September 14, 2022

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

Re: K221707
Trade/Device Name: SafeSept® Transseptal Guidewire (SS-140)
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: August 11, 2022
Received: August 15, 2022

Dear Andrew 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K221707

Device Name

SafeSept® Transseptal Guidewire (SS-140)

Indications for Use *(Describe)*

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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Section 7: 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: September 14, 2022

Identification of the Device

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

Equivalent Legally Marketed Devices

Pressure Products Medical Device Manufacturing LLC., SafeSept® Transseptal Guidewire, K170671

Description of the Device

The SafeSept® .018" Transseptal Guidewire is made of nitinol, a flexible memory wire material, device that is 140cm in length. The proximal end of the wire has 4 sets of laser-etched markings, which increase in quantity toward the proximal end of the wire. An echogenic marker was added along the shaft proximal to the radiopaque coil. A radiopaque coil located along the shaft, made of a platinum/tungsten alloy, aids in visual guidance during transseptal procedures. The sharp distal tip is able to perforate through the fossa ovalis, a thin wall separating the right and left interatrial septum, when it is supported by a transseptal needle and dilator. When the wire is no longer supported, it is atraumatic and operates as typical guidewire.

The components of the SafeSept® include the .018" transseptal guidewire, dispenser and straightener, and sterile packaging and labeling. The model number of the subject device is SS-140. The SafeSept® .018" Transseptal Guidewire is sterilized by 100% ethylene oxide cycle and is for single use-only.

The subject device is used in transseptal procedures to gain access to the left atrium through the right side of the heart. The device is used by a surgeon by inserting the device through the femoral vein. The subject device is then advanced to the fossa ovalis with the support of the transseptal needle and dilator. The guidewire is used in conjunction with a transseptal needle and dilator. Its duration in the body is less than 24 hours. The SafeSept® .018" Transseptal Guidewire is used in a healthcare facility/hospital.

Indications for Use

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.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of this device are similar to the predicate device. There is no difference between the two indications for use. Both the .018" transseptal guidewire and the .014" transseptal guidewire are used with a transseptal needle to puncture the septum. The subject and predicate device are based on the following technological elements:

- Nitinol wire that is super-elastic so that it can have a 'J' shaped curve with a sharp tip

- Radiopaque coil used by the physician to locate the device 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 a transseptal procedure
- Creates the primary puncture of the fossa with the supported sharp tip
- Coil is used to dilate the fossa further so that the needle can then be inserted through the fossa rather than used as the primary puncture.
- Proximal markers along the body of the wire for the physician to use as a guide to understand how far the device is in relation to the supporting devices.

The following are technological modifications to the predicate device:

- The .018" transseptal guidewire includes a larger outer diameter of .018"
- The .018" transseptal guidewire include a longer overall length of 140cm
- The surface finish is silver compared to black oxide
- The proximal markings are replaced with laser-etched markings with different marker locations to accommodate increased quantity of markings
- Adjusted grind profile to accommodate the increase in outer diameter

Performance Testing

The following performance data were provided in support of the substantial equivalence to the predicate:

- Visual and dimensional inspection
- Proximal Marking Integrity Testing
- Lubrication Coating Testing
- 2x Sterile Testing
- *In Vitro* Simulated Use Testing
- Package Testing
- Transit Testing

Bench Testing

For bench testing, dimensional and physical aspects of the device were inspected such as 'J' curve dimensions, tip thickness, outer diameter, overall length, and proximal marking locations. These results were comparable to the predicate device. Tensile and compressive forces during insertion and withdrawal and peak tensile forces were also tested per ISO 11070. The subject device data was comparable to the predicate device. Torsion testing was performed to ensure the subject device was able to withstand torsional forces expected during a transseptal procedure. Transit testing was performed per ASTM D4169, packaging testing per ASTM F88, ASTM 2096, and ASTM F1929. Proximal marking integrity was tested according to ISO 11070 and comparable to the predicate device.

Biocompatibility Data

Biocompatibility testing was performed on the predicate device, The SafeSept® .014" Transseptal Guidewire (K170671). Because the parts are made of the same material as the predicate device, nitinol, the biocompatibility testing was adopted for the SafeSept® .018" transseptal guidewire.

Conclusion

For the bench testing, the subject device puncture force and transit testing was similar to the predicate device. The biocompatibility and animal testing was adopted from the predicate device as the subject device used the same material, coating, and packaging as the predicate device. From the performance data provided, the subject device data was comparable to the predicate device. When compared to the predicate device, the SafeSept® .018" Transseptal Guidewire is substantially equivalent in design, technological characteristics, materials, and performance testing.