June 30, 2022

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

Re: K213582
Trade/Device Name: Epicardial Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 8, 2022
Received: June 10, 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,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics 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.

510(k) Number *(if known)*
K213582

Device Name
Epicardial Access System

Indications for Use *(Describe)*
The Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach.

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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14. 510(K) SUMMARY (K213582)

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. *Company Facsimile*:	(905) 602-5671
E. *Contact Person*:	May Tsai Director, Regulatory Affairs
F. *Summary Prepared on*:	10-Nov-2021

Device Identification

A. *Device Trade Name*:	Epicardial Access System
B. *Device Common Name*:	Catheter Introducer
C. *Classification Name*:	CFR 870.1340 – Catheter Introducer
D. *Product Code*:	DYB
E. *Device Class*:	Class II

Identification of Legally Marketed Device

Table 14.1: Predicate Device

Predicate Device	Manufacturer	510(k)	Indications for Use
Epicardial Access System	Baylis Medical Company Inc.	K191546	The Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach to facilitate electrophysiology studies.

This 510(k) is also citing the legally marketed VersaCross Transseptal Dilator (K190688 and K183655) as a reference device to support material modifications in the subject device.

Indications for Use

The Epicardial Access System is intended to access the epicardial surface of the heart via a subxiphoid approach.

Device Description

The subject Epicardial Access System represents device modifications made to the Epicardial Steerable Guiding Sheath and Epicardial Introducer and Stylet components of the legally marketed Epicardial Access System (K191546). The Epicardial Access Needle component remains unchanged. The System is comprised of the following devices, which are single-use and supplied sterile to the user:

- Epicardial Access Needle
- Epicardial Steerable Guiding Sheath containing:
  - Steerable Sheath
  - Dilator
  - J-tip Guidewire
- Epicardial Introducer and Stylet

The subject device is designed to provide access to the epicardial surface of the heart via a subxiphoid approach. It is used in percutaneous access procedures primarily by Electrophysiologists and Interventional Cardiologists trained in the subxiphoid approach. Procedures using the devices are performed in fully equipped catheter labs with imaging equipment, including fluoroscopy under sterile technique.

The Epicardial Access System's intended use is achieved through the following steps:

- The needle advances through adipose tissue to reach the pericardial sac;
- The needle punctures the pericardial sac;
- The guidewire advances through the needle's inner lumen into the pericardial space;
- The introducer advances over the guidewire and pre-dilates the pericardial sac; and
- The Steerable Sheath (and Dilator) advances over the guidewire into the pericardial space to access the epicardial surface of the heart.

Comparison to Predicate Device

The intended use of subject device is to provide epicardial access to the heart via the subxiphoid approach, which remains unchanged from the predicate Epicardial Access System (K191546). The indications for use statement of the subject device is similar to the predicate, except for the removal of "*to facilitate electrophysiology studies*". This modification clarifies the intended use of the subject device; which is for use in any clinical procedure where epicardial access of the heart via the subxiphoid approach is required. This modification does not constitute a new intended use of the subject device when used as labelled. The subject and predicate device share the same fundamental scientific technology, principles of operation, mechanism of action, and sterilization method (**Table 14.2**).

Differences in design, material, packaging configuration, technological characteristics, and in the indications for use between the subject and predicate device do not raise any new concerns or different questions of safety and effectiveness. The identified reference device, VersaCross Transseptal Dilator (K190688 and K183655), supports the material modifications in the subject device. The results of verification and validation testing provide reasonable assurance of substantial equivalence of the Epicardial Access System with the predicate device and are evaluated through well-established methods.

Table 14.2: Comparison of Subject and Predicate Device

Characteristic	**Subject Device Compared to Predicate Epicardial Access System (K191546)**
Intended Use	Identical
Indications for Use	Similar

Fundamental scientific technology		Identical
Operating principles		Identical
Mechanism of action		Identical
Key technological characteristics		Similar
Materials	Patient contacting	Similar
	Non-patient contacting	Similar
Packaging configuration		Similar
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 and Baylis self-enforced requirements. The following mechanical tests were performed:

Epicardial Steerable Guiding Sheath

- Sheath Torque Transmission + Hub to Shaft Strength of Union
- Sheath Air and Liquid Leakage - Hemostasis Valve
- Sheath Air and Liquid Leakage
- Sheath Strength of Union – Tip to Sheath Body
- Sheath Strength of Union – Hub to Sheath Body
- Sheath Strength of Union – Hub to Hub Cap
- Sheath Strength of Union – Hub to Tubing
- Sheath Strength of Union – Stopcock to Tubing
- Sheath Strength of Union – Crimp to Pull Wire
- Sheath Strength of Union – Inner Knob to Outer Knob Snap Fit
- Sheath Strength of Union – End Cap to Handle Snap Fit
- Sheath Tip Transition
- Snap Fit
- Valve Insertion
- Dilator Torque Transmission – Hub to Tubing Joint
- Dilator Air and Liquid Leakage
- Dilator Strength of Union – Tip to Tubing
- Dilator Strength of Union – Butt Weld Joint
- Dilator Strength of Union – Hub to Tubing

Epicardial Introducer and Stylet:

- Stylet-Cap Tensile
- Introducer Hub-Shaft Tensile
- Introducer Tip Integrity
- Flexural Rigidity

General Physical Testing

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

Epicardial Steerable Guiding Sheath

- Sheath Surface Defects
- Sheath Range of Motion and Geometry
- Sheath Curve Retention and Integrity
- Sheath Friction
- Sheath Handle Lubricity
- Sheath Tip Stiffness
- Compatibility
- Dilator Surface Defects
- Dilator Flexural Modulus
- Sheath Clinical Valve

Epicardial Introducer and Stylet:

- Corrosion Resistance
- Luer Tests

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 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 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 ST72:2019 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 seal strength and sterile barrier integrity was also evaluated to verify compliance with the current applicable requirements of ISO 11607-1:2020 (Parts 1 and 2) 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 and Baylis self-enforced requirements.

Epicardial Access System 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 device share the same intended use, fundamental scientific technology, principles of operation, mechanism of action, and sterilization method, and overall clinical workflow. Differences in design, packaging configuration, technological characteristics, and in the indications for use between the subject and predicate device do not raise any new concerns or different questions of safety and effectiveness. The results of verification and validation activities demonstrate the Epicardial Access System is as safe and as effective as the predicate device, establishing the substantial equivalence of the subject device to the predicate device.