



February 27, 2026

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

Re: K260292

Trade/Device Name: HOTWIRE™ RF Guidewire (901xxx); HOTWIRE™ RF Guidewire (902xxx)
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy catheter
Regulatory Class: Class II
Product Code: DXF
Dated: January 29, 2026
Received: January 29, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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
Katherine N. Trivedi -S
Date: 2026.02.27 21:00:48
-07'00'

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

Indications for Use

510(k) Number (if known)
K260292

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.

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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 Special 510(k) Premarket Notification for the HOTWIRE™ RF Guidewire. The HOTWIRE™ RF Guidewire has previously been cleared under the Traditional 510(k) Program (K252419), in which Atraverse Medical, Inc. is the legal manufacturer.

SUBMITTER [807.92(a)(1)]

Atraverse Medical, Inc.
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Date prepared: January 09, 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 (K252419)

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)
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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 transeptal 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 (K252419). 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™ RF Guidewire with device modifications (“Subject Device”) 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 3**. This table provides a concise comparison between the relevant features of the Subject and the Predicate device.

Table 3: HOTWIRE™ Comparison Table

Characteristic	Subject Device Compared to Predicate Device (K252419)	Comment
Indications for Use	Identical	The subject device and predicate device are indicated for creation of an atrial septal defect in the heart.
Fundamental scientific technology	Identical	The subject device and predicate device a device rely on use of controlled RF energy by the user for transeptal puncture.
Principal of Operation	Identical	The subject device and predicate device are operator controlled. RF energy is delivered via a compatible RF Generator / electrosurgical handpiece to the RF wire distal tip by the operator.
Method of Supply	Identical	Both the subject and predicate device are single use; Sterilized by Gamma radiation – Method VDmax ²⁵ ; Sterility Assurance Level of 10 ⁻⁶
Technological characteristics (Dimensions, design, materials)	Similar	<p>Both the predicate and subject device share the same fundamental design, in terms of:</p> <ul style="list-style-type: none"> • Insulation • Dimensions (e.g., overall outer diameter, overall length) • Configuration (i.e., tip shape) <p>The Subject Device differs from the predicate as follows:</p> <ul style="list-style-type: none"> • Material (i.e., Dymax 1184-M-T) <p>The minor design differences (i.e., adding of material, core wire grind profile) between the Subject and Predicate device do not raise new questions of safety or effectiveness.</p>
Energy Source	Identical	The subject device and predicate device can be used with 510(k) cleared compatible RF electrosurgical generator.
Packaging configuration	Identical	The Subject and Predicate device packaging configuration are identical. The HOTWIRE™ RF Guidewire (K252419) packaging was validated after environmental conditioning per ASTM D4332, transportation simulation per ASTM 4169 and 1 year accelerated aged equivalent.

PERFORMANCE DATA [807.92(b)]

Non-clinical bench top 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 inspection
 - Simulated use test
 - Arc integrity test
 - Fracture resistance test
 - Flexing test
 - Tensile Strength

Biocompatibility: Biocompatibility assessed for subject device. No impact to biocompatibility requirements. Refer to BEP-001 attached to the eSTAR.

CONCLUSION

The HOTWIRE™ RF Guidewire w/ device modifications (Subject Device) 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™ RF Guidewire is substantially equivalent in its intended use, design, material, performance, and the underlying fundamental scientific technology used, to the Predicate device (K252419).