



September 11th, 2025

Baylis Medical Technologies Inc.
Barb Boyce
Senior Regulatory Affairs Specialist
2645 Matheson Blvd. East
Mississauga, ON L4W 5S4
Canada

Re: K251158

Trade/Device Name: PowerWire® 14 Radiofrequency Guidewire Kit
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: August 8, 2025
Received: August 8, 2025

Dear Barb Boyce:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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,

Shelby

Buffington -S

Digitally signed by Shelby
Buffington -S
Date: 2025.09.11 17:25:52
-04'00'

For Gregory O'Connell

Assistant Director

DHT2C: Division of Coronary and
Peripheral Intervention 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)

K251158

Device Name

PowerWire® 14 Radiofrequency Guidewire Kit

Indications for Use (Describe)

The PowerWire® 14 Radiofrequency Guidewire is intended to create a channel in totally occluded peripheral vessels 3 mm or greater, including vessels with stents.

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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510k Summary

21 CFR 807.92

I. Submitter Information

Company Name: Baylis Medical Technologies Inc.

Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

Phone: (905) 948-5800

Contact Person: Barb Boyce

Summary Prepared on: 02-Sep-2025

II. Device Identification

Device Trade Name: PowerWire® 14 Radiofrequency Guidewire Kit

Device Common Name: Catheter for crossing total occlusions

Classification Name: Percutaneous catheter

Device Class: Class II per 21 CFR 870.1250

Device Code: PDU

III. Identification of Predicate Device

The predicate device is the PowerWire Radiofrequency Guidewire, which is cleared under 510(k) Premarket Notification Number K232562 (cleared 28-Feb-2024).

This predicate device has not been the subject of a design-related recall.

IV. Device Description

PowerWire 14 Radiofrequency Guidewire is a sterile, single-use device used to deliver radiofrequency (RF) energy. It is shipped as a sterile device kit containing one (1) PowerWire 14 RF Guidewire and one (1) RFP-100A Connector Cable (separately cleared under K230571) sealed in a double compartment pouch, which is then placed inside a shelf box and then an outer cardboard box. The device is sterilized using ethylene oxide.

The device consists of a core wire surrounded by a polymer insulation. The wire connects to a radiofrequency puncture generator at the proximal end via a connector cable (K230571) and has an active tip at the distal end to deliver radiofrequency energy.

The PowerWire 14 Radiofrequency Guidewire must be used with a cleared generator such as the Baylis Radiofrequency Puncture Generator (Baylis RF Generator K122278) and connector cable such as RFP-100A Connector Cable (K230571). The connector cable connects the generator to the PowerWire 14 RF Guidewire to enable RF energy to be delivered from the Generator to the PowerWire 14 RF Guidewire.

The PowerWire 14 Radiofrequency Guidewire delivers RF energy in a monopolar mode between its distal electrode and a commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrode.

The PowerWire 14 Radiofrequency Guidewire is available in both a 190 cm and 300 cm length with an outside diameter of 0.014". Each length is available in both straight and angled distal configurations which provide physicians with flexibility of choosing the most suitable guidewire for accessing target tissue in tortuous pathways in the body, with either straight or angled distal tips.

Once the occlusion is crossed, the PowerWire 14 Radiofrequency Guidewire can act as a rail for balloon catheters, or can be exchanged for other guidewires or devices cleared for peripheral interventional procedures. The PowerWire 14 Radiofrequency Guidewire is designed to be compatible with balloon catheters approved for use in peripheral interventional procedures.

V. Indications for Use

The PowerWire 14 Radiofrequency Guidewire is intended to create a channel in totally occluded peripheral vessels 3 mm or greater, including vessels with stents.

VI. Comparison to Predicate Device

The PowerWire 14 Radiofrequency Guidewire Kit and its predicate device share the same intended use, principle of operation and mechanism of action.

Comparison to Predicate Device

Detail	Subject Device Compared to Predicate PowerWire Radiofrequency Guidewire (K232562)	Comment
Legal Manufacturer	Identical	Baylis Medical Technologies Inc
FDA Product Code	Identical	PDU
Classification Name	Identical	Catheter For Crossing Total Occlusions
Classification Regulation	Identical	21 CFR 870.1250
Energy Type	Identical	Both use radiofrequency energy
Indications for Use	Identical	Both are intended to create a channel in totally occluded peripheral vessels, 3mm or greater including vessels with stents.
Fundamental Scientific Technology	Identical	Both utilize controlled RF energy to cross vascular occlusions

Mechanism of Action	Identical	Both devices cause tissue vaporization at the tip of the RF guidewire which results in the creation of a channel in the occlusive material.
Operating Principle	Identical	Both devices deliver RF energy in a monopolar mode between its distal electrode and a commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrode
Technological Characteristics (dimensions, design, materials)	Similar	Both the predicate and subject device share the same fundamental design, being an insulated core wire with an active tip. The subject device differs from the predicate device as follows: - Overall length - Wire outer diameter - Materials The differences do not raise different questions of safety or effectiveness.
Prescription/Over the counter use	Identical	Both devices are for prescription use only
Intended Users	Identical	Both are intended to be used by Interventional Radiologists & Vascular Surgeons
Sterilization Method	Identical	Both are single use and ethylene oxide sterilized.
Accessories	Identical	Both are designed to be used with Baylis Medical Company Radiofrequency Puncture Generator: RFP-100A (K122278), RFP-100A Connector Cable (K230571) (included in the kit) and a compatible grounding pad (separately cleared)

VII. Performance Data

In accordance with FDA guidance document: Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling, specified Baylis Medical Technologies requirements and relevant standards for non-clinical testing of medical devices, the following tests were conducted to confirm performance compared to the predicate device:

- Dimensional
- Simulated use
- Tip flexibility
- Proximal stiffness
- Torqueability
- Torque strength
- Radiopacity

- Resistance to user manipulation
- Distal curve retention
- Tensile strength / Tip pull
- Surface defects
- Fracture and kink resistance
- Flexing
- Arcing integrity
- Corrosion resistance
- Stent interaction
- Thermal Impact
- Packaging
- Sterilization

Electrical testing was performed to verify compliance of the device with the applicable clauses of IEC 60601-1, IEC 60601-2-2 and specified Baylis Medical Technologies requirements, including:

- Electrical impedance
- High frequency current leakage
- High frequency dielectric strength
- Mains frequency dielectric withstand

Biocompatibility testing was performed to verify the biological safety of the device as per the requirements of ISO 10993-1 and in accordance with the FDA guidance document “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and included the following tests:

- Cytotoxicity
- Sensitization
- Irritation (intracutaneous reactivity)
- Acute systemic toxicity
- Material mediated pyrogenicity
- Hemocompatibility (PTT, Hemolysis, thrombogenicity, complement activation)

Bench Validation testing was completed to confirm performance of the subject compared to the predicate device for use in various sizes of vessels, with and without stents.

VIII. Conclusions

The subject and predicate devices share the same intended use, principles of operation and mechanism of action. The results of verification and validation testing demonstrate that minor differences in design of the PowerWire 14 Radiofrequency Guidewire is substantially equivalent to the legally marketed predicate device.