July 2014 PMA Approvals

A PDF document that contains the "Approval letter and Summary of Safety and Effectiveness" is being added to this listing for each PMA. The PMA number will appear as a link if this document is available.

PMA Original Approvals

P090029 **7/24/14**	PRESTIGE® LP Cervical Disc	Medtronic Sofamor Danek USA, Incorporated Memphis, TN 38132	Approval for the PRESTIGE® LP Cervical Disc. This device is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The PRESTIGE® LP Cervical Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of non-operative treatment or have had the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of continued non-operative management prior to implantation of the PRESTIGE® LP Cervical Disc.

PMA Supplemental Approvals

N16837/S015 **7/14/14** **Special**	Artegraft Collagen Vascular Graft	Artegraft, Inc. North Brunswick, NJ 08902	Approval for a labeling change to modify the sizing convention from outer diameter to inner diameter of the graft.
P870024/S049 **7/28/14** **180-Day**	Paragon CRT®, Paragon CRT® 100, Paragon RG-4TM Rigid Gas Permeable Contact Lens for Overnight Corneal Refractive Therapy	Paragon Vision Sciences, Inc. Mesa, AZ 85204	Approval for a labeling update to the Package Insert and Patient Information Booklet to include the results from a Section 522 Postmarket Surveillance Study (PAS).
P890003/S297 **7/9/14**	CareLink Encore Programmer, CareLink 2090 Programmer, CareLink Home Monitor, CareLink Express Monitor,	Medtronic, Inc. Mounds View, MN	Approval for the Medtronic Viva CRT-P Model C6TR01 Implantable Pacemaker with Cardiac Resynchronization; Programmer Software Application Model 9995 v8.3; and updates to the Medtronic CareLink Monitor Model

180-Day	CardioSight Reader, Device Data Management Application (DDMA)	55112	2490G, CardioSight Reader Model 2020A and CareLink Express Model 2020B firmware, and to the Model 2491 Device Data Management Application (DDMA).
P890003/S309 **7/3/14** **180-Day**	CareLink Monitor, CardioSight Reader, CareLink Express, Device Data Management Application (DDMA)	Medtronic, Inc. Mounds View, MN 55112	Approval for the Viva/Brava Quadripolar Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices and is indicated for patients who require ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life- threatening ventricular arrhythmias, for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the classifications provided in the labeling.
P890055/S048 **7/15/14** **Special**	MedStream Programmable Infusion System	Codman & Shurtleff, Inc. Raynham, MA 02767	Approval for an additional inspection step in the manufacturing process of the MedStream device to require a post-sterilization Fill Level Sensor (FLS) functional inspection.
P890055/S056 **7/30/14** **Real-Time**	MedStream Programmable Infusion Pump	Codman & Shurtleff, Inc. Raynham, MA 02767	Approval to replace electrical gap welding or laser welding of the MedStream pump's electrical components on the Printed Circuit Board (PCB) with a thermobrazing process, modify the extremity of the Flex FLS, Flex RF, and Battery Ribbon component to include apertures, and eliminate the current in-process micro pull test for each connection.
P890055/S057 **7/11/14** **180-Day**	Codman 3000 Constant-Flow Infusion Pump and MedStream Programmable Infusion	Codman & Shurtleff, Inc. Raynham, MA 02767	Approval for a manufacturing site located at Sterigenics Belgium (Petit-Rechain) S.A. in Verviers, Belgium.
P910023/S336 **7/24/14** **Real-Time**	LATITUDE NXT Patient Management System, LATITUDE NXT Release 3.0	St. Jude Medical Sunnyvale, CA 94085	Approval for cybersecurity updates to the Merlin@Home transmitters.
P910077/S143 **7/16/14**	LATITUDE NXT Patient Management System	Boston Scientific Corporation St. Paul, MN	Approval for the Wave Communicator Model 6280 sw version v1.52.00; Wave Communicator Model 6290 sw version v2.02.00; Wave Communicator Model 6498 sw version v1.52.00; LATITUDE NXT System Software

Real-Time		55112	Model 6460 v.3.00.01; and Communicator Accessory and Literature Kit Model 6250.
P950005/S050 **7/2/14** **135-Day**	Celsius, Celsius RMT, EZ Steer Non-Temp Sensing Ablation Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for applying a change in sterilization release method to the new line of catheters at the Santa Teresa, New Mexico facility.
P950015/S012 **7/23/14** **180-Day**	Heart Laser CO2 TMR System	Novadaq Tehnologies, Inc. Richmond, British Columbia Canada V6V 2A2	Approval for a manufacturing site located at Ethox, in Buffalo, New York.
P950037/S135 **7/16/14** **Real-Time**	REOCOR S/D External Pacermaker	Biotronik, Inc. Lake Oswego, OR 97035	Approval for the replacement of the storage capacitor for the devices.
P960040/S316 **7/16/14** **Real-Time**	TELIGEN, INCEPTA, ENERGEN, PUNCTUA, DYNAGEN, INOGEN, and ORIGEN Family of ICDs	Boston Scientific Corporation St. Paul, MN 55112	Approval for Model 2868 Application Software version 3.04 and Firmware version A_v1.04 with Patch v4.01 and Firmware version B_v1.02 with Patch v3.01 for the devices.
P960058/S108 **7/29/14** **180-Day**	HiResolution Bionic Ear System: Concave Universal Head Piece	Advanced Bionics Valencia, CA 91355	Approval for the Concave Universal Head Piece, a redesigned version of the current Universal Head Piece. The Concave Universal Head Piece supports both behind the ear and body worn Sound Processors and is intended for increase of wearing comfort for the HiRes90K Advantage implant users.
P970003/S169 **7/2/14** **Real-Time**	DemiPulse Implantable Pulse Generator; Aspire HC Implantable Pulse Generator	Cyberonics, Inc. Houston, TX 77058	Approval for a change to the Printed Circuit Board Assembly manufacturing design requirement for voltage measurement accuracy and tolerance associated with its electrical testing.
P970004/S178 **7/25/14**	InterStim Therapy for Urinary Control	Medtronic Neuromodulation Minneapolis, MN	Approval for changes to the labeling to add a warning regarding the risk of increased or uncontrolled bleeding and the use of anticoagulants prior to surgery for

Special		55432	InterStim Therapy.
P980006/S022 **7/11/14** **180-Day**	Bausch & Lomb PureVision2 (balafilcon A) Visibility Tinted Contact Lenses, Bausch & Lomb PureVision2 Multi-Focal (balafilcon A) Visibility Tinted Contact Lenses, Bausch & Lomb PureVision2 Toric (balafilcon A) Visibility Tinted Contact Lenses Equate Monthly Single Vision (balafilcon A) Contact Lens, Equate Monthly Multi-Focal (balafilcon A) Contact Lens, Equate Monthly Toric (balafilcon A) Contact Lenses, and C-Vue ADDvantage Multifocal (balafilcon A) Visibility Tinted Contact Lenses	Bausch & Lomb, Inc. Rochester, NY 14609	Approval for the addition of the following private label trade names: Equate Monthly Single Vision (balafilcon A) Contact Lens, Equate Monthly Multi-Focal (balafilcon A) Contact Lens, Equate Monthly Toric (balafilcon A) Contact Lenses, and C-Vue ADDvantage Multifocal (balafilcon A) Visibility Tinted Contact Lenses. The device, as modified, will be marketed under the trade name the Equate Monthly Single Vision (balafilcon A) Contact Lens and is indicated for daily wear or extended wear from 1 to 30 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care professional. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +8.00D to -20.00D when prescribed for up to 30 days of extended wear and from +20.00D to -20.00D for daily wear or extended wear up to 7 days. The Equate Monthly Single Vision (balafilcon A) Contact Lens is also indicated for therapeutic use. Use as a bandage contact lens for corneal protection and corneal pain relief during treatment of ocular pathologies as well as post-surgical conditions. Applications of the Equate Monthly. Single Vision (balafilcon A) Contact Lenses include but are not limited to conditions such as the following: 1) For corneal protection in conditions such as entropion, trichiasis, tarsal scars, recurrent corneal erosion and post surgical ptosis for corneal protection; 2) For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, post-keratoplasty; 3) For use as a bandage during the healing process of conditions such as chronic epithelial defects, corneal ulcer, neurotrophic keratitis, neuroparalytic keratitis, chemical bums, and post surgical epithelial defects; and, 4) For post-surgical conditions that include bandage use such as LASIK, PRK, PK, PTK, lamellar grafts, corneal flaps, and additional corneal surgical conditions. Equate Monthly Single Vision (balafilcon A) Contact Lenses for therapeutic use can also provide optical correction during healing if required. The device, as modified, will be marketed under the trade name The Equate Monthly Multi-Focal (balafilcon A) Contact Lens is indicated for daily wear or extended wear from 1 to 30 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care professional. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with nondiseased eyes, exhibiting astigmatism of up to 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/ Planned Replacement Wear or Disposable Wear in spherical powers ranging

