PMA Monthly Approvals from 7/1/2019 to 7/31/2019

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N18286/S032	07/02/2019	S - Special CBE	GELFOAM	PFIZER, INC.	Approval for a change in the labeling to identify the potential risk of pseudotumor appearance associated with device use.
N970003/S236	07/08/2019	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval for changes to the printed circuit board assembly in the Model 3300 LATITUDE Programming System.
N970003/S239	07/08/2019	R - Real-Time Proc	PULSAR/PULSAR MAX IMPLANTABLE PULSE GENERATOR SYSTEM WITH CONSULT SOFTWARE	BOSTON SCIENTIFIC CORP.	Approval to modify the Model 3300 LATITUDE Programming System software components.
P830055/S231	07/29/2019	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for a new surgical technique for use with the ATTUNE Knee System and BrainLAB KNEE3 CAS (Computer Aided Surgery). The proposed surgical technique provides guidance and offers boundaries for varus/valgus alignment when recreating a patients specific anatomic alignment and soft tissue balance. The current Knee3 system and instruments are capable of kinematic alignment, but the existing labeling does not offer guidance on a kinematic approach to balancing.
P850048/S051	07/31/2019	R - Real-Time Proc	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl System Software version 5.5.0 to remove a Y-like command that can result in sample sequencing errors for users who are connected to an automation line.
P870024/S051	07/11/2019	O - Normal 180 Day	FLUOROPERM RGP CONTACT LENSES	PARAGON VISION SCIENCES	Approval for a manufacturing site located at Paragon Vision Sciences, Inc., 2120 W. Guadalupe Rd. Suite #112, Gilbert, Arizona 85233.
P890003/S411	07/23/2019	R - Real-Time Proc	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for updates to the Medtronic CareLink 2090 Programmer Model 9986 and CareLink Encore 29901 Programmer Model SW028 Baseline Operating System Software.
P910056/S032	07/03/2019	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 MX60PL.

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P910056/S036	07/02/2019	N - Normal 180 Day	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval of the enVista® One Piece Hydrophobic Acrylic IOL, Model MX60ET, which includes a modification to the intraocular lens (IOL) material formulation of the approved parent lens, enVista® Model MX60T.
P910077/S169	07/08/2019	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval for changes to the printed circuit board assembly in the Model 3300 LATITUDE Programming System.
P910077/S172	07/08/2019	R - Real-Time Proc	VENTAK(R) PRX (TM) MODEL 1700,1705 PULSE GENERATOR	BOSTON SCIENTIFIC	Approval to modify the Model 3300 LATITUDE Programming System software components.
P930027/S021	07/11/2019	S - Special CBE	IMMULITE SYSTEMS PSA & THIRD GENERATION PSA REAGENTS	SIEMENS HEALTHCARE DIAGNOSTICS INC.	Approval for a change to the product quality control (QC) method in order to enhance the safety of IMMULITE® Third Generation PSA High Adjustor (LUPH), IMMULITE® Systems PSA High Adjustor (LPSH) and IMMULITE® 2000 Systems PSA High Adjustor (LPSH).
P930029/S065	07/29/2019	N - Normal 180 Day	ATAKR(TM) RFCA SYSTEM	MEDTRONIC INC.	Approval for labeling, packaging, manufacturing, and product requirement changes for Medtronic RF Ablation Catheters.
P950021/S018	07/25/2019	S - Special CBE	ADVIA CENTAUR & ADVIA CENTAUR CP PSA IMMUNOASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval to improve the instructions for use with regards to the High-Dose Hook Effect claim for Prostate Specific Antigen (PSA) with the value obtained using complexed PSA high dose hook in order to enhance the safety of the ADVIA Centaur PSA, ADVIA Centaur CP PSA and Atellica IM PSA.
P950037/S200	07/18/2019	R - Real-Time Proc	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Approval for PSW 1901.U programmer software.
P960009/S333	07/03/2019	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for the Model A620 Activa DBS Patient Programmer Application.
P960009/S351	07/24/2019	O - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P960040/S434	07/08/2019	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for changes to the printed circuit board assembly in the Model 3300 LATITUDE Programming System.

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P960040/S437	07/08/2019	R - Real-Time Proc	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval to modify the Model 3300 LATITUDE Programming System software components.
P960040/S438	07/31/2019	N - Normal 180 Day	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Approval for modifications to device hardware, MRI labeling, manufacturing and software updates.
P960058/S139	07/18/2019	R - Real-Time Proc	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Approval for a new headpiece variant, the UHP 3D Plus and associated magnets, 3D Magnet Max and 3D Magnet Plus.
P970004/S293	07/25/2019	S - Special CBE	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for alignment of the labeling to an updated Risk Management process. This included addition of adverse events (e.g., changes in sexual function) and additional language to describe the impact of extreme program settings on battery longevity.
P970038/S039	07/31/2019	R - Real-Time Proc	TANDEM-R FREE PSA IMMUNORADIOMETRIC ASSAY/TANDEM-MP FREE PSA IMMUNOENZYMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl System Software version 5.5.0 to remove a Y-like command that can result in sample sequencing errors for users who are connected to an automation line.
P980041/S044	07/31/2019	R - Real-Time Proc	ACCESS AFP IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl System Software version 5.5.0 to remove a Y-like command that can result in sample sequencing errors for users who are connected to an automation line.
P990004/S034	07/24/2019	Y - 135 Review Tra	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEDICAL DEVICES A/S	Approval for a change in the detergent used for the washing/rising cycles in the washing machine in the production of the SURGIFOAM Absorbable Gelatin Sponge.
P990004/S035	07/17/2019	Y - 135 Review Tra	SURGIFOAM ABSORBABLE GELATIN SPONGE, USP	FERROSAN MEDICAL DEVICES A/S	Approval for adding an additional production autoclave for terminal sterilization.
P990013/S038	07/19/2019	R - Real-Time Proc	COLLAMER ULTRAVIOLET ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	STARR SURGICAL CO.	Approval to modify the labeling to include the lioli-24 IOL Delivery System to the current list of recommended delivery systems included in the Directions for Use (DFU) for the NanoFLEX® One-Piece Collamer Intraocular Lens (CIOL), Model CC4204A, and the sphere and toric Visian® ICL Implantable Collamer Lenses (MICL/TMICL).
P000009/S079	07/18/2019	R - Real-Time Proc	PHYLAX AV ICD SYSTEM	BIOTRONIK, INC.	Approval for PSW 1901.U programmer software.

