October 26, 2018

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

Re: K181031
Trade/Device Name: TSI Transseptal Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 13, 2018
Received: April 18, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Rachel E. Neubrander -S

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

Enclosure

Section 6: Indications for Use Statement

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)*
K181031

Device Name
TSI Transseptal Introducer

Indications for Use *(Describe)*
The Transseptal Introducer is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum. The Transseptal Introducer 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: October 24, 2018

Identification of the Device

Proprietary-Trade Name: TSI Transseptal Introducer
Device Class: Class II
Classification Name: Catheter Introducer (CFR 870.1340)
Common/Usual Name: Transseptal Introducer
Product Code: DYB

Equivalent Legally Marketed Devices

Daig Corp. (St. Jude Medical, now Abbott), Fast-Cath Transseptal Guiding Introducer, K964518

Reference Devices

Oscor Inc., Adelante-S Lite (SafeSheath Ultra Lite), K122084
Oscor Inc., Adelante-SII (SafeSheath II), K122084

Description of the Devices

The Transseptal Introducer consists of a high-density polyethylene (HDPE) sheath, a dilator with a lubricious hydrophobic coating, and an uncoated introducer guidewire in a dispenser. The transseptal introducer comes in two French sizes, 8F and 8.5F, two lengths, 63cm and 81cm, and two curves, L0 (50˚) and L1 (40˚, 51˚). The components of the Transseptal Introducer include the transseptal sheath, transseptal dilator, introducer guidewire with dispenser, sterile packaging and labeling. There are eight model numbers: TSIL0863, TSIL1863, TSIL0881, TSIL1881, TSIL08563, TSIL18563, TSIL08581, and TSIL18581. The Transseptal Introducer is sterilized by 100% ethylene oxide cycle and is for single-use only. The Transseptal Introducer is used in a healthcare facility/hospital.

The Transseptal Introducer is used in transseptal procedures to introduce cardiovascular catheters into the left side of the heart after transseptal access was achieved with a transseptal needle and dilator. The device is used by inserting the device through the femoral vein in conjunction with a transseptal needle. The introducer guidewire is inserted through the femoral vein and guides the needle up to the fossa ovalis in the right atrium. The needle punctures the fossa ovalis and the dilator is used to insert and dilate the fossa further where the needle has punctured. This allows the sheath to cross and creates access to the left side of the heart. The introducer's duration in the body is less than 24 hours.

Indications for Use

The Transseptal Introducer is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum. The Transseptal Introducer is intended for single use only.

The Indications for Use statement for the Transseptal Introducer device is identical to the predicate device. Both devices have the same intended use and are used for the introduction of catheters into the heart. The devices are used in conjunction with a transseptal needle. Both

devices are used to create a port to the left side of the heart from the right side so that cardiovascular catheters can be introduced.

Comparison of Technological Characteristics with the Predicate Device
The technological characteristics of this device are similar to the predicate device. The subject and predicate device are based on the follow technological elements:

- Similar materials for the introduction of catheters into the heart
- Marker band tip used by the physician to locate the sheath across the fossa
- Sideholes to allow for fluids to pass through at a sufficient rate
- Device used in conjunction with other transseptal devices such as a transseptal needle or guidewire
- Introducer guidewire used to guide the introducer into the right atrium
- Needle extends past the transseptal dilator to puncture the fossa
- Dilator tip used to dilate fossa ovalis up to the sheath inner diameter
- Dilator shaft to sheath tip transition allows the sheath to pass through the fossa after dilator insertion

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)
- Liquid leakage from sheath introducers under pressure
- Air pressure leak test
- Sideport-stopcock-hub tug test
- Sheath joint pull tests
- Guidewire restriction
- Curve template inspection
- Dilator flexibility testing
- Corrosion resistance
- Guidewire tensile strength
- Fracture and flex testing
- Curve integrity testing
- Packaging testing
- *In vitro* simulated use
- Surface morphology 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 Data
The biocompatibility evaluation for the Transseptal Introducer 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 – Complement Activation Complete with C3a & SC5b-9
- ASTM F2382-17 – Partial Thromboplastin Time (PTT) testing
- Platelet/Leukocyte Count (Guideline: ASTM F2888-13)

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

Conclusion

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