			from +6.00D to -18.00D when prescribed for up to 30 days of Extended wear and from +20.00D to -20.00D for daily wear or extended wear up to 7 days with add powers ranging from +0.75D to +5.00D. The device, as modified, will be marketed under the trade name the Equate Monthly Toric (balafilcon A) For Astigmatism and is indicated for daily wear or extended wear from 1 to 30 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care professional. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +6.00D to -9.00D when prescribed for up to 30 days of extended wear and from +20.00D to -20.00D for daily wear or extended wear up to 7 days. The device, as modified, will be marketed under the trade name the C-Vue ADDvantage Multifocal (balafilcon A) Visibility Tinted Contact Lenses and are indicated for daily wear or extended wear from 1 to 30 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care professional. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or notaphakic persons with non-diseased eyes, exhibiting astigmatism of up to 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +6.00D to - 18.00D when prescribed for up to 30 days of extended wear and from +20.00D to - 20.00D for daily wear or extended wear up to 7 days with add powers ranging from +0.75D to +5.00D.
P980016/S452 **7/9/14** **180-Day**	Maximo II DR, Maximo II VR, Virtuoso II DR, Virtuoso II VR, Secura DR, Secura VR Implantable Cardioverter Defibrillators	Medtronic, Inc. Mounds View, MN 55112	Approval for the Medtronic Viva CRT-P Model C6TR01 Implantable Pacemaker with Cardiac Resynchronization; Programmer Software Application Model 9995 v8.3; and updates to the Medtronic CareLink Monitor Model 2490G, CardioSight Reader Model 2020A and CareLink Express Model 2020B firmware, and to the Model 2491 Device Data Management Application (DDMA).
P980022/S154 **7/10/14** **Real-Time**	Paradigm REAL-Time Revel System	Medtronic Minimed Northridge, CA 91325	Approval to lower the purity specification limit for the Chromium layer on Enlite™ Glucose Sensor (MMT-7008) of the MiniMed 530G System and Sof™ Glucose Sensor (MMT-7002, MMT-7003) of the Paradigm REAL-Time Revel System.

P980023/S057 **7/3/14** **180-Day**	PROTEGO Family of ICD Leads	Biotronik, Inc. Lake Oswego, OR 97035	Approval for the DF4 variants of the currently approved Ilesto/Iforia ICDs/CRT-Ds and LinoxSmart ICD leads.
P980025/S002 **7/22/14** **180-Day**	Logicon Caries Detector	GA Industries Rancho Palos Verdes, CA 90275	Approval for the addition of software module PreScan to Logicon Caries Detector. The device, as modified, will be marketed under the trade name Logicon Caries Detector and has revised indications for use: "The Logicon Caries Detector is a software device that is an aid in the diagnosis of caries that have penetrated into the dentin, on un-restored proximal surfaces of secondary dentition through the statistical analysis of digital intra-oral radiographic imagery. The device provides additional information for the clinician to use in his/her diagnosis of a tooth surface suspected of being carious. It is designed to work in conjunction with an existing Carestream Dental RVG digital x-ray radiographic system with Dental Imaging Software (DIS) for WINDOWS XP or higher."
P980035/S358 **7/9/14** **180-Day**	Advisa DR, Advisa DR MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Approval for the Medtronic Viva CRT-P Model C6TR01 Implantable Pacemaker with Cardiac Resynchronization; Programmer Software Application Model 9995 v8.3; and updates to the Medtronic CareLink Monitor Model 2490G, CardioSight Reader Model 2020A and CareLink Express Model 2020B firmware, and to the Model 2491 Device Data Management Application (DDMA).
P980040/S048 **7/24/14** **180-Day**	TECNIS OptiBlue 1-Piece intraocular lens	Abbott Medical Optics Inc. Santa Ana, CA 92705	Approval for a manufacturing site located at AMO Puerto Rico Manufacturing, Inc., in Anasco, Puerto Rico.
P990004/S024 **7/2/14** **180-Day**	SURGIFOAM Absorbable Gelatin Sponge, USP	Ethicon, Inc. Somerville, NJ 08876	Approval for a manufacturing (packaging) site located at Ferrosan Medical Devices, Koksowa, Poland.
P990071/S027 **7/2/14** **180-Day**	SmartAblate System	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for hardware modifications to the SmartAblate Irrigation Pump that update the hardware from version 1 to version 2.

P000058/S037 **7/24/14** **180-Day**	INFUSE® Bone Graft and INFUSE® Bone GraftLT-Cage Lumbar Tapered Fusion Device	Medtronic Spinal Memphis, TN 38132	Approval for a manufacturing site located at Wyeth Farma, S.A, in De Los Reyes, Spain.
P010012/S355 **7/16/14** **Real-Time**	COGNIS, INECEPTA, ENERGEN, PUNCTUA, DYNAGEN, INOGEN, and ORIGEN family of CRT-Ds and Application Software	Boston Scientific Corporation St. Paul, MN 55112	Approval for Model 2868 Application Software version 3.04 and Firmware version A_v1.04 with Patch v4.01 and Firmware version B_v1.02 with Patch v3.01 for the devices.
P010014/S048 **7/7/14** **Special**	Oxford® Partial Knee System	Biomet U.K. Ltd. Swindon, UK SN3 5HY	Approval to update three contraindications in the Instructions for Use for the Oxford® Partial Knee System.
P010015/S227 **7/9/14** **180-Day**	Viva CRT-P, Consulta CRT-P, Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	Approval for the Medtronic Viva CRT-P Model C6TR01 Implantable Pacemaker with Cardiac Resynchronization; Programmer Software Application Model 9995 v8.3; and updates to the Medtronic CareLink Monitor Model 2490G, CardioSight Reader Model 2020A and CareLink Express Model 2020B firmware, and to the Model 2491 Device Data Management Application (DDMA).
P010030/S051 **7/14/14** **Real-Time**	LifeVest® Wearable Defibrillator	ZOLL Lifecor Corporation Pittsburgh, PA 15238	Approval for a software change that will enable an analog clipping noise detector which will allow the system to better recognize when an input signal may be compromised due to saturation of analog amplifiers in the ECG signal processing circuitry.
P010031/S414 **7/9/14** **180-Day**	Concerto II CRT-D, Maximo II CRT-D, Consulta CRT-D, Consulta CRT-D DF4, Maximo II CRT-D DF4	Medtronic, Inc. Mounds View, MN 55112	Approval for the Medtronic Viva CRT-P Model C6TR01 Implantable Pacemaker with Cardiac Resynchronization; Programmer Software Application Model 9995 v8.3; and updates to the Medtronic CareLink Monitor Model 2490G, CardioSight Reader Model 2020A and CareLink Express Model 2020B firmware, and to the Model 2491 Device Data Management Application (DDMA).
P010031/S442 **7/3/14** **180-Day**	Viva/Brava Quadripolar CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Approval for the Viva/Brava Quadripolar Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices and is indicated for patients who require ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life- threatening

			ventricular arrhythmias, for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the classifications provided in the labeling.
P010032/S075 **7/2/14** **180-Day**	Eon Mini and Protégé Implantable Neurostimulation Systems	St. Jude Medical Plano, Texas 75024	Approval for hardware and software modifications to the Eon Charging System Model 3726.
P010032/S078 **7/7/14** **Real-Time**	Eon Mini and Protégé Implantable Neurostimulation Systems	St. Jude Medical Implantable Electronic Systems Plano, TX 75024	Approval for updating firmware from version 3.0 to version 3.0.1 for Eon Mini (Model 3788) and Protégé (Model 2789) Implantable Pulse Generator that are used in Spinal Cord Stimulation therapy.
P010032/S079 **7/14/14** **Real-Time**	Protégé Implantable Neurostimulation Systems	St. Jude Medical Implantable Electronic Systems Plano, TX 75024	Approval for Rapid Programmer version 3.6 to support the programming of the Protégé neurostimulation devices (Model 3789 Protégé implantable pulse generator and Model 3852 patient programmer) as well as to make minor sustaining enhancements.
P010055/S009 **7/30/14** **180-Day**	ProstaLund CoreTherm System and ProstaLund CoreTherm Accessories	ProstaLund Operation AB Lund, Sweden SE-223	Approval for a manufacturing site located at Orifice Medical AB in Ystad, Sweden.
P010062/S008 **7/28/14** **180-Day**	Boston® Orthokeratology (Oprifocon A) Shaping Lens	Bausch & Lomb Rochester, NY 14609	Approval for a labeling update to the Package Insert and Patient Information Booklet to include the results from a Section 522 Postmarket Surveillance Study (PAS).
P010068/S039 **7/2/14** **135-Day**	Celsius DS, NaviStar DS, NaviStar RMT DS, EZ Steer Nav DS Catheters	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for applying a change in sterilization release method to the new line of catheters at the Santa Teresa, New Mexico facility.
P020045/S054 **7/17/14**	Freezor Cardiac CryoAblation	Medtronic CryoCath LP	Approval for modifications to the Y-block distal diameter and the adhesive used in the Y-block to Shaft

