PMA Monthly approvals from 8/1/2019 to 8/31/2019

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P180050	08/16/2019	PMAO - PMA Origi	BAROSTIM NEO® SYSTEM	CVRX, INC.	Approval for The BAROSTIM NEO System. The device is indicated for the improvement of symptoms of heart failure. quality of life, six-minute hall walk and functional status, for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction <= 35%, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

Total: 1

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S057	08/14/2019	R - Real-Time Proc	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for a change in the colorant of the bellows portion of the device applicator.
P830055/S234	08/15/2019	S - Special CBE	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval for anew inspection method to aid operators during the inspection of product packaging.
P850048/S052	08/09/2019	R - Real-Time Proc	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY	BECKMAN COULTER, INC.	Approval for a modification to the piston rod design in the vacuum pump of the UniCel DxI 600 and 800 instruments, integrating the washer and piston rod into a single unit.
P890003/S412	08/20/2019	N - Normal 180 Day	SYNERGYST II PULSE GENERATOR MODELS 7070 & 7071	MEDTRONIC, INC.	Approval for updated RAMware, Application Software, integrated circuit design changes and associated manufacturing tests.

Data as of 09/04/2019 03:53 AM

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960011/S032	08/05/2019	R - Real-Time Proc	BIOLON 1% SODIUM HYALURONATE VISCOELASTIC SURGICAL AID FLUID	AMRING PHARMACEUTICALS	Approval for material changes to the tip cap and syringe tip cap system over-closure for BIOLON®.
P960016/S079	08/22/2019	O - Normal 180 Day	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Approval for an alternate sterilization site at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri.
P960058/S131	08/30/2019	N - Normal 180 Day	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Approval of the HiRes Fidelity 120 and HiRes Optima sound processing strategies for adults and pediatric patients 12 months and older. Approval of the ClearVoice and Front-End Processing features of StereoZoom, UltraZoom, SoundRelax, WindBlock, and EchoBlock for pediatric population 6 years and older.
P970038/S040	08/09/2019	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 piston rod design in the vacuum pump of the UniCel DxI 600 and 800 instruments, integrating the washer and piston rod into a single unit.
P980016/S701	08/01/2019	Y - 135 Review Tra	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a change to a sub-tier raw material supplier for vanadium pentoxide used during battery cathode fabrication.
P980035/S582	08/01/2019	Y - 135 Review Tra	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for a change to a sub-tier raw material supplier for vanadium pentoxide used during battery cathode fabrication.
P980035/S594	08/20/2019	N - Normal 180 Day	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for updated RAMware, Application Software, integrated circuit design changes and associated manufacturing tests.
P980035/S595	08/22/2019	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for new coating treatment of the battery cathode current collectors in medium-rate batteries.
P980040/S100	08/29/2019	Y - 135 Review Tra	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Approval for adding an alternate supplier of the injection molded screw plunger and pushrod components for the Preloaded TECNIS® 1-Piece IOL, Model PCB00 and TECNIS® iTEC Preloaded Delivery System, Model PMB00.
P980041/S045	08/09/2019	R - Real-Time Proc	ACCESS AFP IMMUNOASSAY SYSTEM	BECKMAN COULTER, INC.	Approval for a modification to the piston rod design in the vacuum pump of the UniCel DxI 600 and 800 instruments, integrating the washer and piston rod into a single unit.

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P000025/S112	08/22/2019	R - Real-Time Proc	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for the SONNET 2 and SONNET 2 EAS audio processors. The SONNET 2 and SONNET 2 EAS audio processors are updates to existing products (SONNET and SONNET EAS).
P000037/S054	08/15/2019	O - Normal 180 Day	ON-X (R) PROSTHETIC HEART VALVE, MODEL ONXA	ON-X LIFE TECHNOLOGIES, INC.	Approval for the revised protocol for the Newly Enrolled On-X Post-Approval Study.
P000039/S067	08/22/2019	O - Normal 180 Day	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	ABBOTT MEDICAL	Approval for an alternate sterilization site at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri.
P000046/S027	08/28/2019	R - Real-Time Proc	STAARVISC II	ANIKA THERAPEUTICS, INC.	Approval for an extension of the shelf-life of Ophthalmic Viscoelastic® from 24 months to 36 months.
P010015/S398	08/01/2019	Y - 135 Review Tra	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for a change to a sub-tier raw material supplier for vanadium pentoxide used during battery cathode fabrication.
P010015/S407	08/22/2019	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for a minor battery design change for Delta 26H3 or medium-rate (MR) batteries.
P010015/S411	08/23/2019	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for updated firmware and software for the EffectivCRT during AF feature.
P010031/S661	08/01/2019	Y - 135 Review Tra	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a change to a sub-tier raw material supplier for vanadium pentoxide used during battery cathode fabrication.
P010031/S672	08/23/2019	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for updated firmware and software for the EffectivCRT during AF feature.
P020024/S057	08/22/2019	O - Normal 180 Day	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	ABBOTT MEDICAL	Approval for an alternate sterilization site at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030011/S073	08/15/2019	S - Special CBE	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, LLC	Approval for the addition of a red key tag with caution statement on the key ring of the Companion 2 Driver key.
P040013/S022	08/19/2019	O - Normal 180 Day	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX	LYNCH BIOLOGICS LLC	Approval to change the supplier who fills the B-TCP cup component of the GEM21S device from A+ Secure Packaging to Alliance Contract Pharma.
P040020/S087	08/26/2019	P - Panel Track	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Approval for the AcrySof® IQ PanOptix® Trifocal Intraocular lens, which is indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL. Approval for the AcrySof® IQ PanOptix® Toric Trifocal Intraocular lens, which is indicated for primary implantation in the capsular bag in the posterior chamber of the eye for the visual correction of aphakia and the reduction of residual refractive astigmatism, in adult patients in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity with a reduced need for eyeglasses, compared to a monofocal IOL.
P040029/S006	08/07/2019	O - Normal 180 Day	JSZ ORTHOKERATOLOGY (OPRIFOCON A) CONTACT LENSES FOR OVERNIGHT WEAR	EUCLID SYSTEMS CORPORATION	Approval for new manufacturing site at Euclid Systems Corporation, 45472 Holiday Drive, Suite 7, Herndon, Virginia.
P040040/S037	08/22/2019	O - Normal 180 Day	AMPLATZER MUSCULAR VSD OCCLUDER	ABBOTT MEDICAL	Approval for an alternate sterilization site at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri.
P050028/S077	08/13/2019	S - Special CBE	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the addition of an instruction to the labeling to visually inspect reagent cassette and vial prior to use.
P060019/S043	08/16/2019	Y - 135 Review Tra	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Approval for changes in the finished device electrical safety test for the Cool Point Irrigation Pump.
P060030/S078	08/13/2019	S - Special CBE	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the addition of an instruction to the labeling to visually inspect reagent cassette and vial prior to use.
P060040/S072	08/12/2019	O - Normal 180 Day	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for a manufacturing site located at Sterigenics in Salt Lake City, Utah for ethylene oxide sterilization of the HeartMate 3 LVAS and HeartMate II LVAS components.