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P000025/S104	07/19/2019	P - Panel Track	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for expanding the cochlear implantation indications to include patients 5 years and above with single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear.
P000025/S106	07/02/2019	N - Normal 180 Day	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval order should be issued for the +FLEX26 Active Electrode and Insertion Electrode (IE) FLEX26.
P010012/S498	07/08/2019	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval for changes to the printed circuit board assembly in the Model 3300 LATITUDE Programming System.
P010012/S502	07/08/2019	R - Real-Time Proc	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Approval to modify the Model 3300 LATITUDE Programming System software components.
P010014/S089	07/19/2019	R - Real-Time Proc	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval of a material change from POM-C for provisionals to alternative materials polyphenylsulfone.
P010032/S150	07/15/2019	O - Normal 180 Day	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Approval to add Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri, as an alternate ethylene oxide sterilization site for numerous neuromodulation products.
P030005/S182	07/08/2019	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval for changes to the printed circuit board assembly in the Model 3300 LATITUDE Programming System.
P030005/S184	07/08/2019	R - Real-Time Proc	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Approval to modify the Model 3300 LATITUDE Programming System software components.
P030016/S037	07/19/2019	R - Real-Time Proc	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Approval to modify the labeling to include the lioli-24 IOL Delivery System to the current list of recommended delivery systems included in the Directions for Use (DFU) for the NanoFLEX® One-Piece Collamer Intraocular Lens (CIOL), Model CC4204A, and the sphere and toric Visian® ICL Implantable Collamer Lenses (MICL/TMICL).

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P030016/S038	07/19/2019	O - Normal 180 Day	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Approval of the revised protocol for the post-approval study (PAS) protocol.
P030017/S326	07/02/2019	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for upgrading the Clinical Programming Software Bionic Navigator 3D to Version 2.20.
P040024/S108	07/31/2019	N - Normal 180 Day	RESTYLANE INJECTABLE GEL	Q-MED AB	Approval for revisions to the clinician and patient labeling of Perlane to include updated safety information based upon post marketing surveillance data.
P040029/S008	07/18/2019	R - Real-Time Proc	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATIO N	Approval for a minor labeling change.
P040050/S012	07/15/2019	N - Normal 180 Day	MACROPLASTIQUE IMPLANTS	UROPLASTY, LLC	Approval for a modified formulation of the polymer resin used in the syringe barrel.
P050023/S130	07/18/2019	R - Real-Time Proc	TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STEROID LV PACING LEAD	BIOTRONIK, INC.	Approval for PSW 1901.U programmer software.
P050031/S005	07/11/2019	O - Normal 180 Day	PARAGON Z CRT (TISILFOCON A) RIGID GAS PERMEABLE CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY	PARAGON VISION SCIENCES	Approval for a manufacturing site located at Paragon Vision Sciences, Inc., 2120 W. Guadalupe Rd. Suite #112, Gilbert, Arizona 85233.
P050047/S069	07/03/2019	R - Real-Time Proc	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for the implementation of the International Council for Harmonisation (ICH) elemental impurities guideline by the raw material supplier for the hyaluronic acid and lidocaine hydrochloride used in the manufacture of the Juvéderm Injectable Gel Implants.
P060037/S058	07/22/2019	R - Real-Time Proc	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Approval for packaging changes to the LPS-Mobile Articular Surface components.
P060037/S059	07/29/2019	R - Real-Time Proc	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Approval for updated labeling, including modified warnings and added MR Conditional language, for the NexGen LPS-Flex and LPS Mobile Bearing Knee Systems.
P070008/S101	07/18/2019	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 1901.U programmer software.

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P070026/S063	07/19/2019	O - Normal 180 Day	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for several changes to the approved post-approval study (PAS) protocol for the 36mm (COC36) newly enrolled subjects including, allowing any AP and Lateral radiographs that provide the required data points, expanding the time window for pre-op radiographs, and allowing telephone follow-up for 3- and 4-year visits.
P080012/S058	07/03/2019	R - Real-Time Proc	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Approval for introducing Software Version 2.00.30 for the Prometra Clinician Programmer, Cat. Nos. 12828 and 13828, used with Prometra and Prometra II Programmable Pumps and minor labeling changes to explain reduced functionality accompanying this revision.
P080025/S188	07/25/2019	S - Special CBE	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for the alignment of the labeling to an updated Risk Management process. This included addition of adverse events (e.g., changes in sexual function) and additional language to describe the impact of extreme program settings on battery longevity.
P090026/S025	07/31/2019	R - Real-Time Proc	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a modification to the UniCel Dxl System Software version 5.5.0 to remove a Y-like command that can result in sample sequencing errors for users who are connected to an automation line.
P090029/S012	07/12/2019	O - Normal 180 Day	PRESTIGE LP CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval of the revised protocol for the post-approval study (PAS) protocol.
P100009/S029	07/09/2019	N - Normal 180 Day	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval for design changes including a wider clip arm and independent and simultaneous gripper actuation.
P100009/S031	07/26/2019	O - Normal 180 Day	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval of the protocol for the post-approval study entitled "Registry-Based Continued Access Protocol Cohort and Real-World Use Surveillances."
P100009/S033	07/26/2019	S - Special CBE	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval for a reduction in the upper tolerance limit of the MitraClip arm tip-to-tip dimension.
P100044/S038	07/24/2019	R - Real-Time Proc	PROPEL	INTERSECT ENT	Approval for the introduction of a delivery system with a straight applicator for ethmoid sinus access and serves as an alternative to the approved delivery system with a curved applicator.
P100047/S134	07/02/2019	N - Normal 180 Day	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for a design change to the HVAD Female Cable Connector to use a mono-body design.
P100047/S138	07/09/2019	R - Real-Time Proc	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Approval for the addition of lubrication to the production process for the power connector pins of the AC and DC adapters and batteries of the HVAD System.
P110033/S044	07/03/2019	R - Real-Time Proc	JUVEDERM VOLUMA XC	ALLERGAN	Approval for the implementation of the International Council for Harmonisation (ICH) elemental impurities guideline by the raw material supplier for the hyaluronic acid and lidocaine hydrochloride used in the manufacture of the Juvéderm Injectable Gel Implants.

