August 27, 2025

Atraverse Medical, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K252419
Trade/Device Name: Hotwire RF Guidewire
Model numbers: 901000, 901001, 901002, 901003, 901004, 901005, 901006, 901007, 901008, 901009, 901010, 901011, 901012, 901013, 901014, 901015, 901016, 901017, 901018, 901019, 901020, 901021, 901022, 901023, 901024, 902001, 902002, 902003, 902004, 902005, 902006, 902007, 902008, 902009, 902010, 902011, 902012, 902013, 902014, 902015, 902016, 902017, 902018, 902019, 902020, 902021, 902022, 902023, 902024, 902025, 902026, 902027, 902028, 902029, 902030, 902031, 902032, 902033, 902034, 902035, 902036
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy catheter
Regulatory Class: Class II
Product Code: DXF
Dated: August 1, 2025
Received: August 1, 2025

Dear Prithul Bom:

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.

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 Katherine N. Trivedi -S
Date: 2025.08.27 16:59:05 -06'00'

Katherine Trivedi
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252419

Device Name
HOTWIRE RF GUIDEWIRE (models 901XXX and 902XXX)

Indications for Use *(Describe)*
The HOTWIRE is indicated for creation of an atrial septal defect in the heart.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

This 510(k) summary for HOTWIRE™ RADIOFREQUENCY (RF) GUIDEWIRE is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendation outlined in FDA Guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]" (issued on July 28, 2014).

Atraverse Medical, Inc. is submitting this traditional 510(k) Premarket Notification for the HOTWIRE™ RF Guidewire. The HOTWIRE™ RF Guidewire ("Predicate device") has previously been cleared under the Traditional 510(k) Program (K240900), in which Atraverse Medical, Inc. is the legal manufacturer.

SUBMITTER [807.92(a)(1)]

Atraverse Medical, Inc.
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Cardiff by the Sea, CA 92007

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Date prepared: June 30, 2025

DEVICE [807.92(a)(2)]

Table 1: Device Information

Trade Name	HOTWIRE™ RF Guidewire
Common Name	Catheter, Septostomy
Classification Name	Catheter, Septostomy
Regulation	21 CFR 870.5175
Product Code	DXF
Regulatory Classification	Class II
Device Panel:	Cardiovascular

PREDICATE DEVICE [807.92(a)(3)]

HOTWIRE™ RF Guidewire (K240900)

REFERENCE DEVICE

DEVICE DESCRIPTION [807.92(a)(4)]

HOTWIRE™ Kit (901XXX):
The HOTWIRE™ is a sterile, single-use guidewire device that delivers radiofrequency (RF) power in a monopolar mode to a distal electrode segment for the creation of an atrial septal defect in the heart. The HOTWIRE™ is intended to be used in conjunction with compatible third-party intravascular sheaths and/or dilators, such as the Agilis NXT Steerable Introducer, St. Jude Medical/Abbott (K081645), and third-party RF electrosurgical generator(s), such as the Valleylab FT10 Electrosurgical Platform (K151649) which utilizes a commercially-available Patient Return Electrode (PRE) which is in compliance with IEC 60601-2-2, such as the Valleylab E7507DB (K822572).

Table 2: Devices that have undergone Compatibility Testing

Manufacturer	Device	510(k)
St Jude Medical / Abbott	Agilis NXT Steerable Introducer	K081645
Medtronic	FlexCath Steerable Sheath	K183174
Biosense Webster	CARTO VIZIGO Sheath	K170997
Valleylab	FT10 Electrosurgical Platform	K151649
Valleylab	E7507 Return Electrode	K822572

The HOTWIRE™ is comprised of a stainless steel core wire. The main body of the wire is jacketed with an insulating polymer that provides electrical insulation and facilitates smooth movement of the device through vascular dilators and/or sheaths. The floppy distal segment of the wire has an atraumatic tip with an uninsulated stainless-steel coil, which serves as an electrode, and also provides fluoroscopic and echogenic visualization. A tungsten marker coil at the tip provides additional radiopacity. The stiff body of the HOTWIRE™ provides support for advancing wire-guided devices into the left atrium after the distal segment has traversed the septum. The proximal insulated portion of the wire has visual markers that align the electrode tip with third-party transseptal sheaths and/or dilators. A portion of the proximal wire is uninsulated for placement of an included Adapter Pin that connects to hand pieces used with compatible third-party RF electrosurgical generators.

