May 9, 2022

Baylis Medical Company Inc.
May Tsai
Director of Regulatory Affairs
5825 Explorer Dr.
Mississauga, Ontario L4W 5P6
Canada

Re: K220414
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: April 11, 2022
Received: April 13, 2022

Dear May Tsai:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

Enclosure

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)*
K220414

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.

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13. 510(K) SUMMARY (K220414)

Submitter Information

A. *Company Name*: Baylis Medical Company Inc.

B. *Company Address*: 5825 Explorer Drive
Mississauga, Ontario L4W 5P6
Canada

C. *Company Phone*: (905) 602-4875

D. *Contact Person*: May Tsai
Director, Regulatory Affairs

E. *Date Summary Prepared*: 21-April-2022

Device Identification

A. *Device Trade Name*: VersaCross Connect™ Transseptal Dilator

B. *Device Common Name*: Dilator, Vessel, For Percutaneous Catheterization

C. *Classification Name*: CFR, 870.1310 - Dilator, Vessel, 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
ExpanSure™ Large Access Transseptal Dilator	Baylis Medical Company Inc.	K201288	The ExpanSure Large Access Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.

This 510(k) is also citing the legally marketed VersaCross Transseptal Sheath, dilator component (VCD) (K183655) and Portage System, Portage Knot Pusher component (K161878) as reference devices to support material modifications in the subject device.

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 device is comprised of the following components, which are single-use and supplied sterile to the user:

- One Dilator
- One J-tipped Guidewire

The subject VersaCross Connect™ Transseptal Dilator represents modifications made to the legally marketed ExpanSure™ Large Access Transseptal Dilator (K201288) (comprising a dilator and J-tipped 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.

The dilator can be used with separately cleared compatible introducer/access sheaths such as WATCHMAN™ Access sheaths. 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. It is used in catheterization procedures primarily by Electrophysiologists and Interventional Cardiologists. Procedures using the devices are performed in fully equipped catheter labs with imaging equipment, including fluoroscopy and echocardiography under sterile technique.

Comparison to Predicate Device

The intended use and indications for use of the of the VersaCross Connect™ Transseptal Dilator remains unchanged from the ExpanSure™ Large Access Transseptal Dilator (K201288).

The subject and predicate devices also share the same fundamental scientific technology, including principles of operation and mechanism of action.

Differences in technological characteristics 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 VersaCross Connect™ Transseptal Dilator with the predicate device.

Table 13.2: Comparison of Subject and Predicate Device

Characteristic	**Subject Device Compared to Predicate ExpanSure™ Large Access Transseptal Dilator (K201288)**
Intended Use	Identical
Indications for Use	Identical
Fundamental scientific technology	Identical
Operating principles	Identical
Mechanism of action	Identical
Technological characteristics (Materials, dimensions, design)	Similar
Packaging configuration	Identical
Sterilization method	Identical

Performance Testing

Non-clinical performance testing was completed for the subject device to demonstrate its safety and effectiveness for its intended use and to support substantial equivalence to the predicate device. The following verification and validation activities were completed to support the device modifications:

Mechanical Testing

Mechanical verification was conducted for the subject device to verify compliance with the applicable requirements of ISO 11070:2014/Amd.1:2018 and Baylis self-enforced 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

General Physical Testing

General physical verification was conducted for the subject device to verify compliance with the applicable requirements of ISO 11070:2014/Amd.1:2018, ISO 80369-7, and Baylis self-enforced requirements. The following general physical tests were 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 self-enforced 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 4, 2020 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 device was performed through adoption of biological data from Baylis Medical Company Inc.'s legally marketed devices; the predicate device ExpanSure Large Access Transseptal Dilator (K201288), reference devices VersaCross® Transseptal Sheath, dilator component (VCD) (K183655) and Portage Knot Pusher (component of legally marketed Portage System (K161878)).

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 and ISO 10993-7:2008/Cor.1:2009. 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 ST72:2011/(R)2016 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 seal strength and 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 11070:2014/Amd.1:2018 and Baylis self-enforced requirements.

The VersaCross Connect™ Transseptal Dilator met all test requirements as specified by applicable standards and test protocols. The verification and validation activities 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 in technological characteristics 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 VersaCross Connect™ Transseptal Dilator to the predicate device.