Real-Time	System	Quebec, Canada H9R 5Z8	bond.
P030011/S024 **7/2/14** **180-Day**	SynCardia temporary Total Artificial Heart (TAH-t) System	SynCardia Systems, Inc. Tucson, AZ 85713	Approval for use of the SynHall valve in the SynCardia temporary Total Artificial Heart (TAH-t).
P030031/S044 **7/1/14** **180-Day**	Navistar RMT Thermocool Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for a manufacturing site located at Biosense Webster, Inc., in Chihuahua, Mexico.
P030054/S268 **7/24/14** **Real-Time**	FAMILY OF MERLIN@HOME TRANSMITTERS	St. Jude Medical Sunnyvale, CA 94085	Approval for cybersecurity updates to the Merlin@Home transmitters.
P040002/S048 **7/14/14** **Real-Time**	AFX Bifurcated Stent Graft Delivery System	Endologix, Inc. Irvine, CA 92618	Approval for changes to the retraction stop on the inner core of the AFX Bifurcated Stent Graft Delivery System.
P040002/S049 **7/30/14** **Real-Time**	AFX Endovascular AAA System	Endologix, Inc. Irvine, CA 92618	Approval to modify the anchor bonding process of the front tip subassembly on the AFX Accessory Stent Graft Delivery System.
P040013/S018 **7/11/14** **Special**	GEM 21S (GROWTH-FACTOR ENHANCED MATRIX)	Luitpold Pharmaceuticals, Inc. Norristown, PA 19403	Approval for the revision of the GEM 21S package insert.
P040033/S027 **7/30/14** **Real-Time**	Birmingham Hip Resurfacing (BHR) System	Smith & Nephew Orthopaedics Cordova, TN 38016	Approval for an instrument to assist in femoral component sizing and positioning.

P040036/S032 **7/1/14** **180-Day**	Celsius RMT Thermocool Catheter	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for a manufacturing site located at Biosense Webster, Inc., in Chihuahua, Mexico.
P040044/S056 **7/30/14** **180-Day**	Mynx Vascular Closure Device Product Family	Access Closure, Inc. Santa Clara, CA 95054	Approval to expand the indications for use to include closure of venous access sites in addition to the currently approved use for closure of arterial access sites. The device, as modified, will be marketed under the trade name MynxGrip Vascular Closure Device and is indicated for use to seal femoral arterial and femoral venous access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F or 7F procedural sheath.
P050010/S013 **7/31/14** **180-Day**	PRODISC L Total Disc Replacement	DePuy Synthes Spine Raynham, MA 02767	Approval for modified labeling to reflect findings of the post-approval study (PAS).
P050023/S076 **7/3/14** **180-Day**	Ilesto/Iforia DF4 ICDs/CRT-Ds	Biotronik, Inc. Lake Oswego, OR 97035	Approval for the DF4 variants of the currently approved Ilesto/Iforia ICDs/CRT-Ds and LinoxSmart ICD leads.
P050031/S001 **7/28/14** **180-Day**	Paragon Z CRT® Lens	Paragon Vision Sciences, Inc. Mesa, AZ 85204	Approval for a labeling update to the Package Insert and Patient Information Booklet to include the results from a Section 522 Postmarket Surveillance Study (PAS).
P050033/S016 **7/17/14** **Real-Time**	Hydrelle	Anika Therapeutics Incorporated Bedford, MA 01730	Approval for changes to the stability protocol.
P050053/S015 **7/24/14** **180-Day**	INFUSE® Bone Graft and INFUSE® Bone GraftLT-Cage Lumbar Tapered Fusion Device	Medtronic Spinal Memphis, TN 38132	Approval for a manufacturing site located at Wyeth Farma, S.A, in De Los Reyes, Spain.

P060025/S013 **7/30/14** **180-Day**	Medtronic 3f Aortic Bioprosthesis	Medtronic Structural Heart Santa Ana, CA 92705	Approval for a manufacturing site located at Medtronic in Santa Ana, California.
P060037/S026 **7/18/14** **180-Day**	NexGen Complete Knee Solution, Legacy Knee – Posteriorly Stabilized (LPS), and LPS-Flex Mobile Bearing Knee	Zimmer, Inc. Warsaw, IN 46581	Approval for a manufacturing site located at Synergy Health located in Daniken, Switzerland.
P060038/S020 **7/15/14** **180-Day**	MitroFlow Aortic Pericardial Heart Valve (MAPHV™)	Sorin Group USA, Inc. Canada V5J 5M1	Approval of the post-approval study protocol.
P060040/S036 **7/27/14** **Real-Time**	Thoratec HeartMate II Left Ventricular Assist Device	Thoratec Corporation Pleasanton, CA 94588	Approval for software changes to the Backup Application of the Pocket Controller.
P070014/S044 **7/18/14** **180-Day**	Bard® LifeStent® Vascular Stent System	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Approval for a smaller stent diameter (5mm) with an identical design/cut pattern to the current LifeStent.
P070014/S045 **7/11/14** **180-Day**	LifeStent Vascular Stent Systems	Bard Peripheral Vascular, Inc. Tempe, AZ 85280	Approval of the post-approval study protocol.
P070027/S039 **7/16/14** **180-Day**	Talent Converter Stent Graft System & Talent Occluder System	Medtronic Vascular Santa Rosa, CA 95403	Approval of the post-approval study protocol.
P080011/S030 **7/8/14** **135-Day**	CooperVision Comfilcon A Soft Extended-Wear Contact Lenses	CooperVision, Inc. Pleasanton, CA 94588	Approval for a new manufacturing line at the Puerto Rico facility.

P080025/S074 **7/25/14** **Special**	InterStim Therapy for Bowel Control	Medtronic Neuromodulation Minneapolis, MN 55432	Approval for changes to the labeling to add a warning regarding the risk of increased or uncontrolled bleeding and the use of anticoagulants prior to surgery for InterStim Therapy.
P100003/S004 **7/16/14** **180-Day**	SECURE®-C Artificial Cervical Disc	Globus Medical, Inc. Audobon, PA 19403	Approval of the post-approval study protocol.
P100009/S004 **7/9/14** **Real-Time**	MitraClip Clip Delivery System	Abbott Vascular Menlo Park, CA 94025	Approval for a new patient brochure.
P100021/S038 **7/8/14** **Special**	Endurant and Endurant II Stent Graft System	Medtronic Vascular Santa Rosa, CA 95403	Approval for introducing a lamp mandrel as a manufacturing tool for radiopaque contralateral gate marker inspection of Endurant and Endurant II Bifurcated Stent Grafts and a coil dispenser as a visual aid during the pre-kitting process of Endurant II Stent Grafts.
P100026/S017 **7/9/14** **Real-Time**	RNS® System	NeuroPace, Inc. Mountain View, CA 94043	Approval to use 20 micron thick separators in the QMR model 2570 battery.
P100027/S018 **7/30/14** **Real-Time**	INFORM HER2 Dual ISH DNA Probe Cocktail System	Ventana Medical Systems, Inc. Tucson, AZ 85755	Approval for the extension of stability dating for the INFORM HER2 Dual ISH DNA Probe Cocktail system, which includes the following products: INFORM HER2 Dual ISH DNA Probe Cocktail, ultraView Red ISH DIG Detection Kit, ultraView SISH DNP Detection Kit.
P100030/S004 **7/31/14** **180-Day**	PreveLeak Surgical Sealant	Tenaxis Medical, Inc. Mountain View, CA 94043	Approval for a product trade name change from ArterX® Surgical Sealant to PreveLeak Surgical Sealant. The device, as modified, will be marketed under the trade name PreveLeak Surgical Sealant and is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

