June 12, 2020

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

Re: K201288
Trade/Device Name: ExpanSure™ Large Access Transseptal Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: May 13, 2020
Received: May 14, 2020

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)*
K201288

Device Name
ExpanSure Large Access Transseptal Dilator

Indications for Use *(Describe)*
The ExpanSure Large Access 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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7. 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*:	(905) 602-4875
D. *Company Facsimile*:	(905) 602-5671
E. *Contact Person*:	May Tsai Manager, Regulatory Affairs
F. *Summary Prepared on*:	13-May-2020

Device Identification

A. *Device Trade Name*:	ExpanSure™ Large Access 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 7.1: Predicate Device

Predicate Device	Manufacturer	510(k)	Indications for Use
ExpanSure™ Transseptal Dilation System	Baylis Medical Company Inc.	K182064	The ExpanSure™ Transseptal Dilation System is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.

Indications for Use

The ExpanSure™ Large Access Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.

Device Description

The subject ExpanSure™ Large Access Transseptal Dilator represents a modification to the dilator component of the legally marketed ExpanSure™ Transseptal Dilation System (K182064). The modification was for the addition of a metallic marker coil to the dilator distal tip for increased visibility under imaging during procedures.

The subject device is comprised of a dilator (ExpanSure Dilator) and J-tip guidewire, which are single-use and supplied sterile to the user. The ExpanSure Dilator is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The dilator consists of an inner and outer polyethylene layer containing radio-pacifier for visibility under imaging during procedures. The inner and outer shaft layers are separated by a braid material for torqueability. The dilator distal tip includes a metallic marker coil to facilitate visualization under imaging during procedures. The outer surface of the dilator is coated with a silicone lubricant. The ExpanSure Dilator is compatible with 0.032” and 0.035” transseptal devices/guidewires and 12.5 Fr introducer sheaths. The J-tip guidewire is comprised of stainless steel.

Comparison to Predicate Device

The intended use and indications for use of the ExpanSure™ Large Access Transseptal Dilator remains unchanged from the predicate ExpanSure™ Transseptal Dilation System (K182064).

The subject and predicate device share the same fundamental scientific technology, principles of operation, mechanism of action, packaging configuration, and sterilization method (**Table 7.2**). Differences in design and technological characteristics between the subject and predicate devices do not raise any new concerns or different questions of safety and effectiveness. The results of verification and validation testing provide reasonable assurance of substantial equivalence of the ExpanSure™ Large Access Transseptal Dilator with the predicate device.

Table 7.2: Comparison of Subject and Predicate Device

Characteristic		Subject Device Compared to Predicate ExpanSure™ Transseptal Dilation System (K182064)
Intended Use		Identical
Indications for Use		Identical
Fundamental scientific technology		Identical
Operating principles		Identical
Mechanism of action		Identical
Technological characteristics		Similar
Materials	Patient contacting	Identical
	Non-patient contacting	Similar
Packaging configuration		Identical
Sterilization method		Identical
Accessory devices		Identical

Performance Testing

Non-clinical performance testing was completed for the subject device 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:

1. Strength of Union – Tip Cap Deflection
2. Strength of Union – Tip Cap Tensile

General Physical Testing

General physical 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 general physical tests were performed:

1. Visual Analysis
2. Measurements

Pyrogen Testing
The subject device is supplied non-pyrogenic. Limulus Amoebocyte Lysate (LAL) testing was performed using the Kinetic Chromogenic method, as per ANSI/AAMI ST72:2011 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.

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.

In addition, the below evaluations were completed to confirm the subject device meets the following performance requirements:

Biocompatibility Verification
Biological safety was evaluated for the subject device to verify compliance with the current applicable requirements of ISO 10993-1:2009/Cor.1:2010 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.*"

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 ANSI/AAMI/ISO 11607:2006/(R)2010 (Parts 1 and 2) over the proposed intended shelf life of the subject device.

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, respectively. Sterilization was performed with Ethylene Oxide to a Sterility Assurance Level (SAL) of 10^{-6}.

The ExpanSure™ Large Access 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 device share the same intended use and indications for use, fundamental scientific technology, principles of operation, mechanism of action, packaging configuration, and sterilization method. Design differences 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 substantial equivalence of the ExpanSure™ Large Access Transseptal Dilator to the predicate device.