June 26, 2026

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

Re: K261745
Trade/Device Name: LightningWire Transseptal Puncture System (TPS)
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy catheter
Regulatory Class: Class II
Product Code: DXF
Dated: May 26, 2026
Received: May 27, 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 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 Katherine N. Trivedi -S
Date: 2026.06.26 10:50:17 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261745

Device Name
LightningWire™ Transseptal Puncture System (TPS)

Indications for Use *(Describe)*
The LightningWire TPS is used to create an atrial septal defect in the heart, whereby various cardiovascular catheters are introduced.

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

510(k) Number: K_____ or TBD [**X**]

Date Prepared: May 4, 2026

Table 1: Submitter Information

Manufacturer: ElectroWire Medical 143 Industrial Drive Lexington, SC 29072 USA US FDA ERN: Pending	Manufacturer's Contact Person: Jennifer Willner, President JW Regulatory Consulting LLC Phone: (612) 240 - 8904 Email: Jennifer@JWRegulatoryConsulting.com

Table 2: Device Information

Trade Name	LightningWire™ Transseptal Puncture System (TPS)
Common Name	LightningWire Transseptal Puncture System (TPS)
Classification Name	Catheter, Septostomy
Regulation	21 CFR 870.5175
Product Code	DXF
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The LightningWire TPS is substantially equivalent to the previously cleared VersaCross RF Wire Predicate Device (**Table 3**) which has not been subject to a design-related recall.

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
VersaCross RF Wire (formerly Protrack RF Anchor Wire)	Boston Scientific (formerly Baylis Medical)	K150709

Device Description

The LightningWire Transseptal Puncture System (TPS) is a needle-free, powered, wire-based TPS that is used to create an inter-atrial septal defect, enabling transseptal access to the left atrium, whereby various catheter devices are introduced. The LightningWire TPS consists of a LightningWire with proprietary hydrophobic coating and an Activation Cable. The LightningWire TPS is provided in sterile condition, is labeled as non-pyrogenic and is for single use only.

The LightningWire TPS is a monopolar transcatheter electrosurgical accessory, wherein the tip of the LightningWire is the active electrode. Monopolar radiofrequency (RF) energy is delivered between the tip of the LightningWire and a commercially available dispersive electrode which is in compliance with IEC 60601-2-2, such as the ConMed SureFit™ Dual Dispersive Electrode (K120322). The LightningWire is designed to be inserted through a commercially available

transseptal introducer set, such as the Agilis NxT (K061363, K110450) or Fast-Cath SL1 (K061015), and features visible markers along its length to assist with aligning the LightningWire tip in a compatible transseptal sheath and/or dilator assembly. The LightningWire is radiopaque and echogenic for visibility by fluoroscopy and/or echocardiography. The LightningWire outer surface is jacketed in conformal, polymeric, electrically isolating coating for safe use with RF energy delivery. The LightningWire outer diameter is a maximum of 0.0326" (0.83mm) and is available in two lengths: 180 cm (Model 01-180) or 260 cm (Model 01-260).

The LightningWire TPS is reversibly connected to a commercially available electrosurgical generator (ESG), such as the Megadyne Megapower 1000 (K050579), by the Activation Cable, which includes an Activation Button that controls the flow of RF energy. The length of the Activation Cable is 3 meters.

Indications for Use

The LightningWire TPS is used to create an atrial septal defect in the heart, whereby various cardiovascular catheters are introduced.

Comparison of Technological Characteristics with the Predicate Device

The Subject and Predicate Device (K150709) both offer systems to access the left side of the heart by creating an atrial septal defect. They are based on the same technological elements of delivering RF power in a monopolar mode between their distal tip electrode and a commercially available dispersive electrode. Both devices are also loaded through commercially available transseptal introducer sets and have connections at their proximal end to a RF generator.

