December 20, 2023

Baylis Medical Company Inc.
Shilpa Sharma
Senior, Regulatory Affairs Specialist
5825 Explorer Dr.
Mississauga, Ontario L4W 5P6
Canada

Re: K231227
Trade/Device Name: SureFlex HD Steerable Sheath, VersaCross HD Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 17, 2023
Received: November 20, 2023

Dear Shilpa Sharma:

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,

for Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2023.12.20 12:45:12 -05'00'

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,

Diagnostic and Monitoring Devices
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.

Submission Number *(if known)*

K231227

Device Name

SureFlex HD Steerable Sheath, VersaCross HD Steerable Sheath

Indications for Use *(Describe)*

The sheath is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

The sheath curve can be visualized when used with impedance-based electroanatomical mapping systems.

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.

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12.0 510(K) SUMMARY - K231227

Submitter Information

A.	*Company Name:*	Baylis Medical Company Inc.
B.	*Company Address:*	5825 Explorer Dr. Mississauga, Ontario, L4W 5P6 Canada
C.	*Company Phone:*	+1 (905) 602-4875
D	*Company Facsimile:*	+1 (905) 602-5671
E.	*Contact Person:*	Shilpa Sharma Senior, Regulatory Affairs Specialist
F.	*Summary Prepared on:*	27-April-2023

Device Identification

A.	*Device Trade Name:*	SureFlex HD Steerable Sheath, VersaCross HD Steerable Sheath
B.	*Device Common Name:*	Catheter Introducer
C.	*Classification Name:*	Catheter Introducer (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:*	CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath
B.	*Manufacturer:*	Biosense Webster Inc.
C.	*510(k)*	K170997
D.	*Indications for Use*	The Biosense Webster CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The sheath curve can be visualized when used with compatible CARTO® 3 EP Navigation Systems.

This 510(k) is also citing the legally marketed VersaCross and TorFlex Transseptal Dilators (K190688) as reference devices to support dimensional and material aspects of the subject device's transseptal dilator component (TFD-M and VCD). The transseptal dilator component

of the subject device is identical in all aspects to the legally marketed reference device, VersaCross and TorFlex Transseptal Dilator (K190688). Both reference and subject dilators are used with the corresponding steerable sheath and are intended for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

This 510(k) is also citing the legally marketed SureFlex Steerable Sheath (K122926) and EPstar Diagnostic Fixed Electrophysiology Lumen Catheter (K183632) as reference devices to support material aspects of the subject device's steerable sheath component (MSS and VMS).

Indications for Use

The sheath is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

The sheath curve can be visualized when used with impedance-based electroanatomical mapping systems.

Device Description

The Traditional 510(k) premarket notification includes two proposed subject device families:

- **The SureFlex Platform**: SureFlex HD Steerable Sheath models
- **The VersaCross Platform**: VersaCross HD Steerable Sheath models

The proposed SureFlex HD Steerable Sheath and VersaCross HD Steerable Sheath subject devices are non-pyrogenic, single use devices that are supplied sterile to the user. The HD Steerable Sheath families are comprised of the following components that are packaged together:

- One Steerable Sheath
- One Transseptal Dilator
- One J-tip Mechanical Guidewire

The SureFlex and VersaCross HD Steerable Sheaths are intended for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum. The sheath curve can be visualized when used with separately cleared impedance-based electroanatomical mapping (EAM) systems. The steerable sheath component used in conjunction with a compatible transseptal dilator can facilitate transseptal puncture using separately cleared compatible needle or wire-based puncture devices. The steerable sheath component is connected to the impedance-based EAM system via a compatible legally

marketed accessory cable. The subject device is used in a sterile environment where facilities are appropriately equipped and staffed to perform transseptal procedures.

The steerable sheath component is 8.5 Fr with a 63 cm or 73 cm useable length and is available in three curve options (small, medium, large). It is flexible and bi-directionally deflectable at the distal end (180 degrees clockwise and counterclockwise). The radiopaque tip (containing a platinum/iridium marker band) maximizes visualization of the sheath during manipulation. The sheath contains 4 electrodes equi-spaced along the shaft to enable shaft visualization. The sheath has two distal sideports and the proximal end includes a hemostasis valve and a 3-way stopcock to facilitate the injection or aspiration of fluids. A silicone lubricant is applied to the outer surface of the shaft for smoother device manipulation. The sheath handle allows the user to control the deflection of the sheath tip through rotation of the knob in the direction of desired distal deflection.

The compatible dilator component is 8.5F with a 95cm or 85cm usable length and is comprised of HDPE material with a tungsten radiopaque marker coil at the tip for visualization. The dilator has a tapered distal tip that provides support for the sheath. The compatible mechanical guidewire (0.032” or 0.035”) component is J-tipped, 180 cm in length and is comprised of a stainless-steel core mandrel with a PTFE coating.

Comparison of Technological Characteristics with Predicate Device

The proposed SureFlex and VersaCross HD Steerable Sheaths and predicate device CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath (K170997) have identical intended use, fundamental scientific technology, sterility, environment, and principle of operation (including mechanism of action) as well as similar indications for use. Differences in technological characteristics (design, materials and packaging) between the subject and predicate device do not raise any new or different questions of safety and effectiveness. The results of verification and validation activities demonstrates substantial equivalence of the proposed SureFlex HD Steerable Sheath and VersaCross HD Steerable Sheath subject devices with the predicate device. **Table 12.1** below shows technological comparison of the subject device with the predicate device.

