May 1, 2024

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

Re: K240900
Trade/Device Name: HOTWIRE™ RF Guidewire
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy catheter
Regulatory Class: Class II
Product Code: DXF
Dated: April 1, 2024
Received: April 1, 2024

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,

Katherine N. Trivedi
-S

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)*
K240900

Device Name
HOTWIRE™ RADIOFREQUENCY (RF) GUIDEWIRE

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.

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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, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)],* dated 28 July, 2014.

SUBMITTER [807.92(a)(1)]

Atraverse Medical, Inc.
2611 S Coast Hwy 101 #204
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Date prepared:	March 13, 2024

DEVICE [807.92(a)(2)]

Name of Device:	HOTWIRE™ RADIOFREQUENCY (RF) GUIDEWIRE
Common or Usual Name:	Catheter, Septostomy
Classification Name:	Catheter, Septostomy
Product Code:	DXF
Regulatory Class:	Class II
Submission Type:	Traditional 510(k)
Regulation Number:	21 C.F.R. 870.5175

PREDICATE DEVICE [807.92(a)(3)]

ProTrack RF Anchor Wire (K150709)

DEVICE DESCRIPTION [807.92(a)(4)]

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 (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 10-1: Devices that have undergone Compatibility Testing

Manufacturer	Device	510(k)
St Jude	Agilis NXT Steerable Introducer	K081645
Medtronic	FlexCath Steerable Sheath	K183174
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 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 3rd 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.

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 ProTrack RF Anchor Wire (K150709). Substantial equivalence is determined based on the following similarities:

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

Table 1 comprises the comparison between HOTWIRE™ (Subject Device) and ProTrack RF Anchor Wire (Predicate Device, K150709).

Table 1: Predicate Devices vs. Subject Device Comparison Table

Feature	ProTrack RF Anchor Wire K150709 [Predicate Device]	HOTWIRE™ RADIOFREQUENCY (RF) GUIDEWIRE [Subject Device]	Effect on Substantial Equivalence
Product Code	DXF	Same	None. Identical
Regulatory Class	Class II	Same	None. Identical
Regulation Number	21 CFR. 870.5175	Same	None. Identical
Regulation Name	Catheter, Septostomy	Same	None. Identical
Generic Name	Catheter, Septostomy	Same	None. Identical
Indications for Use Statement	Indicated for the creation of an atrial septal defect in the heart.	Same	None. Identical
Intended Use	Intended for the creation of an atrial septal defect in the heart.	Same	None. Identical

Performance			
Anatomical Location	General intravascular use, including cardio vasculature.	Same	None. Identical
Energy Source	Compatible RF electrosurgical generator such as BMC RFP-100A Puncture Generator (K122278).	Compatible RF electrosurgical generator such as Valleylab FT10 Electrosurgical Platform (K151649).	Both devices can be used with 510(k) cleared compatible RF electrosurgical generator. The HOTWIRE™ is determined to be equivalent to the predicate. The difference in RF generator source does not raise new questions of safety or effectiveness
Design			
Overall Length	180 cm and 230 cm	180 cm and 230 cm	None. Identical

Guidewire Outer Diameter	0.035”	0.032” and 0.035”	Identical: 0.035” Outer Diameter Similar: Subject device also offered in 0.032”. The additional diameter option does not raise new questions of safety or effectiveness
Core wire configuration	180cm – 230cm Stainless Steel Insulated Polymer	180 cm – 230 cm Stainless Steel Insulated Polymer	None. Identical
Tip Configuration	J Tip Pigtail	Straight J Tip Pigtail	Identical: Both devices offered in J-tip and Pigtail configurations. Similar: Subject device also offered in a Straight configuration. The additional configuration does not raise new questions of safety or effectiveness
Other Attributes			
Method of supply	Sterile and single use	Same	None. Identical
Sterilization method	Ethylene oxide gas	Gamma irradiation	Both the HOTWIRE™ and predicate device are supplied sterile with a Sterility Assurance Level of 10^{-6} and labeled for Single Use. The HOTWIRE™ is determined to be equivalent to the predicate. The difference in sterilization method does not raise new questions of safety or effectiveness
Disposal Instructions	Treat the used device(s) as biohazardous waste and dispose of in compliance with standard hospital procedures.	Same	None. Identical

Accessories	Connector Cable, Tip Straightener	Adaptor Pin, Tip Straightener	Identical: Both devices offer a tip straightener. Similar: The HOTWIRE™ utilizes an adaptor pin for compatibility with electrosurgical pencil / generator. The minor difference in connector types does not raise new questions of safety or effectiveness
Package configuration	Placed into a Dispenser hoop, sterile barrier pouch, shelf box, and shipper	Same	None. Identical

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing and Animal Testing: Results of the performance bench testing and animal testing (**Table 2**) indicate that HOTWIRE™ (Subject Device) meets established performance requirements, and is substantially equivalent for its intended use.