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P070026/S065	08/06/2019	O - Normal 180 Day	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for a manufacturing site located at DePuy (Ireland) , Loughbeg, Ringaskiddy Co. CORK, Ireland, for coating, machining, cleaning, and packaging of the Summit femoral stems.
P070026/S067	08/14/2019	S - Special CBE	CERAMAX CERAMIC HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Approval for the addition of an updated packaging inspection.
P080006/S139	08/27/2019	O - Normal 180 Day	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Approval for labeling updates to the clinical study summary for the post approval study.
P090016/S028	08/29/2019	N - Normal 180 Day	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Approval for use of Belotero Balance with Integral Lidocaine for injection into the mid-to-deep dermis for correction of moderate-to-severe facial wrinkles and folds such as nasolabial folds.
P090026/S026	08/09/2019	R - Real-Time Proc	ACCESS HYBRITECH P2PSA ON THE ACCESS IMMUNOASSAY SYSTEMS	BECKMAN COULTER, INC.	Approval for a modification to the piston rod design in the vacuum pump of the UniCel DxI 600 and 800 instruments, integrating the washer and piston rod into a single unit.
P100009/S034	08/30/2019	S - Special CBE	MITRACLIP NT, NTR, XTR, G4 CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval for manufacturing process changes to reduce Clip Arm spread variability and to implement an inspection for final Clip Arm spread.
P100026/S070	08/01/2019	O - Normal 180 Day	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for the following protocol changes and associated changes to data collection and informed consent forms: 1) Increase the upper limit on the number of subjects that can be implanted per study site; 2) Simplify the text to remove references to activities that are not study-specific (i.e. are standard in the management of the RNS System); 3) Revise inclusion/exclusion criteria to only include study-specific criteria; 4) Add the option of phone appointments for specific follow-up time points; and 5) Minor clarifications and administrative changes. for the post-approval studies (PAS) protocol.
P110015/S005	08/29/2019	Y - 135 Review Tra	GASTRIC EMPTYING BREATH TEST (GEBT)	ADVANCED BREATH DIAGNOSTICS	Approval for changing the manufacturing site for the unit dose packaged 13C-Spirulina/egg mix that constitutes the diagnostic drug product in the Gastric Emptying Breath Test (GEBT).
P110016/S063	08/22/2019	O - Normal 180 Day	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC. (IRVINE BIOMEDICAL)	Approval for an alternate sterilization site at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri.
P110033/S042	08/29/2019	N - Normal 180 Day	JUVEDERM VOLUMA XC	ALLERGAN	Approval for an update to the labeling for Juvederm Voluma XC to include the use of cannula.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110037/S048	08/13/2019	S - Special CBE	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the addition of an instruction to the labeling to visually inspect reagent cassette and vial prior to use.
P120005/S082	08/20/2019	R - Real-Time Proc	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for changes to improve drop impact resistance to the receiver component of the Dexcom G4 PLATINUM Continuous Glucose Monitoring System and Dexcom G5 Mobile Continuous Glucose Monitoring System.
P120021/S012	08/22/2019	O - Normal 180 Day	AMPLATZER PFO OCCLUDER	ABBOTT MEDICAL	Approval for an alternate sterilization site at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri.
P130008/S043	08/06/2019	R - Real-Time Proc	INSPIRE II UPPER AIRWAY STIMULATOR	INSPIRE MEDICAL SYSTEMS	Approval for proposed changes to the Inspire systems MRI Guidelines Manual.
P130021/S058	08/16/2019	P - Panel Track	MEDTRONIC COREVALVE SYSTEM	MEDTRONIC COREVALVE LLC	Approval for the Medtronic CoreValve Evolut R System and Medtronic CoreValve Evolut PRO System for expanding the indication to include patients at low risk for surgical aortic valve replacement. The devices are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.
P130022/S025	08/18/2019	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATIO N	Approval for a change in the approved packaging for the IPG (NIPG1500, NIPG2000), Lead Extension kits (MADP2008-25B M8, SADP2008-25B S8), and Lead Adapter kits (LEAD2008-25B, LEAD2008-35B, LEAD2008-60B) of your Senza Spinal Cord Stimulation (SCS) System.
P130026/S048	08/22/2019	O - Normal 180 Day	TACTICATH QUARTZ SET	ST. JUDE MEDICAL	Approval for an alternate sterilization site at Midwest Sterilization Corporation, 1204 Lenco Avenue, Jackson, Missouri.
P140029/S017	08/13/2019	R - Real-Time Proc	RESTYLANE REFYNE, RESTYLANE DEFYNE	Q-MED AB	Approval for reclassification of impurity C in lidocaine HCl.
P140031/S085	08/16/2019	P - Panel Track	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Approval for the Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System for expanding the indication to include patients at low risk for surgical aortic valve replacement. The devices are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.
P140031/S090	08/15/2019	S - Special CBE	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Approval for a revision to the Instructions for Use (IFU) for the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System with the Edwards SAPIEN 3 Ultra Delivery System to add a warning related to balloon burst during the valve deployment process.
P140031/S091	08/21/2019	R - Real-Time Proc	SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCE S, LLC.	Approval for updates to the labeling of the SAPIEN 3 Ultra Transcatheter Heart Valve System regarding the option to use the Commander delivery system with the eSheath for the delivery and deployment of the SAPIEN 3 Ultra valve.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150005/S047	08/23/2019	R - Real-Time Proc	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a material change to the proximal extension tubing of the BSC Open Irrigation Ablation Catheters
P150031/S011	08/19/2019	N - Normal 180 Day	VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for MR Conditional labeling of the Vercise Gevia Deep Brain Stimulation (DBS) System.
P150033/S050	08/01/2019	Y - 135 Review Tra	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for a change to a sub-tier raw material supplier for vanadium pentoxide used during battery cathode fabrication.
P160001/S039	08/20/2019	R - Real-Time Proc	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for updating the Touch Dispenser software to disable the touchscreen recalibration functionality.

