtained from peripheral blood or bone marrow aspirates of patients diagnosed with acute myelogenous leukemia (AML). The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom RYDAPT® (midostaurin) treatment is being considered. The LeukoStrat CDx FLT3 Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA® (gilteritinib) treatment is being considered. The test is for use on the 3500xL Dx Genetic Analyzer.
P160043/S032	05/28/2020	N - Normal 180 Day	RESOLUTE ONYX ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Approval for revisions to the labeling to increase the maximum stent inner diameter (MSID) by 0.25 mm for all sizes of the Resolute Onyx Zotarolimus-Eluting Coronary Stent System.
P160050/S005	05/12/2020	O - Normal 180 Day	BARRICAID ANULAR CLOSURE DEVICE (ACD)	INTRINSIC THERAPEUTICS	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160050/S006	05/19/2020	O - Normal 180 Day	BARRICAID ANULAR CLOSURE DEVICE (ACD)	INTRINSIC THERAPEUTICS	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
P160055/S009	05/22/2020	O - Normal 180 Day	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P160055/S011	05/21/2020	R - Real-Time Proc	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for the software modifications for Light Delivery Device (LDD) system: (1) Update to allow patient data to be entered and saved prior to treatment session; (2) Update to treatment Summary report format to include 2D barcode, in addition to text File; (3) Update GUI (graphical user interface) display; and (4) Update to the self-test routine to include additional confirmation of power reading prior to treatment.
P170003/S017	05/14/2020	R - Real-Time Proc	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Approval for a new tie-layer material in the inner catheter shaft.
P170019/S011	05/06/2020	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval to include a companion diagnostic indication for detection of MET single nucleotide variants (SNVs) and indels that lead to MET exon 14 skipping in non-small cell lung cancer patients who may benefit from treatment with TABRECTA (capmatinib).
P170019/S015	05/19/2020	P - Panel Track	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval to expand the intended use of FoundationOne®CDx to include a companion diagnostic indication for homologous recombination repair (HHR) gene alterations in patients with metastatic castration resistant prostate cancer who may benefit from treatment with Lynparza®(olaparib).
P170024/S003	05/20/2020	N - Normal 180 Day	SURPASS STREAMLINE FLOW DIVERTER	STRYKER NEUROVASCULAR	Approval for a change in the design of the approved Surpass Streamline Flow Diverter that consists of a new delivery system, smaller gauge wire in the stent to enable delivery through a smaller microcatheter, and reduce the number of cobalt chromium wires used in the stent braid.
P170038/S002	05/22/2020	O - Normal 180 Day	CENTRIMAG CIRCULATORY SUPPORT SYSTEM	ABBOTT	Approval of the revised protocol for the post-approval study (PAS) protocol.
P180011/S028	05/19/2020	O - Normal 180 Day	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Corp. in Ballybrit Business Park Galway, Ireland for sterilization.
P180013/S005	05/26/2020	O - Normal 180 Day	VICI VENOUS STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval for the revised protocol for the post-approval study (PAS) protocol.
P190014/S003	05/08/2020	N - Normal 180 Day	MYCHOICE HRD CDX	MYRIAD GENETIC LABORATORIES, INC	Approval for Myriad myChoice® CDx to include a companion diagnostic indication for homologous recombination deficiency (HRD) in ovarian cancer patients who may benefit from maintenance treatment with Lynparza® (olaparib)".

Total: 116

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16837/S026	05/06/2020	X - 30-Day Notice	ARTEGRAFT{TM} AND REINFORCED ARTEGRAFT {TM}	ARTEGRAFT, INC.	Implementation of an additional cleanroom and water system.
P810002/S111	05/12/2020	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ST. JUDE MEDICAL, INC.	Alternative BET batch sampling plan.
P810002/S112	05/26/2020	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ST. JUDE MEDICAL, INC.	Extension in shelf life for the vascular graft component.
P810031/S067	05/11/2020	X - 30-Day Notice	HEALON, HEALON GV, HEALON5 PRODUCTS SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES	JOHNSON & JOHNSON SURGICAL VISION, INC.	Removal of an in-process raw material quality control test affecting the sodium hyaluronate (NaHy) raw material for the Healon EndoCoat® Ophthalmic Viscosurgical Device (OVD).
P830055/S245	05/19/2020	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Changes to implement an alternate piece of CNC equipment used for the machining operation of the Femoral BOSS feature of the ATTUNE Revision CRS Femoral Components.