P100034/S008 **7/24/14** **180-Day**	NovoTTF-100A System	NovoCure, Ltd. Rye Beach, NH 03871	Approval for 1) design changes to the NovoTTF-100A connection cable to enhance its durability and 2) the addition of UNIXTAR Technology, Inc. as a second source supplier of the connection cables.
P100034/S009 **7/25/14** **Real-Time**	NovoTTF-l00A System	NovoCure, Ltd. Rye Beach, NH 03871	Approval to replace the current Tyvek pouch packaging material for the INE transducer arrays with an aluminum foil moisture barrier and to extend the shelf life for these transducer arrays from 6 to 9 months.
P100049/S010 **7/22/14** **Special**	Linx Reflux Management System	Torax Medical, Inc. Shoreview, MN 55126	Approval for labeling alterations including adverse event information about erosion of the LINX device, clarifications or contraindications regarding nickel, warnings regarding storage and use above 60 degrees C, additional potential risk of saliva/mucus build-up, and directions which add the removal of sutures after the clasp ends are fully engaged.
P110002/S005 **7/15/14** **180-Day**	Mobi-C Cervical Disc	LDR Spine USA, Inc. Austin, TX 78750	Approval of the post-approval study protocol.
P110009/S005 **7/15/14** **180-Day**	Mobi-C Cervical Disc	LDR Spine USA, Inc. Austin, TX 78750	Approval of the post-approval study protocol.
P110010/S083 **7/18/14** **Real-Time**	PROMUS Element™ Plus and Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ and Over-The-Wire)	Boston Scientific Corporation Maple Grove, MN 55311	Approval for the extension of the shelf life from 12 months to 18 months.
P110019/S063 **7/3/14** **135-Day**	XIENCE PRIME® Everolimus Eluting Coronary Stent System, XIENCE XPEDITION™ Everolimus Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval to remove a stent inspection step.

P110019/S068 **7/3/14** **Real-Time**	XIENCE Xpedition™ Everoliums Eluting Coronary Stent System, XIENCE Xpedition™ LL Everolimus Eluting Coronary Stent System, XIENCE Xpedition™ SV Everolimus Eluting Coronary Stent System	Abbott Vascular Temecula, CA 92591	Approval to change the outer layer thickness specification for the inner member catheter component for the Xience Xpedition, Xience Xpedition SV, and Xience Xpedition LL Everolimus Eluting Coronary Stent Over the Wire (OTW) System.
P110033/S002 **7/30/14** **135-Day**	JUVÉDERM VOLUMA XC	Allergan Goleta, CA 93117	Approval for increased dryer capacity in JUVÉDERM VOLUMA XC manufacturing.
P120005/S019 **7/11/14** **Real-Time**	Dexcom G4™ PLATINUM Continuous Glucose Monitoring System	Dexcom, Inc. San Diego, CA 92121	Approval for a change to the transmitter that combines the components from two printed circuit board assemblies (PCBAs) into a single board transmitter (SBT) with one printed circuit board (PCB).
P120010/S021 **7/10/14** **Real-Time**	MiniMed 530G System	Medtronic Minimed Northridge, CA 91325	Approval to lower the purity specification limit for the Chromium layer on Enlite™ Glucose Sensor (MMT-7008) of the MiniMed 530G System and Sof™ Glucose Sensor (MMT-7002, MMT-7003) of the Paradigm REAL-Time Revel System.
P120020/S004 **7/10/14** **135-Day**	Supera Peripheral Stent System	Abbott Vascular Santa Clara, CA 95054	Approval for implementation of a semi-automated passivation process and a change to the passivation of stent couplings by an alternate vendor.
P130016/S002 **7/1/14** **Real-Time**	Nucleus® Hybrid™ Implant System	Cochlear Americas Centennial, CO 80111	Approval for an MR indication at 1.5 tesla under specific scanning conditions with the magnet surgically removed prior to the MR scan, for the Hybrid L24 Implant System.

30-Day Notices (135 Day Supplement was not required)

P790007/S042 **7/23/14**	Hancock® Modified Orifice Valved Conduit	Medtronic, Inc. Santa Ana, CA 92705	Addition of a new porcine tissue supplier.
P830060/S080 **7/30/14**	VENTAK AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) SYSTEM	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P830061/S109 **7/16/14**	CAPSURE SENSE LEADS	Medtronic, Inc. Mounds View, MN 55112	Implementation of an equivalent sterilizer and aerator.
P840001/S270 **7/2/14**	RestoreSensor Rechareable Neurostimulator, RestoreSensor SureScan MRI Rechareable Neurostimulator	Medtronic Neuromodulation Minneapolis, MN 55432	Update to the process flow at the IC Supplier.
P840001/S271 **7/3/14**	ITREL, RESTORE, and SYNERGY SYSTEMS	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacturing change associated with incoming inspection activities.
P840001/S272 **7/17/14**	ITREL,RESTORE, and SYNERGY SYSTEMS	Medtronic Neuromodulation Minneapolis, MN 55432	Use alternate lasers for the laser bonding process.
P840001/S274 **7/22/14**	SCS Neurostimulators Implantable Restore Family	Medtronic Neuromodulation Minneapolis, MN 55432	Use a new software test package.
P860004/S208 **7/3/14**	SYNCHROMED SYSTEM	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacturing change associated with incoming inspection activities.

P860004/S209 7/24/14	SYNCHROMED SYSTEM	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacturing line move on the same Chaska, Minnesota campus, change in the inspection assembly process, removal of a cleaning step, and will discontinuing a manual fingerpull test.
P870078/S026 7/23/14	Hancock® Low Porosity Valved Conduit	Medtronic, Inc. Santa Ana, CA 92705	Addition of a new porcine tissue supplier.
P880086/S244 7/9/14	Accent SR RF, Accent DR RF	St. Jude Medical Sylmar, CA 91342	Modify the Device Post Sterilization Test (DPST) at ATE for the RF telemetry of the devices.
P900033/S037 7/3/14	INTEGRA Artificial Skin Dermal Regeneration Template	Integra Life Sciences Corporation Plainsboro, NJ 08536	Change in the Cleaning Validation to extend the Dirty hold time of Tanks TK-01 and TK-02 used in the Wet Processing Formulation.
P900056/S140 7/24/14	Rotablator Rotational Atherectomy System	Boston Scientific Corporation Maple Grove MN 55311	Change to the device component quality inspection process.
P910023/S340 7/10/14	Current+, Ellipse, Fortify, and Fortify Assura Families of ICD Devices	St. Jude Medical, Sylmar, CA 91342	Change in the temperature cycling range for hybrid assemblies.
P910023/S341 7/18/14	Fortify and Fortify Assura families of ICD devices	St. Jude Medical, Sylmar, CA 91342	Modification to the connector reinforcement process for hybrid assemblies.
P910073/S127 7/30/14	ENDOTAK LEAD SYSTEM	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.

P910077/S145 **7/30/14**	VENTAK PRX AND VENTAK MINI	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P920015/S132 **7/10/14**	Sprint Quattro Lead	Medtronic CRDM Mounds View, MN 55112	Modified testing frequency for the destructive pull test of the devices.
P920015/S134 **7/28/14**	Sprint Quattro Lead	Medtronic CRDM Mounds View, MN 55112	Addition of an alternate supplier for manufacture of the bifilar electrode coil for the devices.
P920048/S008 **7/24/14**	Rapid fFN Control Kit	Hologic, Inc. Sunnyvale, CA 94089	Change to add an intermediate solution in the manufacturing process of Positive Reference Calibrator, to modify the personnel in charge of in-process manufacturing testing and to increase the number of replicates in bulk solution concentration verification procedure for both Positive Reference Calibrator and Positive Control. The Positive Reference Calibrator and the Positive Control are components of the Rapid fFN Control kit for use with the TLiIQ Analyzer and fFN ELISA Test.
P930014/S073 **7/16/14**	AcrySof Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Addition of an alternate component supplier.
P930035/S027 **7/30/14**	VENTAK P2 PACEMAKER	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P930039/S110 **7/8/14**	CapSureFix Novus Lead	Medtronic, Inc. Mounds View MN, 55112	Add a helix linearity inspection at the final functional inspection and a helix linearity fixture to facilitate this linearity inspection.