HOTWIRE™ + Handpiece Kit (902XXX):
The HOTWIRE™ + Handpiece Kit is a sterile, single-use guidewire device that delivers radiofrequency (RF) power in a monopolar mode to a distal electrode segment for the creation of an atrial septal defect in the heart. The HOTWIRE™ + Handpiece Kit is intended to be used in conjunction with compatible third-party intravascular sheaths and/or dilators, such as the Agilis NXT Steerable Introducer, St. Jude Medical/Abbott (K081645), and the HOTWIRE™ System

RF Generator, which utilizes a commercially-available Patient Return Electrode (PRE) which is in compliance with IEC 60601-2-2, such as the Valleylab E7507DB (K822572).

Table 3: Devices that have undergone Compatibility Testing

Manufacturer	Device	510(k)
St Jude Medical / Abbott	Agilis NXT Steerable Introducer	K081645
Medtronic	FlexCath Steerable Sheath	K183174
Biosense Webster	CARTO VIZIGO Sheath	K170997
Atraverse Medical	HOTWIRE™ System RF Generator	
Valleylab	E7507 Return Electrode	K822572
McKesson Argent	22-ESRSC Return Electrode	K092761

The HOTWIRE™ is comprised of a stainless steel core wire. The main body of the wire is jacketed with an insulating polymer that provides electrical insulation and facilitates smooth movement of the device through vascular dilators and/or sheaths. The floppy distal segment of the wire has an atraumatic tip with an uninsulated stainless-steel coil, which serves as an electrode, and also provides fluoroscopic and echogenic visualization. A tungsten marker coil at the tip provides additional radiopacity. The stiff body of the HOTWIRE™ provides support for advancing wire-guided devices into the left atrium after the distal segment has traversed the septum. The proximal insulated portion of the wire has visual markers that align the electrode tip with third-party transseptal sheaths and/or dilators. A portion of the proximal wire is uninsulated for placement of an included handpiece that connects with the HOTWIRE™ System RF Generator.

INDICATIONS FOR USE [807.92(a)(5)]

The HOTWIRE™ is indicated for creation of an atrial septal defect in the heart.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The technological characteristics of the HOTWIRE™ is highly analogous to the technological characteristics of the Predicate device (K240900). Substantial equivalence is determined based on the following similarities:

- Same intended use/indications for use
- Same principles of operation
- Same fundamental scientific technology
- Same basic guidewire design
- Same guidewire construction material

Atraverse Medical, Inc. shall demonstrate that the device modifications made to the Predicate device remains substantially equivalent to the Predicate device. Specifics of this substantial equivalence determination is included in the discussion below.

The HOTWIRE™ + Handpiece Kit has identical or similar intended use, technological characteristics, and principles of operation as the Predicate device. A device comparison table is provided in this section in **Table 4**. This table provides a concise comparison between the relevant features of the HOTWIRE™ + Handpiece Kit and the Predicate device.