P160001/S042	08/08/2019	O - Normal 180 Day	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval of the revised protocol for the post-approval study protocol. The Obalon Balloon System Post-Approval Study is a prospective, open-label, single-arm study of the safety and effectiveness of the Obalon 6-month Balloon System, as an adjunct to weight loss for obese adults 22 years of age and older with a Body Mass Index (BMI) of 30 kg/m2 to 40 kg/m2. This is a 12-month follow-up study in which subjects will be treated during the first 6 months with placement (via swallow) of up to three Obalon Balloons in conjunction with a moderate intensity weight loss and behavioral modification program standardized throughout the sites, followed by observational evaluation for an additional 6 months after device removal. This study will include Obalon balloons contained in animal-based capsules (approved in original PMA) and plant-based hydroxy propyl methyl cellulose (HPMC) capsules (being approved under PMA S003). A total of 200 subjects will be enrolled at 10 to 15 sites in the United States; 180 evaluable subjects will be available at 6 months, including a minimum of 50 patients receiving animal-based gelatin capsules and a minimum of 50 patients receiving plant-based HPMC capsules. The primary endpoint is to evaluate the safety of Obalon by assessing the rate of device- or procedure-related Serious Adverse Event(s) (SAEs) (composite safety endpoint). Where the SAE is defined as any AE that results in death or persistent/significant disability and/or incapacity, which may include emergency room visits, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or requires medical/surgical intervention to prevent any of the above, through 6 months of treatment with the Obalon 6-month Balloon System. The observed rate will be compared to a performance goal of 10% at 6 months assuming an expected 4.5% device or procedure related SAEs rate. The secondary effectiveness endpoint is comprised (1) the mean % Total Body Loss (%TBL) and (2) the proportion of subjects achieving at least -5% TBL through the first 6 months after the device is implanted. Additional endpoints include observational safety and effectiveness analyses including the percentage of subjects and frequency of individual Adverse Events (AEs) that are device- or procedure-related, frequency and cause of early explantations, rates of gastric ulceration, esophageal tear, balloon deflation, means of other weight loss metrics such as % Excess Weight Loss (EWL), Weight Loss (WL) in pounds, and BMI change, percentage of subjects with at least 6%, 7%, 8%, 9%, and 10% TBL, percentage of subjects with at least 25% EWL, patient-reported outcomes assessing tolerability of device and/or quality of life, weight loss metrics by number of balloons placed, weight loss metrics by frequency of weight loss and behavioral modification program counseling. Descriptive analyses will be presented and stratified by capsule type. Follow-up assessments will be in office visits at Day 0, monthly during the first 6 months and at 12 months after initial implant. The Obalon 6-month Balloon System requires removal of all 3 balloons at the end of the 6-month period. Subjects will be followed for an additional 6-month period to ensure there are no Adverse Events as a result of balloon removal or residual events due to balloon use. Subjects with gastric ulcerations at the time of device explant will be followed with endoscopic evaluation every 8 weeks until the ulcer has visually resolved.

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P160022/S011	08/09/2019	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 design changes to achieve compliance with EN 60601-1-2 (4th edition), PCB layout and parts changes, and minor mechanical changes to the speaker, printer, and display assemblies.
P160035/S005	08/05/2019	R - Real-Time Proc	EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE	BERLIN HEART INC.	Approval for a change in the wiring system at the nurse call relay switch of the EXCOR IKUS driver.
P160048/S011	08/29/2019	N - Normal 180 Day	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	Approval for a design change to the sensor component of the Eversense Continuous Glucose Monitoring System.
P160054/S019	08/12/2019	O - Normal 180 Day	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Approval for a manufacturing site located at Sterigenics in Salt Lake City, Utah for ethylene oxide sterilization of the HeartMate 3 LVAS and HeartMate II LVAS components.
P160055/S005	08/06/2019	R - Real-Time Proc	LIGHT ADJUSTABLE LENS (LAL) AND LIGHT DELIVERY DEVICE (LDD)	RXSIGHT, INC.	Approval for the addition of a barcode scanner, internalization of the (optional) external LDD camera and update to the red reticle to enhance LAL visualization and alignment monitoring (called Align Assist), addition of an alternate supplier and model for the system computer and graphics card, and modification to LDD table legs to meet pinch point IEC 60601-1 testing requirements.
P170019/S009	08/21/2019	S - Special CBE	FOUNDATIONONE CDX	FOUNDATION MEDICINE, INC.	Approval for changing the reporting of some microsatellite stable results to Microsatellite Status-Cannot be Determined and to add a disclaimer in your report where you report microsatellite status and in the limitations section of the report indicating Patients with Microsatellite Status-Cannot be Determined should be retested with an orthogonal (alternative) method.
P170030/S003	08/29/2019	O - Normal 180 Day	ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM	BIOTRONIK, INC	Approval for test protocols addressing the bench-top performance testing.
P170036/S001	08/02/2019	O - Normal 180 Day	M6-C ARTIFICIAL CERVICAL DISC	SPINAL KINETICS LLC	Approval of the protocol for the Post-Approval Study (PAS) protocol.

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P180002/S007	08/01/2019	Y - 135 Review Tra	ZEPHYR ENDOBRONCHIAL VALVE SYSTEM	PULMONX CORPORATIO N	Approval to implement a revised process for the lot release testing sampling plan for Zephyr Endobronchial Valve System products.
P180036/S002	08/13/2019	R - Real-Time Proc	OPTIMIZER SMART SYSTEM	IMPULSE DYNAMICS (USA), INC.	Approval for changes to the circuit components of the OPTIMIZER Smart IPG to improve manufacturability, robustness, and reliability.

