July 26, 2018

Greatbatch Medical
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K181855
Trade/Device Name: RadialSeal Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 9, 2018
Received: July 11, 2018

Dear Mark Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000979673, cn=Finn E. Donaldson -S
Date: 2018.07.26 08:48:43 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181855

Device Name
RadialSeal™ Introducer Kit

Indications for Use *(Describe)*
The RadialSeal™ Introducer Kit is used to facilitate placing a catheter through the skin into the radial artery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter's Name: Greatbatch Medical
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Date Prepared July 19, 2018

Device Information

Trade Name: RadialSeal™ Introducer Kit
Common Name: Introducer Sheath
Classification Name: Introducer, Catheter
Product Code: DYB
Regulatory Class: Class II 21 CFR 870.1340
Panel: Cardiovascular

Predicate Device

Greatbatch Medical is identifying the Terumo Glidesheath Slender® (*K142183*) as the predicate device. The Terumo Glidesheath Slender has not been subject to a design related recall.

Device Description

The RadialSeal™ Introducer Kit consists of an introducer (a sheath and a dilator), and either a needle or a stainless steel guidewire or an IV catheter with a plastic guidewire which has a pre-shaped distal tip. The kit is used to facilitate placing a catheter through the skin into the radial artery. The thin-walled introducer sheath is coated for reduced friction and has a hemostasis valve to minimize blood loss and air intake. The side port on the introducer sheath hub has a 3-way stopcock for flushing and infusion. The dilator and sheath cannula contain radiopaque material for visualization under fluoroscopy.

An entry needle is provided to facilitate entry into the vessel. The entry needle is offered in either a stainless steel bare version, or as part of an IV catheter. A guidewire (0.021" diameter) is inserted through the bare entry needle or the cannula of the IV catheter, and maintains access to the puncture site upon removal of the needle and before insertion of the introducer (sheath and dilatorassembly).

A dilator facilitates the entry of the sheath introducer by forming an atraumatic transition from the skin through the subcutaneous tissue to the vessel. The introducer is inserted over the guidewire and through the skin into the radial artery. Once the introducer is situated in the vessel, the dilator and guidewire are removed to allow access by the treatment device(s).

The introducers are available in French sizes of 4, 5, and 6, and in lengths of 10, 16, and 25cm. The 0.054 cm (0.021" diameter) guidewire is available in either 45 cm (17.7 in) or 80 cm (31.5 in) length, and is comprised of either stainless steel spring coil or plastic (poly-jacketed Nitinol) material.

Indications for Use

The RadialSeal™ Introducer Kit is used to facilitate placing a catheter through the skin into the radial artery.

The differences in technology between the RadialSeal™ Introducer Kit and the predicate device do not alter the intended therapeutic use of the device. Both the subject and predicate device have the same intended use.

The conclusions drawn from the non-clinical and pre-clinical testing on the RadialSeal™ Introducer Kit demonstrate that the device is as safe, as effective and performs as well as the legally marketed predicate device (Terumo Glidesheath Slender® (K142183).

Technological Characteristics Comparison

The RadialSeal™ Introducer Kit has the same indication for use and principles of operation as the market cleared Terumo Glidesheath Slender® (K142183). In addition, functional characteristics of the RadialSeal™ Introducer are substantially equivalent to the Glidesheath Slender, with similar materials, dimensions, and method of construction. The design modifications to the new device include differences in material for the coating and the sheath, and the elimination of a metal ferrule. Additional sizes are also available with the new device (4F and 25cm).

The RadialSeal Introducer Kit is comparable to the predicate device in terms of intended use, duration of use, principles of operation, insertion method and anatomical location. The results of the non-clinical performance and biocompatibility testing indicates that the new device performs as well as the predicate device.

A risk analysis was conducted in accordance with ISO 14971 taking into account the modifications to the previous device and it was determined that there are no new issues of safety or effectiveness**.**

Predicate Device (Glidesheath Slender) Comparison to RadialSeal

Device Characteristic	***Predicate Device* Terumo Glidesheath Slender® (K142183)**	***Proposed Device* RadialSeal™ Introducer Kit**
Indications for Use	The Glidesheath Slender® is used to facilitate placing a catheter through the skin into the Radial artery.	**Same**
FDA Classification	Class II, DYB	**Same**
Anatomical Region	Radial Artery	**Same**
Basic Principles of Operation	The Glidesheath Slender® is operated manually or by a manual process.	**Same**

Predicate Device (Glidesheath Slender) Comparison to RadialSeal Continued

Device Characteristic	***Predicate Device* Terumo Glidesheath Slender® (K142183)**	***Proposed Device* RadialSeal™ Introducer Kit**
Device Configuration	5, 6, or 7F sheath of usable length 10 or 16cm Plastic or stainless steel guidewire	4, 5, or 6F sheath of usable length 10, 16, or 25cm Plastic or stainless steel guidewire
French Sizes	5F, 6F, 7F	4F, 5F, 6F
Useable Length	100mm, 160mm	100mm, 160mm, 250mm
Kit Contents	Dilator Sheath Plastic or stainless steel guidewire (0.018", 0.021", 0.025", 0.035" OD) and 45 or 80 cm length) Stainless steel entry needle or SurfloIV Catheter	Dilator Sheath Plastic or stainless steel guidewire (0.021" OD, 45 cm or 0.021"OD 80 cm length) Stainless steel entry needle or IV catheter
Device Features	Side-port with three-way stopcock Hemostasis valve	Side-port with three-way stopcock Hemostasis valve