The following technological differences exist between the Subject and Predicate Devices:

- Materials of construction
  - The Subject and Predicate Devices both include electrosurgical guidewires with stainless steel cores, and both have PTFE coverings to improve electrosurgical and mechanical performance and safety. The Predicate Device uses a PTFE jacket, while the Subject Device combines a PTFE jacket with a proprietary, low-PTFE, low-friction (GlideMed®) coating.
- Core wire diameters
  - The Subject Device's core wire diameter along the body of the guidewire is approximately 0.0305 inches, while the Predicate Device's core wire diameter along the body of the guidewire is approximately 0.025 inches.
- Tip assembly
  - The Subject device uses an assembly of stainless steel hypotubes to secure the other guidewire components (core wire, coil, and PTFE jacket) at the tip assembly. The Predicate Device uses a reverse taper on its most distal guidewire core wire to secure the other guidewire components (coil and PTFE jacket) at the tip assembly.

These differences do not impact the intended use or raise new questions regarding safety or effectiveness of the device.

Performance Standards

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

- ISO 14971:2019, Medical devices – Application of risk management to medical devices
- IEC 62366-1:2015+A1:2020, Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 10993-1:2025, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", September 2023
- IEC 60601-1:2020, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014+A1:2020, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- IEC 60601-2-2:2017+A1:2023, 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
- IEC 60601-4-2:2016, Medical Electrical Equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ISO 11135:2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- AAMI TIR42:2021 Evaluation of Particulate Associated with Vascular Medical Devices
- ISO 11607-1:2019+A1:2023, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM D4169:2022, Standard Practice for Performance Testing of Shipping Containers

and Systems

- ISO 15223-1:2021+A1:2025, 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 11070:2014, Sterile single-use intravascular introducers, dilators and guidewires

Nonclinical Performance Data

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

Biocompatibility

Biocompatibility testing was performed on the LightningWire TPS in accordance with ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*. The panel of biocompatibility testing included the following recommended tests:

- Cytotoxicity
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Sensitization
- Hemocompatibility:
  - Hemolysis
  - Complement Activation
  - Partial Thromboplastin Time (PTT)
  - Heparinized Platelet and Leukocyte (PL&L) Count Assay with Comparison Article
  - In Vivo Thrombogenicity in Ovine
- Material Mediated Pyrogenicity

The results demonstrate that LightningWire TPS meets the requirements of ISO 10993-1 and is biocompatible for its intended use.

Sterilization

Sterilization validation adoption was performed on the LightningWire TPS in accordance with ISO 11135:2014 *Sterilization of health-care products- Ethylene Oxide- Requirements for development, validation and routine control of a sterilization process for medical devices*. The LightningWire TPS is subjected to a similar ethylene oxide (EO) sterilization process as the Predicate Devices to meet a sterility assurance level (SAL) of 10^{-6}.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the LightningWire TPS. The testing complies with the applicable sections of IEC 60601-1:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* IEC 60601-1-2: 2014 +A1: 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 60601-2-2:2023, *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.

Bench Testing

Design verification testing was performed on the LightningWire TPS at 2 time points: immediately after manufacturing (T=0) and after 1 year of accelerated aging (T=1 Yr AA). Devices were subjected to 2X sterilization and distribution simulation before the following types of testing were conducted:

- Packaging Integrity
- Label Integrity
- Visual & Dimensional
- Compatibility (ESG & introducer set)
- Electrical Functionality/Compatibility
- Mechanical Functionality
- RF Integrity (aka Arc Integrity)
- Flexibility
- Fracture
- Torqueability
- Tensile Strength
- Lubricity
- Particulate Generation
- Coating Integrity
- Radiopacity
- Echogenicity
- Corrosion Resistance

Substantial Equivalence

In comparison with the Predicate VersaCross Device (K150709), the LightningWire TPS has the same intended use and similar indications, technological characteristics and principles of operation as described in the comparison table below.

