November 1, 2024

Baylis Medical Company
Neethi Murali
Senior Regulatory Affairs Specialist
5825 Explorer Drive
Mississauga, ON L4W5P6
Canada

Re: K242076
Trade/Device Name: VersaCross™ RF Wire
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy Catheter
Regulatory Class: Class II
Product Code: DXF
Dated: October 3, 2024
Received: October 4, 2024

Dear Neethi Murali:

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.

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,

Kalkidan Molla -S

Kalkidan Molla
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)*
K242076

Device Name
VersaCross RF Wire

Indications for Use *(Describe)*
The VersaCross™ RF Wire 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

12. 510(K) SUMMARY

Submitter Information

A. *Company Name*:	Baylis Medical Company Inc.
B. *Company Address*:	5825 Explorer Drive Mississauga, Ontario L4W 5P6 Canada
C. *Company Phone*:	+1 (905) 602-4875
D. *Contact Person*:	Neethi Murali Senior Regulatory Affairs Specialist
E. *Date Summary Prepared*:	15-July-2024

Device Identification

A. *Device Trade Name*:	VersaCross™ RF Wire
B. *Device Common Name*:	Septostomy catheter
C. *Classification Name*:	CFR 870.5175 – Septostomy Catheter
D. *Product Code*:	DXF
E. *Device Class*:	Class II

Identification of Legally Marketed Device

Table 12.1: Predicate Device

Predicate Device	Manufacturer	510(k)	Indications for Use
ProTrack™ RF Anchor Wire	Baylis Medical Company Inc.	K150709	The ProTrack™ RF Anchor Wire is indicated for creation of an atrial septal defect in the heart.

Intended Use/ Indications for Use

The VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

Device Description

The subject VersaCross™ RF Wire is a single-use device that is supplied sterile to the user.

The subject device is comprised of an RF Wire and separately cleared Connector Cable (K023334) that are packaged together. The RF Wire is indicated for the creation of an atrial septal defect in the heart. The RF Wire delivers radiofrequency (RF) power in a monopolar mode between its distal active electrode and a commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrode/grounding pad. The RF Wire is used with a separately cleared compatible generator, such as the Baylis RF Puncture Generator (K122278).

The VersaCross™ RF Wire is comprised of a core stainless steel wire. The RF Wire body is covered with an insulating material to facilitate smooth advancement of the device in conjunction with providing electrical insulation. The floppy distal end of the RF Wire is curved and the active tip is rounded to be atraumatic to cardiac tissue unless RF energy is applied. A

marker coil and radio-opaque band is positioned on the distal curve and distal tip, respectively, to facilitate RF Wire placement at the target puncture site during procedures under appropriate imaging guidance such as fluoroscopy, echocardiography and/or electroanatomic mapping (EAM) guidance. The main body of the RF Wire provides a rail for advancing ancillary devices into the left atrium following creation of an atrial septal defect. The RF Wire features visible proximal markers along its length to assist with aligning the wire tip in compatible transseptal sheath and/or dilator assemblies. The proximal end of the RF Wire is bare metal to facilitate connection with the included connector cable. The other end of the included connector cable connects to the compatible Baylis RF Puncture Generator.

Comparison of Characteristics with Predicate Device

The intended use and indications for use of the proposed VersaCross™ RF Wire remains unchanged from the predicate ProTrack™ RF Anchor Wire (K150709). The subject and predicate device also share the same fundamental scientific technology, including principles of operation and mechanism of action and sterilization method. The subject device incorporates technological modifications to support the use of different devices, such as larger bore therapy catheters, to access the left atrium following transseptal puncture.

The technological differences between the subject and predicate devices do not raise new or different questions of safety and effectiveness. The results of verification and validation testing support substantial equivalence of the proposed VersaCross™ RF Wire with the predicate device. **Table 13.2** below provides a comparison of the subject and predicate devices.