P930039/S111 7/16/14	CAPSUREFIX NOVUS LEADS	Medtronic, Inc. Mounds View, MN 55112	Implementation of an equivalent sterilizer and aerator.
P950001/S027 7/30/14	SELUTE LEAD SYSTEM	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P950029/S091 7/16/14	Reply SR, Reply DR, Esprit SR, Esprit DR	Sorin CRM USA, Inc Arvada, CO 80004	Change to the in-process verifications for tantalum capacitors used in the devices.
P950029/S092 7/28/14	Reply SR, Reply DR, Esprit SR, Esprit DR	Sorin CRM USA, Inc Arvada, CO 80004	Change to a single pass process for screen printing and reflow soldering.
P950037/S136 7/11/14	Selox, TILDA, Solox Leads	Biotronik, Inc. Lake Oswego, OR 97035	Additional supplier for the conductor wires used in the manufacture of the leads.
P960004/S066 7/30/14	THIN/LINE/FINELINE FAMILY OF ENDOCARDIAL PACING LEADS	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P960006/S043 7/30/14	SWEET TIP RX, SWEET PICOTIP RX, AND FLEXTEND LEADS	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P960009/S196 7/3/14	ACTIVA, KINETRA, SOLETRA SYSTEMS	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacturing change associated with incoming inspection activities.

P960040/S319 **7/8/14**	INCEPTA, ENERGEN, PUNCTUA, TELIGEN, VITALITY, DYNAGEN, INOGEN, ORIGEN IMPLANTABLE CARDIOVERTER DEFIBRILLATORS	Boston Scientific St. Paul, MN 55112	Add a functionally equivalent sterilization chamber; 2) add a third Abator to be used with the additional sterilizer; and 3) include sterilizer chamber enhancements required for the existing and additional sterilizer chambers.
P960040/S321 **7/11/14**	ORIGEN™ EL ICD; INOGEN™ EL ICD; DYNAGEN™ EL ICD; ORIGEN™ MINI ICD; INOGEN™ MINI ICD; DYNAGEN™ MINI ICD	Boston Scientific St. Paul, MN 55112	Add the laser etched scratches inspection criteria for the devices.
P960040/S322 **7/8/14**	PUNCTUA ICDs, TELIGEN ICDs, INCEPTA ICDs, ORIGEN ICDs, DYNAGEN ICDs	Boston Scientific Corporation St. Paul, MN 55112	Add a replacement automated optical (AOI) inspection equipment for device identification and torque wrench verification.
P960040/S323 **7/30/14**	ICD ORIGEN, ICD INOGEN, ICD DYNAGEN, ICD PUNCTUA, ICD TELIGEN, ICD ENERGEN, ICD INCEPTA, ICD VITALITY	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P960040/S324 **7/28/14**	DYNAGEN™ EL ICD; INOGEN™ EL ICD; ORIGEN™ EL ICD; DYNAGEN™ MINI ICD; NOGEN™ MINI ICD; ORIGEN™ MINI ICD	Boston Scientific Corporation St. Paul, MN 55112	Blister sealer process setting changes for the devices.
N970003/S165 **7/8/14**	INSIGNIA, ALTRUA, INGENIO, ADVANTIO, VITALIO, FORMIO PACEMAKERS	Boston Scientific St. Paul, MN 55112	Add a functionally equivalent sterilization chamber; 2) add a third Abator to be used with the additional sterilizer; and 3) include sterilizer chamber enhancements required for the existing and additional sterilizer chambers.
N970003/S166 **7/30/14**	PG INSIGNIA, PG ADVANTIO, PG INGENIO, PG VITALIO, PG FORMIO, PG ALTRUA	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.

P970003/S172 **7/17/14**	VNS Therapy System	Cyberonics, Inc. Houston, TX 77058	Automate a weld angle measurement process.
P970004/S176 **7/2/14**	SNS Urinary Verify Screening Trialing Systems (including Temporary Leads)	Medtronic Neuromodulation Minneapolis, MN 55432	Update to the process flow at the IC Supplier.
P970004/S177 **7/3/14**	SNS Urinary Extensions, SNS Urinary Leads	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacturing change associated with incoming inspection activities.
P970004/S179 **7/30/14**	Medtronic Verify External Neurostimulator (ENS)	Medtronic Neuromodulation Minneapolis, MN 55432	Acceptance to expand the manufacturing acceptance criterion.
P970031/S046 **7/23/14**	Freestyle® Aortic Root Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of a new porcine tissue supplier.
P980016/S486 **7/11/14**	Marquis DR ICD; Marquis VR ICD; Maximo DR ICD; Maximo VR ICD	Medtronic CRDM Mounds View, MN 55112	Supplier change and specification update to p(ETFE) used in Medtronic CRDM lithium-organic electrolyte batteries.
P980016/S487 **7/17/14**	Maximo II, Protecta, Protecta XT, Secura, Virtuoso II DR/VR ICDs	Medtronic CRDM Mounds View, MN 55112	Change in the epoxy dispense process for the devices.
P980016/S488 **7/9/14**	Evera S DR ICD; Evera S VR ICD; Evera XT DR ICD; Evera XT VR ICD; Maximo II ICD; Protecta ICD; Protecta XT ICD; Secura ICD; Virtuoso II DR/VR ICD	Medtronic CRDM Mounds View, MN 55112	Reduction of Sonoscan detection method for the devices.

P980016/S490 7/30/14	Evera S DR ICD, Evera S VR ICD, Evera XT DR ICD, Evera XT VR ICD	Medtronic CRDM Mounds View, MN 55112	Additional equipment for the fill hole seal weld for the high voltage capacitor.
P980016/S491 7/22/14	Evera S DR/VR, Evera XT DR/VR, Maximo II, Protecta, Secura, Virtuoso DR/VR ICDs	Medtronic CRDM Mounds View, MN 55112	Modification on laser seam welder equipment at a final device manufacturing facility for the devices.
P980022/S157 7/18/14	Paradigm REAL-Time Revel System	Medtronic MiniMed Inc. Northridge, CA, 91325	Addition of a functional test during manufacture of the MySentry System (MMT-9100). The MySentry System (MMT-9100) consists of the MySentry Monitor (MMT-9101) and MySentry Outpost (MMT-9102) and is approved for use with the Paradigm REALTime Revel System.
P980022/S158 7/24/14	Paradigm® REAL-Time System and Paradigm® REAL-Time Revel System	Medtronic MiniMed Inc. Northridge, CA 91325	Change in the concentration of a raw material used during manufacture of the EnliteTM Glucose Sensor (MMT-7008) of the MiniMed 530G System and SofTM Glucose Sensor (MMT-7002, MMT-7003) of the Paradigm® REAL-Time System and Paradigm® REAL-Time Revel System.
P980023/S059 7/11/14	LINOX SMART SD, VIGILA, VOLTA	Biotronik, Inc. Lake Oswego, OR 97035	Additional supplier for the conductor wires used in the manufacture of the leads.
P980024/S013 7/16/14	PathVysion HER-2 DNA Probe Kit	Abbott Molecular, Inc. Des Plaines, IL 60018	Modify the validated test method MDP00644 “Fragmented DNA Agarose Gel Electrophoresis” of the manufacturing process of Vysis ALK Break Apart FISH Probe Kit, PathVysion HER-2 DNA Probe Kit and UroVysion Bladder Cancer Kit.
P980035/S380 7/11/14	Advisa DR IPG; Advisa DR MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Supplier change and specification update to p(ETFE) used in Medtronic CRDM lithium-organic electrolyte batteries.
P980035/S381	Adapta, Versa, Sensia IPG	Medtronic, Inc. Mounds View, MN	Implementation of an equivalent sterilizer and

7/16/14		55112	aerator.
P980035/S383 7/28/14	Adapta, Versa, Sensia IPG	Medtronic, Inc. Mounds View, MN 55112	Update to seam weld parameters for the devices.
P980043/S046 7/11/14	Hancock® II Porcine Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of a new sewing machine for use with the cloth cover.
P980043/S047 7/23/14	Hancock® II Porcine Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of a new porcine tissue supplier.
P980049/S100 7/16/14	Paradym VR, Paradym DR, Paradym RF VR, Paradym RF DR, Paradym RF VR, Paradym RF DR	Sorin CRM USA, Inc Arvada, CO 80004	Change to the in-process verifications for tantalum capacitors used in the devices.
P990034/S032 7/3/14	Drug Delivery Catheters, Drug Delivery Kits for Revisions	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacturing change associated with incoming inspection activities.
P990064/S055 7/11/14	Mosaic® Porcine Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of a new sewing machine for use with the cloth cover.
P990064/S056 7/23/14	Mosaic® Porcine Bioprosthesis	Medtronic, Inc. Santa Ana, CA 92705	Addition of a new porcine tissue supplier.
P000029/S078 7/31/14	Deflux Injectable Gel	Salix Pharmaceuticals, Inc. Raleigh, NC	Qualify an alternate supplier of the ready-prepared solutions of NaOH and HCL used for the manufacturing of Deflux device.