Total: 69

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S060	08/02/2019	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Installation of a duplicate dehumidifier unit for SURGICEL¿ Absorbable Hemostats manufactured at the Ethicon SARL, Neuchatel Switzerland site.
N12159/S061	08/02/2019	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Addition of a fourth pass of humidified intermediate fine fibers during the roller compactor/ sieving manufacturing process of SURGICEL Powder at the Ethicon, San Lorenzo, Puerto Rico facility.
N12159/S062	08/14/2019	X - 30-Day Notice	SURGICEL BRAND ABSORBABLE HEMOSTAT	ETHICON, INC.	Process changes from manual to automated Foiling and Cartoning for SURGICEL Nu-Knit Absorbable Hemostat manufactured at the Ethicon SARL, Neuchatel Switzerland site.
N970012/S166	08/30/2019	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESIS, AND AMS AMBICOR INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Change of the supplier for packaging trays for the Inflatable Penile Prosthesis and Artificial Urinary Sphincter devices.
P810032/S070	08/01/2019	X - 30-Day Notice	MODELS B-13F (P-10) & B-1H (P-11)	ALCON LABORATORI ES	Addition of a 100% Ethylene Oxide (EO) sterilization chamber, integrated aeration cell, and supporting equipment at the Alcon Huntington manufacturing facility.
P830055/S233	08/01/2019	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Changes to the current processing of the ATTUNE Revision Tibial Sleeve Blanks at the DePuy vendor site (Tecomet [Symmetry Medical Manufacturing, Inc.]) in Lansing, Michigan.
P840001/S439	08/14/2019	X - 30-Day Notice	ITREL(R) TOTALLY IMPLANTABLE SPINAL CORD STIM. SYS	MEDTRONIC NEUROMODU LATION	Use of newer test instrumentation for testing the electrolyte material and for updates to the test method used for the testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S441	08/22/2019	X - 30-Day Notice	RESTORE, ITREL, SYNERGY AND INTELLIS SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic rework at Medtronic¿s final device manufacturing facilities-Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico.
P840060/S047	08/01/2019	X - 30-Day Notice	SM-1, CR-1, & GR-1 IOLS	ALCON LABORATORIES	Addition of a 100% Ethylene Oxide (EO) sterilization chamber, integrated aeration cell, and supporting equipment at the Alcon Huntington manufacturing facility.
P860004/S335	08/14/2019	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Use of newer test instrumentation for testing the electrolyte material and for updates to the test method used for the testing.
P860004/S337	08/20/2019	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Update the manufacturing process to plate the leads of the electrical components with lead/tin solder for the Medtronic SynchroMed II and Medtronic Implantable System for Remodulin.
P880087/S029	08/01/2019	X - 30-Day Notice	KELMAN MULTIFLEX 2 MODELS: MT3-MT7 & MT2U-MT7U	ALCON LABORATORIES	Addition of a 100% Ethylene Oxide (EO) sterilization chamber, integrated aeration cell, and supporting equipment at the Alcon Huntington manufacturing facility.
P890017/S020	08/21/2019	X - 30-Day Notice	PALMAZ BALLOON EXPANDABLE STENT	CORDIS CORP.	Transfer Receiving Inspection and Final Release documentation review activities between internal sites.
P900033/S082	08/08/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Reduce the sample size for Bacterial Endotoxin Testing for Integra products in conformance with ANSI/AAMI ST-072 standard.
P900033/S083	08/28/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE AND INTEGRA MESHED DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Change to the Water for Injection Pretreatment System for INTEGRA Dermal Regeneration Template and INTEGRA Meshed Dermal Regeneration Template.
P900033/S084	08/28/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Implement new peristaltic pumps used in the manufacture of Integra Dermal Regeneration Template, Integra Meshed Dermal Regeneration Template and Integra Omnigraft Dermal Regeneration Matrix.
P900033/S085	08/28/2019	X - 30-Day Notice	INTEGRA DERMAL REGENERATION TEMPLATE, INTEGRA MESHED DERMAL REGENERATION TEMPLATE AND INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX	INTEGRA LIFESCIENCES CORP.	Implement a change of designation of meshed collagen product as master product and alignment of MIDRT bioburden specification with other members in the same sterilization product family

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P910023/S417	08/19/2019	X - 30-Day Notice	CADENCE(R) TIERED THERAPY DEFIBRILLATION SYSTEM	ST. JUDE MEDICAL	Add an alternative solder paste dispensing method for hybrid circuit boards.
P910056/S038	08/06/2019	X - 30-Day Notice	SOFLEX UV-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Elimination of the In-Vitro Pyrogen Testing (IPT) at product release during the Finished Product Inspection of all models of the enVista Hydrophobic Acrylic Intraocular Lens (IOL).
P910066/S030	08/02/2019	X - 30-Day Notice	ORTHOLOGIC (TM)1000 BONE GROWTH STIMULATOR	DJO, LLC	Proposing a process change which introduces an upgraded version of the Automated Calibration System (ACS) for the SpinaLogic, OL1000 Dual Coil, and OL1000 Single Coil (SC) (sizes 1, 2, 3, 4) Bone Growth Stimulator devices.
P920047/S117	08/23/2019	X - 30-Day Notice		BOSTON SCIENTIFIC CORP.	Update Maestro 4000 Controller FW from version 5.14 to version 5.23 (market approved) in the field.
P930014/S123	08/01/2019	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Addition of a 100% Ethylene Oxide (EO) sterilization chamber, integrated aeration cell, and supporting equipment at the Alcon Huntington manufacturing facility.
P930014/S125	08/19/2019	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Use of coating solutions prepared at the manufacturing facility in West Virginia in the manufacture of UltraSert and AcrySert nozzle components.
P950005/S072	08/02/2019	X - 30-Day Notice	CELSIUS CATHETER	BIOSENSE WEBSTER, INC	Alternate supplier for tip electrode components.
P960009/S354	08/14/2019	X - 30-Day Notice	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Use of newer test instrumentation for testing the electrolyte material and for updates to the test method used for the testing.
P960009/S356	08/22/2019	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic rework at Medtronics final device manufacturing facilities-Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico.
P960043/S106	08/21/2019	X - 30-Day Notice	PROSTAR 9 FR. PERCUTANEOUS VASCULAR SURGICAL (PVS) SYSTEM	ABBOTT VASCULAR INC.	Alternate supplier for a packaging pouch.
P960058/S141	08/23/2019	X - 30-Day Notice	CLARION MULTI-STRATEGY COCHLEAR IMPLANT	ADVANCED BIONICS	Alternative supplier for the Electrode Platinum Contact on the HiFocus Mid-Scala Electrode.
P960058/S142	08/27/2019	X - 30-Day Notice	HIRESOLUTION BIONIC EAR SYSTEM	ADVANCED BIONICS	Facility move for the testing of cochlear implant capacitors.
P970004/S295	08/14/2019	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Use of newer test instrumentation for testing the electrolyte material and for updates to the test method used for the testing.

