



March 13, 2026

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

Re: K253799

Trade/Device Name: SafeSept RF Transseptal Guidewire (SSRF132; SSRF132R; SSRF135;
SSRF135R; SSRF232; SSRF232R; SSRF235; SSRF235R)

Regulation Number: 21 CFR 870.5175

Regulation Name: Septostomy Catheter

Regulatory Class: Class II

Product Code: DXF

Dated: March 6, 2026

Received: March 6, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

Katherine N. Trivedi -S
Digitally signed by
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Katherine Trivedi
Assistant Director
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Enclosure

Indications for Use

510(k) Number (if known)
K253799

Device Name
SafeSept RF Transseptal Guidewire

Indications for Use (Describe)

The SafeSept RF Transseptal Guidewire is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. The SafeSept RF 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.

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510(k) Summary

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Submitter

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Contact Person: Andrew Armour
Prepared: March 13, 2026

Identification of the Device

Proprietary-Trade Name: SafeSept RF Transseptal Guidewire
Device Class: Class II
Classification Name: Septostomy Catheter (21 CFR §870.5175)
Common/Usual Name: RF Transseptal Guidewire
Product Code: DXF

Legally Marketed Predicate Device

Baylis Medical Company Inc., VersaCross™ RF Wire, K242076

Reference Device

Pressure Products Medical Device Manufacturing LLC., SafeSept Needle Free Transseptal Guidewire, K172893

Description of the Device

The SafeSept RF Transseptal Guidewire is a sterile, 180 cm or 230cm long, 0.032" or 0.035" diameter nitinol guidewire specifically designed to provide access to the left atrium via the right atrium in the same manner as the SafeSept Needle Free Transseptal Guidewire. The distal end of the wire is configured in either a J-shape or retention curve with a rounded edge tip. The RF Transseptal Guidewire uses a maximum of 10 Watts of radiofrequency energy to cross the septum. Once across the fossa ovalis, the guidewire becomes atraumatic due to its curve shape. The guidewire features a radiopaque coil that transitions to the nitinol wire. The guidewire has echogenic markers located along the shaft proximal to the radiopaque coil, which aid in visual guidance during transseptal procedures. The proximal end of the wire has laser-etched markings, which help determine the location of the guidewire tip relative to the introducer. When the wire is no longer supported, it is atraumatic and operates as a typical guidewire. The RF Transseptal Guidewire is used in conjunction with a monopolar electrosurgical generator or radiofrequency (RF) generator with selectable power settings in watts such as the Valleylab Force FX Electrosurgical Generator.

The components of the SafeSept RF Transseptal Guidewire include the RF Transseptal Guidewire, dispenser and straightener, adapter clip, and sterile packaging and labeling. The model numbers of the subject device are SSRF132, SSRF132R, SSRF135, SSRF135R, SSRF232, SSRF232R, SSRF235, and SSRF235R. The SafeSept RF Transseptal Guidewire is sterilized by 100% ethylene oxide cycle and is for single use only.

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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 physician by inserting the device through the femoral vein. The subject device, with the support of the transseptal introducer and a supplied energy of up to 10 Watts, is advanced to the fossa ovalis for puncture. The guidewire is used in conjunction with a transseptal introducer and allows for safer access through the atrial septum than a transseptal needle and provides safer penetration through the atrial septum to the left atrium. Its duration in the body is less than 24 hours. The SafeSept RF Transseptal Guidewire is used in a healthcare facility/hospital.

Intended Use/Indications for Use

The SafeSept Transseptal Guidewire is used in conjunction with a transseptal introducer to create the primary puncture in the interatrial septum and to guidewire the dilator and introducer through the septum from the right side of the heart to the left side.

Indicated for use in procedures where access to the left atrium via the transseptal technique is desired. The SafeSept RF Transseptal Guidewire is intended for single use only.

The SafeSept Transseptal Guidewire and the VersaCross™ RF Wire are designed to cross the interatrial septum and provide access to the left atrium.

Comparison of Technological Characteristics with the Predicate Device

The subject device, the SafeSept RF Transseptal Guidewire, is a modification of the previously cleared SafeSept Needle Free Transseptal Guidewire (reference device, K172893). Both the reference and subject device are manufactured by Pressure Products Medical Device Manufacturing LLC. The subject device incorporates additional technological features, including the ability to deliver radiofrequency (RF) energy, while maintaining the same fundamental clinical purpose of facilitating transseptal access to the left atrium during transseptal catheterization procedures.

For purposes of demonstrating substantial equivalence, the Baylis Medical VersaCross™ RF Wire has been identified as the primary predicate device, as it similarly utilizes RF energy to facilitate crossing of the interatrial septum.