		27615	
P000046/S025 7/8/14	Staarvisc, Optivisc, NuVisc, Anikavisc Sodium Hyaluronate	Anika Therapeutics, Inc. Bedford, MA 01730	Change to the syringe residual solvent testing from a supplier's contract laboratory to the supplier's in-house facility for Anika's ophthalmic devices.
P010012/S358 7/8/14	INCEPTA, ENERGEN, PUNCTUA, COGNIS, DYNAGEN, INOGEN, ORIGEN CRT-DEFIBRILLATORS	Boston Scientific St. Paul, MN 55112	Add a functionally equivalent sterilization chamber; 2) add a third Abator to be used with the additional sterilizer; and 3) include sterilizer chamber enhancements required for the existing and additional sterilizer chambers.
P010012/S360 7/11/14	DYNAGEN™ CRT-D; DYNAGEN™ X4 CRT-D; INOGEN™ CRT-D; INOGEN™ X4 CRT-D; ORIGEN™ CRT-D; ORIGEN™ X4 CRT-D	Boston Scientific St. Paul, MN 55112	Add the laser etched scratches inspection criteria for the devices.
P010012/S361 7/8/14	PUNCTUA CRT-Ds, ENERGEN CRT-Ds, INCEPTA CRT-Ds, ORIGEN CRT-Ds, INOGEN CRT-Ds, DYNAGEN CRT-Ds	Boston Scientific Corporation St. Paul, MN 55112	Add a replacement automated optical (AOI) inspection equipment for device identification and torque wrench verification.
P010012/S362 7/9/14	EASYTRAK 2 IS-1 Coronary Venous Pace/Sense Leads	Boston Scientific Corporation St. Paul, MN 55112	Extend the expiration term for plasma treatment and to add a process monitor.
P010012/S363 7/30/14	ACCESSORY, ORIGEN CRT-D, INOGEN CRT-D, DYNAGEN CRT-D, PUNCTUA CRT-D; ENERGEN CRT-D; INCEPTA CRT-D	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P010012/S364	DYNAGEN™ CRT-D DYNAGEN™ X4 CRT-DG; INOGEN™ CRT-D; INOGEN™ X4 CRT-D; ORIGEN™	Boston Scientific Corporation St. Paul, MN	Blister sealer process setting changes for the devices.

7/28/14	CRT-D; ORIGEN™ X4 CRT-D	55112	
P010015/S241 7/11/14	Consulta CRT-P; Syncra CRT-P	Medtronic, Inc. Mounds View, MN 55112	Supplier change and specification update to p(ETFE) used in Medtronic CRDM lithium-organic electrolyte batteries.
P010015/S243 7/24/14	Viva CRT-P	Medtronic, Inc. Mounds View, MN 55112	Manufacturing changes to align the production of Viva CRT-P with existing market approved products.
P010031/S448 7/11/14	InSync III Marquis ICD; InSync Maximo ICD	Medtronic, Inc. Mounds View, MN 55112	Supplier change and specification update to p(ETFE) used in Medtronic CRDM lithium-organic electrolyte batteries.
P010031/S449 7/17/14	Concerto II, Maximo II, Protecta, Protecta XT CRT-Ds, Consulta ICDs	Medtronic CRDM Mounds View, MN 55112	Change in the epoxy dispense process for the devices.
P010031/S450 7/9/14	Brava CRT-D; Concerto II CRT-D; Consulta ICD; Maximo II CRT-D; Protecta CRT-D; Protecta XT CRT-D; Viva S CRT-D; Viva XT CRT-D	Medtronic CRDM Mounds View, MN 55112	Reduction of Sonoscan detection method for the devices.
P010031/S452 7/30/14	Brava CRT-D, Viva S CRT-D, Viva XT CRT-D	Medtronic CRDM Mounds View, MN 55112	Additional equipment for the fill hole seal weld for the high voltage capacitor.
P010031/S453 7/24/14	Brava Quad, Viva Quad C, Viva Quad S, Viva Quad XT CRT-Ds	Medtronic, Inc. Mounds View, MN 55112	Manufacturing changes to align the production of Viva and Brava models with existing market approved products.
P010031/S454 7/22/14	Brava, Brava Quad, Concerto II, Consulta, Maximo II, Protecta, Protecta XT, Viva Quad S/XT, Viva	Medtronic CRDM Mounds View, MN 55112	Modification on laser seam welder equipment at a final device manufacturing facility for the devices.

	S/XT CRTDs		
P010032/S082 7/17/14	Eon Implantable Pulse Generator, Eon Mini Implantable Pulse Generator, Protégé Implantable Pulse Generator	St. Jude Medical Neuromodulation Plano, Texas 75024	Upgrade the welding equipment used in a manufacturing process.
P010047/S035 7/2/14	Progel® Pleural Air Leak Sealant	Neomend, Inc. Irvine, CA 92618	Alternate Extended Applicator Spray Tip supplier.
P020004/S098 7/2/14	Excluder AAA Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of Fourier Transform Infrared Spectroscopy, Bacterial Endotoxin Testing, Heavy Metals as Lead (HMAL) and Non-Volatile Residue (NVR) testing in the East Coast Testing Center.
P020004/S099 7/2/14	EXCLUDER® AAA Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an alternate bioburden extraction method and updating existing documents to allow for use of alternative/ additional organism strains and/or removal of specific microorganism strain designations and updated nomenclature in accordance with USP <61> and USP <62>.
P020004/S100 7/2/14	Excluder AAA Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Updated hardware and software for FTIR spectrophotometer computers.
P020004/S101 7/2/14	Excluder® AAA Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an additional moisture analyzer and implementation of additional functionality of the analyzer.
P020004/S102 7/21/14	Excluder® AAA Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	New tooling used in a molding process, replication of the molding process at an additional facility, and a new supplier of the molded component.

P020025/S062 **7/14/14**	BLAZER II XP CARDIAC ABLATION CATHETER-IntellaTip MiFi Filter Module, IntellaTip MiFi Reference Cable	Boston Scientific Corporation San Jose, CA 95134	Update to the current Manufacturing Execution System (MES).
P020025/S063 **7/18/14**	IntellaTip MiFi XP Temperature Ablation Catheter	Boston Scientific Corporation San Jose, CA 95134	Manufacturing change of the final electrical inspection test method.
P020045/S056 **7/9/14**	Freezor Cardiac CryoAblation System	Medtronic CryoCath LP Quebec, Canada H9R 5Z8	Addition of an inspection procedure for the Low Pressure Regulator during manufacturing, as well as the replacement of an analog pressure gauge used during installation and maintenance with a digital one.
P020045/S058 **7/25/14**	FREEZOR CARDIAC CRYOABLATION CATHETER, XTRA SURGICAL CRYOABLATION CATHETER, MAX SURGICAL CARDIAC CRYOABLATION CATHETER-Coaxial Umbilical Cable	Medtronic CryoCath LP Mounds View, MN 55112	Alternate supplier for connectors and connector fittings and acceptance of an alternate adhesive curing process.
P030005/S111 **7/8/14**	INVIVE, CONTAK RENEWAL, INTUA CRT-PACEMAKERS	Boston Scientific St. Paul, MN 55112	Add a functionally equivalent sterilization chamber; 2) add a third Abator to be used with the additional sterilizer; and 3) include sterilizer chamber enhancements required for the existing and additional sterilizer chambers.
P030005/S112 **7/30/14**	INVIVE CRT-P, INTUA CRT-P	Boston Scientific Corporation St. Paul, MN 55112	Change in the Bioburden sampling frequency in the Clonmel and St Paul facilities for the devices.
P030009/S079 **7/31/14**	Integrity Coronary Stent System	Medtronic Vascular Santa Rosa, CA 95403	Changes to the sub-assembly manufacturing process.