Table 13.2: Comparison of Subject and Predicate Devices

Characteristic	Subject Device Compared to Predicate ProTrack™ RF Anchor Wire (K150709)	Comment
Intended Use / Indications for Use	Identical	Both subject and predicate device are indicated for creation of an atrial septal defect in the heart.
Fundamental scientific technology	Identical	Both subject and predicate device rely on use of controlled RF energy by the user for transseptal puncture.
Operating principle	Identical	Both subject and predicate device are operator controlled. The RF energy is delivered via the BMC RF Puncture Generator to the Wire's distal tip by the operator.
Mechanism of action	Identical	The mechanism of action for both subject and predicate device is cell vaporization and dielectric breakdown by RF energy.
Environment of Use	Identical	Both the subject and predicate device is used in facilities equipped with staff to perform diagnostic and interventional procedures.
Technological characteristics (Dimensions, design, materials)	Similar	Both the predicate and subject device share the same fundamental design. The subject device differs from the predicate device as follows: • Device usable length • Core wire shaft outer diameter • Distal taper length • Heat shrink insulation wall thickness • Presence of proximal markers

		• Clear instead of blue PTFE insulation
Packaging configuration	Similar	The predicate device is supplied in a dispenser coil with a tip straightener, placed in a double Tyvek®/Nylon pouch. The subject device is supplied in a dispenser coil with tip straightener in a tray with a lid, placed in a Tyvek®/Nylon pouch.
Sterilization method	Identical	Both subject and predicate device are Single Use, Ethylene Oxide sterilized

Summary of Non-Clinical Performance Testing

Non-clinical performance testing was completed to demonstrate safety and effectiveness and substantial equivalence of the subject device to the predicate device. All test requirements were met as specified by applicable standards and test protocols. The following verification and validation activities were completed to demonstrate the safety and effectiveness of the subject device:

Mechanical Testing

Mechanical verification was conducted for the subject device to ensure compliance with the applicable requirements of ISO 11070:2014/Amd.1:2018 and Baylis Medical Company Inc. requirements. The following mechanical tests were performed:

- Corrosion Resistance Test
- Distal Curve integrity test
- Joint Bending Test
- Flex test
- Fracture test
- Tensile test
- Bumper stiffness

Electrical Testing

Electrical testing was conducted for the subject device to ensure compliance of the device with relevant aspects of IEC 60601-2-2:2017, 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.

- HF Current leakage
- HF Dielectric Strength Test
- Mains Frequency Dielectric Withstand Test
- Electrical Resistance test

Thermal Testing

Arc Integrity testing to ensure compatibility of the subject device with the BMC RF Puncture Generator was conducted to verify compliance with Baylis self-enforced requirements.

General Physical Testing

General physical verification testing was conducted for the subject device to verify compliance with Baylis self-enforced requirements. The following general physical tests were performed:

- J curve Retention Test
- Pigtail Curve Retention Test

Biocompatibility Verification

The biological safety was evaluated for the subject device to verify compliance with the current applicable requirements of ISO 10993-1:2020 and the September 8, 2023 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".*

Sterilization Verification

Sterilization and residual limit verification were evaluated for the subject device to verify compliance with the current applicable requirements of ISO 11135:2014/A1:2019 and ISO 10993-7:2008/A1:2022. Sterilization was performed with Ethylene Oxide to a Sterility Assurance Level (SAL) of $10^{-6.}$

Pyrogen Testing

The subject device is supplied non-pyrogenic. Limulus Amoebocyte Lysate (LAL) testing was evaluated using the Kinetic Chromogenic method, as per ANSI/AAMI ST72:2019 and the FDA guidance document, *"Guidance for Industry – Pyrogens and Endotoxins Testing: Questions and Answers,"* to verify the subject device meets current FDA and USP pyrogen limit specifications.

Packaging Verification

Ship testing was evaluated to verify the integrity of the subject device packaging through the rigors of shipping and handling as well as storage over time. The sterile barrier integrity was also evaluated to verify compliance with the current applicable requirements of ISO 11607-1:2020 over the proposed intended shelf life of the subject device.

Benchtop Validation

Customer requirements were validated through benchtop validation activities. Benchtop validation testing evaluated subject device design, compatibility with commercial impedance based electroanatomical mapping (EAM) systems and performance during normal and worse case intended use and was completed using an appropriate representative anatomical model.

Non-clinical Performance Testing recommended per FDA guidance Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommend Labeling

- Dimensional verification and Visual Inspection
- Repeated Simulated use
- Tensile strength
- Torque strength
- Torqueability
- Kink resistance

The proposed VersaCross™ RF Wire met all test requirements as specified by applicable standards and test protocols. The verification and validation activities for safety and effectiveness, along with the testing completed for the design changes demonstrated the subject device meets its intended use and is as safe, as effective, and performs in a manner that is substantially equivalent to the predicate device.

Conclusion

The subject and predicate device share the same intended use, indications for use and fundamental scientific technology, including principles of operation and mechanism of action. Technological differences between the subject and predicate devices do not raise new or different questions of safety and effectiveness. The results of verification and validation activities support substantial equivalence of the proposed VersaCross™ RF Wire to the predicate device.