Table 2: Performance Bench Testing and Animal Testing Summary

Performance Bench Testing		
Tests	**Test Method Summary**	**Results**
Visual and Dimensional Inspection	Test samples were visually inspected for damage under 2.5X magnification. Inspect dimensions for overall length, outer diameter, distal shape per product specification, marker locations, and minimum marker length.	All test samples passed testing.
Simulated Use	Verify the *in vitro* performance of cardiovascular guidewires under simulated use conditions.	All test samples passed testing.

Performance Bench Testing		
Tests	**Test Method Summary**	**Results**
Arc Integrity	Test samples were visually inspected for damage under 2.5X magnification after successful arcing of the device	All test samples passed testing.
Tensile Strength	The minimum force to break the guidewire was tested per ISO 11070.	All test samples passed testing.
Corrosion Resistance	The test article is immersed in sodium chloride solution before being placed in boiling distilled or deionized water. Subsequently, the test article is examined visually for evidence of corrosion.	All test samples passed testing.
Torque Strength	Torque strength was determined by number of turns-to-failures.	All test samples passed testing.
Torqueability	Rotational input to output ratio (torqueability value) is compared to the predicate device.	All test samples passed testing.
Fracture Resistance and Flexing Test	Testing was conducted to determine the guidewire's resistance to damage by flexing and resistance to fracture per ISO 11070.	All test samples passed testing.
Tip Flexibility	Flexibility testing was conducted to determine the force required to induce buckling deformation when the device is held at 5, 10 and 20 mm from distal tip as compared to the predicate device	All test samples passed testing.
Particulate Characterization	Particulate matter in injections of the device were quantified.	All test samples passed testing.
Design Verification and Packaging Validation	This test is to evaluate the device design and packaging design and to demonstrate that the device will meet the product specification requirements at t=1 year	All test samples passed testing.

Performance Bench Testing		
Tests	**Test Method Summary**	**Results**
	time-point after exposing to 1x gamma irradiation sterilization.	
Performance Animal Testing		
Animal Testing (GLP)	Animal testing is to evaluate the *in vivo* performance of the device in an acute porcine model. Trackability and handling of the guidewire, radiopacity, compatibility with introducer kits and accessories, and thrombogenicity were assessed.	All test samples passed testing.

Biocompatibility: Results of the biocompatibility testing (**Table 3**) indicate that HOTWIRE™ (Subject Device) is biocompatible and is substantially equivalent for its intended use.

Table 3: Biocompatibility Test Summary

Test	Results	Conclusion
MEM Elution Cytotoxicity Assay (ISO) **ISO 10993-5**	The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity).	Non-toxic
Guinea Pig Maximization Test, 2 Extracts (ISO) **ISO 10993-10**	The test article extract showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.	Did not elicit sensitization response
Intracutaneous Reactivity Test, 2 Extracts (ISO) **ISO 10993-23**	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control article extract overall mean score was 0.0 and 0.0 for the NS and SSO test article extracts, respectively.	Non-irritant

Test	Results	Conclusion
Acute Systemic Toxicity Test, 2 Extracts (ISO) **ISO 10993-11**	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.	Non-toxic
Material Mediated Pyrogenicity Test (ISO / USP) **ISO 10993-11**	The test article met the requirements for the absence of pyrogens.	Non-pyrogenic
ASTM Hemolysis Assay, Direct and Extract Methods (ISO) **ISO 10993-4**	The test article in direct contact with blood had a mean blank corrected % hemolysis (hemolytic index) of 0.00% when compared to the negative control, and the test article extract had a mean blank corrected % hemolysis (hemolytic index) of 0.00% when compared to the negative control. Both the test article in direct contact with blood and the test article extract were Non-Hemolytic.	Non-Hemolytic
Complement Activation Assay, SC5b-9 Method (ISO) **ISO 10993-4**	The mean concentration of SC5b-9 in the test article sample was 9219.4 ng/mL and was higher, but was not statistically different ($p = 0.2594$) than the activated NHS (at 37°C) control and was higher, but was not statistically different ($p = 0.5832$) than the negative control. As a result, the test article was considered to be a non-activator of the complement system.	Passed
***In Vivo* Thrombogenicity Evaluation** **ISO 10993-4**	An *in vivo* evaluation of the HOTWIRE™ was performed to identify any potential thrombus formation associated with the HOTWIRE™ both locally and systemically. The thrombogenicity assessment was successfully completed for the HOTWIRE™ and Predicate Device. The HOTWIRE™ and Predicate Device both received a passing result of 0 on the Thrombus Formation Score, "Thrombus non-existent or minimal and, if present, appears to be associated with implant venotomy site. passing results".	Passed Comparison to the *in vivo* implant revealed a lack of thrombus formation associated with the article or in the major organs following acute implantation in a clinically relevant, heparinized model.