Materials Comparison

Device Characteristic		***Predicate Device* Terumo Glidesheath Slender® (K142183)**	***Proposed Device* RadialSeal™ Introducer Kit**
Sheath	**Valve/ Lubricant**	Silicone rubber	Silicone rubber with silicone liquid lubricant
	Coating	Hydrophilic coating on sheath	Hydrophilic coating on sheath
	Hub	Polypropylene	Nylon 12 w/10% Glass
	Strain Relief	Styrene-ethylene-butylene- styrene block copolymer	Santoprene, colored
	Shaft	Ethylene-Tetraflouoroethylene copolymer (ETFE), Bismuth trioxide(Bi2O3), with stainless steel ferrule	Ethylene- Tetrafluoroethylene-Hexafluoropropylene-Fluoroterpolymer (EFEP) w/Barium Sulfate (BaSO4), Sodium Naphthalene

Materials Comparison Continued

Device Characteristic		***Predicate Device* Terumo Glidesheath Slender® (K142183)**	***Proposed Device* RadialSeal™ Introducer Kit**
Sheath Side-port Assembly		Polybutadiene, polyethylene, polypropylene, polycarbonate	Carbothane, polycarbonate, Delrin
IV Catheter	**Hub**	Polypropylene	Polypropylene
	Bushing	Stainless steel	Stainless steel
	Cannula	Ethylene-Tetrafluoroethylene copolymer (ETFE), barium sulfate	Fluorinated Ethylene Propylene
	Needle hub	Polycarbonate	Methyl methacrylate- acrylonitrile-butadiene-styrene (MABS), clear
	Needle	Stainless steel	Stainless steel
	Filter assembly	Polystyrene, Polyester- chlorinated polyvinyl chloride	Versapor acrylic MABS, clear
Introducer Needle	**Hub**	Polycarbonate	Polycarbonate
	Cannula	Stainless Steel	Stainless Steel
Guidewire – stainless steel		Stainless Steel	Stainless Steel
Guidewire – plastic		Nickel-Titanium alloy Tungsten, Polyurethane	Nickel-Titanium alloy Black Polyurethane, 50%Tungsten
J straightener		Polyethylene	Polypropylene, natural

Materials Comparison Continued

Device Characteristic		***Predicate Device*** **Terumo Glidesheath Slender® (K142183)**	***Proposed Device*** **RadialSeal™ Introducer Kit**
Dilator	**Shaft**	Polypropylene with bismuth subcarbonate (BiO)2CO3	Polypropylene with Barium Sulfate (BaSO4)
	Hub	Polypropylene with stainless steel ferrule	Polypropylene, colored
	Lubricant	Unknown	Silicone

Performance Testing

Non-Clinical performance bench testing is summarized in the following tables. Results indicated that no new issues of safety and effectiveness were raised and the results were within the predetermined acceptance criteria.

Side by side testing between the predicate device and RadialSeal was performed against ISO 11070 section A.1. Side by side testing between the predicate device and RadialSeal also was performed for valve insertion force, introducer insertion force, external surface sliding force, hydrophilic coating separation resistance, (cycle testing) and In Vitro Particulate Evaluation. The devices performed equivalently.

Sheath Performance Testing

Sheath Performance Testing	Method
Surface	ISO 11070 Sec 4.3
Corrosion Resistance	ISO 11070 Sec 4.4
Radio-detectability	ISO 11070 Sec 4.5
Dimensions- Size Designation	ISO 11070 Sec 7.2
Sheath Introducer leakage (Freedom from Leakage from Sheath Introducer)	ISO 11070 Sec 7.3
Hemostasis (Freedom from Leakage through Hemostasis Valve)	ISO 11070 Sec 7.4
Peak Tensile Force (Force at Break)	ISO 11070 Sec 7.6
Sheath to dilator fit, rollback test, Puncture model test, Kink Angle, Radius of Curvature	ISO 11070 Sec A.1
Valve Insertion Force	Internal Standard
Introducer Insertion Force	Internal Standard
External surface sliding force	Internal Standard
Hydrophilic coating separation resistance(cycle testing)	Internal Standard
Hydrophilic coating particulate evaluation (In vitro particulate test)	FDA Guidance, USP 788
Dimensional Verification	ISO 11070 Sec 7.2
Hub	ISO 11070 Sec 7.5, ISO 594-1, ISO 594-2

Stainless Steel Needle Performance Testing

Stainless Steel Needle Performance Testing	Method
Surface (surface defects)	ISO11070 Sec 4.3
Corrosion Resistance	ISO 11070 Sec. 4.4
Dimensional Verification	ISO 11070 Sec. 5.2
Needle Point	ISO 11070 Sec 5.3
Conical Fitting	ISO 11070 Sec. 5.4.1; ISO 594-1, ISO 594-2
Strength of Union (Needle Tube to Hub)	ISO 11070 Sec. 5.4.2
Radio-detectability	ISO 11070 Sec 4.5