P840001/S460	05/07/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Change requested to update the existing Soft Straight-Line Finish (SLF) cosmetic rework process at the Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico. The change also requested other related minor documentation updates
P840001/S461	05/08/2020	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Change requested to modify the procedure for the assessment of device bioburden at Medtronic's final device manufacturing facilities-Medtronic Puerto Rico Operations Company, located in Juncos, Puerto Rico .The change also requested other related administrative changes which update the procedure.
P860004/S356	05/08/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Change requested to modify the procedure for the assessment of device bioburden at Medtronic's final device manufacturing facilities-Medtronic Puerto Rico Operations Company, located in Juncos, Puerto Rico .The change also requested other related administrative changes which update the procedure.
P860004/S357	05/14/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	SynchroMed II Implantable Infusion Pump and Implantable System for Remodulin the creation of new supplier tooling, automation of an existing supplier test system, and modification of supporting component and device drawings for component assemblies.
P860004/S358	05/20/2020	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implantation of additional controls at the bulkhead assembly process for the SynchroMed Infusion System, Ascenda Intrathecal Catheters, and Implantable System for Remodulin devices.
P880047/S035	05/20/2020	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Supplier change to increase the quantity of black pigment in the HAPA UV cured ink used to print artwork graphics on the exterior of the GYNECARE INTERCEED Adhesion Barrier foil pouches manufactured on the automated Foiling Line (G11719) at the EthiconSARL, Neuchâtel, Switzerland site.
P880047/S036	05/21/2020	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Installation of a duplicate dehumidifier unit for GYNECARE INTERCEED Absorbable Adhesion Barrier manufactured at the Ethicon SARL, Neuchatel Switzerland site.
P880086/S313	05/21/2020	X - 30-Day Notice	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Implementation of an automated system, Vaisala EMS, for process monitoring to replace existing chart recorders and electronic monitoring systems at the Abbott/St. Jude Medical Scottsdale, Arizona component manufacturing site.
P910023/S427	05/21/2020	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Implementation of an automated system, Vaisala EMS, for process monitoring to replace existing chart recorders and electronic monitoring systems at the Abbott/St. Jude Medical Scottsdale, Arizona component manufacturing site.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930014/S130	05/05/2020	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON LABORATORIES, INC.	Alternate material for the IOL optic mold subcomponent used in the manufacture of AcrySof(R) Intraocular Lenses.
P960009/S373	05/07/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change requested to update the existing Soft Straight-Line Finish (SLF) cosmetic rework process at the Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico. The change also requested other related minor documentation updates .
P960009/S374	05/08/2020	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Change requested to modify the procedure for the assessment of device bioburden at Medtronic's final device manufacturing facilities-Medtronic Puerto Rico Operations Company, located in Juncos, Puerto Rico .The change also requested other related administrative changes which update the procedure.
P960042/S069	05/06/2020	X - 30-Day Notice	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM & LASER SHEATH	SPECTRANETICS CORP.	Change in supplier of extruded outer jacket and inner extension tubing components.
P960058/S148	05/28/2020	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Facility move for the current supplier for manufacturing of the Printed Circuit Board Assemblies (PCBAs) for the Ultra Family of Implants, and the qualification of an alternate supplier to assemble the PCBAs for the Ultra 3D Implants.
P970004/S309	05/07/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change requested to update the existing Soft Straight-Line Finish (SLF) cosmetic rework process at the Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico. The change also requested other related minor documentation updates .
P970004/S310	05/08/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Change requested to modify the procedure for the assessment of device bioburden at Medtronic's final device manufacturing facilities-Medtronic Puerto Rico Operations Company, located in Juncos, Puerto Rico .The change also requested other related administrative changes which update the procedure.
P980016/S739	05/04/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the manufacturing inspection methods and manufacturing inspection specifications for the connector preparation process.
P980016/S740	05/27/2020	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement previously approved changes for the Cobalt/Chrome device family.
P980035/S625	05/04/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Changes to the manufacturing inspection methods and manufacturing inspection specifications for the connector preparation process.
P980035/S626	05/26/2020	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Minor manufacturing update for the component stiffener frame component that is consumed into Medtronic implantable pulse generators.
P980043/S073	05/06/2020	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	New inspection method for detecting pin sized gaps between valve leaflets.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000039/S072	05/23/2020	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Add a new sterilization cycle at an approved sterilization facility including the implementation of a new final pack configuration and optimized shippers.
P010015/S435	05/04/2020	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Changes to the manufacturing inspection methods and manufacturing inspection specifications for the connector preparation process.