The subject device and predicate device share several fundamental technological characteristics associated with guidewire-based transseptal access systems. Both devices:

- Are guidewire devices intended for use in transseptal procedures
- Are introduced through a compatible transseptal introducer system
- Are used to facilitate crossing of the interatrial septum to access the left atrium
- Allow advancement of a transseptal introducer or supporting catheter over the wire once septal access is achieved
- Provide visualization at the distal end of the device to assist the physician in positioning the device during the procedure
- Incorporate RF energy delivery to assist with septal crossing

While the subject device and the predicate device differ in certain materials and design features, both devices employ RF energy to facilitate transseptal access and are used within the same procedural workflow. These technological differences do not alter the fundamental intended use or mechanism of action and do not raise new questions of safety or effectiveness.

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Table 1: Comparison Table of Subject Device, Predicate Device, and Reference Device

	Predicate Device	Reference Device	Subject Device
Name of Device	VersaCross RF Wire (K242076)	SafeSept Needle Free Transseptal Guidewire, model SSNF (K172893)	SafeSept RF Transseptal Guidewire, model SSRF132, SSRF132R, SSRF135, SSRF135R, SSRF232, SSRF232R, SSRF235, SSRF235R
Intended Use	The VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.	The SafeSept Transseptal Guidewire is used in conjunction with a transseptal introducer to create the primary puncture in the interatrial septum and to guidewire the dilator and introducer through the septum from the right side of the heart to the left side.	Same as reference device
Indication for Use	The VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.	Indicated for use in procedures where access to the left atrium via the transseptal technique is desired. The SafeSept Needle Free Transseptal Guidewire is intended for single use only.	Same as reference device
Practitioner Use	In clinical setting (physician) (prescription use)	In clinical setting (physician) (prescription use)	No change
Material	Core stainless steel wire with an insulating material, marker coil and radiopaque band	Superelastic nitinol wire, platinum wire, silicone dispersion coating	Same as reference device

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Energy Source	Compatible with a separately cleared compatible generator, such as the Baylis RF Puncture Generator (K122278)	Not applicable	Compatible RF electrosurgical generator such as Valleylab Fx Electrosurgical Generator (K944602)
Length	180cm and 230cm	180cm	180cm and 230cm
Diameter	.035 inches	0.0315 inches	0.032 and 0.035 inches
Coil	Equipped with a marker coil and radiopaque band	.0175" platinum radiopaque coil located on distal end	Same as reference device
Tip Shape	J-tip, pigtail	Wire assumes 'J' shape when unsupported	Wire assumes 'J' shape or retention shape when unsupported
Markings	Proximal white, printed marker bands to determine location of tip	Proximal white, printed marker bands to determine location of tip	Laser-etched dark marker bands to determine location of tip
Dispenser	Dispenser coil	Dispenser material: HDPE	Same as reference device
Guidewire Advancer	Tip straightener	.059" diameter, material	Short dilator with locking mechanism, HDPE
Sterilization	100% ethylene oxide	100% ethylene oxide	No change
Packaging and Labeling	Supplied in a tray with a lid, placed in a Tyvek/Nylon pouch	Single pouch, five pouches per box	Same as reference device
Use	Single time use	Single time use	No change

Performance Testing

The following performance data were provided in support of the substantial equivalence to the predicate in addition to the previous performance testing leveraged from the reference device:

- Visual and dimensional inspection
- Proximal Marking Integrity Testing
- 2x Sterile Testing
- *In Vitro* Simulated Use Testing
- Package Testing
- Transit Testing
- Electrical Safety and EMC Testing

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was conducted on the SafeSept RF Transseptal Guidewire in compliance with IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements

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and Tests and IEC 60601-2-2 Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories. The testing was completed using the Valleylab Force FX Electrosurgical Generator.

Biocompatibility Data

Biocompatibility testing was leveraged from the reference device, SafeSept Needle Free Transseptal Guidewire (K172893). The materials in the SafeSept RF Transseptal Guidewire can be categorized as contacting and non-contacting components. The contacting components include the guidewire (nitinol) and radiopaque coil (platinum). The short dilator is used to replace the advancer for the retention wire models. The dilator is for packaging purposes only. The short dilator with the locking mechanism does not contact the body during the procedure. Because the parts are made of the same material as the reference device, process methods, coating, and cleaning, the biocompatibility testing was adopted for SafeSept RF Transseptal Guidewire. The biocompatibility evaluation for the SafeSept Needle Free Transseptal Guidewire was conducted in accordance with FDA 510(k) Memorandum- #G95-1 “Use of International Standard ISO- 10993, ‘Biological Evaluation of Medical Device 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.

- 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 – In-vivo Dog Thromboresistance
- ISO 10993-4 Hemocompatibility – Complement Activation Complete with C3a & SC5b-9

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

Conclusion

When compared to the predicate device, the SafeSept RF Transseptal Guidewire has been determined to be substantially equivalent with respect to design, technological characteristics, materials, and performance testing. The differences identified in the technological characteristics do not raise new questions of safety or effectiveness. Therefore, it is concluded that the SafeSept RF Transseptal Guidewire is substantially equivalent to the legally marketed predicate device, as required under 21 CFR 807.92(b)(3).