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P970004/S296	08/22/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS URINARY)	MEDTRONIC NEUROMODULATION	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic rework at Medtronics final device manufacturing facilities-Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico.
P970051/S189	08/27/2019	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of an automated punch and form tool for coil and hardball crimps.
P980003/S090	08/23/2019	X - 30-Day Notice	MAESTRO 4000 CONTROLLER FIRMWARE	BOSTON SCIENTIFIC CORP.	Update Maestro 4000 Controller FW from version 5.14 to version 5.23 (market approved) in the field.
P980016/S716	08/06/2019	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic work.
P980016/S717	08/30/2019	X - 30-Day Notice	PROTECTA ICD, PROTECTA VR, XT ICD AND SECURA ICD, SECURA DR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Automated tester equipment conversion from LTX to SPEA.
P980022/S208	08/14/2019	X - 30-Day Notice	CONTINUOUS GLUCOSE MONITORING SYSTEM	MEDTRONIC MINIMED	Automation of an inspection method at a contract manufacturer used during the packaging of components for the MiniLink REAL-Time transmitter, Guardian Link Transmitter, Guardian Link (3) Transmitter, Guardian Connect System, and iPro2 Recorder. The MiniLink REAL-Time transmitter is a component of the Minimed 530g System, Paradigm REAL-Time Revel System, and the Paradigm REAL-Time System. The Guardian Link Transmitter is a component of the Minimed 630G Insulin Pump System. The Guardian Link (3) Transmitter is a component of the MiniMed 670G System. The Guardian Link Transmitter is a component of the Medtronic MiniMed 630G Insulin Pump System. The Guardian Connect Transmitter is a component of the Guardian Connect System. The iPro2 Recorder is a component of the Ipro2 Continuous Glucose Monitoring System with Enlite Sensor.
P980035/S602	08/06/2019	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic work.
P980035/S603	08/27/2019	X - 30-Day Notice	ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG	MEDTRONIC INC.	Change the functional test sequence from the XYZ tester to the Titan Device Tester single axis test system.
P980035/S604	08/30/2019	X - 30-Day Notice	ADVISA DR MRI AND ADVISA DR/DR MRI IPG	MEDTRONIC INC.	Automated tester equipment conversion from LTX to SPEA.

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P980040/S105	08/07/2019	X - 30-Day Notice	SENSAR SOFT ACRYLIC UV-LIGHT ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	JOHNSON & JOHNSON SURGICAL VISION, INC.	Alternate testing facility to evaluate bioburden for the TECNIS® 1-Piece IOL with TECNIS iTec Preloaded Delivery System Model PCB00 and TECNIS® iTec Preloaded Delivery System, Model PMB00.
P980053/S017	08/29/2019	X - 30-Day Notice	DURASPHERE INJECTABLE BULKING AGENT	CARBON MEDICAL TECHNOLOGIES, INC.	New vendor to supply the glucan powder for the subject device.
P000006/S052	08/21/2019	X - 30-Day Notice	TITAN INFLATABLE PENILE PROSTHESIS	COLOPLAST CORP.	Process change to the kink resistant tubing tests for the Titan Inflatable Penile Prosthesis.
P000015/S039	08/27/2019	X - 30-Day Notice	Nucleus Auditory Brainstem Implant System	COCHLEAR AMERICAS	Addition of an automated punch and form tool for coil and hardball crimps.
P000029/S085	08/29/2019	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Replacement of a wall section with a door in the 3:125B clean room at the Q-Med manufacturing site.
P000053/S106	08/30/2019	X - 30-Day Notice	AMS 800 ARTIFICIAL URINARY SPHINCTER	BOSTON SCIENTIFIC CORP.	Change of the supplier for packaging trays for the Inflatable Penile Prosthesis and Artificial Urinary Sphincter devices.
P010001/S020	08/09/2019	X - 30-Day Notice	CERAMIC TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Addition of polishing machine used for polishing the intake and polishing the inner sphere of the ceramic inserts of the Transcend Hip Articulation System.
P010003/S036	08/14/2019	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Change to the in-process incoming inspection of pouched, irradiated BioGlue syringes.
P010014/S090	08/06/2019	X - 30-Day Notice	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Site change for the Izod evaluation testing of the Ultra-High Molecular Weight Polyethylene (UHMWPE) tibial meniscal bearing components of the Oxford® Partial Knee System.
P010015/S416	08/06/2019	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic work.
P010015/S417	08/27/2019	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Change the functional test sequence from the XYZ tester to the Titan Device Tester single axis test system.
P010015/S418	08/30/2019	X - 30-Day Notice	CONSULTA, SYNCA AND VIVA CRT-P	MEDTRONIC INC.	Automated tester equipment conversion from LTX to SPEA.
P010019/S073	08/30/2019	X - 30-Day Notice	LOTRAFILCON A AND B SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Qualification of a new X-Ray Photoelectron Spectrophotometer used for the measurement of lens plasma coating during in-process quality control inspection in the production of Alcon lotrafilcon A and lotrafilcon B soft contact lenses for daily and extended wear.

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P010030/S123	08/09/2019	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Automated test system for the LifeVest 4000 electrode belts and a minor test flow change.
P010031/S677	08/06/2019	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic work.
P010031/S678	08/30/2019	X - 30-Day Notice	CONSULTA, SYNCA AND VIVA CRT-P	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Automated tester equipment conversion from LTX to SPEA.
P020025/S121	08/23/2019	X - 30-Day Notice	MAESTRO 4000 CONTROLLER FIRMWARE	BOSTON SCIENTIFIC	Update Maestro 4000 Controller FW from version 5.14 to version 5.23 (market approved) in the field.
P030031/S099	08/02/2019	X - 30-Day Notice	CELSIUS, EZ STEER, AND NAVISTAR THERMOCOOL CATHETER	BIOSENSE WEBSTER, INC.	Alternate supplier for tip electrode components.
P030052/S026	08/26/2019	X - 30-Day Notice		ABBOTT MOLECULAR	Update to software.
P030054/S369	08/19/2019	X - 30-Day Notice	ST JUDE MEDICAL EPIC HF SYSTEM	ST. JUDE MEDICAL	Add an alternative solder paste dispensing method for hybrid circuit boards.
P040002/S063	08/16/2019	X - 30-Day Notice	ENDOLOGIX POWERLINK SYSTEM	ENDOLOGIX, INC.	Modifications to the routine endotoxin (pyrogen) testing sampling plan for the AFX Endovascular AAA System.
P040014/S037	08/28/2019	X - 30-Day Notice	THERAPY ABLATION , THERAPY 4MM THERMISTOR ABLATION CATHETER	IRVINE BIOMEDICAL, INC.	Change to the catheter shaft bonding process.
P040020/S091	08/01/2019	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Addition of a 100% Ethylene Oxide (EO) sterilization chamber, integrated aeration cell, and supporting equipment at the Alcon Huntington manufacturing facility.
P040036/S068	08/02/2019	X - 30-Day Notice	CELSIUS, EZ STEER, AND NAVISTAR THERMOCOOL CATHETER	BIOSENSE WEBSTER, INC.	Alternate supplier for tip electrode components.