Test	Results	Conclusion
Heparinized Platelet and Leukocyte Count Assay (ISO) Extraction Ratio: 12cm^2/mL **ISO 10993-4**	The test article average platelet count was 80 to 120% of the vehicle control and the test article average platelet percentage value was at least 30% above the positive control. As a result, the test article met the requirements of the test.	Passed

EMC + Electrical Safety: Results of the EMC + Electrical Safety testing indicate that HOTWIRE™ is safe and is substantially equivalent for its intended use. The HOTWIRE™ meets applicable requirements listed out in IEC 60601-1 Ed. 3.2 en:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 60601-2-2:2018, IEC 60601-1-6:2010+A2:2021, and IEC 62366-1:2015+A1:2020

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: The packaging validation, T=1 year accelerated aging 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™.

Bacterial Endotoxin (LAL): The bacterial endotoxin (LAL) validation, was performed on the HOTWIRE™. The results from bacterial endotoxin (LAL) testing conducted on HOTWIRE™ showed that the acceptance criteria were met. Therefore, we can conclude the HOTWIRE™ bacterial endotoxin levels meet regulation requirements and that the device does not inhibit or enhance the detection of bacterial endotoxins.

Performance Standards

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

Standard	Title
EN ISO 13485:2016 EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971
BS EN 62366-1:2015 + AC:2015 +A1:2020	Medical devices-Application of usability engineering to medical devices
EN ISO 11137-1:2015 EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
ISO 11137-2:2015+A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11137-3:2017	Sterilization of health care products. Radiation-Guidance on dosimetric aspects of development, validation and routine control
EN ISO 11737-1:2018 EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices – Microbiological methods – Part 1: Estimation of population of microorganisms on products.
ISO 11737-2:2020	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process.
EN ISO 11607-1:2020 + A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020 + A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ASTM D4332-22	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F2096-11(2019)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection.
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
IS0 7000:2019	Graphical symbols for use on equipment - Registered symbols
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
ISO 10993-1:2018	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2017	Biological Evaluation of Medical Devices – Part4: Selection of Tests for Interactions with blood
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization
ISO 10993-11:2017	Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity
ISO 10993-17:2002	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
ISO 10993-18:2020 AMD 1:2022	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
ISO/TR 10993-19:2020	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO 10993-23:2021	Biological Evaluation of Medical Devices – Part 23: Tests for irritation
ASTM F756-17	Standard Practice for Assessment of Hemolytic Properties of Materials
ASTM F2382-18	Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)
ASTM F2888-19	An In-Vitro Measure For Hemocompatibility Assessment Of Cardiovascular Materials
ANSI/AAMI ST72	Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing.
IEC 60601-1, Ed. 3.2 EN:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-2:2018	Medical electrical equipment-Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-1-6:2010+A2:2021	Medical electrical equipment-General requirements for basic safety and essential performance. Collateral standard: Usability
IEC 62366-1:2015+A1:2020	Application of usability engineering to medical devices
EN ISO 11070:2014 EN ISO 11070:2014+A1:2018	Sterile Single Use Intravascular Introducers, Dilators and Guidewires
BS EN ISO 10555-1:2013+A1:2017	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements
FDA Guidance (2012) “Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers”	
USP Pharmacopeia Chapter <85>, Bacterial Endotoxin Test	
USP <788> Particulate Matter in Injections	
FDA Guidance (2019) "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling"	
FDA Guidance (2023) "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process""	
FDA Guidance (2019) "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations"	
FDA Guidance (2014) "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)"]	
FDA Guidance (2023) "How to Prepare a Traditional 510(k)"	
FDA Guidance (2023) "Electronic Submission Template for Medical Device 510(k) Submissions"	
FDA Guidance (2016) "Applying Human Factors and Usability Engineering to Medical Devices"	

CONCLUSIONS

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, ProTrack RF Anchor Wire (K150709)