P030017/S200 7/11/14	Precision Spectra™ Spinal Cord Stimulator (SCS) System	Boston Scientific Corporation Neuromodulation Valencia, CA 91355	Alternate capacitor supplier.
P030019/S020 7/8/14	Staarvisc, Optivisc, NuVisc, Anikavisc Sodium Hyaluronate	Anika Therapeutics, Inc. Bedford, MA 01730	Change to the syringe residual solvent testing from a supplier's contract laboratory to the supplier's in-house facility for Anika's ophthalmic devices.
P030019/S021 7/25/14	Orthovisc, High Molecular Weight Hyaluronan	Anika Therapeutics, Inc. Bedford, MA 01730	Changes in the manufacturing equipment.
P030035/S122 7/9/14	ANTHEM RF CRT-PS	St. Jude Medical Sylmar, CA 91342	Modify the Device Post Sterilization Test (DPST) at ATE for the RF telemetry of the devices.
P030052/S015 7/16/14	UroVysion Bladder Cancer Kit	Abbott Molecular, Inc. Des Plaines, IL 60018	Modify the validated test method MDP00644 "Fragmented DNA Agarose Gel Electrophoresis" of the manufacturing process of Vysis ALK Break Apart FISH Probe Kit, PathVysion HER-2 DNA Probe Kit and UroVysion Bladder Cancer Kit.
P030053/S018 7/30/14	Mentor MemoryGel Silicone Gel-Filled Breast Implants	Mentor Worldwide LLC Santa Barbara, CA 93111	Change to remove the in process Gel cohesion test that is performed during the manufacture of the Gel that is used to fill the Mentor MemoryGel Silicone Gel-Filled Breast Implants at Mentor's Irving, Texas facility.
P030054/S271 7/10/14	Promote+, Promote Quadra, Unify, Unify Quadra, Unify Assura, and Quadra Assura Families of CRT-D Devices	St. Jude Medical, Sylmar, CA 91342	Change in the temperature cycling range for hybrid assemblies.
P030054/S272	Quadra Assura, Unify, Unify Assura,	St. Jude Medical,	Modification to the connector reinforcement process

7/18/14	and Unify Quadra families of CRT-D Devices	Sylmar, CA 91342	for hybrid assemblies.
P040002/S050 7/7/14	AFX Endovascular AAA System	Endologix, Inc. Irvine, CA 92618	Alternate supplier for the laser welding process for the delivery system inner core subassemblies.
P040002/S051 7/11/14	AFX Endovascular AAA System	Endologix, Inc. Irvine, CA 92618	Alternate polytetrafluoro- ethylene (PTFE) resin.
P040002/S052 7/9/14	AFX Endovascular AAA System	Endologix, Inc. Irvine, CA 92618	Alternate method for the heat-shrink process.
P040020/S054 7/16/14	AcrySof Intraocular Lenses	Alcon Research, Ltd. Fort Worth, TX 76134	Addition of an alternate component supplier.
P040024/S075 7/1/14	Restylane, Perlane, Restylane-L, and Perlane-L Injectable Gels	Valeant Pharmaceuticals North America Bridgewater, NJ 08807	Introduction of an intermediate storage system (ISS) in the manufacturing process used in Factory 2.
P040027/S034 7/2/14	VIATORR TIPS Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of Fourier Transform Infrared Spectroscopy, Bacterial Endotoxin Testing, Heavy Metals as Lead (HMAL) and Non-Volatile Residue (NVR) testing in the East Coast Testing Center.
P040027/S035 7/2/14	VIATORR® TIPS Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an alternate bioburden extraction method and updating existing documents to allow for use of alternative/ additional organism strains and/or removal of specific microorganism strain designations and updated nomenclature in accordance with USP <61> and USP <62>.

P040027/S036 7/2/14	VIATORR TIPS Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Updated hardware and software for FTIR spectrophotometer computers.
P040027/S037 7/2/14	VIATORR® TIPS Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an additional moisture analyzer and implementation of additional functionality of the analyzer.
P040037/S066 7/2/14	VIABAHN Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of Fourier Transform Infrared Spectroscopy, Bacterial Endotoxin Testing, Heavy Metals as Lead (HMAL) and Non-Volatile Residue (NVR) testing in the East Coast Testing Center.
P040037/S067 7/2/14	VIABAHN® Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an alternate bioburden extraction method and updating existing documents to allow for use of alternative/ additional organism strains and/or removal of specific microorganism strain designations and updated nomenclature in accordance with USP <61> and USP <62>.
P040037/S068 7/2/14	VIABAHN Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Updated hardware and software for FTIR spectrophotometer computers.
P040037/S069 7/2/14	VIABAHN® Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an additional moisture analyzer and implementation of additional functionality of the analyzer.
P040037/S070 7/31/14	GORE VIABAHN Endoprosthesis and VIABAHN with Heparin Bioactive Surface	W.L. Gore & Associates Phoenix, AZ 85085	Automation of the presentation and cutting process for catheter manufacturing and removal of related inspections.

P040043/S063 7/2/14	TAG Thoracic Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of Fourier Transform Infrared Spectroscopy, Bacterial Endotoxin Testing, Heavy Metals as Lead (HMAL) and Non-Volatile Residue (NVR) testing in the East Coast Testing Center.
P040043/S064 7/2/14	TAG® Thoracic Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an alternate bioburden extraction method and updating existing documents to allow for use of alternative/ additional organism strains and/or removal of specific microorganism strain designations and updated nomenclature in accordance with USP <61> and USP <62>.
P040043/S065 7/2/14	TAG Thoracic Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Updated hardware and software for FTIR spectrophotometer computers.
P040043/S066 7/2/14	TAG® Thoracic Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an additional moisture analyzer and implementation of additional functionality of the analyzer.
P040045/S045 7/23/14	VISTAKON Contact Lenses	Johnson & Johnson Vision Care, Inc. Jacksonville, FL 32256	Add a second supplier for the senofilcon A monomer used for manufacturing VISTAKON (senofilcon A) brand contact lenses.
P040047/S036 7/16/14	Coaptite Injectable Implant	Merz North America, Inc. Franksville, WI 53126	Changes to the sterilization process for the Coaptite Injectable Implant.
P050006/S039 7/2/14	HELEX Septal Occluder	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of Fourier Transform Infrared Spectroscopy, Bacterial Endotoxin Testing, Heavy Metals as Lead (HMAL) and Non-Volatile Residue (NVR) testing in the East Coast Testing Center.

P050006/S040 **7/2/14**	HELEX® Septal Occluder	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an alternate bioburden extraction method and updating existing documents to allow for use of alternative/ additional organism strains and/or removal of specific microorganism strain designations and updated nomenclature in accordance with USP <61> and USP <62>.
P050006/S041 **7/2/14**	HELEX Septal Occluder	W.L. Gore & Associates Phoenix, AZ 85085	Updated hardware and software for FTIR spectrophotometer computers.
P050006/S042 **7/2/14**	HELEX® Septal Occluder	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an additional moisture analyzer and implementation of additional functionality of the analyzer.
P050047/S039 **7/9/14**	Juvéderm Hyaluronate Gel Implants	Allergan Goleta, CA 93117	Removal of an in-process control test used during the manufacture of Juvéderm Hyaluronate Gel Implants.
P050047/S041 **7/30/14**	Juvederm Hyaluronate Gel Implants	Allergan Goleta, CA 93117	Change in the incoming inspection procedure for the Sodium Hyaluronate (NaHA) raw material.
P060001/S021 **7/1/14**	Protégé GPS and Protégé RX Carotid Stent System	ev3 Inc. Plymouth, MN 55441	Change from a manual to an automated stent cleaning process.
P060006/S063 **7/18/14**	Express SD Renal Monorail Premounted Stent System	Boston Scientific Corp. Maple Grove, MN 55311	Changing the manual inspection of a component weld to a semi-automated inspection.
P060027/S067 **7/16/14**	Paradym CRT-D, Paradym RF, CRT-D, Paradym RF CRT-D	Sorin CRM USA, Inc Arvada, CO	Change to the in-process verifications for tantalum capacitors used in the devices.

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P060040/S037 7/17/14	Thoratec® HeartMate II® LeftVentricular Assist System	Thoratec Corporation Pleasanton, CA 94588	Manufacturing process changes to the printed circuit board (PCB) of the device controller.
P070008/S052 7/11/14	Corox OTW, CELERITY Leads	Biotronik, Inc. Lake Oswego, OR 97035	Additional supplier for the conductor wires used in the manufacture of the leads.
P080025/S072 7/2/14	SNS Bowel Verify Screening Trialing Systems (including Temporary Leads)	Medtronic Neuromodulation Minneapolis, MN 55432	Update to the process flow at the IC Supplier.
P080025/S073 7/3/14	SNS Bowel, SNS Bowel Leads	Medtronic Neuromodulation Minneapolis, MN 55432	Manufacturing change associated with incoming inspection activities.
P080025/S075 7/30/14	Medtronic Verify External Neurostimulator (ENS)	Medtronic Neuromodulation Minneapolis, MN 55432	Acceptance to expand the manufacturing acceptance criterion.
P090012/S009 7/7/14	MelaFind	MELA Sciences Incorporated Irvington, NY 10533	Added 3rd Party operating system installation software to version registry; and Deployment of new software build and installation workstations.
P090013/S144 7/11/14	Revo MRI IPG	Medtronic, Inc. Mounds View, MN 55112	Supplier change and specification update to p(ETFE) used in Medtronic CRDM lithium-organic electrolyte batteries.