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P040042/S043	08/28/2019	X - 30-Day Notice	THERAPY ABLATION , THERAPY 4MM THERMISTOR ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Change to the catheter shaft bonding process.
P050018/S027	08/22/2019	X - 30-Day Notice	ANGIOSCULPT PTCA SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Change in the final device labeling software.
P050042/S039	08/13/2019	X - 30-Day Notice	ARCHITECT ANTI-HCV ASSAY; ARCHITECT ANTI-HCV CALIBRATOR; ARCHITECT ANTI-HCV CONTROL	ABBOTT LABORATORIES INC	Manufacturing location change for a supplier of a critical raw material.
P050047/S072	08/27/2019	X - 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS (ULTRA, ULTRA XC AND ULTRA PLUS XC)	ALLERGAN	Implement a new incoming warehouse for the storage of raw materials and packaging items for Juvéderm injectable gel implants in the Pringy II building.
P060037/S061	08/07/2019	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Removal of the cytotoxicity test requirement from the routine process monitoring of the final cleaning process for the NexGen® Complete Knee Solution, Legacy® Knee ¿ Posterior Stabilized (LPS) and the LPS-Flex Mobile Bearing Knee femoral components, at the Shannon, Ireland facility.
P080004/S024	08/21/2019	X - 30-Day Notice	HOYA ISPHERIC MODEL YA-60BB INTRAOCULAR LENS	HOYA SURGICAL OPTICS, INC.	Modifications to the 1-piece IOL haptic inspection method and acceptance criteria.
P080011/S095	08/09/2019	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION MANUFACTURING, LTD.	Software update to the wet Automated Inspection System (AIS) used for Biofinity (comfilcon A) soft (hydrophilic) extended wear contact lenses manufactured at the CooperVision Manufacturing, Ltd. facility in Hamble, United Kingdom.
P080012/S059	08/07/2019	X - 30-Day Notice	PROMETRA PROGRAMMABLE INFUSION PUMP SYSTEM	FLOWONIX MEDICAL, INC.	Alternate supplier for the bellows component of the Prometra II Programmable Infusion Pump System.
P080025/S190	08/14/2019	X - 30-Day Notice	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Use of newer test instrumentation for testing the electrolyte material and for updates to the test method used for the testing.
P080025/S191	08/22/2019	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM AND VERIFY EVALUATION SYSTEM (SNS BOWEL)	MEDTRONIC NEUROMODULATION	Implementation of process controls for Soft Straight-Line Finish (SLF) cosmetic rework at Medtronics final device manufacturing facilities-Medtronic Puerto Rico Operations Company (MPROC), located in Juncos, Puerto Rico.
P100014/S022	08/29/2019	X - 30-Day Notice	DEFLUX INJECTABLE GEL	PALETTE LIFE SCIENCES	Replacement of a wall section with a door in the 3:125B clean room at the Q-Med manufacturing site.
P100026/S073	08/08/2019	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Modify the PXI Vader automated test equipment (ATE) software to improve yield of the components used to manufacture the RNS® Neurostimulator (model RNS-320) during the custom packaged integrated circuit (Cassandra) and printed circuit assembly (PCA) testing. In addition, this submission includes an update to PXI Vader ATE software for final electrical test to support future product changes currently under development.

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P100026/S074	08/26/2019	X - 30-Day Notice	NEUROPAC RNS SYSTEM	NEUROPACE INC	Addition of an alternate laser welder, the IPG Laser Weld System, to perform laser welding on the RNS Neurostimulator during manufacturing operations at NeuroPace (455 N. Bernardo Ave. Mountain, California).
P100042/S025	08/27/2019	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORAT ED	Remove or modify QC testing for reagent labels.
P100047/S143	08/23/2019	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	MEDTRONIC	Component change to the battery pack assembly.
P110010/S168	08/20/2019	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL (MR) AND OVER-THE-WIRE (OTW) AND PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL)	BOSTON SCIENTIFIC CORP.	Addition of extrusion lines for manufacturing distal outer tubes.
P110012/S019	08/26/2019	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Update of software.
P110013/S099	08/12/2019	X - 30-Day Notice	RESOLUTE INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Implementation of a new dishwasher and water purification system in the shared glassware cleaning area within the Medtronic Ireland manufacturing facility.
P110033/S048	08/27/2019	X - 30-Day Notice	JUVEDERM INJECTABLE GEL IMPLANTS (ULTRA, ULTRA XC AND ULTRA PLUS XC)	ALLERGAN	Implement a new incoming warehouse for the storage of raw materials and packaging items for Juvéderm injectable gel implants in the Pringy II building.
P120007/S023	08/27/2019	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Remove or modify QC testing for reagent labels.
P120010/S132	08/14/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Automation of an inspection method at a contract manufacturer used during the packaging of components for the MiniLink REAL-Time transmitter, Guardian Link Transmitter, Guardian Link (3) Transmitter, Guardian Connect System, and iPro2 Recorder. The MiniLink REAL-Time transmitter is a component of the Minimed 530g System, Paradigm REAL-Time Revel System, and the Paradigm REAL-Time System. The Guardian Link Transmitter is a component of the Minimed 630G Insulin Pump System. The Guardian Link (3) Transmitter is a component of the MiniMed 670G System. The Guardian Link Transmitter is a component of the Medtronic MiniMed 630G Insulin Pump System. The Guardian Connect Transmitter is a component of the Guardian Connect System. The iPro2 Recorder is a component of the Ipro2 Continuous Glucose Monitoring System with Enlite Sensor.

