April 17, 2019

Baylis Medical Company Inc.
May Tsai
Regulatory Affairs Manager
2580 Matheson Blvd. E
Mississauga, Ontario L4W 4J1
Canada

Re: K190688
Trade/Device Name: VersaCross Steerable Sheath, VersaCross Transseptal Dilator
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 15, 2019
Received: March 18, 2019

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/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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K190688

Device Name
VersaCross Steerable Sheath
VersaCross Transseptal Dilator

Indications for Use *(Describe)*
The VersaCross Steerable Sheath and VersaCross Transseptal Dilator is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

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:

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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."*

# 7. 510(k) Summary

## 7.1 Submitter Information

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

B. *Company Address*: 2580 Matheson Blvd. East
Mississauga, Ontario L4W 4J1
Canada

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

D. *Company Facsimile*: (905)602-5671

E. *Contact Person*: May Tsai

F. *Summary Prepared on*: 15-Mar-2019

## 7.2 Device Identification

A. *Device Trade Name*: VersaCross Steerable Sheath
VersaCross Transseptal Dilator

B. *Device Common Name*: Catheter introducer

C. *Classification Name*: 21 CFR 870.1340, *Catheter introducer*

D. *Product Code*: DYB

E. *Device Class*: Class II

## 7.3 Identification of Predicate Device

The predicate for the VersaCross Steerable Sheath kit is listed in **Table 1**.

**Table 1**: Legally Marketed Predicate Device

| Predicate Device | Manufacturer | Intended Use | 510(k) |
|---|---|---|---|
| SureFlex Steerable Guiding Sheath | Baylis Medical Company Inc. | Indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum | K122926 |

## 7.4 Indications for Use

The VersaCross Steerable Sheath and VersaCross Transseptal Dilator is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

## 7.5 Device Description

The VersaCross Steerable Sheath kit is a sterile, single-use device designed for safe and easy catheterization and angiography of specific heart chambers and locations. The VersaCross Steerable Sheath kit is comprised of a steerable sheath, a transseptal dilator and a J-tip guidewire. The steerable sheath is comprised of a stainless steel braided nylon tube with a Pebax distal tip. The sheath has a platinum/iridium marker band positioned near the distal tip to facilitate tracking and placement of the sheath under fluoroscopy during procedures. The sheath is finished at the proximal end with a hemostatic valve and two distal side ports and has a 3-way stopcock to facilitate the injection or aspiration of fluids. The sheath is available in three curve options (i.e. small, medium, and large) that can be deflected 90° counter-clockwise and 180° clockwise. The transseptal dilator is comprised of a high density polyethylene (HDPE) tube and a stainless steel hypotube. The dilator also has a tungsten coil positioned near the distal tip to facilitate tracking and placement of the dilator under fluoroscopy during procedures. The dilator has a tapered tip and a male luer hub connector at the proximal end for connection to the sheath. The J-tip guidewire is comprised of stainless steel coated with polytetrafluoroethylene (PTFE).

## 7.6 Comparison to Predicate Device

The characteristics of the proposed and predicate devices are compared in **Table 2**.

**Table 2**: Comparison between Characteristics of Proposed and Predicate Devices

| Characteristic | Status |
|---|---|
| Intended Use | Identical |
| Indications for Use | Identical |
| Fundamental scientific technology | Identical |
| Operating principles | Identical |
| Mechanism of action | Identical |
| Materials | Similar |
| Key technological characteristics (e.g. dimensions) | Similar |
| Accessory devices | Identical |
| Packaging configuration | Similar |
| Environment of use | Identical |
| Sterility and Reusability | Identical |
| Sterilization method | Identical |

## 7.7 Performance Testing

Non-clinical performance testing was completed for the VersaCross Steerable Sheath kit to support its safety and effectiveness with regards to the intended use as well as substantial equivalence[1] to the predicate device. The following verifications and validations were completed to support the changes incorporated in the proposed device:

1. Biocompatibility Verification: The biological safety of the VersaCross Steerable Sheath kit was verified as per the requirements of ISO 10993-1:2009/Cor.1:2010 and FDA's modified ISO guidelines 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".*
2. General Physical Verification: General physical verification was performed to verify compliance of the VersaCross Steerable Sheath kit with ISO 11070:2014, ISO 594-1:1986, ISO 594-2:1998 and specified Baylis Medical requirements.
3. Mechanical Verification: Mechanical verification was performed to verify compliance of the VersaCross Steerable Sheath kit with ISO 11070:2014 and specified Baylis Medical requirements.
4. Packaging Verification: Ship testing verification was performed to ensure the integrity of the packaging of VersaCross Steerable Sheath kit through the rigors of shipping and handling. Stability testing was also completed to demonstrate the integrity of the primary packaging (i.e. sterile barrier) as per ANSI/AAMI/ISO 11607-1:2006 and ANSI/AAMI/ISO 11607-2:2006 over the proposed device shelf life.
5. Sterilization Verification: Sterilization verification was performed to verify that the VersaCross Steerable Sheath kit is sterilized as per ISO 11135:2014 to a sterility assurance level of $10^{-6}$ and meets the requirements of ISO 10993-7:2008/Cor.1:2009.
6. Bench Validation: Validation testing was completed to evaluate the performance of the kit during normal use as per specified Baylis Medical requirements. Testing was also completed to validate the radiopacity of the kit as per ISO 11070:2014.

The VersaCross Steerable Sheath kit met all requirements as specified by the test protocols.

[1] This document uses the term "substantial equivalence" as defined in 21 CFR 807.100 and not as defined in Title 35 of the U.S. Code. Any statement made in conjunction with this submission regarding substantial equivalence as well as any reference to features being "identical" with respect to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, ". . . a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without premarket approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42.520 et seg. (1977).

## 7.8 Conclusion

The proposed and predicate devices share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. Design and technological differences between the proposed and predicate devices do not raise any new concerns of safety and effectiveness. The results of verification and validation testing demonstrate that the VersaCross Steerable Sheath kit is as safe, as effective, and performs in a manner that is substantially equivalent to the predicate device.