Table 12.1 Comparison of Technological Characteristics of the Subject and Predicate Device

Characteristic	Comparison Results	Comments
Intended Use	Identical	The intended use of the subject device is identical to the predicate device. Both devices are used to introduce catheters to the left side of the heart with shaft visualization when used with a compatible mapping system.
Indications for Use	Similar	The indications for use of the subject device is similar to that of the predicate device, with a difference in reference to the compatible mapping systems. The subject device's compatibility and ability to be visualized on impedance-based EAM systems encompasses the predicate device's compatible mapping system (CARTO navigation systems). Appropriate validation testing has been completed to demonstrate the subject device meets its user requirements, ensures compatibility with accessory / ancillary devices (for use with any impedance-based EAM systems), and achieves its intended use. Differences in indications for use do not raise new or different questions of safety or effectiveness.
Fundamental Scientific Technology	Identical	Both subject and predicate device rely on user controlled mechanical manipulation to percutaneously gain access to vasculature and chambers of the heart, with shaft visualization when used with a compatible mapping system.
Operating Principles	Identical	The principles of operation for both subject and predicate device rely on the user to direct the device assembly to the desired site to facilitate introduction of cardiovascular catheters to the heart.
Mechanism of Action	Identical	The mechanism of action for both subject and predicate device include a steerable sheath with manual actuation to provide steerability and to track to target anatomy, while using an impedance-based electroanatomical mapping system to support sheath visualization.

Characteristic	Comparison Results	Comments
Environment	Identical	Both subject and predicate device are used in a sterile environment where facilities are appropriately equipped and staffed to perform transseptal procedures.
Materials	Similar	Appropriate biocompatibility verification testing has been conducted for the subject device and results demonstrate the device meets biological safety requirements as per ISO 10993-1 and FDA guidance. Differences in material between the subject and predicate devices do no raise new or different questions of safety or effectiveness.
Technological Characteristics	Similar	The technological characteristics of the subject device are similar to that of the predicate device. Appropriate verification and validation testing have been conducted for the subject device and results demonstrate that the device meets its intended use and requirements of ISO 11070. Differences in dimensions and compatibility with accessory/ancillary devices do not raise new or different questions of safety or effectiveness.
Packaging	Similar	The packaging configuration of the subject device is similar to that of the predicate device. Appropriate packaging verification and validation testing have been conducted for the subject device and results demonstrate that the packaging provides adequate protection and maintains the sterile barrier. Differences in packaging material and configuration do no raise new or different questions of safety or effectiveness.
Sterilization	Identical	Both subject and predicate device are single use, ethylene oxide sterilized.

Performance Testing Summary

Performance testing was completed to demonstrate substantial equivalence of the subject device to the predicate device. All test requirements were met as specified by applicable standards and test protocols. The device was subjected to the following verification and validation activities:

Mechanical Testing

Mechanical verification testing was conducted for the subject device to ensure compliance with the requirements of ISO 11070:2014/A1:2018 and Baylis Medical Company Inc. self-enforced requirements. The following mechanical tests were performed:

- Hemostasis Valve Liquid Leakage
- Sheath Hub Assembly Air Leakage
- Sheath Liquid Leakage
- Tip Stiffness
- Shaft Limit Load
- Electrode Shaft Pull
- Steering Limit Load
- Handle Structure Limit Load
- Shaft Stiffness
- Curve Range

Electrical Safety Testing

Electrical safety testing was conducted for the subject device to verify compliance with applicable requirements of IEC 60601-1:2005/A1:2012 and Baylis self-enforced requirements. The following general physical tests were performed:

- Resistance and Insulation
- Cable Compatibility
- Air Clearances
- Electrical Safety Tests
- Spillage Protection
- Electrical Limit Load

General Physical Testing

General physical verification testing was conducted for the subject device to verify compliance with the applicable requirements of ISO 11070:2014/A1:2018, ISO 80369-7, ISO 594-1:1986, ISO 594-2:1998 and Baylis self-enforced requirements. The following general physical tests were performed:

- Particulate Test
- Corrosion Resistance
- Clinical Valve Catheter Manipulation

- Snap Force Test
- Dilator Locking
- Dilator Compatibility and Protrusion
- Dilator Bend to Unlock
- Cap Pry Test
- Cap Torque Test
- Valve Insertion Force
- Tip Transition
- Operational Durability
- Curve Retention

Biocompatibility Verification

The subject device is categorized as an externally communicating device contacting circulating blood and indirect blood path for a limited duration up to a maximum of 24 hours. The biological safety of the subject device was verified in accordance with the requirements of ISO 10993-1:2020 and 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.*" The following biocompatibility endpoints were evaluated:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Material-Mediated Pyrogenicity
- Hemocompatibility

Sterilization Verification

Sterilization verification for the subject device was completed in accordance with the requirements of ISO 11135:2014/A1:2019. Sterilization was performed using a validated Ethylene Oxide (EtO) process to a Sterility Assurance Level (SAL) of 10^{-6}. Residual limits for the subject device are in accordance with ISO 10993-7:2008/A1:2022.

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

Packaging performance and stability testing was completed to verify the integrity of the subject device through the rigors of shipping and handling as well as storage over time. This testing was completed in accordance with ISO 11607-1:2020 (Parts 1 and 2) over the proposed intended shelf life of the subject device.

Pre-Clinical Validation Testing - Simulated Use Animal Study

Customer requirements / user needs were validated through simulated use animal validation study. Pre-clinical validation testing evaluated the subject device design and performance during normal clinical and intended use and was completed using an appropriate representative anatomical model.

Conclusion

The proposed SureFlex and VersaCross HD Steerable Sheaths and predicate device CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath (K170997) have identical intended use, fundamental scientific technology, sterility, environment, and principle of operation (including mechanism of action) as well as similar indications for use. Differences in technological characteristics (design, materials and packaging) do not raise any new or different questions of safety and effectiveness. The results of verification and validation activities demonstrates substantial equivalence of the proposed SureFlex HD Steerable Sheath and VersaCross HD Steerable Sheath subject devices with the predicate device.