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P130008/S041	07/22/2019	R - Real-Time Proc	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for a change in the method used to incorporate serial numbers inside the Model 4063 leads IS-1 connector boot.
P130022/S023	07/18/2019	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATIO N	Approval to modify the patient remote cosmetically and to reduce the size; update the patient remote model numbers to PTR2300 and PTR2500; update the firmware for patient remote, model PTR2500 and the clinician programmer, model CLPG2000/CLPG2500 to support 5 stimulation therapy settings; and update the firmware to the IPG (renamed Omnia Senza IPG, Model NIPG2500) to support up to 5 stimulation settings.
P130026/S049	07/24/2019	S - Special CBE	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for manufacturing modifications to the crimp joint and the device pouch inspections.
P140002/S019	07/26/2019	Y - 135 Review Tra	MISAGO PERIPHERAL SELF-EXPANDING STENT SYSTEM	TERUMO MEDICAL CORPORATIO N	Approval for modifications to the sterilization cycle parameters, loading configuration, and requirements for product release from the sterilization process.
P140009/S047	07/15/2019	O - Normal 180 Day	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Approval for a manufacturing site located at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri, as an alternate ethylene oxide sterilization site for numerous neuromodulation products.
P140031/S087	07/29/2019	N - Normal 180 Day	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Approval for updates to the labeling of the SAPIEN 3 Transcatheter Heart Valve and Accessories and SAPIEN 3 Ultra Transcatheter Heart Valve and Accessories regarding additional valve-in-valve sizing guidance for implantation inside the Edwards INSPIRIS RESILIA aortic valve model 11500A.
P140032/S032	07/10/2019	R - Real-Time Proc	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Approval for minor design and related minor manufacturing changes to the pumphead roller arm assembly of the SynchroMed® II Pump for Implantable System for Remodulin.
P150001/S065	07/09/2019	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for design and manufacturing changes to the retainer ring component of the pump case assembly.
P150001/S066	07/18/2019	R - Real-Time Proc	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Approval for alternative packaging for the Contour Next glucose test strips.
P150004/S030	07/31/2019	R - Real-Time Proc	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Approval for removal of the small curve delivery sheath from DRG SlimTip Trial Lead Kit (model MN10350-50A) and DRG SlimTip Implant Lead Kit (model MN10450-50A).
P150012/S073	07/08/2019	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIE NTIFIC	Approval for changes to the printed circuit board assembly in the Model 3300 LATITUDE Programming system.
P150012/S076	07/08/2019	R - Real-Time Proc	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIE NTIFIC	Approval to modify the Model 3300 LATITUDE Programming System software components.

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P150013/S016	07/30/2019	P - Panel Track	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for the PD-L1 IHC 22C3 pharmDx. 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. Companion Diagnostic Indications Tumor Indication PD-L1 Expression Level Intended Use NSCLC TPS greater than or equal to 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 greater than or equal to 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 greater than or equal to 10 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying esophageal squamous cell cancer patients for treatment with KEYTRUDA® (pembrolizumab). Cervical Cancer CPS greater than or equal to 1 PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying cervical cancer patients for treatment with KEYTRUDA® (pembrolizumab). Urothelial Carcinoma CPS greater than or equal to 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 for treatment with KEYTRUDA® (pembrolizumab). ** **See the KEYTRUDA® product label for specific clinical circumstances guiding PD-L1 testing. For in vitro diagnostic use.

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P150017/S010	07/11/2019	N - Normal 180 Day	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Approval for the addition of 6 mm and 12 mm sizes of the Cartiva SCI device to the previously approved 8 mm and 10 mm sizes of the device.
P150017/S011	07/12/2019	O - Normal 180 Day	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Approval for changes to the labeling to reflect the findings of the Post-Approval Study (PAS) protocol.
P150040/S004	07/25/2019	O - Normal 180 Day	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Approval of the protocol for the post-approval study (PAS) protocol.