Table 4: HOTWIRE™ Comparison Table

Characteristic	Subject Device Compared to Predicate Device (K240900)	Subject Device Compared to Reference Device (K150709)	Comment
Indications for Use	Identical	Identical	The subject device, predicate device and reference device are indicated for creation of an atrial septal defect in the heart.
Fundamental scientific technology	Identical	Identical	The subject device, predicate device and reference device rely on use of controlled RF energy by the user for transseptal puncture.
Principal of Operation	Similar	Similar	The subject device, predicate device and reference device are operator controlled. RF energy is delivered via a compatible RF Generator / electrosurgical handpiece to the RF wire distal tip by the operator. The minor design differences do not raise new questions of safety or effectiveness.
Method of Supply	Identical	Similar	Both the subject and predicate device are single use; Sterilized by Gamma radiation – Method VDmax^{25}; Sterility Assurance Level of 10^{-6} The Reference device similar achieves a Sterility Assurance Level of 10^{-6}. The Reference device utilizes Ethylene Oxide to achieve Sterility Assurance Level.
Technological characteristics (Dimensions, design, materials)	Identical	Similar	Both the predicate and subject device share the same fundamental design, in terms of: • Materials, • Insulation • Dimensions (i.e., diameter, length) • Configuration (i.e., tip shape) The Subject Device differs from the predicate as follows: • Distal taper length The Reference device includes a distal taper length similar to that of the Subject device. The minor design differences between the Subject and Predicate device do not raise new questions of safety or effectiveness.

Characteristic	Subject Device Compared to Predicate Device (K240900)	Subject Device Compared to Reference Device (K150709)	Comment
Energy Source	Similar	Similar	The subject device, predicate device and reference device can be used with 510(k) cleared compatible RF electrosurgical generator. Risks associated with change in energy source from predicate were adequately mitigated and verified. The addition of a compatible RF electrosurgical generator source does not raise new questions of safety or effectiveness.
Packaging configuration	Similar	Similar	The Subject device packaging configuration differs in dimensions and accessories included as compared to the predicate device. The HOTWIRE™ packaging was validated after environmental conditioning per ASTM D4332, transportation simulation per ASTM 4169 and 1 year accelerated aged equivalent. The Subject device packaging configuration has been determined to be equivalent to that of the predicate device. The minor difference in packaging does not raise new questions of safety or effectiveness

PERFORMANCE DATA [807.92(b)]

Non-clinical bench top and *in vivo* performance testing was completed to demonstrate safety and effectiveness and substantial equivalence of the subject device to the predicate device. All test requirements were met as specified by applicable standards and test protocols. The following verification and validation activities were completed to demonstrate the safety and effectiveness of the subject device:

- RF Guidewire Testing
  - Visual and dimensional inspection
  - Simulated use test
  - Arc integrity test
  - Tensile strength test
  - Torque strength test
  - Torquability test
  - Fracture resistance test
  - Flexing test
  - Tip flexibility test
- Handpiece Testing:
  - Cable flex test
  - Cable tensile strength test
  - EEPROM functionality test

    - Cable length dimensional inspection
    - Retention test
    - Activation button test
- *In vivo* testing

***In vivo* Testing:** Customer requirements were validated by *in vivo* testing utilizing a porcine model. Design validation testing evaluated subject device design performance during normal intended use, including compatibility with commercially-available introducer sheaths, intracardiac echocardiography (ICE) catheters, and fluoroscopic visualization.

Shelf life: The accelerated shelf life testing for HOTWIRE™ has been conducted (T=1 years accelerated aging) with test results confirmed that all acceptance criteria were met. No new questions of safety or effectiveness are raised. Based on the results, we can conclude that HOTWIRE™ will perform as intended to the Design Specification. HOTWIRE™ will be labeled for 1-year shelf life.

Packaging: Packaging validation was performed on the HOTWIRE™. The results from packaging testing conducted on HOTWIRE™ showed that the acceptance criteria were met. Therefore, we can conclude the HOTWIRE™ packaging will provide the adequate and effective protection and sterile barrier requirements.

Sterilization: HOTWIRE™ is sterilized using gamma radiation. HOTWIRE™ is sold sterile, for single use and single patient only. The sterilization validation was performed and is documented. The sterilization validation results showed that the sterilization dose and routine sterilization process was validated to achieve an SAL of 10^{-6} for the HOTWIRE™.

CONCLUSION

The HOTWIRE™ met all specified criteria and did not raise new safety or performance questions. Based on the 510(k) summary and information provided herein, we conclude that the subject device, HOTWIRE™, is substantially equivalent in its intended use, design, material, performance, and the underlying fundamental scientific technology used, to the Predicate device (K240900)