October 20, 2017

Pressure Products Medical Device Manufacturing LLC
Andrew Armour
Managing Director
1 School Street
Morton, Pennsylvania 19070

Re: K170671
Trade/Device Name: Safesept Transseptal Guidewire
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: September 20, 2017
Received: September 21, 2017

Dear Mr. Armour:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Nicole G. Ibrahim -S

for 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)*
K170671

Device Name
SafeSept Transseptal Guidewire

Indications for Use *(Describe)*
The SafeSept is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. The SafeSept Transseptal Guidewire is intended for single use only.

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

Pressure Products Medical Device Manufacturing LLC.
1 School Street
Morton, PA 19070
Phone: 610-285-9858
Fax: 610-285-9859

Contact Person: Andrew Armour
Prepared: October 19, 2017

Identification of the Device

Proprietary-Trade Name: SafeSept® Transseptal Guidewire
Device Class: Class II
Classification Name: Trocar (CFR 870.1390)
Common/Usual Name: Transseptal Guidewire
Product Code: DRC

Equivalent Legally Marketed Devices

Oscor, SafeSept® Transseptal Trocar Guidewire, K081986

Description of the Devices

The SafeSept® Transseptal Guidewire is 0.014" in diameter and 135cm long and consists of a flexible memory wire material called nitinol. The components of the SafeSept include the 0.014" transseptal guidewire, dispenser and straightener, and sterile packaging and labeling. There is one model number for the SafeSept, SS-135. The SafeSept is sterilized by 100% ethylene oxide cycle and is for single-use only. The SafeSept is used in a healthcare facility/hospital.

The SafeSept is used in transseptal procedures to gain access to the left atrium through the right side of the heart. The device is used by inserting the device through the femoral vein. The SafeSept is then advanced to the fossa ovalis with the support of the needle and dilator. The SafeSept's sharp distal tip is able to perforate through the fossa ovalis, a thin wall between the right and left atrium, when it is supported by a transseptal needle and dilator. When the wire is no longer supported, it is atraumatic and operates as a typical 0.014" diameter guidewire. A radiopaque coil located along the shaft allows for fluoroscopic visualization of the wire within the left atrium and proximal marker bands help determine the location of the guidewire tip in relation to the tip of the needle. The guidewire's duration in the body is less than 24 hours.

Indications for Use

The SafeSept® is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. The SafeSept Transseptal Guidewire is intended for single use only.

The Indications for Use statement for the SafeSept transseptal guidewire device is identical to the predicate device. Both devices have the same intended use and are used in conjunction with a transseptal needle to create the primary puncture in the interatrial septum. The devices guide the needle, dilator, and introducer through the septum from the right side of the heart to the left side.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of this device are the same as the predicate device. The main difference between the subject device and the predicate device is the length of the guidewire. The predicate SafeSept device is 120cm in length and the currently marketed SafeSept is 135cm. The subject and predicate device are based on the follow technological elements:

- The guidewire is manufactured from nitinol wire that is super-elastic so that it can have a 'J' curve with a sharp tip
- Radiopaque coil used by the physician to locate SafeSept and to guide supporting devices like the transseptal needle, dilator, and sheath across the fossa
- Device inserted through the transseptal needle so that it can be used in the transseptal procedure
- Creates the primary puncture of the fossa with the sharp tip
- Coil is used to dilate the fossa further so that the needle can then be inserted through the fossa rather then used as the primary puncture
- Printed markers are along the body for the physician to use as a guide to understand how far the SafeSept is in relation to the supporting devices

Performance Testing

The following performance tests were performed in support of substantial equivalence to the predicate:

- Visual and dimensional inspection
- Particulate testing (USP <788>, Light Obscuration Method)
- Surface finish assessment
- Corrosion resistance
- Guidewire tensile strength
- Fracture and Flex testing
- Curve Integrity testing
- Torque Testing
- Packaging testing
- Radiopacity assessment

In addition, the sterilization conditions have been validated in accordance with ANSI/AAMI/lSO 11135-1, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of sterilization process for medical devices. The device is sterilized to a SAL of 10-6. The results of the testing demonstrated the subject device performed equivalently to the predicate device.

Biocompatibility Testing

The biocompatibility evaluation for the SafeSept was conducted in accordance with FDA 510(k) Memorandum- #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' " June 16, 2016, and International Standard ISO 10993- "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. The following tests were performed:

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitization
- ISO 10993-10 Irritation/Intracutaneous Reactivity

- ISO 10993-11 Acute Systemic Toxicity
- ISO 10993-11 Pyrogenicity
- ISO 10993-3 Genotoxicity
- ISO 10993-4 Hemocompatibility – ASTM Hemolysis Complete
- ISO 10993-4 Hemocompatibility – In-vivo Dog Thromboresistance
- ISO 10993-4 Hemocompatibility – Complement Activation Complete with C3a & SC5b-9

The SafeSept transseptal guidewire is considered an external communicating device with circulating blood contact and limited exposure (less than 24 hours). The SafeSept met the requirements set forth in ISO-10993.

Conclusion

When compared to the predicate device, the SafeSept transseptal guidewire is substantially equivalent in design, technological characteristics, materials and performance testing.