August 12, 2025

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

Re: K252083
Trade/Device Name: HOTWIRE™ System RF Generator and Footswitch (optional accessory)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 24, 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.

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2025.08.12 17:51:01 -04'00'

James Jang, Ph.D.
Acting Assistant Director

DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252083

Please provide the device trade name(s).

HOTWIRE System RF Generator and Footswtich (optional accessory)

Please provide your Indications for Use below.

The HOTWIRE System RF Generator and Footswitch (optional accessory) is to be used with separately cleared RF puncture devices in cardiovascular transseptal access procedures to create an atrial septal defect.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

This 510(k) summary for HOTWIRE™ System RF Generator and Footswitch (optional accessory) is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendation outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)],* dated 28 July, 2014.

SUBMITTER [807.92(a)(1)]

Atraverse Medical, Inc.
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Date prepared: July 24, 2025

DEVICE [807.92(a)(2)]

Table 1: Device Information

Trade Name	HOTWIRE™ System RF Generator and Footswitch (optional accessory)
Common Name	Radiofrequency Generator
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation	21 CFR 878.4400
Product Code	GEI
Regulatory Classification	Class II
Device Panel:	General & Plastic Surgery

PREDICATE DEVICE [807.92(a)(3)]

Cross Vascular RF Generator and Footswitch (optional accessory) (K232809)

REFERENCE DEVICE

Baylis Medical Company Radiofrequency Perforation Generator, Model RFP-100A and optional footswitch (Model: RFA-FS) (K122278)

DEVICE DESCRIPTION [807.92(a)(4)]

The HOTWIRE™ System RF Generator (**Figure 1**) is a AC mains power-operated device used with compatible, separately cleared RF device (i.e., HOTWIRE™ RF guidewire - K240900) which

are connected to the RF Generator through a HOTWIRE™ System Handpiece. The RF Generator delivers power in a monopolar mode between the distal tip electrode and a commercially available patient return electrode such as the Valleylabs Patient Return Electrode Model #E7507 (K822572). An optional HOTWIRE™ System Footswitch may be used with the RF Generator. Refer to **Table 2** for the Model Numbers of the HOTWIRE™ System RF Generator and accessory devices covered by this application.

Table 2: Model Numbers for Subject Device and Accessories

Device Name/Description	Model Number
HOTWIRE™ System RF Generator	HB1
HOTWIRE™ System Footswitch	FS1

The HOTWIRE™ System RF Generator is used with HOTWIRE™ RF Guidewire in transseptal surgical procedures to puncture the fossa ovalis and gain access from the right side of the heart to the left atrium. The RF Generator is used to provide RF energy through the HOTWIRE™ System Handpiece and into the RF Guidewire to facilitate the septal puncture.

Figure 1: HOTWIRE™ System RF Generator

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

The HOTWIRE™ System RF Generator and Footswitch (optional accessory) is to be used with separately cleared RF puncture devices in cardiovascular transseptal access procedures to create an atrial septal defect.

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

The Subject and Predicate Devices are based on the same technological elements of generating, controlling and delivering RF power in a monopolar mode between the distal tip electrode of an RF device and commercially available Patient Return Electrode. The Subject and Predicate Devices both connect to RF devices through a connection cable, are electrically powered and have an optional, separately provided footswitch.

The minor differences do not impact the intended use and do not raise new questions regarding safety or effectiveness.