P010030/S137	05/14/2020	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Change of the manufacturing test criteria for the gas generator in the LifeVest Model 4000 Therapy Electrodes.
P010031/S700	05/04/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Changes to the manufacturing inspection methods and manufacturing inspection specifications for the connector preparation process.
P010031/S701	05/27/2020	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implement previously approved changes for the Cobalt/Chrome device family.
P010032/S160	05/06/2020	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Supplier manufacturing site location change for the Flex Assembly component used in the manufacture of Proclaim and Infinity Implantable Pulse Generator devices.
P010032/S161	05/06/2020	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Implement an updated Helium Leak Test System Software used during assembly of Orion family (Proclaim SCS, Infinity DBS, Proclaim DRG) Implantable Pulse Generators (IPGs).
P010032/S163	05/30/2020	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Alternative bacterial endotoxin test method.
P020024/S063	05/23/2020	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Add a new sterilization cycle at an approved sterilization facility including the implementation of a new final pack configuration and optimized shippers.
P020036/S042	05/29/2020	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Updates to the software and mechanical components of the control system for Vessel 2 and Vessel 4 at the Steris, El Paso, TX ethylene oxide sterilization facility.
P030017/S336	05/13/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the inspection frequency for the O.R. Cables.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S337	05/15/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Modification of the Printed Circuit Board Assembly inspections for the Implantable Pulse Generators of the Precision Spectra System, Spectra Wave Writer System, Precision Novi System, Precision Montage and Precision Montage MRI Systems.
P030017/S339	05/27/2020	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Use of the Continuous Monitoring System at the Implantable Pulse Generator manufacturing site at Clonmel, Ireland.
P030035/S181	05/21/2020	X - 30-Day Notice	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Implementation of an automated system, Vaisala EMS, for process monitoring to replace existing chart recorders and electronic monitoring systems at the Abbott/St. Jude Medical Scottsdale, Arizona component manufacturing site.
P030036/S120	05/11/2020	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Iimplementation of a welding rework process and a microscope¿s reticle to perform the scratches inspection.
P030047/S040	05/29/2020	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS CORP.	Updates to the software and mechanical components of the control system for Vessel 2 and Vessel 4 at the Steris, El Paso, TX ethylene oxide sterilization facility.
P030054/S378	05/21/2020	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Implementation of an automated system, Vaisala EMS, for process monitoring to replace existing chart recorders and electronic monitoring systems at the Abbott/St. Jude Medical Scottsdale, Arizona component manufacturing site.
P040037/S138	05/22/2020	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	New curing equipment for creating delivery system bonds.
P040040/S042	05/23/2020	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Add a new sterilization cycle at an approved sterilization facility including the implementation of a new final pack configuration and optimized shippers.
P040047/S058	05/18/2020	X - 30-Day Notice	COAPTITE	MERZ NORTH AMERICA, INC	Use of an alternative particle size analyzer.
P050028/S082	05/14/2020	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Additional of a second supplier source for a manufacturing component.
P050037/S104	05/18/2020	X - 30-Day Notice	RADIESSE 1.3CC AND 0.3CC	MERZ NORTH AMERICA, INC	Use of an alternative particle size analyzer.
P050047/S075	05/27/2020	X - 30-Day Notice	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Change to the cleaning process of manufacturing equipment used during the manufacturing of Juvéderm injectable gel products.
P050052/S122	05/18/2020	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Use of an alternative particle size analyzer.
P060011/S021	05/26/2020	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Update and add to existing dimensional measuring equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060030/S083	05/14/2020	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Additional of a second supplier source for a manufacturing component.
P080007/S023	05/29/2020	X - 30-Day Notice	BARD E-LUMINEXX VASCULAR STENT	BARD PERIPHERAL VASCULAR, INC.	Qualification of lasers currently used in manufacturing for additional purposes.
P080025/S204	05/07/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change requested to update the existing Soft Straight-Line Finish (SLF) cosmetic rework process at the Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico. The change also requested other related minor documentation updates.
P080025/S205	05/08/2020	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Change requested to modify the procedure for the assessment of device bioburden at Medtronic's final device manufacturing facilities-Medtronic Puerto Rico Operations Company, located in Juncos, Puerto Rico .The change also requested other related administrative changes which update the procedure.
P100010/S104	05/20/2020	X - 30-Day Notice	ARCTIC FRONT CRYOCATHETER SYSTEM	MEDTRONIC CRYOCATH LP	Alternate automated outer balloon bond inspection method with associated fixture that incorporates a high definition camera and monitor.