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P160001/S031	07/05/2019	O - Normal 180 Day	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for The Obalon Navigation Touch System (NTS) Post-Approval Study. The study is a prospective, observational, open-label, multi-center study designed to evaluate the risk of esophageal inflation during Obalon balloon administration in eligible patients. This is a stand-alone, new enrollment study with primary data collection, with no retrospective data acquisition from other sources (i.e., retrospective chart review; data abstraction from existing registries or other data sources). Safety of balloon administration is the focus of this short-term study. Therefore, follow-up of participants ends on the day of balloon administration. However, patients who experience any adverse events related to balloon administration will be followed until resolution of the adverse event. Subjects may re-enter the study for additional balloons as indicated. The co-primary endpoints are: esophageal inflation; and NTS Success defined as balloon inflation in the stomach with the use of the NTS only (without radiography) or correctly determining failed balloon transit (device in the esophagus) as confirmed by endoscopic removal. The study will include a minimum of 3,951 evaluable balloon administrations with at least 1,317 balloon administrations for an individual balloon administration number (1st, 2nd or 3rd). An evaluable balloon administration is achieved if the device capsule passes the upper esophageal sphincter. The sample size of 3,951 is based on the higher sample size required (between the co-primary endpoints) for the esophageal inflation endpoint. The study will enroll a minimum of 1,400 subjects at up to 40 U.S. sites. A participating physician must not exceed 792 (20% of the total) evaluable balloon administrations or 264 for individual balloon type (Balloon 1, 2, or 3). The study will enroll a minimum of 1,000 subjects The first co-primary endpoint, esophageal inflation, is met if none of the Obalon Balloon administrations in the study resulted in an esophageal inflation and the 97.5% one-sided upper exact confidence bound for the estimated esophageal inflation rate is less than 0.1% based on 80% power. The second co-primary endpoint, NTS Success, is met if the one-sided 97.5% lower exact confidence bound is greater than 97% based on 80% power. Other study endpoints include the following: individual device or procedure related adverse event rates; Product Performance Observations (PPO) rates; and percentage of balloon administrations with the following Obalon Navigation System Stomach Location Indicators: Capsules significantly offsets (left lateral) from initial vertical track; Capsules track accelerates; Capsule rotates from vertical to horizontal configuration; and Capsule up/ down movement with deep respiration (breath).
P160007/S020	07/29/2019	R - Real-Time Proc	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Approval for a minor software design change to fix a software anomaly in the Guardian Connect Mobile Application.
P160017/S061	07/09/2019	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for design and manufacturing changes to the retainer ring component of the pump case assembly.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160017/S062	07/18/2019	R - Real-Time Proc	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Approval for alternative packaging for the Contour Next glucose test strips.
P160022/S010	07/03/2019	R - Real-Time Proc	X SERIES®, R SERIES®, AED PRO®, AED 3¿ BLS PROFESSIONAL DEFIBRILLATORS, PRO-PADZ RADIOTRANSPARENT ELECTRODE, SUREPOWER ¿ BATTERY PACK, SUREPOWER II¿ BATTERY PACK, AED PRO® NON-RECHARGEABLE LITHIUM BATTERY PACK, AED 3 ¿ BATTERY PACK, SUREPOWER¿ CHARGER, AND SUREPOWER ¿ SINGLE BAY CHARGER	ZOLL MEDICAL CORPORATION	Approval for hardware and software changes to achieve compliance with an FDA-recognized consensus standard for electromagnetic compatibility.
P160026/S007	07/16/2019	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 material change for the J507 connector on the Angelina PCBA for the LIFEPAK 1000 defibrillator.
P160026/S009	07/10/2019	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 hardware changes to the power PCBA component and the battery power cable assembly component.
P160033/S002	07/25/2019	N - Normal 180 Day	POWERHEART® G5 AED, POWERHEART® AED G3 PLUS, AND POWERHEART® AED G3	CARDIAC SCIENCE CORPORATION	Approval for updates to the Powerheart AED G5 device.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160042/S007	07/24/2019	R - Real-Time Proc	REVANESSE ULTRA	PROLLENIUM MEDICAL TECHNOLOGIES INC.	Approval for 2-year shelf-life of Revanesse Versa.
P170006/S013	07/29/2019	R - Real-Time Proc	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Approval for changes to the liquid chemical sterilization cycle parameters for the Avalus Bioprosthesis.
P170019/S004	07/01/2019	N - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order for extending the label claim to include an indication for LYNPARZA (olaparib) in ovarian cancer patients with BRCA1/2 alterations.
P170019/S008	07/01/2019	N - Normal 180 Day	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval order for extending the label claim to include an indication for TAGRISSO (osimertinib) in non-small cell lung cancer patients with EGFR exon 19 deletions and EGFR exon 21 L858R alterations.
P180002/S005	07/30/2019	N - Normal 180 Day	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval for the Zephyr 5.5-LP Endobronchial Valve (EBV) and the Zephyr 5.5 Dual Mark Endobronchial Delivery Catheter (EDC).
P180002/S006	07/19/2019	Y - 135 Review Tra	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Approval to use an alternate supplier, Laserage (Waukegan, IL), for the retainer component of the Zephyr 4.0 Endobronchial Valve.
P180029/S002	07/22/2019	O - Normal 180 Day	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Approval of the protocol for the post-approval study (PAS) protocol.