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P120010/S133	08/26/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Addition of new sterilization equipment at two previously approved sterilization facilities for the sterilization of the Enlite and Guardian Sensor (3) continuous glucose monitoring sensors. The Enlite sensor is a component of the MiniMed 530G system, the MiniMed 630G system, the Paradigm Real-Time Revel system, and the iPro2 with Enlite sensor system. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.
P120014/S009	08/26/2019	X - 30-Day Notice	THXID BRAF ASSAY KIT	BIOMERIEUX, INC.	Manufacturing site change for a raw material (critical component).
P130001/S005	08/30/2019	X - 30-Day Notice	EPI PROCOLON	EPIGENOMICS AG	Change of storage and distribution facility.
P130021/S061	08/19/2019	X - 30-Day Notice	COREVALVE EVOLUT R SYSTEM AND COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Modification to the nitinol capsule frame used in the 18F and 20F delivery systems.
P130021/S062	08/23/2019	X - 30-Day Notice	COREVALVE EVOLUT R SYSTEM AND COREVALVE EVOLUT PRO SYSTEM	MEDTRONIC COREVALVE LLC	Reduce the number of units required to be tested for routine Bacterial Endotoxin Testing (BET) for the EnVeo R and EnVeo PRO Delivery Catheter System and Loading System.
P130028/S026	08/09/2019	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Addition of alternative suppliers for the housing subcomponent and the spring/coil contact block subcomponent of the Algovita® Internal Pulse Generator (IPG).
P130028/S027	08/28/2019	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Implementation of an update to the injection molding process for the distal subassembly of the Algovita® 12-Electrode Percutaneous Leads, Trial Leads, and Lead Extensions.
P140018/S016	08/12/2019	X - 30-Day Notice	RESOLUTE INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR INC	Implementation of a new dishwasher and water purification system in the shared glassware cleaning area within the Medtronic Ireland manufacturing facility.
P140030/S010	08/14/2019	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Automation of a stent expansion process and an ultrasonic cleaning process.
P140032/S037	08/14/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Use of newer test instrumentation for testing the electrolyte material and for updates to the test method used for the testing.
P140032/S038	08/20/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Update the manufacturing process to plate the leads of the electrical components with lead/tin solder for the Medtronic SynchroMed II and Medtronic Implantable System for Remodulin.
P140032/S039	08/27/2019	X - 30-Day Notice	IMPLANTABLE SYSTEM FOR REMODULIN	MEDTRONIC, INC.	Facility improvements with the goal of achieving the ISO 14644-1 Class 8 Cleanroom certification.
P140033/S046	08/30/2019	X - 30-Day Notice	TENDRIL MRI STEROID ELUTING CARDIAC LEADS	ST. JUDE MEDICAL, INC.	Add an additional packaging integrity testing laboratory site.

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P150001/S072	08/14/2019	X - 30-Day Notice	MINIMED 630G SYSTEM WITH SMARTGUARD(TM)	MEDTRONIC MINIMED	Automation of an inspection method at a contract manufacturer used during the packaging of components for the MiniLink REAL-Time transmitter, Guardian Link Transmitter, Guardian Link (3) Transmitter, Guardian Connect System, and iPro2 Recorder. The MiniLink REAL-Time transmitter is a component of the Minimed 530g System, Paradigm REAL-Time Revel System, and the Paradigm REAL-Time System. The Guardian Link Transmitter is a component of the Minimed 630G Insulin Pump System. The Guardian Link (3) Transmitter is a component of the MiniMed 670G System. The Guardian Link Transmitter is a component of the Medtronic MiniMed 630G Insulin Pump System. The Guardian Connect Transmitter is a component of the Guardian Connect System. The iPro2 Recorder is a component of the Ipro2 Continuous Glucose Monitoring System with Enlite Sensor.
P150001/S073	08/26/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC MINIMED	Addition of new sterilization equipment at two previously approved sterilization facilities for the sterilization of the Enlite and Guardian Sensor (3) continuous glucose monitoring sensors. The Enlite sensor is a component of the MiniMed 530G system, the MiniMed 630G system, the Paradigm Real-Time Revel system, and the iPro2 with Enlite sensor system. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.
P150002/S006	08/15/2019	X - 30-Day Notice	INCRAFT(R) AAA STENT GRAFT SYSTEM	CORDIS CORPORATION	Relocate the stent manufacturing line to another location within the same building.
P150003/S051	08/09/2019	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Alternate process to automate top assembly process steps for the manufacture of stent delivery catheters.
P150003/S052	08/20/2019	X - 30-Day Notice	PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL (MR) AND OVER-THE-WIRE (OTW) AND PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL)	BOSTON SCIENTIFIC CORPORATION	Addition of extrusion lines for manufacturing distal outer tubes.
P150006/S004	08/26/2019	X - 30-Day Notice		VASORUM LTD	Expanded e-beam sterilization dose range.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150019/S057	08/14/2019	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Automation of an inspection method at a contract manufacturer used during the packaging of components for the MiniLink REAL-Time transmitter, Guardian Link Transmitter, Guardian Link (3) Transmitter, Guardian Connect System, and iPro2 Recorder. The MiniLink REAL-Time transmitter is a component of the Minimed 530g System, Paradigm REAL-Time Revel System, and the Paradigm REAL-Time System. The Guardian Link Transmitter is a component of the Minimed 630G Insulin Pump System. The Guardian Link (3) Transmitter is a component of the MiniMed 670G System. The Guardian Link Transmitter is a component of the Medtronic MiniMed 630G Insulin Pump System. The Guardian Connect Transmitter is a component of the Guardian Connect System. The iPro2 Recorder is a component of the Ipro2 Continuous Glucose Monitoring System with Enlite Sensor.
P150019/S058	08/26/2019	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Addition of new sterilization equipment at two previously approved sterilization facilities for the sterilization of the Enlite and Guardian Sensor (3) continuous glucose monitoring sensors. The Enlite sensor is a component of the MiniMed 530G system, the MiniMed 630G system, the Paradigm Real-Time Revel system, and the iPro2 with Enlite sensor system. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.
P150021/S043	08/13/2019	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of manufacturing space at Abbott Diabetes Care for the sensor component manufacturing process. The sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P150021/S044	08/15/2019	X - 30-Day Notice	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Change to introduce an alternate supplier of a sensor component for the Libre sensor. The Libre sensor is a component of the Freestyle Libre Pro Flash Glucose Monitoring System and the Freestyle Libre 14 day Flash Glucose Monitoring System.
P150029/S030	08/14/2019	X - 30-Day Notice	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Automation of an inspection method at a contract manufacturer used during the packaging of components for the MiniLink REAL-Time transmitter, Guardian Link Transmitter, Guardian Link (3) Transmitter, Guardian Connect System, and iPro2 Recorder. The MiniLink REAL-Time transmitter is a component of the Minimed 530g System, Paradigm REAL-Time Revel System, and the Paradigm REAL-Time System. The Guardian Link Transmitter is a component of the Minimed 630G Insulin Pump System. The Guardian Link (3) Transmitter is a component of the MiniMed 670G System. The Guardian Link Transmitter is a component of the Medtronic MiniMed 630G Insulin Pump System. The Guardian Connect Transmitter is a component of the Guardian Connect System. The iPro2 Recorder is a component of the Ipro2 Continuous Glucose Monitoring System with Enlite Sensor.
P150029/S031	08/26/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC MINIMED	Addition of new sterilization equipment at two previously approved sterilization facilities for the sterilization of the Enlite and Guardian Sensor (3) continuous glucose monitoring sensors. The Enlite sensor is a component of the MiniMed 530G system, the MiniMed 630G system, the Paradigm Real-Time Revel system, and the iPro2 with Enlite sensor system. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160007/S024	08/14/2019	X - 30-Day Notice	GUARDIAN CONNECT SYSTEM	MEDTRONIC MINIMED	Automation of an inspection method at a contract manufacturer used during the packaging of components for the MiniLink REAL-Time transmitter, Guardian Link Transmitter, Guardian Link (3) Transmitter, Guardian Connect System, and iPro2 Recorder. The MiniLink REAL-Time transmitter is a component of the Minimed 530g System, Paradigm REAL-Time Revel System, and the Paradigm REAL-Time System. The Guardian Link Transmitter is a component of the Minimed 630G Insulin Pump System. The Guardian Link (3) Transmitter is a component of the MiniMed 670G System. The Guardian Link Transmitter is a component of the Medtronic MiniMed 630G Insulin Pump System. The Guardian Connect Transmitter is a component of the Guardian Connect System. The iPro2 Recorder is a component of the Ipro2 Continuous Glucose Monitoring System with Enlite Sensor.
P160007/S025	08/26/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC MINIMED	Addition of new sterilization equipment at two previously approved sterilization facilities for the sterilization of the Enlite and Guardian Sensor (3) continuous glucose monitoring sensors. The Enlite sensor is a component of the MiniMed 530G system, the MiniMed 630G system, the Paradigm Real-Time Revel system, and the iPro2 with Enlite sensor system. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.
P160017/S069	08/14/2019	X - 30-Day Notice	MINIMED 670G SYSTEM	MEDTRONIC MINIMED, INC.	Automation of an inspection method at a contract manufacturer used during the packaging of components for the MiniLink REAL-Time transmitter, Guardian Link Transmitter, Guardian Link (3) Transmitter, Guardian Connect System, and iPro2 Recorder. The MiniLink REAL-Time transmitter is a component of the Minimed 530g System, Paradigm REAL-Time Revel System, and the Paradigm REAL-Time System. The Guardian Link Transmitter is a component of the Minimed 630G Insulin Pump System. The Guardian Link (3) Transmitter is a component of the MiniMed 670G System. The Guardian Link Transmitter is a component of the Medtronic MiniMed 630G Insulin Pump System. The Guardian Connect Transmitter is a component of the Guardian Connect System. The iPro2 Recorder is a component of the Ipro2 Continuous Glucose Monitoring System with Enlite Sensor.
P160017/S070	08/26/2019	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC MINIMED, INC.	Addition of new sterilization equipment at two previously approved sterilization facilities for the sterilization of the Enlite and Guardian Sensor (3) continuous glucose monitoring sensors. The Enlite sensor is a component of the MiniMed 530G system, the MiniMed 630G system, the Paradigm Real-Time Revel system, and the iPro2 with Enlite sensor system. The Guardian Sensor (3) is a component of the MiniMed 630G system, the Guardian Connect system, and the MiniMed 670G system.

