March 5, 2021

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

Re: K210328
Trade/Device Name: SafeSept Blunt Needle
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: February 3, 2021
Received: February 4, 2021

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210328

Device Name
SafeSept Blunt Needle

Indications for Use *(Describe)*
The SafeSept Blunt Needle is used in conjunction with a transseptal guidewire to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access. The SafeSept Blunt Needle 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.

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Section 7: 510(k) Summary

Submitter

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

Contact Person: Andrew Armour
Prepared: February 3, 2021

Identification of the Device

Proprietary-Trade Name: SafeSept Blunt Needle
Device Class: Class II
Classification Name: Trocar (CFR 870.1390)
Common/Usual Name: Transseptal Extended Cannula
Product Code: DRC

Equivalent Legally Marketed Devices

Pressure Products Medical Device Manufacturing LLC., Needle Free Transseptal Cannula, K172934

Description of the Devices

The Transseptal Extended Cannula is a stainless-steel device that comes in three lengths, 71cm, 89cm and 98cm. The body of the Transseptal Extended Cannula is equivalent to the transseptal cannula length, 69.7cm for the 71cm extended cannula, 87.7cm for the 89cm extended cannula, and 96.7cm for the 98cm extended cannula, and two distal curves, Curve0 and Curve1. The size is 18 gauge with an inner diameter of .0325” at the proximal body and necks down to 21 gauge with an inner diameter of 0.0195” at the distal end, terminating with a radiused tip. The components of the Transseptal Extended Cannula include the transseptal extended cannula, sterile packaging and labeling. There are six model numbers for the cannula: SBN071, SBN089, SBN098, SBN171, SBN189, and SBN198. The Transseptal Extended Cannula is sterilized by 100% ethylene oxide cycle and is for single use-only. The Transseptal Extended Cannula is used in a healthcare facility/hospital.

The transseptal extended cannula is used in transseptal procedures to provide structural support to a transseptal guidewire to gain access to the left atrium through the right side of the heart. The device is used by a physician by inserting the device through a transseptal dilator and sheath assembly. The devices are inserted in the femoral vein. The transseptal guidewire is then advanced to the fossa ovalis with the support of the cannula and dilator. This allows physicians to use a transseptal guidewire in difficult cases where there is a particularly tough septum as the transseptal cannula provides the extra support needed. The cannula’s duration in the body is less than 24 hours.

Indications for Use

The SafeSept Blunt Needle is used in conjunction with a transseptal guidewire to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access. The SafeSept Blunt Needle is intended for single use only.

The Transseptal Cannula is used in conjunction with a transseptal guidewire to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

Both the transseptal extended cannula and the transseptal cannula are used in transseptal catheterization procedures to gain left heart access. There is no difference between the two indications for use. The transseptal extended cannula includes a necked down portion to be used with a smaller diameter transseptal guidewire (<0.018”), whereas the transseptal cannula is used with a larger diameter guidewire (<0.032”). Because the two devices are made of the same material, stainless steel, both cannulas provide structural support to a transseptal introducer. The transseptal cannulas with a transseptal guidewire provide a safer method of crossing the septum then the most common transseptal procedure performed with a BRK transseptal needle. Because of the similarities between the transseptal cannula and the transseptal extended cannula, the transseptal cannula is the predicate device for the transseptal extended cannula.

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 extended cannula and the transseptal cannula are used with a transseptal guidewire to puncture the septum. The subject and predicate device are based on the follow technological elements:

- Stainless steel that provides structural support in the transseptal procedure
- Smooth inner diameter so devices can pass through the body of the devices smoothly
- Devices are inserted through the transseptal dilator and sheath assembly so that it can be used in the transseptal procedure
- Devices come in 71, 89, and 98cm lengths (body lengths: 69.7cm, 87.7cm, and 96.7cm)
- Devices come in two curves, Curve0 and Curve1
- Devices assembled through the transseptal introducer system match curve shapes
- Devices used with transseptal guidewires in the introducer assembly
- Non-skiving device because of the radius tip
- Hub is clear and light to allow visualization of the introduction of devices

The following are technological modifications to the predicate device:

- The transseptal extended cannula includes an extension portion that necks down to 21 gauge with an inner diameter of 0.0195” at the distal end, terminating with a radiused tip
- The tip of the transseptal extended cannula extends past the dilator while the cannula radius tip is stopped in the transseptal dilator
- Used with smaller diameter transseptal guidewires (<0.018”)

Performance Testing

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

- Visual and dimensional inspection
- Particulate testing (USP<788>, Light Obscuration Method)
- Mating Joint Pull test (Handle to Hub)
- Mating Joint Pull test (Cannula to Extension)
- Strength of Union Cannula Hub and Cannula
- Guidewire Restriction Inspection
- Radius Tip Inspection
- Hub Female Luer Taper
- Water Leak Testing
- Air Leak Testing
- Packaging Testing

Biocompatibility Data

Biocompatibility testing was performed on the predicate device, Needle Free™ Transseptal Cannula (K172934). Because the parts are made of the same material as the predicate device, 304 stainless steel, the biocompatibility testing was adopted for the transseptal extended cannula. The biocompatibility evaluation for the Needle Free™ Transseptal Cannula 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 10993-1 “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 on the device as it is categorized as an externally communicating device with circulating blood contact, and limited exposure (less than 24 hours).

- 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 – Complement Activation Complete with C3a & SC5b-9

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

Conclusion

When compared to the predicate device, the Transseptal Extended Cannula is substantially equivalent in design, technological characteristics, materials and performance testing.