Total: 91

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S058	07/11/2019	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Addition of a duplicate Particle Size Analyzer for SURGICEL Powder Absorbable Hemostatic Powder.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S059	07/23/2019	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Change to the resin components within the sealant film used in the foil pouch packaging for GYNECARE INTERCEED Absorbable Adhesion Barrier and SURGICEL Absorbable Hemostats during manual and automated manufacturing processes.
N970012/S165	07/11/2019	X - 30-Day Notice	AMS 700 SERIES PRODUCT LINE AND THE DYNAFLEX INFLATABLE PENILE PROSTHESES	BOSTON SCIENTIFIC CORP.	Changes to the milling and molding process for the reservoir adapter component.
P790005/S066	07/18/2019	X - 30-Day Notice	OSTEOSTIM(R)	EBI, LLC	Qualify and approve an alternate, proposed supplier, Vesta Intermediate Funding d/b/a Lubrizol Life Sciences to provide a silicone over-extruded cable to manufacture and assemble implantable stimulator leads for the subject devices (OsteoGen Surigically Implantable Bone Growth Stimulators and SpF Implantable Spinal Fusion Stimulators).
P790007/S061	07/17/2019	X - 30-Day Notice	HANCOCK MODIFIED ORIFICE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Use of a new stainless steel solution complex system for the storage and distribution of manufacturing solutions.
P830061/S174	07/22/2019	X - 30-Day Notice	STEROID TIP(TM) MODEL 4503&4003 TRANSVENOUS PACING	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the incoming inspection and component specification for TiO2 pigment paste.
P840001/S437	07/05/2019	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Process change for software upgrades to the Factory Works Manufacturing Execution System.
P840001/S438	07/29/2019	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODULATION	Alternate supplier for the A08826 part family of coils.
P850007/S042	07/03/2019	X - 30-Day Notice	PHYSIO-STIM(TM) I & II MODEL 6000 & 7000	ORTHOFIX, INC.	Modification in the verification step for the coil winding procedure and to add equipment to cut and split the ribbon cable to the desired specifications.
P850035/S055	07/18/2019	X - 30-Day Notice	EBI SPF IMPLANTABLE SPINAL FUSION STIMULATOR	EBI, LLC	Qualify and approve an alternate, proposed supplier, Vesta Intermediate Funding d/b/a Lubrizol Life Sciences to provide a silicone over-extruded cable to manufacture and assemble implantable stimulator leads for the subject devices (OsteoGen Surigically Implantable Bone Growth Stimulators and SpF Implantable Spinal Fusion Stimulators).
P850089/S143	07/22/2019	X - 30-Day Notice	CAPSURE SP, CAPSURE, CAPSURE 2 LEADS, EXCELLENCE S, IMPULSE, IMPLUSE II EXCELLENCE SS, LEADS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the incoming inspection and component specification for TiO2 pigment paste.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860004/S333	07/05/2019	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Process change for software upgrades to the Factory Works Manufacturing Execution System.
P870024/S052	07/03/2019	X - 30-Day Notice	FLUOROPERM RGP CONTACT LENSES	PARAGON VISION SCIENCES	Removal of a quality control batch release test.
P870078/S046	07/17/2019	X - 30-Day Notice	HANCOCK PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Use of a new stainless steel solution complex system for the storage and distribution of manufacturing solutions.
P880047/S032	07/23/2019	X - 30-Day Notice	INTERCEED TC7 ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Change to the resin components within the sealant film used in the foil pouch packaging for GYNECARE INTERCEED Absorbable Adhesion Barrier and SURGICEL Absorbable Hemostats during manual and automated manufacturing processes.
P890003/S415	07/02/2019	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Transfer electrode assemblies from the Medtronic Energy and Component Center facility to the Medtronic Rice Creek and Medtronic Puerto Rico Operations Company facilities for completion and final inspection.
P890003/S417	07/22/2019	X - 30-Day Notice	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Update the incoming inspection and component specification for TiO2 pigment paste.
P900033/S081	07/15/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Qualification of an alternate manufacturing facility for Integra Meshed Dermal Regeneration Template.
P900060/S060	07/26/2019	X - 30-Day Notice	CARBOMEDICS PROSTHETIC HEART VALVE (CPHV)	SORIN GROUP ITALIA S.R.L	Modification to the valve orifice carbon coating process.
P920015/S235	07/22/2019	X - 30-Day Notice	MEDTRONIC(R) TRANSVENE LEAD SYSTEM	MEDTRONIC INC.	Update the incoming inspection and component specification for TiO2 pigment paste.
P930031/S065	07/25/2019	X - 30-Day Notice	WALLSTENT(R) TIPS ENDOPROSTHESIS WITH UNISTEP PLUS DELIVERY SYSTEM	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P930039/S203	07/22/2019	X - 30-Day Notice	MEDTRONIC(R) CAPSUREFIX LEAD MODEL 4068,4067,4568	MEDTRONIC, INC.	Update the incoming inspection and component specification for TiO2 pigment paste.
P940019/S056	07/25/2019	X - 30-Day Notice	WALLSTENT(R) ILIAC ENDOPROSTHESIS	BOSTON SCIENTIFIC SCIMED, INC.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P950020/S098	07/25/2019	X - 30-Day Notice	FLEXATOME CUTTING BALLOON	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950024/S086	07/02/2019	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Transfer electrode assemblies from the Medtronic Energy and Component Center facility to the Medtronic Rice Creek and Medtronic Puerto Rico Operations Company facilities for completion and final inspection.
P950024/S087	07/22/2019	X - 30-Day Notice	MEDTRONIC(R) CAPSURE (R) EPI PACING LEAD MODEL 4695	MEDTRONIC INC.	Update the incoming inspection and component specification for TiO2 pigment paste.
P950029/S123	07/29/2019	X - 30-Day Notice	CHORUS RM MODEL 7034 DDDR PACEMAKER INCL. OPUS RM MODEL 4534 SSIR PACEMAKER	MICROPORT CRM USA INC.	Introduce automatic testing equipment for the control of Bal Seal springs in IS1 connector cavities.
P950037/S203	07/19/2019	X - 30-Day Notice	DROMOS DR/DR-A AND DROMOS SR/SR-B CARDIAC PACING SYSTEMS	BIOTRONIK, INC.	Automate the assembly and battery preparation of the Edora family of IPGs and CRT-Ps.
P960009/S352	07/05/2019	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Process change for software upgrades to the Factory Works Manufacturing Execution System.
P960009/S353	07/29/2019	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Alternate supplier for the A08826 part family of coils.
P960043/S105	07/30/2019	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Duplication of a manufacturing line for the Perclose ProGlide Suture-Mediated Closure System and expansion of a cleanroom within the existing approved manufacturing facility.
P960058/S140	07/03/2019	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Changes to the manufacturing process for sealing the top and bottom cover of the headpiece component.
P970004/S291	07/05/2019	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODU LATION	Process change for software upgrades to the Factory Works Manufacturing Execution System.
P970031/S066	07/17/2019	X - 30-Day Notice	MEDTRONIC FREESTYLE AORTIC ROOT BIOPROSTHESIS	MEDTRONIC, INC.	Use of a new stainless steel solution complex system for the storage and distribution of manufacturing solutions.
P970051/S186	07/02/2019	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of an x-ray screening step post shot 1 silicone molding.

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P980016/S711	07/11/2019	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the Electronic Module Assembly manufacturing requirements and associated design drawings to clarify the required electrical interconnect sequence for the Laser Ribbon Bond connections.
P980016/S712	07/18/2019	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the Parallel Gap Welding (PGW) equipment controller, the test method to detect weak welds, and to leverage the PGW process to standardize work.
P980016/S714	07/26/2019	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Process changes to the surface mount tantalum capacitor used in sub-assemblies for ICDs and IPGs.
P980016/S715	07/22/2019	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Update the incoming inspection and component specification for TiO2 pigment paste.
P980033/S055	07/25/2019	X - 30-Day Notice	WALLSTENT ENDOPROSTHESIS	BOSTON SCIENTIFIC CORPORATIO N	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P980035/S598	07/11/2019	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the Electronic Module Assembly manufacturing requirements and associated design drawings to clarify the required electrical interconnect sequence for the Laser Ribbon Bond connections.
P980035/S599	07/18/2019	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update the Parallel Gap Welding (PGW) equipment controller, the test method to detect weak welds, and to leverage the PGW process to standardize work.
P980035/S600	07/26/2019	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Process changes to the surface mount tantalum capacitor used in sub-assemblies for ICDs and IPGs.