IV Needle Performance Testing

IV Needle Performance Testing	Method
Surface	ISO11070 Sec. 4.3
Corrosion Resistance	ISO 11070 Sec. 4.4
Radio-detectability	ISO 11070 Sec. 4.5
Dimensional Verification	ISO 11070 Sec. 5.2
Needle Point	ISO 11070 Sec. 5.3
Conical Fitting	ISO 594-2 ISO 11070 section 5.4.1
Strength of Union (Needle tube to hub)	ISO 11070 Sec. 5.4.2

Catheter Performance Testing

IV Catheter Performance Testing	Method
Surface (Surface defects)	ISO 11070 Sec. 4.3
Corrosion Resistance	ISO 11070 Sec. 4.4
Radio-detectability	ISO 11070 Sec. 4.5
Catheter to needle Fit	ISO 11070 Sec. 6.2
Peak Tensile Force	ISO 11070 Sec. 6.3
Size Designation	ISO 11070 Sec. 6.5
Conical Fitting/Hub	ISO 594-1 ISO 11070 section 6.4
Strength of Union (Needle Tube to Hub)	ISO11070 Sec.7.6.
Dimensional Verification	ISO 11070 Sec 7.2

Plastic Guidewire Performance Testing

Plastic Guidewire Performance Testing	Method
Surface	ISO11070 Sec 4.3
Radio-detectability	ISO11070 Sec.4.5
Dimensional Verification	ISO11070 Sec. 8.2
Test for Fracture	ISO11070 Sec. 8.4
Test for Flexing	ISO11070 Sec. 8.5
Strength of Jacket and Core	ISO11070 Sec. 8.6

Stainless Steel Guidewire Performance Testing

Stainless Steel Guidewire Performance Testing	Method
Surface	ISO11070 Sec 4.3
Corrosion Resistance	ISO11070 Sec 4.4
Radio-detectability	ISO11070 Sec. 4.5
Dimensional Verification	ISO11070 Sec. 8.2
Test for Fracture	ISO11070 Sec. 8.4
Test for Flexing	ISO11070 Sec. 8.5
Strength of Jacket and Core	ISO11070 Sec. 8.6

Dilator Performance Testing

Dilator Performance Testing	Method
Surface	ISO 11070 Sec 4.3
Corrosion Resistance	ISO 11070 Sec 4.4
Strength of Union (dilator to hub)	ISO 11070 Sec. 9.3.3
Dimensional Verification	ISO 11070 Sec. 9.2
Conical Fitting	ISO 594-2, ISO 11070 Sec. 9.3.2
Radio-detectability	ISO 11070 Section 4.5

Biocompatibility

Biocompatibility of the new device was evaluated based upon ISO 10993-1. The new device including the sheath, dilator, guidewire and entry needed are classified as externally communicating devices, circulating blood, limited contact (<24 hours). This is the same classification as the predicate device.

Biocompatibility testing was completed on final, finished (fully assembled and sterilized) RadialSeal™ Introducer Kit devices per ISO 10993-1:2009. The testing included Chemical Characterization with Toxicological Risk Assessment, Cytotoxicity-MEM Elution, Sensitization-Guinea Pig Maximization, Intracutaneous Reactivity, Acute Systemic Toxicity, Materials Mediated Pyrogen, Hemolysis- Direct and Indirect, C3a and SC5b-9 Complement Activation, In Vivo Thromboresistance.

Sterilization / Packaging / Shelf Life

The new device is sterilized by ethylene oxide to an SAL level of 10^{-6}. The sterilization method and SAL are identical to the predicate device. The RadialSeal™ Introducer Kit is terminally sterilized using a 100% ETO sterilization cycle. The sterilization validation method used follows ISO 11135-1:2007 Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of sterilization process for medical devices and TIR28:2009 product adoption and process equivalency for ethylene oxide sterilization.

Package integrity testing included ASTM F2096, ASTM F88, and ASTM F1886 after conditioning per ISTA 2A and ASTM D4169.

Shelf life testing was performed to support 6 months shelf life.

Animal testing

Performance testing was conducted on both devices in an animal model, where both devices were found to perform equivalently. The GLP Acute Animal Porcine study was conducted at American Preclinical Services between new device and predicate device. The tests were applied to the assembled device, sheath introducer, valve, dilator, guidewire and bare needle and IV catheter.

Statement of Equivalence

The RadialSeal™ Introducer Kit is substantially equivalent in its intended use, principles of operation, design features, materials, performance as the market cleared Terumo Glidesheath Slender® (K142183). Verification testing was conducted and demonstrated that the RadialSeal Device meets design inputs and equivalent requirements as the predicate device, the Glidesheath Slender, for relevant standards as described in the summary of testing. The differences between the predicate device and proposed device do not raise any new issues regarding safety and effectiveness. In conclusion, the RadialSeal™ Introducer Kit is considered substantially equivalent to the predicate device.