P090013/S145 **7/8/14**	CapSureFix MRI Lead	Medtronic, Inc. Mounds View MN, 55112	Add a helix linearity inspection at the final functional inspection and a helix linearity fixture to facilitate this linearity inspection.
P090013/S146 **7/16/14**	CAPSUREFIX MRI SURESCAN LEAD	Medtronic, Inc. Mounds View, MN 55112	Implementation of an equivalent sterilizer and aerator.
P090022/S023 **7/9/14**	SOFTEC HD Intraocular Lenses	Lenstec, Inc. Saint Petersburg, FL 33716	Add three component washers for the use in the final clean area and inspection department to reduce bioburden and endotoxin of the intraocular lenses.
P090026/S011 **7/7/14**	Access Hybritech p2PSA reagents on the Access Immunoassay Systems	Beckman Coulter, Inc. Chaska, MN 55318	Modification to the Quality Control prefill and postfill reagent pack procedures.
P090031/S002 **7/8/14**	Staarvisc, Optivisc, NuVisc, Anikavisc Sodium Hyaluronate	Anika Therapeutics, Inc. Bedford, MA 01730	Change to the syringe residual solvent testing from a supplier's contract laboratory to the supplier's in-house facility for Anika's ophthalmic devices.
P100009/S006 **7/16/14**	MitraClip System	Abbott Vascular Menlo Park, CA 94025	Second supplier, a change in the heat treatment process and establishment of a defined range of acceptable raw material hardness for the Actuator Coupler of the MitraClip Clip Delivery System.
P100010/S036 **7/2/14**	Artic Front® and Artic Front Advance™	Medtronic, Cryocath LP Mounds View, MN 55112	New supplier, inspection change, and minor updates to the specification of the bellows component.
P100010/S038 **7/9/14**	Arctic Front CryoCatheter System	Medtronic CryoCath LP Quebec, Canada H9R 5Z8	Addition of an inspection procedure for the Low Pressure Regulator during manufacturing, as well as the replacement of an analog pressure gauge used during installation and maintenance with a digital one.

P100010/S040 **7/25/14**	ARTIC FRONT CYROABLATION CATHETER, ARTIC FRONT ADVANCE CRYOABLATION CATHETER	Medtronic CryoCath LP Mounds View, MN 55112	Alternate supplier for connectors and connector fittings and acceptance of an alternate adhesive curing process.
P100026/S019 **7/9/14**	Neuropace RNS System	NeuroPace, Inc. Mountain View, CA 94043	Use a replacement detergent to clean certain parts.
P100042/S003 **7/7/14**	Aptima® HPV Assay	Gen-Probe Incorporated San Diego, CA 92121	Change to revise an internal control QC release test specification for the Aptima® HPV Assay.
P110002/S007 **7/23/14**	LDR Spine Mobi-C Cervical Disc Prosthesis for use at One Level	LDR Spine USA Inc. Austin, TX 78750	Add back-up equipment for the machining of the Mobi-C superior and inferior endplates.
P110009/S007 **7/23/14**	LDR Spine Mobi-C Cervical Disc Prosthesis for use at Two Levels	LDR Spine USA Inc. Austin, TX 78750	Add back-up equipment for the machining of the Mobi-C superior and inferior endplates.
P110012/S006 **7/16/14**	Vysis ALK Break Apart FISH Probe Kit	Abbott Molecular, Inc. Des Plaines, IL 60018	Modify the validated test method MDP00644 “Fragmented DNA Agarose Gel Electrophoresis” of the manufacturing process of Vysis ALK Break Apart FISH Probe Kit, PathVysion HER-2 DNA Probe Kit and UroVysion Bladder Cancer Kit.
P110013/S043 **7/31/14**	Resolute Integrity Zotarolimus-Eluting Coronary Stent System	Medtronic Vascular Santa Rosa, CA 95403	Changes to the sub-assembly manufacturing process.
P110023/S008 **7/2/14**	EverFlex Self-Expanding Peripheral Stent System	ev3 Inc. Plymouth, MN 55441	Allow internal production of a braid component for the EverFlex outer catheter.

P110023/S009 7/1/14	EverFlex Self-Expanding Peripheral Stent System	ev3 Inc. Plymouth, MN 55441	Change from a manual to an automated stent cleaning process.
P110033/S010 7/30/14	Juvederm Voluma XC	Allergan Goleta, CA 93117	Change in the incoming inspection procedure for the Sodium Hyaluronate (NaHA) raw material.
P120005/S022 7/10/14	Dexcom G4 PLATINUM Continuous Glucose Monitoring System	Dexcom, Inc. San Diego, CA 92121	Change to the conditioning step of manufacturing the sensor wire subcomponent of the G4 Sensor. The G4 Sensor is a component of the G4 PLATINUM Continuous Glucose Monitoring System.
P120005/S023 7/14/14	Dexcom G4 PLATINUM Continuous Glucose Monitoring System	Dexcom, Inc. San Diego, CA 92121	Changes to the shipping and storage temperature range specifications for two reagents used in the manufacture of the device.
P120005/S024 7/16/14	Dexcom G4™ PLATINUM Continuous Glucose Monitoring System	Dexcom, Inc. San Diego, CA 92121	Manufacturing process change for the sensor layer deposition process for the G4 PLATINUM Sensor. The G4 PLATINUM Sensor is a component of the Dexcom G4™ PLATINUM Continuous Glucose Monitoring System.
P120005/S025 7/24/14	Dexcom G4 PLATINUM Continuous Glucose Monitoring System	Dexcom, Inc. San Diego, CA 92121	Change in the manufacturing process of the transmitter packaging tray to increase mold capacity at their supplier. The transmitter is a component of the Dexcom G4 PLATINUM Continuous Glucose Monitoring System.
P120010/S025 7/2/14	MiniMed 530G System	Medtronic MiniMed Inc. Northridge, CA 91325	Change in the manufacturing process for the EnliteTM Glucose Sensor (Model Numbers: MMT-7008A, MMT-7008B) to add a new sensor fabrication configuration to include a 48-up sensor mask. The EnliteTM Glucose Sensor is a component of the MiniMed 530G System.
P120010/S027	MiniMed 530G System	Medtronic MiniMed Inc.	Change in the concentration of a raw material used during manufacture of the EnliteTM Glucose Sensor

7/24/14		Northridge, CA 91325	(MMT-7008) of the MiniMed 530G System and SofTM Glucose Sensor (MMT-7002, MMT-7003) of the Paradigm® REAL-Time System and Paradigm® REAL-Time Revel System.
P120010/S028 7/22/14	MiniMed 530G System	Medtronic MiniMed Inc. Northridge, CA 91325	Change to the needle hub assembly tooling which is used in the manufacture of the Enlite Sensor (MMT-7008). The Enlite Sensor (MMT-7008) is a component of the MiniMed 530G System.
P130006/S006 7/2/14	VIABAHN Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of Fourier Transform Infrared Spectroscopy, Bacterial Endotoxin Testing, Heavy Metals as Lead (HMAL) and Non-Volatile Residue (NVR) testing in the East Coast Testing Center.
P130006/S007 7/2/14	VIABAHN® Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an alternate bioburden extraction method and updating existing documents to allow for use of alternative/ additional organism strains and/or removal of specific microorganism strain designations and updated nomenclature in accordance with USP <61> and USP <62>.
P130006/S008 7/2/14	VIABAHN Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Updated hardware and software for FTIR spectrophotometer computers.
P130006/S009 7/2/14	VIABAHN® Endoprosthesis	W.L. Gore & Associates Phoenix, AZ 85085	Implementation of an additional moisture analyzer and implementation of additional functionality of the analyzer.
P130006/S010 7/31/14	GORE VIABAHN Endoprosthesis and VIABAHN with Heparin Bioactive Surface	W.L. Gore & Associates Phoenix, AZ 85085	Automation of the presentation and cutting process for catheter manufacturing and removal of related inspections.

Summary of PMA Originals & Supplements Approved

- Originals: 1

- Supplements: 81

Summary of PMA Originals Under Review

- Total Under Review: 50
- Total Active: 24
- Total On Hold: 26

Summary of PMA Supplements Under Review

- Total Under Review: 522
- Total Active: 424
- Total On Hold: 128

Summary of All PMA Submissions

- Received Originals: 4
- Supplements: 99

Summary of PMA Supplement PMA Approval/Denial Decision Times

- Number of Approvals: 81
- Number of Denials: 0
- Average Days Fr Receipt to Decision (Total Time): 200.4
- Days FDA Time: 132.2 Days
- Days MFR Time: 68.2 Days