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P980037/S075	07/25/2019	X - 30-Day Notice	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P980040/S104	07/18/2019	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Expansion of the manufacturing facility in Puerto Rico.
P980043/S071	07/17/2019	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC, INC.	Use of a new stainless steel solution complex system for the storage and distribution of manufacturing solutions.
P990009/S056	07/26/2019	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Addition of an alternate supplier of the sodium chloride salt used to prepare the prefilled 0.9% sodium chloride solution syringes for the Floseal Hemostatic Matrix at the Baxter Healthcare Corporation facility located in Hayward, California.
P990009/S057	07/19/2019	X - 30-Day Notice	FLOSEAL MATRIX/ FLOSEAL MATRIX HEMOSTATIC SEALANT/ PROCEED HEMOSTATIC SEALANT	BAXTER HEALTHCARE CORP.	Change to add an additional packaging material supplier.
P990013/S039	07/26/2019	X - 30-Day Notice	COLLAMER ULTRAVIOLET ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	STARR SURGICAL CO.	Addition of the microbiology laboratory at the STAAR Surgical, Monrovia facility, as an alternate provider of environmental monitoring services for cleanrooms used to manufacture and process finished devices.
P990038/S029	07/18/2019	X - 30-Day Notice	DIASORIN ETI MAK-2 PLUS ASSAY	DIASORIN, INC.	Relocation of reagent manufacture from one room to another within the same establishment
P990041/S028	07/18/2019	X - 30-Day Notice	DIASORIN ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Relocation of reagent manufacture from one room to another within the same establishment
P990042/S025	07/18/2019	X - 30-Day Notice	DIASORIN ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Relocation of reagent manufacture from one room to another within the same establishment
P990043/S029	07/18/2019	X - 30-Day Notice	DIASORIN ETI-EBK PLUS ASSAY	DIASORIN, INC.	Relocation of reagent manufacture from one room to another within the same establishment
P990044/S026	07/18/2019	X - 30-Day Notice	DIASORIN ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Relocation of reagent manufacture from one room to another within the same establishment
P990045/S026	07/18/2019	X - 30-Day Notice	DIASORIN ETI-AB-COREK PLUS ASSAY	DIASORIN, INC.	Relocation of reagent manufacture from one room to another within the same establishment
P990064/S079	07/17/2019	X - 30-Day Notice	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC, INC.	Use of a new stainless steel solution complex system for the storage and distribution of manufacturing solutions.

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P990075/S045	07/24/2019	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Change in manufacturing process for the Plug Cap for the Spectrum Saline-filled Breast Implants from a transfer molding process to a liquid injection molding process.
P000015/S037	07/02/2019	X - 30-Day Notice	NUCLEUS 24 AUDITORY BRAINSTEM IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of an x-ray screening step post shot 1 silicone molding.
P000054/S053	07/24/2019	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Replacement for the tendon slicer at the Collagen Manufacturing Center (CMC) Building.
P000058/S072	07/24/2019	X - 30-Day Notice	INFUSE BONE GRAFT/LT-CAGE LUMBAR TAPERED FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Replacement for the tendon slicer at the Collagen Manufacturing Center (CMC) Building.
P010012/S507	07/18/2019	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Move optional rework steps to the standard assembly process for LV-1 pulse generators.
P010015/S410	07/11/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the Electronic Module Assembly manufacturing requirements and associated design drawings to clarify the required electrical interconnect sequence for the Laser Ribbon Bond connections.
P010015/S413	07/18/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the Parallel Gap Welding (PGW) equipment controller, the test method to detect weak welds, and to leverage the PGW process to standardize work.
P010015/S414	07/26/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Process changes to the surface mount tantalum capacitor used in sub-assemblies for ICDs and IPGs.
P010015/S415	07/22/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update the incoming inspection and component specification for TiO2 pigment paste.
P010030/S119	07/18/2019	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Updates to the servicing and reconditioning processes for the LifeVest 4000 electrode belts.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010030/S120	07/29/2019	X - 30-Day Notice	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Change to the solder joint of the pulse wires within the electrode belt distribution node.
P010031/S671	07/11/2019	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Electronic Module Assembly manufacturing requirements and associated design drawings to clarify the required electrical interconnect sequence for the Laser Ribbon Bond connections.
P010031/S673	07/18/2019	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the Parallel Gap Welding (PGW) equipment controller, the test method to detect weak welds, and to leverage the PGW process to standardize work.
P010031/S675	07/26/2019	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Process changes to the surface mount tantalum capacitor used in sub-assemblies for ICDs and IPGs.
P010031/S676	07/22/2019	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the incoming inspection and component specification for TiO2 pigment paste.
P010032/S152	07/17/2019	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Implement a manufacturing process change that changes the in-process electrode cleaning method for the S-Series Leads from one ultrasonic cleaning method to another.
P010032/S153	07/29/2019	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ABBOTT MEDICAL	Move FMI manufacturing operations from its current site at Elk Grove Village, Illinois, USA to a facility in Lincolnshire, Illinois, USA. FMI is the currently approved supplier for molded silicone parts that go into the finished assembly and packaging of implantable pulse generators (IPGs), leads, lead extensions, lead adapters, and lead accessories.