Table 3: Substantial Equivalence Comparison Table

Description	Subject Device	Predicate Device (K232809)	Reference Device (K122278)	Conclusion
Product Name	HOTWIRE™ System RF Generator	Cross Vascular RF Generator	Baylis Medical Company Radiofrequency Perforation Generator	
Manufacturer	Atraverse Medical, Inc.	Cross Vascular, Inc.	Baylis Medical Company Inc.	
Product Code / Regulation	GEI / 21 CFR 878.4400	GEI / 21 CFR 878.4400	GEI / 21 CFR 878.4400	Identical
Indications for Use	The HOTWIRE™ System RF Generator and Footswitch (optional accessory) is to be used with separately cleared RF puncture device (i.e., HOTWIRE™ RF Guidewire - K240900) in cardiovascular transseptal access procedures to create an atrial septal defect.	The Cross Vascular RF Generator and Footswitch (optional accessory) are to be used with separately cleared RF puncture devices in cardiovascular transseptal access procedures to create an atrial septal defect.	The BMC Radiofrequency Perforation Generator is indicated for use in general surgical procedures to cut and coagulate soft tissue	Similar. The difference in compatible RF device does not raise new questions of safety or effectiveness. The Subject device shall be specifically used with the HOTWIRE™ RF Guidewire (K240900).
Device Components	RF Generator	RF Generator	RF Generator	Identical
	N/A – device is not battery operated	Battery	N/A – device is not battery operated	Similar, minor design differences do not raise new questions of safety or effectiveness. Identical to Reference Device
		Charger		
	Footswitch (Optional)	Footswitch (Optional)	Footswitch (Optional)	Identical
Energy Delivery Type	Radiofrequency 470 kHz, Sinusoidal	Radiofrequency 462 kHz, Sinusoidal	Radiofrequency 468 kHz, Sinusoidal	Similar. Minor design differences do not raise new questions of safety or effectiveness.
Power Source	AC Mains	Lithium Ion Battery	AC Mains	Similar. Minor design differences do not raise new questions of safety or effectiveness. Identical to Reference Device
Output Power	Maximum 50 Watts	Maximum 25 Watts	Maximum 50 Watts	Identical to Reference Device
Output Current	Maximum 0.6 A	Maximum 0.5 A	Maximum 1.27 A	Similar, minor design differences do not raise new questions of safety or effectiveness.
Output Voltage	Maximum 494.98 V	Maximum 246 V	Maximum 565.77 V	Similar, minor design differences do not raise new questions of safety or effectiveness.
Measuring Accuracy: Power & Impedance	Impedance Range / Accuracy 200-800 ohm: ± 10% 800-3500 ohm: ± 20%	Impedance Range / Accuracy 200-800 ohm: ± 10% 800-3500 ohm: ± 20%	Impedance Range / Accuracy 100-1000 ohm: ± 10% 1000-3200 ohm: ± 15% 3200 – 6000 ohm: ± 20%	Identical to Predicate Device
Output Modes	Single Mode 100% Duty Cycle	Single Mode 100% Duty Cycle	100% Duty Cycle (“Constant”) Mode Or 30% Duty Cycle (“Pulse”) Mode	Identical to Predicate
Output Polarity	Monopolar	Monopolar	Monopolar	Identical
Neutral Electrode (NE) Type	Conductive	Conductive	Conductive	Identical
Dimensions	Width: 4.5 inches (11.4 cm) Length: 10.1 inches (25.7 cm) Height 4.6 inches (11.7 cm) Power Cord: 10 ft	Width: 7.8 inches (19.8 cm) Length: 9.7 inches (24.6 cm) Height (legs closed): 4.9 inches (12.4 cm) Height (legs extended): 6.2 inches (12.7 cm)	Width: 11.25 inches (28.5 cm) Length: 15.6 inches (39.6 cm) Height: 7 inches (17.8 cm) Power Cord: 10 ft	Similar, minor design differences do not raise new questions of safety or effectiveness.

Description	Subject Device	Predicate Device (K232809)	Reference Device (K122278)	Conclusion
Weight	4.90 lb (2.2 kg)	5.5 lb. (2.5 kg)	20lb. (9.1 kg)	Similar, minor design differences do not raise new questions of safety or effectiveness.
Storage Environmental Requirements	Temp: -20°C to 50°C Humidity: 90% non-condensing Pressure: 500 to 1060 millibar	Temp: -20°C to 50°C Humidity: 90% non-condensing Pressure: 500 to 1060 millibar	Temp: -20°C to 50°C Humidity: 90% non-condensing Pressure: 500 to 1060 millibar	Identical
Operating Environmental Requirements	Temp: 15°C to 40°C Humidity: 15% to 90% non-condensing Pressure: 700 to 1060 millibar	Temp: 15°C to 40°C Humidity: 15% to 90% non-condensing Pressure: 700 to 1060 millibar	Temp: 15°C to 40°C Humidity: 15% to 90% non-condensing Pressure: 700 to 1060 millibar	Identical

