May 20, 2019

Baylis Medical Company Inc.  
Meghal Khakhar  
VP, Regulatory and Scientific  
2645 Matheson Blvd. East  
Mississauga, L4W 4J1 Canada  

Re: K183655  
Trade/Device Name: VersaCross Transseptal Sheath  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter Introducer  
Regulatory Class: Class II  
Product Code: DYB  
Dated: April 24, 2019  
Received: April 25, 2019

Dear Ms. Khakhar:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 E. Neubrander -S

for Nicole Ibrahim
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
Indications for Use

Device Name
VersaCross Transseptal Sheath

Indications for Use (Describe)
The VersaCross Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture.

Type of Use (Select one or both, as applicable)

- [X] 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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510(K) SUMMARY

Submitter Information
A. Company Name: Baylis Medical Company Inc.
B. Company Address: 2580 Matheson Blvd. East
Mississauga, Ontario, L4W 4J1 Canada
C. Company Phone: +1 (905) 602-4875
D. Company Facsimile: +1 (905) 602-5671
E. Contact Person: Meghal Khakhar
VP, Regulatory & Scientific Affairs
F. Summary Prepared on: 19-DEC-2018

Device Identification
A. Device Trade Name: VersaCross™ Transseptal Sheath
B. Device Common Name: Introducer Sheath kit
C. Classification Name: Introducer, Catheter (21 CFR 870.1340)
D. Product Code: DYB
E. Review Panel: Cardiovascular
F. Device Class: Class II

Identification of Legally Marketed Device
A. Predicate Device: Torflex Transseptal Guiding Sheath
B. Manufacturer: Baylis Medical Company Inc.
C. 510(k) K102948
D. Indications for Use: The Torflex™ Transseptal Guiding Sheath is used for the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal perforation / puncture.

Indications for Use
The VersaCross™ Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture.
Device Description
The VersaCross™ Transseptal Sheath is a sterile, single-use introducer catheter device. The device is comprised of a sheath (VersaCross™ Sheath), a dilator (VersaCross™ Dilator) and a j-tipped guidewire.

The VersaCross™ Transseptal Sheath is designed for catheterization and angiography of specific heart chambers and locations. 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 for the VersaCross™ Transseptal Sheath remains unchanged from the predicate TorFlex™ Transseptal Guiding Sheath (K102948). The indications for use of the subject device is identical to that of the predicate except for the addition of guidewires in addition to cardiovascular catheters as devices that can be introduced to the heart. This difference provides clarification only and does not change the intended use of the subject device as compared to the predicate device.

The proposed and predicate devices share the same fundamental scientific technology, including principles of operation and mechanism of action (see Table 11.1 below). The differences in design and technological characteristics between the proposed and predicate devices do not raise different questions of safety and effectiveness. The results of verification and validation testing provide reasonable assurance of substantial equivalence of the VersaCross™ Transseptal Sheath with the predicate device.

Table 11.1: Comparison of Subject and Predicate Device

<table>
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<tr>
<th>Characteristic</th>
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<tr>
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<tr>
<td>Packaging and Sterilization</td>
<td>Identical</td>
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Performance Testing Summary
Performance Testing has been completed to demonstrate substantial equivalence of the subject device and predicate device. All test requirements were met as specified by applicable standards and the test protocols. The device was subjected to the following verification and validation activities.

Mechanical Testing
Mechanical verification testing was conducted for the subject VersaCross™ Transseptal Sheath to ensure compliance with the requirements of ISO
11070:2014 and Baylis Medical Company Inc. self-enforced requirements. The following tests were performed:

- Sheath Mechanical Tests:
  - Torque Transmission + Hub to Shaft Joint Torque
  - Shaft Stiffness Bend
  - Tip Stiffness
  - Air and Liquid Leakage – Sheath
  - Air and Liquid Leakage – Hemostasis Valve
  - Tensile Tests
  - Cap Integrity Tests
  - Valve Insertion Force
  - Snap Force
- Dilator Mechanical Tests:
  - Torque Transmission
  - Strength of Union – Torque Withstand
  - Strength of Union – Pull Test Hub to Body
  - Flexural Rigidity

**General Physical Testing**
General physical verification testing was conducted for the subject VersaCross™ Transseptal Sheath to ensure compliance with ISO 11070:2014 and Baylis Medical Company Inc. self-enforced requirements. The following tests were performed:

- Sheath General Physical Tests:
  - Curve Relaxation
  - Surface Defects
  - Corrosion Resistance
  - Shaft Lubricity
  - Coating Particulate
- Dilator General Physical Tests:
  - Air Leakage
  - Liquid Leakage
  - Shapeability
  - Luer Tests
  - Corrosion Resistance

**Biocompatibility Verification**
The biological safety of the subject VersaCross™ Transseptal Sheath was verified in accordance with the requirements of ISO 10993-1:2009/Cor.1:2010 and the June 16, 2016 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 verification was completed for the subject VersaCross™ Transseptal Sheath to the requirements of ISO 11135-1:2014. Sterilization is performed with Ethylene Oxide to a Sterility Assurance Level (SAL) of $10^{-6}$. Residual limits are in accordance with ISO 10993-7:2008/Cor.1:2009.
Packaging
Ship testing was performed to ensure the integrity of the device packaging through the rigors of shipping and handling. The seal strength and sterile barrier integrity was validated per ANSI/AAMI/ISO 11607:2006 (Parts 1 and 2) over the proposed shelf life of the device.

Pyrogen Testing
The subject VersaCross™ Transseptal Sheath is supplied non-pyrogenic. LAL testing using the Kinetic Chromogenic method was conducted to ensure the device meets current FDA and USP pyrogen limit specifications.

Bench-top Validation
Bench-top validation testing was conducted to assess valve durability of the sheath, radiopacity, compatibility with other devices and to evaluate the design and function.

Conclusion
The intended use and fundamental scientific technology, including principles of operation and mechanism of action, of the subject VersaCross™ Transseptal Sheath remain unchanged from the predicate TorFlex™ Transseptal Guiding Sheath (K102948). Differences in design and technological characteristics do not raise any different questions of safety and effectiveness. The results of verification and validation activities support the substantial equivalence of the subject VersaCross™ Transseptal Sheath to the predicate device.