June 7, 2019

Baylis Medical Company Inc.
Meghal Khakhar
Vice President, Regulatory & Scientific Affairs
2580 Matheson Blvd. East
Mississauga, Ontario L4W 4J1
Canada

Re: K183632
Trade/Device Name: Diagnostic Fixed Electrophysiology Catheter, Diagnostic Electrophysiology Cable
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: April 17, 2019
Received: April 18, 2019

Dear Meghal 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/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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac Electrophysiology,
Diagnostics and Monitoring 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)*
K183632

Device Name
Diagnostic Fixed Electrophysiology Lumen Catheter
Diagnostic Electrophysiology Cable

Indications for Use *(Describe)*
The Diagnostic Fixed Electrophysiology Lumen Catheter and Diagnostic Electrophysiology Cable can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

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*:	Meghal Khakhar
F. *Summary Prepared on*:	19-Dec-2018

Device Identification

A. *Device Trade Name*:	Diagnostic Fixed Electrophysiology Lumen Catheter Diagnostic Electrophysiology Cable
B. *Device Common Name*:	Electrode recording catheter
C. *Classification Name*:	21 CFR 870.1220 *Catheter, Electrode Recording, Or Probe, Electrode Recording*
D. *Product Code*:	DRF
E. *Device Class*:	Class II

Identification of Predicate Device

The predicate for the Diagnostic Fixed Electrophysiology Lumen Catheter is listed in **Table 1**.

Table 1: Predicate Device

Predicate Device	Manufacturer	510(k)	Product Code
Response Electrophysiology Catheter with Lumen	St. Jude Medical	K120544	DRF

Indications for Use

The Diagnostic Fixed Electrophysiology Lumen Catheter and Diagnostic Electrophysiology Cable can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

Device Description

The Diagnostic Fixed Electrophysiology Lumen Catheter is a sterile, single-use 6F diagnostic catheter with multiple electrodes and a fixed distal curve. The catheter body is a continuous tube with a central lumen for fluid infusion through a last chance filter (LCF) female luer connector. The catheter is intended to be placed in the heart percutaneously to facilitate electrophysiology studies of the heart, such as the coronary sinus and atrioventricular annulus. The catheter is connected to separately cleared diagnostic electrophysiology equipment via an accessory, the Diagnostic Electrophysiology Cable. The cable is supplied sterile and is reusable.

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	**Comment**
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

Performance Testing

Non-clinical performance testing was completed for the Diagnostic Fixed Electrophysiology Lumen Catheter and accessory cable to support their safety and

effectiveness with regards to the intended use as well as substantial equivalence to the predicate device. The following verifications and validations were completed:

1. Biocompatibility Verification: The biological safety of the catheter 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. Mechanical Verification: Mechanical testing was performed to verify compliance of the catheter with ISO 10555-1:2013 and specified Baylis Medical requirements. The accessory cable was verified to meet applicable IEC 60601-1:2005+A1:2012 and specified Baylis Medical requirements

3. Electrical Verification: Electrical testing was performed to verify compliance of the catheter and accessory cable with applicable IEC 60601-1:2005+A1:2012 and specified Baylis Medical requirements.

4. Bench Validation: Validation testing of the catheter was performed to validate the design of the device with regards to insertability, radiopacity, compatibility with ancillary devices and torquability. Validation testing of the accessory cable was performed to evaluate the design and function of the cable.

5. Cleaning and Re-Sterilization Validation: Validation testing was performed to demonstrate that the accessory cable could be cleaned and re-sterilized in accordance with the FDA guidance document *Reprocessing Medical Devices in Health Care Settings: Validations Methods and Labeling.*

6. Reuse Verification: Testing was performed to verify compliance of the accessory cable with specified Baylis Medical requirements when reused as per the device labelling.

7. Packaging Validation: Ship testing was performed to ensure the integrity of the device packaging 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 of the catheter and accessory cable.

The Diagnostic Fixed Electrophysiology Lumen Catheter and accessory cable met all requirements as specified by the test protocols.

Conclusions

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 Diagnostic Fixed Electrophysiology Lumen Catheter and the accessory cable are as safe, as effective, and perform in a manner that is substantially equivalent to the predicate device.