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P020012/S030	07/11/2019	X - 30-Day Notice	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Implement a modification to the existing environmental sampling and monitoring plan of the Company's ISO Class 7 and Class 8 Cleanrooms.
P020012/S031	07/08/2019	X - 30-Day Notice	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Lowering the manufacturing water for injection (WFI) tank and loop system alert temperature from 80 degree C to 70 degree C.
P030004/S020	07/24/2019	X - 30-Day Notice	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Change to the Biological Indicator (BI) Bacillus atrophaeus STN 062MG that is used in the dry heat sterilization of the Onyx Liquid Embolic System.
P030005/S187	07/18/2019	X - 30-Day Notice	CONTAK RENEWAL MODELS H125 AND H120 WITH THE MODEL 2865 VERSION 1.8 APPLICATION SOFTWARE	GUIDANT CORP.	Move optional rework steps to the standard assembly process for LV-1 pulse generators.
P030011/S071	07/18/2019	X - 30-Day Notice	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Change of a component supplier for the Companion 2 Driver System.
P030016/S039	07/26/2019	X - 30-Day Notice	VISIAN ICL (IMPLANTABLE COLLAMER LENS)	STAAR SURGICAL COMPANY	Addition of the microbiology laboratory at the STAAR Surgical, Monrovia facility, as an alternate provider of environmental monitoring services for cleanrooms used to manufacture and process finished devices.
P030036/S112	07/22/2019	X - 30-Day Notice	MEDTRONIC SELECTSECURE LEAD MODEL 3830	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update the incoming inspection and component specification for TiO2 pigment paste.
P030053/S052	07/12/2019	X - 30-Day Notice	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Reconfiguration of the MemoryGel® Silicone Gel-Filled Breast Implant shell assembly and laser marking process steps from a batch process to a single piece flow manufacturing line. The change is applicable to the steps after the shells have been manufactured but before they are filled with gel and cured. The batch to single piece flow manufacturing process change is specific to the smooth shell surface version of the implants and is not applicable to the textured shell implant versions.
P040034/S029	07/11/2019	X - 30-Day Notice	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Use of an additional freezer for the production of the DuraSeal Dural Sealant System and DuraSeal Exact Spine Sealant System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050006/S078	07/11/2019	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Removal of cytotoxicity and infrared spectroscopy inspections for the GORE CARDIOFORM ASD Occluder incoming components.
P050019/S031	07/25/2019	X - 30-Day Notice	CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P050027/S019	07/25/2019	X - 30-Day Notice	KARL STORZ PHOTODYNAMIC DIAGNOSTIC D-LIGHT C (PDD) SYSTEM	KARL STORZ ENDOSCOPY-AMERICA, INC.	Process change to the manufacturing method for the BG Supply Cable of the D- Light C Light Source.
P050051/S035	07/03/2019	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Implement a process scale-up for two kit reagent bulks.
P050053/S044	07/25/2019	X - 30-Day Notice	INFUSE BONE GRAFT	MEDTRONIC INC.	Replacement for the tendon slicer at the Collagen Manufacturing Center (CMC) Building.
P060006/S097	07/25/2019	X - 30-Day Notice	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P060011/S018	07/31/2019	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Revision of acceptance limits for the environmental monitoring process, moving environmental sampling in-house, and changes to the routine purified water sampling/test schedule.
P060037/S060	07/03/2019	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Process change to eliminate a cytotoxicity test requirement for the monitoring of the final cleaning process.
P070008/S105	07/19/2019	X - 30-Day Notice	STRATOS LV CRT-P AND STRATOS LV-T CRT-P, COROX OTW BP LEAD AND COROX OTW-S BP LEAD	BIOTRONIK, INC.	Automate the assembly and battery preparation of the Edora family of IPGs and CRT-Ps.
P070015/S145	07/12/2019	X - 30-Day Notice	XIENCE AND PROMUS EVEROLIMUS ELUTING CORONARY STENT SYSTEMS	ABBOTT VASCULAR INC.	Changes to the gowning regime and reclassification of the manufacturing environment.
P080006/S138	07/22/2019	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Update the incoming inspection and component specification for TiO2 pigment paste.

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P080007/S022	07/11/2019	X - 30-Day Notice	BARD E-LUMINEXX VASCULAR STENT	BARD PERIPHERAL VASCULAR, INC.	Addition of an in-process weld inspection step.
P080013/S017	07/11/2019	X - 30-Day Notice	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCES CORPORATION	Use of an additional freezer for the production of the DuraSeal Dural Sealant System and DuraSeal Exact Spine Sealant System.
P080025/S186	07/05/2019	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Process change for software upgrades to the Factory Works Manufacturing Execution System.
P090003/S048	07/25/2019	X - 30-Day Notice	EXPRESS LD ILIAC PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P090016/S033	07/31/2019	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Change to the analytical method used for the determination of residual BDDE concentration in Belotero Balance.
P100009/S032	07/18/2019	X - 30-Day Notice	MITRACLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Use of an additional alternative Bacterial Endotoxin testing laboratory for the MitraClip NTR/XTR and G4 devices.
P100018/S021	07/15/2019	X - 30-Day Notice	PIPELINE EMBOLIZATION DEVICE	MICRO THERAPEUTICS DBA EV3 NEUROVASCULAR	Manufacturing facility relocation at a metal wire critical component supplier.
P100047/S141	07/05/2019	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Use of an electronic acceptable quality level (AQL) sampling feature within the Camstar Manufacturing Existing System (MES).
P100049/S026	07/15/2019	X - 30-Day Notice	LINX REFLUX MANAGEMENT SYSTEM	TORAX MEDICAL	Implementation of new packaging equipment and packaging testing.
P110004/S033	07/17/2019	X - 30-Day Notice	PRESILLION PLUS COCR CORONARY STENT RX SYSTEM	MEDINOL LTD.	Transfer of supervisory sterilization responsibilities from the sponsor to the contract sterilizer.
P110010/S167	07/25/2019	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.

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P110019/S105	07/12/2019	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Changes to the gowning regime and reclassification of the manufacturing environment.
P110028/S020	07/31/2019	X - 30-Day Notice	ABSOLUTE PRO VASCULAR SELF-EXPANDING STENT SYSTEM	ABBOTT VASCULAR INC.	Modify the packaging.
P110035/S051	07/25/2019	X - 30-Day Notice	EPIC SELF-EXPANDING NITINOL STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P110042/S126	07/11/2019	X - 30-Day Notice	SUBCUTANEOUS IMPLANTABLE DEFIBRILLATOR (S-ICD) SYSTEM	BOSTON SCIENTIFIC CORPORATION	Software change to the automated laser fusion-weld machine used in welding the EMBLEM S-ICD battery case.
P120010/S131	07/18/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Changes to a drying process at a contract manufacturer in order to reduce waste. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P120011/S016	07/19/2019	X - 30-Day Notice	IDEAL IMPLANT SALINE-FILLED BREAST IMPLANT	IDEALIMPLANT	Revision of grit size specification for alumina blasting media used for mandrel surface finishing from 120 to 100-120.
P130004/S007	07/25/2019	X - 30-Day Notice	RESURE SEALANT	OCULAR THERAPEUTICS, INC.	Modification to the radiation dose range for sterilization of the ReSure® Sealant.
P130008/S045	07/25/2019	X - 30-Day Notice	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Reduce the energy used in the seam welding process of the sensor component of the Model 4340 and Model 4323 Sensor Lead at the contract manufacturer Cirtec Medical.
P130012/S007	07/15/2019	X - 30-Day Notice	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Modify the purchase of mesh raw material and addition of processing steps.
P130012/S008	07/03/2019	X - 30-Day Notice	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Implement a new anode rolling press.
P130013/S032	07/09/2019	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Implement an alternate inspection method for the occluder fabric.

