February 21, 2018

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

Re: K172950
Trade/Device Name: TSN Transseptal Needle
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: January 16, 2018
Received: January 17, 2018

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.

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.

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172950

Device Name
TSN Transseptal Needle

Indications for Use *(Describe)*

The Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access. The Transseptal 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.

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: February 16, 2018

Identification of the Device

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

Equivalent Legally Marketed Devices

St. Jude Medical, BRK Transseptal Needle, K122587

Description of the Devices

The Transseptal Needle consists of a stainless-steel needle and stylet. The needle comes in three lengths equivalent to the lengths of a conventional Brockenbrough (BRK) needle (predicate) - 71cm, 89cm, and 98cm, and two curves, Curve0 and Curve1. The needle size is 18 gauge with an inner diameter of .033" at the proximal body and necks down to 21 gauge with an inner diameter of .018" at the distal end, terminating with an angled tip. The components of the Transseptal Needle include the Transseptal Needle and Stylet, and sterile packaging and labeling. There are six model numbers for the Transseptal Needle, TSN071, TSN089, TSN098, TSN171, TSN189, and TSN198. The Transseptal Needle is sterilized by 100% ethylene oxide cycle and is for single-use only. The Transseptal Needle is used in a healthcare facility/hospital.

The Transseptal needle is used in transseptal procedures to puncture the fossa ovalis and gain access to the left atrium through the right side of the heart. The device is used by inserting the device through a transseptal dilator and sheath assembly. The devices are inserted in the femoral vein. The Transseptal needle tip is able to perforate through the fossa ovalis, a thin wall between the right and left atrium. The needle's duration in the body is less than 24 hours.

Indications for Use

The Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access. The Transseptal Needle is intended for single use only.

The Indications for Use statement for the Transseptal Needle device is identical to the predicate device. Both devices have the same intended use and are used to create the primary puncture in the interatrial septum. The devices are used in conjunction with a transseptal dilator and sheath. Both devices are used to cross the septum and provide access to the left side of the hearth from the right side.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of this device are similar to the predicate device. The main difference between the subject device and the predicate device is the orientation of the bevel.

The proposed device has a reverse bevel. The subject and predicate device are based on the following technological elements:

- Smooth inner diameter so guidewires 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
- Both have stylet wire that come in 76cm, 94cm, and 103cm lengths
- Devices come in two curves, Curve0 and Curve1
- Devices assembled through the transseptal introducer system match curve shapes
- Puncture force of the Transseptal needle is equivalent to the puncture force of the BRK transseptal needle

The following are technological modifications to the predicate device:

- Needle tip has a reverse bevel
- Hub is clear instead of stainless steel so that it is lighter and allows visualization of the introduction of devices
- Stylet handle is a male luer lock cap
- Stylet wire diameter is .015" diameter compared to .0135" diameter for the predicate device
- Transseptal Needle is a non-skiving device

Performance Testing

The following performance tests were performed 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)
- Guidewire Restriction Inspection
- Strength of Union Cannula Hub and Cannula
- Needle Point Inspection
- Hub Female Luer Taper
- Water Leak Testing
- Air Leak Testing
- Packaging Testing

Biocompatibility Data

The biocompatibility evaluation for the Transseptal Needle 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:

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

Conclusion

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