P100020/S051	05/14/2020	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Catalyst change in consumable pipette tip (CO-RE Tips with filter 1ml) for cobas HPV Test for use on the cobas 4800 System.
P100022/S035	05/15/2020	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK IRELAND, LTD.	Changes to the process challenge devices used for routine sterilization processing and routine sterilization requalification.
P100047/S161	05/06/2020	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Second source sub-tier supplier for the overlay component used on the HeartWare Left Ventricular Assist System controller.
P110007/S012	05/11/2020	X - 30-Day Notice	HEALON ENDOCOAT OPVISCOSURGICAL OPHTHALMIC DEVICE (OVD) (3% SODIUM HYALURONATE)	JOHNSON & JOHNSON SURGICAL VISION, INC.	Removal of an in-process raw material quality control test affecting the sodium hyaluronate (NaHy) raw material for the Healon EndoCoat® Ophthalmic Viscosurgical Device (OVD).
P110010/S178	05/06/2020	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Changes to introduce new equipment to the secondary pack process.
P110033/S054	05/27/2020	X - 30-Day Notice	JUVEDERM VOLUMA XC	ALLERGAN	Change to the cleaning process of manufacturing equipment used during the manufacturing of Juvéderm injectable gel products.
P110037/S053	05/14/2020	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Additional of a second supplier source for a manufacturing component.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110042/S138	05/28/2020	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Introduce a human visual inspection acceptance activity for the terminal ring empty lumen component to detect cracks in the S-ICD Lead.
P120002/S017	05/29/2020	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS CORP.	Updates to the software and mechanical components of the control system for Vessel 2 and Vessel 4 at the Steris, El Paso, TX ethylene oxide sterilization facility.
P120021/S017	05/23/2020	X - 30-Day Notice	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Add a new sterilization cycle at an approved sterilization facility including the implementation of a new final pack configuration and optimized shippers.
P130006/S077	05/22/2020	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	New curing equipment for creating delivery system bonds
P130017/S040	05/12/2020	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Addition of an alternate supplier.
P130021/S074	05/01/2020	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Increase to the established action limits used in the bioburden monitoring process and the establishment of new alert limits.
P130021/S075	05/05/2020	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Implementation of a new serial tag printer, a serial tag printing sequence change, and a new vision system for an additional inspection used in the manufacturing of CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems.
P130024/S036	05/04/2020	X - 30-Day Notice	LUTONIX DRUG COATED BALLOON PTA CATETER	LUTONIX	Change in mixing ball used in the coating solution preparation process.
P130026/S060	05/28/2020	X - 30-Day Notice	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Manufacturing change to the luer component on the TactiCath Contact Force Ablation Catheter, Sensor Enabled (TactiCath SE).
P130029/S008	05/29/2020	X - 30-Day Notice	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Qualification of lasers currently used in manufacturing for additional purposes.
P140009/S056	05/06/2020	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Supplier manufacturing site location change for the Flex Assembly component used in the manufacture of Proclaim and Infinity Implantable Pulse Generator devices.
P140009/S057	05/06/2020	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Implement an updated Helium Leak Test System Software used during assembly of Orion family (Proclaim SCS, Infinity DBS, Proclaim DRG) Implantable Pulse Generators (IPGs).
P140009/S059	05/30/2020	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Alternative bacterial endotoxin test method.
P140031/S115	05/21/2020	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Alternate manufacturing method for components of the Commander Delivery System handle.
P140032/S053	05/08/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Change to modify the procedure for the assessment of device bioburden at Medtronic's final device manufacturing facilities-Medtronic Puerto Rico Operations Company, located in Juncos, Puerto Rico .The change also requested other related administrative changes which update the procedure.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140032/S054	05/14/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	SynchroMed II Implantable Infusion Pump and Implantable System for Remodulin the creation of new supplier tooling, automation of an existing supplier test system, and modification of supporting component and device drawings for component assemblies.
P140032/S055	05/20/2020	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Implantation of additional controls at the bulkhead assembly process for the SynchroMed Infusion System, Ascenda Intrathecal Catheters, and Implantable System for Remodulin devices.
P140033/S058	05/21/2020	X - 30-Day Notice	ASSURITY MRI AND ENDURITY MRI PACEMAKERS, TENDRIL MRI LEAD, MRI ACTIVATOR, MERLIN PCS PROGRAMER SOFTWARE	ST. JUDE MEDICAL, INC.	Implementation of an automated system, Vaisala EMS, for process monitoring to replace existing chart recorders and electronic monitoring systems at the Abbott/St. Jude Medical Scottsdale, Arizona component manufacturing site.