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P130021/S060	07/02/2019	X - 30-Day Notice	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Addition of a new sewing aid for final valve assembly of Evolut R and Evolut PRO Transcatheter Aortic Valves.
P130028/S024	07/03/2019	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Incorporate a process improvement to the injection molding process for the distal subassembly of the 12 Electrode Percutaneous Leads and Trial Leads with compact spacing.
P130030/S061	07/25/2019	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P140003/S055	07/03/2019	X - 30-Day Notice	IMPELLA 2.5 SYSTEM	ABIOMED, INC.	Addition of a second supplier for a component of the Impella CP with SmartAssist.
P140008/S018	07/19/2019	X - 30-Day Notice	ORBERA INTRAGASTRIC BALLOON	APOLLO ENDOSURGERY INC	Additional supplier for the balloon shell and sheath components of your device and changing bioburden alert and action limits.
P140009/S048	07/29/2019	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ABBOTT MEDICAL	Move FMI manufacturing operations from its current site at Elk Grove Village, Illinois, USA to a facility in Lincolnshire, Illinois, USA. FMI is the currently approved supplier for molded silicone parts that go into the finished assembly and packaging of implantable pulse generators (IPGs), leads, lead extensions, lead adapters, and lead accessories.
P140017/S015	07/17/2019	X - 30-Day Notice	MELODY TRANSCATHETER PULMONARY VALVE (TPV), ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (DS)	MEDTRONIC INC.	Use of a new stainless steel solution complex system for the storage and distribution of manufacturing solutions.
P140028/S041	07/25/2019	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P140032/S035	07/05/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Process change for software upgrades to the Factory Works Manufacturing Execution System.
P150001/S070	07/12/2019	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Addition of a new final functional tester for the motor assembly component. The motor assembly is a component of the MiniMed 630G and MiniMed 670G systems.
P150001/S071	07/18/2019	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Changes to a drying process at a contract manufacturer in order to reduce waste. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150002/S005	07/10/2019	X - 30-Day Notice	INCRAFT(R) AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Automation of the wire wrapping process for the pleating of limb grafts by the supplier.

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P150003/S050	07/25/2019	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P150004/S031	07/29/2019	X - 30-Day Notice	AXIUM NEUROSTIMULATOR SYSTEM	ABBOTT MEDICAL	Move FMI manufacturing operations from its current site at Elk Grove Village, Illinois, USA to a facility in Lincolnshire, Illinois, USA. FMI is the currently approved supplier for molded silicone parts that go into the finished assembly and packaging of implantable pulse generators (IPGs), leads, lead extensions, lead adapters, and lead accessories.
P150019/S056	07/18/2019	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Changes to a drying process at a contract manufacturer in order to reduce waste. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150029/S029	07/18/2019	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Changes to a drying process at a contract manufacturer in order to reduce waste. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P150039/S004	07/02/2019	X - 30-Day Notice	TRYTON SIDE BRANCH STENT	TRYTON MEDICAL, INC.	Add new equipment, leak testers and hot air boxes, for use on the Tryton product during the manufacturing and testing process.
P160001/S040	07/03/2019	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Change high pressure regulator and low pressure regulator target setpoints, the final release testing acceptance criteria for the regulator pressures, and the associated in-process and final acceptance activities.
P160001/S041	07/03/2019	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Change a manufacturing fixture component and tighten a process set-up acceptance criterion relating to balloon welding.
P160001/S043	07/25/2019	X - 30-Day Notice	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Implementation of a programming equipment and manufacturing step change for the Touch Dispenser.
P160007/S023	07/18/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Changes to a drying process at a contract manufacturer in order to reduce waste. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.
P160017/S066	07/12/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of a new final functional tester for the motor assembly component. The motor assembly is a component of the MiniMed 630G and MiniMed 670G systems.
P160017/S067	07/18/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Changes to a drying process at a contract manufacturer in order to reduce waste. The Guardian Sensor (3) is a component of the MiniMed 670G, the Guardian Connect, and the MiniMed 630G System. The Enlite Sensor is a component of the MiniMed iPro 2, MiniMed Paradigm Real-Time Revel, MiniMed 530G, and MiniMed 630G Systems.

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P160048/S010	07/24/2019	X - 30-Day Notice	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Modification of equipment and processes used to encase the Eversense sensor. The Eversense sensor is a component of the Eversense Continuous Glucose Monitoring system.
P170006/S015	07/17/2019	X - 30-Day Notice	AVALUS(TM) BIOPROSTHESIS	MEDTRONIC INC.	Use of a new stainless steel solution complex system for the storage and distribution of manufacturing solutions.
P170008/S018	07/17/2019	X - 30-Day Notice	ELUNIR¿ RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Transfer of supervisory sterilization responsibilities from the sponsor to the contract sterilizer.
P180002/S008	07/17/2019	X - 30-Day Notice	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATION	Addition of an alternate supplier of the funnel component of the Endobronchial Loader System (ELS).
P180011/S009	07/25/2019	X - 30-Day Notice	ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.
P180029/S005	07/11/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Addition of braid component manufacturing at the Penang, Malaysia facility.
P180029/S007	07/25/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replacement of the current software with new software to collect and process manufacturing test data, and track and trend capability data for various manufacturing areas.

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