May 17, 2024

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

Re: K241042
Trade/Device Name: SafeSharp Transseptal Needle (CLICK071, CLICK171, CLICK098, CLICK198)
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: April 16, 2024
Received: April 17, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Alexandra K. Manaras -S

for Katherine Trivedi
Acting 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.

510(k) Number *(if known)*
K241042

Device Name
SafeSharp 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.

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510(k) Summary

Submitter

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Morton, PA 19070
Phone: 610-285-9858
Fax: 610-285-9859

Contact Person: Andrew Armour
Prepared: April 16, 2024

Identification of the Device

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

Equivalent Legally Marketed Devices

Pressure Products Medical Device Manufacturing LLC., TSN Transseptal Needle, K172950 (primary predicate)
Pressure Products Medical Device Manufacturing LLC., SafeSept Transseptal Guidewire, K170671 (reference device)

Description of the Devices

The Transseptal Sharp Needle consists of a stainless-steel needle and nitinol stylet. The needle comes in two lengths equivalent to the lengths of the TSN Transseptal Needle (predicate) – 71cm and 98cm, and two curves, Curve0 (59˚) and Curve1 (72˚). 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 0.0230” at the distal end with a sharp a-bevel offset tip. The transseptal sharp needle includes a 0.018” diameter nitinol stylet wire with an intermediate 0.013” section, a bulbous distal tip, and a proximal clear plastic handle with an internal mechanism configured to both provide feedback on the position of the stylet tip and as well as to maintain the stylet tip in the extended position to reduce the possibility for further penetration of the needle after the initial crossing of the septum. The components of the Transseptal Sharp Needle include the transseptal sharp needle, stylet, sterile packaging, and labeling.

There are four model numbers for the transseptal sharp needle: CLICK071, CLICK098, CLICK171, and CLICK198. The Transseptal Sharp Needle is sterilized by 100% ethylene oxide cycle and is for single use-only. The Transseptal Sharp Needle is used in a healthcare facility/hospital.

The transseptal sharp 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 assembly. The devices are inserted in the femoral vein. The transeptal sharp needle is then advanced to the fossa ovalis. This mimics the procedure with the predicate device, TSN Transseptal Needle. Both the proposed device and the predicate device (K17950) have a needle point, made of stainless steel, have similar hub and handle, and have similar dimensions, design, and functionality. 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 Transseptal Needle is used to create the primary puncture in the interatrial septum during a transseptal procedure to gain access to the left side of the heart.

Both the TSN transseptal needle and the transseptal sharp needle are used in transseptal catheterization procedures to gain left heart access. There is no difference between the two indications for use. The Transseptal Needle is similar to the transseptal sharp needle except the transseptal sharp needle has an a-bevel sharp tip. The Transseptal Sharp Needle with a stylet provides a safe method of crossing the septum. Because of the similarities between the Transseptal Needle and the Transseptal Sharp Needle, the Transseptal Needle is the predicate device for the Transseptal Sharp Needle.

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 predicate device and the subject device are used to create the primary puncture and gain left heart access. The subject and predicate device are based on the follow technological elements:

- Stainless steel that creates primary puncture 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 71and 98cm lengths
- Devices come in two curves, Curve0 and Curve1
- Hub is clear and light to allow visualization of the introduction of devices

The following are technological modifications to the predicate device:

- The transseptal sharp needle has a sharp a-bevel with an offset.
- The transseptal needle is a two-piece needle instead of one piece
- The proposed device includes an 0.018” diameter nitinol stylet wire with an intermediate 0.013” diameter section, a bulbous distal tip, and a proximal clear plastic handle with an internal mechanism

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

- Visual and dimensional inspection
- Particulate testing (AAMI TIR42)
- Mating Joint Pull test (Handle to Hub)
- Mating Joint Pull test (Needle to Insert)
- Mating Joint Pull test (Stylet Tip to Stylet)
- Strength of Union Needle Hub and Needle
- Guidewire Restriction Inspection
- Water Leak Testing
- Air Leak Testing
- Packaging Testing
- Simulated Use

Biocompatibility Data
Biocompatibility testing was performed on the predicate device, Transseptal Needle (K172950). Because the parts are made of the same material as the predicate device, 304 stainless steel, and the reference device, nitinol stylet, biocompatibility testing was leveraged for the transseptal needle.

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

Conclusion

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