P150003/S061	05/06/2020	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Changes to introduce new equipment to the secondary pack process.
P150004/S035	05/06/2020	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Supplier manufacturing site location change for the Flex Assembly component used in the manufacture of Proclaim and Infinity Implantable Pulse Generator devices.
P150004/S036	05/06/2020	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Implement an updated Helium Leak Test System Software used during assembly of Orion family (Proclaim SCS, Infinity DBS, Proclaim DRG) Implantable Pulse Generators (IPGs).
P150004/S038	05/30/2020	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Alternative bacterial endotoxin test method.
P150005/S055	05/28/2020	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Add Dynamic Sensor Placement (DSP) equipment in the manufacturing process to automate placement of the Aurora Sensor on the catheter.
P150012/S094	05/04/2020	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIE NTIFIC	Add a second supplier to supply the pin cap and the sleeve-weld components for the INGEVITY lead family.
P150014/S036	05/14/2020	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Additional of a second supplier source for a manufacturing component.
P150015/S038	05/14/2020	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Additional of a second supplier source for a manufacturing component.
P150031/S032	05/13/2020	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Update to the inspection frequency for the O.R. Cables.
P150031/S033	05/15/2020	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Modification of the Printed Circuit Board Assembly inspections for the Implantable Pulse Generators (IPGs) of the Vercise PC and Vercise Gevia DBS Systems.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150031/S035	05/27/2020	X - 30-Day Notice	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Use of the Continuous Monitoring System at the Implantable Pulse Generator manufacturing site at Clonmel, Ireland.
P150033/S072	05/21/2020	X - 30-Day Notice	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Modifications to the rework instructions.
P160012/S004	05/13/2020	X - 30-Day Notice	LIFEPAK CR® PLUS DEFIBRILLATOR, LIFEPAK EXPRESS® DEFIBRILLATOR, AND CHARGE-PAK® BATTERY CHARGER	PHYSIO-CONTROL. INC.	Manufacturing change of the outer enclosure during assembly of LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators.
P160035/S014	05/06/2020	X - 30-Day Notice	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Implement changes for injection molding of the blood pump housing and modifications to the stabilization ring, de-airing port, and driving tube connection.
P160041/S029	05/14/2020	X - 30-Day Notice	COBAS CMV	ROCHE MOLECULAR SYSTEMS, INC.	Additional of a second supplier source for a manufacturing component.
P160045/S020	05/26/2020	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	New primary storage location.
P160047/S010	05/06/2020	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 to improve a manufacturing process of the Interface PCB and modification of inspection steps of the Internal Balloon.
P170003/S018	05/04/2020	X - 30-Day Notice	LUTONIX® 035 DRUG COATED BALLOON PTA CATHETER, MODEL 9010	LUTONIX	Change in mixing ball used in the coating solution preparation process.
P170018/S006	05/20/2020	X - 30-Day Notice	LIFEPAK® CR2 DEFIBRILLATOR	PHYSIO-CONTROL, INC	Change to create a duplicate manufacturing line for the LIFEPAK CR2 defibrillator.
P170019/S018	05/13/2020	X - 30-Day Notice	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Re-execution of the Test Method Validation.
P180011/S031	05/21/2020	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Visual inspection standard change.
P180025/S007	05/26/2020	X - 30-Day Notice	MANTA VASCULAR CLOSURE DEVICE	ESSENTIAL MEDICAL, INC.	Implementation of an automated tray component packaging inspection process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180029/S023	05/13/2020	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATIO N	Alternative method to the existing two-site manufacturing process for the Post Tops component.
P190016/S001	05/06/2020	X - 30-Day Notice	TULA® SYSTEM	TUSKER MEDICAL, INC.	Modification to the receiving inspection test method for the Barrel Cam, a component of the Tula Tube Delivery System.
P190025/S001	05/06/2020	X - 30-Day Notice	ALINITY M HCV	ABBOTT MOLECULAR, INC.	Instrument component change by a supplier.
P190028/S001	05/05/2020	X - 30-Day Notice	COBAS HPV FOR USE ON THE COBAS 6800/8800 SYSTEMS	ROCHE MOLECULAR SYSTEMS, INC.	Change of a suppliers manufacturing site for a critical component.
Total: 107					