December 14, 2023

Baylis Medical Company, Inc.
Christina Dowd
Senior Regulatory Affairs Specialist
5825 Explorer Drive
Mississauga, ON L4W5P6
Canada

Re: K233647
Trade/Device Name: VersaCross Connect™ Transseptal Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: November 13, 2023
Received: November 14, 2023

Dear Christina Dowd:

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

for Rachel Neubrander
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K233647

Device Name
VersaCross Connect™ Transseptal Dilator

Indications for Use *(Describe)*
The VersaCross Connect™ Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(K) SUMMARY (K233647)

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*:	Christina Dowd Senior Regulatory Affairs Specialist
E. *Date Summary Prepared*:	13-Nov-2023

Device Identification

A. *Device Trade Name*:	VersaCross Connect™ Transseptal Dilator
B. *Device Common Name*:	Dilator
C. *Classification Name*:	CFR 870.1310 – Vessel dilator for percutaneous catheterization
D. *Product Code*:	DRE
E. *Device Class*:	Class II

Identification of Legally Marketed Device

Table 13.1: Predicate Device

Predicate Device	Manufacturer	510(k)	Indications for Use
VersaCross Connect™ Transseptal Dilator	Baylis Medical Company Inc.	K220414	The VersaCross Connect™ Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.

Intended Use/ Indications for Use

The VersaCross Connect™ Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.

Device Description

The subject VersaCross Connect™ Transseptal Dilator is a single-use device that is supplied sterile to the user. The device is comprised of a single dilator.

The subject VersaCross Connect™ Transseptal Dilator represents modifications made to the dilator component of the legally marketed VersaCross Connect™ Transseptal Dilator (K220414) (comprising of a dilator and J-tipped guidewire). A guidewire is not supplied with the subject device. However, the end user can use a separately cleared compatible 0.035" guidewire.

The VersaCross Connect™ Transseptal Dilator is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The dilator provides torque control and is flexible. The dilator features a tapered tip and a shaft that can be reshaped manually. The echogenic shaft and tip and radiopaque tip maximize visualization of the dilator during manipulation in procedures.

The dilator can be used with separately cleared compatible access sheaths such as FARADRIVE™ Steerable sheaths. The dilator may also be used as a standalone device to facilitate access to the left atrium following transseptal puncture. The dilator provides support and helps guide separately cleared compatible transseptal wires to the atrial septum for puncture. The dilator subsequently dilates the atrial septal defect to enable larger diameter devices to cross the septum. The subject device can be used by electrophysiologists, interventional cardiologists, and other users trained in catheter techniques for any procedure that requires left atrial access via transseptal puncture.

Procedures using the devices are performed in fully equipped catheter labs with imaging equipment, including fluoroscopy and echocardiography under sterile technique.

Comparison of Characteristics with Predicate Device

The intended use and indications for use of the proposed VersaCross Connect™ Transseptal Dilator remains unchanged from the predicate VersaCross Connect™ Transseptal Dilator (K220414). The subject and predicate devices also share the same fundamental scientific technology, including principles of operation and mechanism of action, packaging configuration and sterilization method.

The differences between the predicate and subject device are due to dimensional and design updates for compatibility with separately cleared compatible access sheaths, removal of a guidewire supplied with the device, and labeling update to reflect use of the subject dilator with and without a compatible access sheath.

Differences between the subject and predicate devices do not raise new or different questions of safety and effectiveness (**Table 13.2**). The results of verification and validation testing provide reasonable assurance of substantial

equivalence of the proposed VersaCross Connect™ Transseptal Dilator with the predicate device.

Table 13.2: Comparison of Subject and Predicate Device

Characteristic	Subject Device Compared to Predicate VersaCross® Connect™ Transseptal Dilator (K220414)	Comment
Intended Use	Identical	Both subject and predicate device are indicated for use in procedures where access to the left atrium via the transseptal technique is desired.
Indications for Use	Identical	
Fundamental scientific technology	Identical	Both subject and predicate device rely on transfer of mechanical force to achieve tissue dilation.
Operating principles	Identical	The principles of operation for both subject and predicate device is the transfer of mechanical force to achieve tissue dilation.
Mechanism of action	Identical	Both subject and predicate device dilate tissue to achieve its intended use.
Environment of Use	Identical	Both the predicate and subject device are used in facilities equipped with staff to perform diagnostic and interventional procedures.
Material	Identical	Both the predicate and subject device contain the same patient contacting materials.
Technological characteristics (Dimensions, design)	Similar	Both the predicate and subject device share the same fundamental design. The subject device differs from the predicate device as follows: • Dilator shaft dimensional changes • Taper tip length change

		• Snap fit hub geometry change • No guidewire supplied with dilator • One curve size option; Update to curve radius and reach
Labeling	Similar	Option to use without a compatible sheath.
Packaging configuration	Identical	The predicate and subject device contain the same packaging (pouch, die cut card, shelf box and shipper box).
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 substantial equivalence 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:

- Torque Transmission
- Torque Withstand
- Hub-Shaft Tensile
- Flexural Rigidity
- Shapeability
- Curve Retention
- Tip to Tip Cap Cantilever and Tensile

- Clamshell Tensile
- Clamshell Cantilever
- Shaft Joint Tensile Strength
- Shaft Friction test

General Physical Testing

General physical verification was conducted for the subject device to ensure compliance with the applicable requirements of ISO 11070:2014/Amd.1:2018, ISO 80369-7: 2021, and Baylis Medical Company Inc. requirements. The following general physical test was performed:

- Luer Tests
- Air and Liquid Leakage Tests
- Corrosion Test

System Verification Testing

System verification tests were conducted for the subject device to verify the compatibility with compatible guidewires, introducer and accessory sheaths as well as to verify the force required to snap and unsnap the subject device and the compatible accessory sheath based on Baylis Medical Company Inc. requirements.

- Compatibility Test
- Snap Force Test

Biocompatibility Verification

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.*"

Biocompatibility verification of the subject VersaCross™ Connect Transseptal Dilator was conducted through adopted biological data of the predicate device VersaCross® Connect Transseptal Dilator (K220414).

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 was performed to validate the performance of the subject device during normal intended use as per current applicable requirements of ISO 11070:2014/Amd.1:2018 and Baylis requirements.

The proposed VersaCross Connect™ Transseptal Dilator met all test requirements as specified by applicable standards and test protocols. The verification and validation activities for safety and effectivenenss, 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.

Conclusions

The subject and predicate devices share the same indications for use, intended use, and fundamental scientific technology, including principles of operation and mechanism of action. 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 Connect™ Transseptal Dilator to the predicate device.