February 28, 2024

Baylis Medical Technologies Inc.
Stephanie Gallone
Director of Quality, Regulatory, & Scientific Affairs
2645 Matheson Blvd. East
Mississauga, ON L4W5S4
Canada

Re: K232562
Trade/Device Name: PowerWire Radiofrequency Guidewire Kit
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: August 23, 2023
Received: August 24, 2023

Dear Stephanie Gallone:

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/tray. 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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.02.28 14:21:06 -05'00'

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

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)*
K232562

Device Name
PowerWire Radiofrequency Guidewire Kit

Indications for Use *(Describe)*

The PowerWire 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.

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: Stephanie Gallone

Summary Prepared on: 28-Feb-2024

II. Device Identification

Device Trade Name: PowerWire 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 K101615 (cleared 28-Jul-2010).
This predicate device has not been the subject of a design-related recall.

IV. Device Description

PowerWire 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 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 Radiofrequency Guidewire must be used with an approved Baylis Radiofrequency Puncture Generator (Baylis RF Generator K122278) and RFP-100A Connector Cable (K230571). The connector cable connects the RFP-100A BMC Radiofrequency Puncture Generator (RFP-100A Generator) to the PowerWire RF Guidewire to enable radiofrequency (RF) power to be delivered from the Generator to a PowerWire RF Guidewire.
The PowerWire Radiofrequency Guidewire delivers radiofrequency (RF) power in a monopolar mode between its distal electrode and a commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrode.

All models of the PowerWire Radiofrequency Guidewire have a usable length of 250cm and an outside diameter of 0.035". The various straight and curved distal configurations of the wires 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 Radiofrequency Guidewire can act as a rail for balloon or stent catheters, or can be exchanged for other guidewires or devices cleared for peripheral interventional procedures. The PowerWire Radiofrequency Guidewire is designed to be compatible with most balloon and stent catheters approved for use in peripheral interventional procedures.

V. Indications for Use

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

VII. Comparison to Predicate Device

The PowerWire Radiofrequency Guidewire Kit and its predicate device share the same intended use and fundamental technological characteristics, including principle of operation and mechanism of action. The results of verification and validation testing demonstrate the subject device does not raise new questions of safety or effectiveness as compared to the predicate device.

Table 14.2: Comparison to Predicate Device

Characteristic	**Proposed PowerWire RF Guidewire Kit Compared to PowerWire RF Guidewire (K101615)**
Intended Use	Identical
Indications for Use	Similar
Target Population/conditions of use	Identical
Fundamental technology	Identical
Operating principles	Identical
Mechanism of action	Identical
Device Models	Similar*
Performance	Identical

Characteristic	Proposed PowerWire RF Guidewire Kit Compared to PowerWire RF Guidewire (K101615)
Sterility	Identical
Packaging configuration	Identical
Environment of Use	Identical

The subject PowerWire Radiofrequency Guidewire Kit incorporates the design, materials, and methods of manufacture of the PowerWire Radiofrequency Guidewire predicate device (K101615).
*The subject device includes additional curved/angled models of the PowerWire RF Guidewire which only differ from the straight predicate device, in that they incorporate a curved/angled tip.

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
- Peak Tensile force / Tip pull
- Surface defects
- Fracture resistance
- Damage with repeated flexing
- Arcing integrity
- Corrosion resistance
- Bending fatigue

The 0-Day testing from the predicate device application (K101615) was leveraged for this device.

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
- Defibrillation

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 compared to the predicate device for use in vessels with stents and included Device-Stent Interaction Testing (simulated device use in stents, thermal safety and embolization).

A literature review was completed to evaluate the safety and performance of PowerWire when used for crossing totally occluded stents. The results of the literature review did not raise any new questions of safety and effectiveness and were used to determine the acceptability of the benefit-risk profile of PowerWire when used for crossing totally occluded stents.

VIII. Conclusions

The subject and predicate devices share the same intended use and fundamental scientific technology, including principles of operation, mechanism of action, design and technology. Differences in the indications for use between the proposed and predicate device do not raise any new concerns of safety and effectiveness. The results of verification and validation testing demonstrate that the PowerWire Radiofrequency Guidewire device does not raise new questions of safety or effectiveness and performs in a manner that is substantially equivalent to the predicate device.