PERFORMANCE STANDARDS

The HOTWIRE™ System RF Generator has been developed in conformance with the following standards and FDA guidance, as applicable:

- IEC 60601-1:2005 + AMD1:2012 + AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- IEC 60601-2-2:2017 + AMD1:2023, 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
- IPC-A-600, Acceptability of Printed Boards Endorsement Program
- IPC-A-610, Acceptability of Electronic Assemblies
- ISTA Procedure 2A , [Shipping of] Packaged-Products weighing 150 lb (68 kg) or Less
- ROHS 2015/863/EU, Restriction of Hazardous Substances (RoHS)
- UL Standard 94, Standard for Tests for Flammability of Plastic Materials for Parts in Devices and Appliances (Ed. 6)
- IEC 62304:2015, Medical device software — Software life cycle processes
- FDA-2021-D-1158, Guidance on Cybersecurity in medical devices, September 2023
- FDA-2021-D-0775, FDA Guidance on Content of Premarket Submissions for Device Software Functions (June 14, 2023)
- ISO 15223-1:2021, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
- ISO 20417:2021, Medical devices – Information to be supplied by the manufacturer
- ISO 60417:2002, Graphical symbols for use on equipment
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff - September 27, 2023
- AAMI TIR57:2016 Principles for medical device security—Risk management
- Postmarket Management of Cybersecurity in Medical Devices – December 28, 2016
- Cybersecurity for Networked Medical Devices Containing Off- The-Shelf (OTS) Software - January 14, 2005
- Off-The-Shelf (OTS) Software Use in Medical Devices – September 27, 2019

NONCLINCAL PERFORMANCE DATA [807.92(b)(1)]

The following performance data were provided in support of the substantial equivalence determination.

Software Testing (including Cybersecurity)

The HOTWIRE™ System RF Generator software (SW) is custom software responsible for controlling the user interface and all device settings and outputs. The HOTWIRE™ System RF Generator SW integrates user input to control the following device states:

- SELF-TEST State
- Standby States
- Ready State
- RF On State
- Setting State
- Error State

The HOTWIRE™ System RF Generator SW is considered a Major Level of Concern whose risk has been appropriately assessed and mitigated and has undergone software validation and cybersecurity testing.

***In-Vivo* Evaluation**

Non-clinical *in vivo* performance and useability testing was completed to demonstrate safety and effectiveness of the subject device. All test requirements were met as specified by applicable standards and test protocols.

Bench Testing

Design Verification testing was conducted on the HOTWIRE™ System RF Generator and accessories (Footswitch) after being subjected to simulated transit conditions. The following types of testing were conducted:

- Transit Testing
- Labeling Verification
- Visual Inspection
- Unit Verification
    - Weight
    - Operational States
    - Display
- Functionality
    - Electrical

  - Footswitch
  - Alerts
- Compatibility
  - Footswitch
  - Neutral Electrode
- Durability

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the HOTWIRE™ System RF Generator. The testing complies with the applicable sections of IEC 60601-1:2005 + AMD1:2012 + AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, IEC 60601-1-2:2020, *Medical electrical equipment – Part 1-2: General requirements for the basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*, and IEC 60601-2-2:2017 + AMD1:2023, *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*. This testing is consistent with that conducted by the Predicate Device Cross Vascular RF Generator, Model RFG-01-00 and optional footswitch (Model: RFG-01-FS) (K232809).

CONCLUSIONS [807.92(b)(3)]

The HOTWIRE™ System RF Generator is of similar design to the Predicate Device and has similar technical requirements. The RF Generator performs as intended and presents no unacceptable risks to the intended patient population or end user. The software validation, electrical compatibility and safety testing, non-clinical bench, and animal study data support the safety of the device and demonstrate that the HOTWIRE™ System RF Generator performs as intended in the specified use conditions.

The HOTWIRE™ System RF Generator is substantially equivalent to the Predicate Device, Cross Vascular RF Generator, Model RFG-01-00, and optional footswitch (Model: RFG-01-FS) (K232809).