Table 4: Substantial Equivalence Comparison Table

Description	Subject Device	Predicate Device (K150709)	Analysis of Difference(s)
Product Name	LightningWire Transseptal Puncture System (TPS)	VersaCross RF Wire (formerly Protrack RF Anchor Wire)	
Manufacturer	ElectroWire Medical	Boston Scientific (formerly Baylis Medical)	
Product Code / Regulation	DXF / 21CFR 870.5175	DXF / 21CFR 870.5175	Same as PD
Indications for Use	LightningWire TPS is used to create an atrial septal defect in the heart, whereby various cardiovascular catheters are introduced	The [VersaCross RF Wire] is indicated for the creation of an atrial septal defect in the heart	Same as PD with addition of last clarifying phrase; no impact to safety or effectiveness
Principle of Operation	The LightningWire TPS is an RF-enabled guidewire that delivers localized electrical energy at its distal tip to enable precise, controlled crossing of the interatrial septum during transseptal puncture with reduced mechanical force.	Same	Same as PD
Energy Delivery	RF (monopolar mode)	RF (monopolar mode)	Same as PD
Energy Source	Compatible RF electrosurgical generator (ESG) such as the Megadyne Megapower 1000 (K050579)	Compatible Baylis RF Generator RFP-100A (K122278)	Similar to PD. Both devices use continuous, sinusoidal RF energy at frequencies of ~400-500 kHz; the difference in RF source does not raise new questions of safety or effectiveness.

ElectroWire

Description	Subject Device	Predicate Device (K150709)	Analysis of Difference(s)
Key Device Components	• LightningWire • Activation Cable with Handswitch and ESG Connector • Tip Straightener	• VersaCross RF Wire • Connector Cable with ESG Connector • Tip Straightener	Same as PD with addition of switch available to operator on sterile field as opposed to assistant outside of sterile field; no impact to safety or effectiveness
Size / Dimension	Diameter: 0.032" (≤ 0.83mm) Length: 180 cm and 260 cm Tip: Pigtail Coating Location: starts approximately 3 cm from the proximal end of the wire and ends underneath the PTFE jacket distally approximately 11 cm from the distal tip	Diameter: 0.035" (0.89 mm) Length: 180 cm and 230 cm Tip: J-tip or Pigtail Coating Location: starts approximately 4 cm from the proximal end of the wire and runs underneath the PTFE jacket distally, ending approximately 19 cm from the distal tip	Similar to PD; minor dimensional differences do not impact safety or effectiveness
Device Materials (Patient Contacting)	Wire Material: Stainless Steel Tip Material: Stainless Steel, Coating / Surface Material: PTFE jacket (distal), proprietary hydrophobic coating (proximal) Proximal Ramp: UV adhesive	Wire Material: Stainless Steel Tip Material: Unknown, likely precious metal tip Coating / Surface Material: Unknown material, insulated polymer (e.g. PTFE)	Similar to PD with addition of proprietary hydrophobic coating; no impact to safety or effectiveness
Packaging	Trayed in a Sterile Pouch and within a Shelf Carton	Trayed in a Sterile Pouch and within a Shelf Carton	Same as PD
Sterilization Method / SAL	EO / 10^{-6}	EO / 10^{-6}	Same as PD
Single-Use Devices?	Yes	Yes	Same as PD
Radiopaque?	Yes, radiopaque tip coil	Yes, radiopaque tip coil	Same as PD

Description	Subject Device	Predicate Device (K150709)	Analysis of Difference(s)
Shelf-Life	1 year, however may extend (e.g., ≥ 2 years) upon successful completion of testing to identical protocol	2 years	Similar to PD; 2-year shelf life for Subject Device to be assessed in future
Non-pyrogenic?	Yes	Yes	Same as PD

Conclusions

The LightningWire TPS is similar in material and design to the Predicate Device and has similar technical requirements. The LightningWire TPS performs as intended and presents no unacceptable risks to the intended patient population or end user. The non-clinical bench data supports the safety of the device and demonstrates that the LightningWire TPS performs as intended in the specified use conditions. The LightningWire TPS is substantially equivalent in intended use, technological characteristics, and safety and performance characteristics to the legally marketed Predicate Device (K150709).