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P160022/S012	08/22/2019	X - 30-Day Notice	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	Addition of a conformal coating and hipot test to the analog board, and updates to the system level testing.
P160025/S008	08/14/2019	X - 30-Day Notice	ASTRON PULSAR STENT SYSTEM, PULSAR-18 STENT SYSTEM	BIOTRONIK, INC.	Automation of a stent expansion process and an ultrasonic cleaning process.
P160030/S036	08/13/2019	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Addition of manufacturing space at Abbott Diabetes Care for the sensor component manufacturing process. The sensor is a component of the FreeStyle Libre Pro Flash Glucose Monitoring System and Freestyle Libre Flash Glucose Monitoring System.
P160030/S037	08/15/2019	X - 30-Day Notice	FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	Change to introduce an alternate supplier of a sensor component for the Libre sensor. The Libre sensor is a component of the Freestyle Libre Pro Flash Glucose Monitoring System and the Freestyle Libre 14 day Flash Glucose Monitoring System.
P160033/S004	08/20/2019	X - 30-Day Notice	POWERHEART® G3, G3 PLUS AND G5 AEDS	CARDIAC SCIENCE CORPORATION	Update to the Smart Packing Software to automate a verification step.
P160034/S001	08/20/2019	X - 30-Day Notice	POWERHEART® G3, G3 PLUS AND G5 AEDS	CARDIAC SCIENCE CORPORATION	Update to the Smart Packing Software to automate a verification step.
P160038/S013	08/08/2019	X - 30-Day Notice	PRAXIS EXTENDED RAS PANEL	ILLUMINA, INC.	Changing the source of two raw materials.
P160043/S026	08/12/2019	X - 30-Day Notice	RESOLUTE INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC VASCULAR	Implementation of a new dishwasher and water purification system in the shared glassware cleaning area within the Medtronic Ireland manufacturing facility.
P160045/S016	08/19/2019	X - 30-Day Notice	ONCOMINE DX TARGET TEST	LIFE TECHNOLOGIES CORPORATION	Relocation of a formulation room within your manufacturing facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P160048/S013	08/29/2019	X - 30-Day Notice	EVERSENSE CONTINUOUS GLUCOSE MONITORING SYSTEM	SENSEONICS, INCORPORATED	New manufacturing site for the electronics assembly and encasement process for the sensor component of the Eversense continuous glucose monitoring system.
P160054/S020	08/25/2019	X - 30-Day Notice	HEARTMATE 3™ LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORPORATION	Add an alternate supplier for the Spline Pump Cover component.
P170008/S020	08/16/2019	X - 30-Day Notice	ELUNIR RIDAFOROLIMUS ELUTING CORONARY STENT SYSTEM	MEDINOL, LTD.	Modification of the supporting tools used for a Quality Control Leak test procedure for the EluNIR Ridaforolimus Eluting Coronary Stent System.
P170035/S004	08/01/2019	X - 30-Day Notice	BAUSCH + LOMB ULTRA (SAMFILCON A) CONTACT LENSES	BAUSCH AND LOMB, INC.	Changing the in-process acceptance criteria for a component of the Ultra (samfilcon A) Visibility Tinted Contact Lens.
P180025/S005	08/06/2019	X - 30-Day Notice	MANTA VASCULAR CLOSURE DEVICE	ESSENTIAL MEDICAL, INC.	Reduce the number of in-process inspections for pouch seal strength testing.
P180029/S009	08/15/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Automation of a manual dimensional inspection.
P180029/S010	08/21/2019	X - 30-Day Notice	LOTUS EDGE VALVE SYSTEM	BOSTON SCIENTIFIC CORPORATION	Change to bonding equipment used to bond the MLE tube to the distal end cap of the delivery system.

Total: 129