December 19, 2022

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

Re: K221351
Trade/Device Name: Mechanical Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 22, 2022
Received: November 22, 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,

Samuel G. Raben -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221351

Device Name
Mechanical Guidewire

Indications for Use *(Describe)*
The mechanical guidewire is intended for complex diagnostic and interventional procedures where increased body, flexibility, and low surface friction of the wire guide are needed. The guidewire is intended for peripheral vasculature use only, not intended for coronary or neurovascular use.

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.

510(K) SUMMARY

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
E.	*Contact Person:*	May Tsai Director, Regulatory Affairs
F.	*Summary Prepared on:*	05-May-2022

Device Identification

A.	*Device Trade Name:*	Mechanical Guidewire
B.	*Device Common Name:*	Guidewire
C.	*Classification Name:*	Wire, Guide, Catheter (21 CFR 870.1330)
D.	*Product Code:*	DQX
E.	*Review Panel:*	Cardiovascular
F.	*Device Class:*	Class II

Identification of Legally Marketed Device

A.	*Predicate Device:*	Lunderquist Wire Guide
B.	*Manufacturer:*	William Cook Europe ApS
C.	*510(k)*	K061670
D.	*Indications for Use*	Intended for complex diagnostic and interventional procedures where increased body, flexibility, and low surface friction of the wire guide are needed.

Device Description

The Mechanical Guidewire consists of a stainless-steel core wire with a flexible, J-tip stainless steel distal tip. A green polytetrafluoroethylene (PTFE) coating is present on the entire length of the guidewire and provides a lubricious surface for tracking through compatible ancillary devices. The distal curve allows visualization under appropriate imaging guidance during diagnostic and interventional procedures. The device is offered in a 180 cm length, with two outside diameters (0.032” and 0.035”), and one distal curve shape (J-tip). The tip curve radius for the Mechanical Guidewire measures 3 mm.

Indications for Use

The Mechanical Guidewire (MGW) is intended for complex diagnostic and interventional procedures where increased body, flexibility, and low surface friction of the wire guide are needed. The guidewire is intended for peripheral vasculature use only, not intended for coronary or neurovascular use.

Comparison to Predicate Device

Table 11.1 Comparison of Subject and Predicate Device.

Characteristic	Comparison Results
Intended Use	Identical
Indications for Use	Identical
Fundamental Scientific Technology	Identical
Operating Principles	Identical
Mechanism of Action	Identical
Materials	Similar
Technological Characteristics	Similar
Packaging and Sterilization	Identical

Performance Testing Summary

Performance Testing was completed to demonstrate performance and 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 Mechanical Guidewire to ensure compliance with the requirements of the FDA Guidance Document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommend Labeling*" and Baylis Medical Company Inc. self-enforced requirements. The following mechanical tests were performed:

- Flexure Test
- Fracture Test
- Peak Tensile Force Test
- Corrosion Resistance Test
- Torque Strength and Torqueability

- Tip Buckling Resistance

General Physical Testing

General physical verification testing for the lubricious green PTFE coating was conducted for the proposed MGW device. This testing was informed by Baylis Medical Company Inc. self-enforced requirements, and the FDA Guidance Document "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommend Labeling*". The following tests were performed:

- Coating Particulate Testing
- Adhesion Testing

Biocompatibility Verification

The biological safety of the proposed MGW 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 tests were performed:

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

Sterilization Verification

Sterilization verification for the proposed MGW 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 MGW device are in accordance with ISO 10993-7:2008+A1:2022.

Pyrogen Testing

The Mechanical Guidewire is supplied non-pyrogenic. Limulus Amoebocyte Lysate (LAL) testing was evaluated using the Kinetic Chromogenic method, as per ANSI/AAMI

ST72:2019 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 proposed MGW 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 over the proposed 1-year intended shelf life of the subject device.

Benchtop Validation Testing

Benchtop validation testing was completed to assess the compatibility of the proposed MGW device with ancillary devices. In addition, the radiopacity and integrity of the green PTFE coating were assessed in a simulated clinical use model.

Conclusion

The intended use and fundamental scientific technology, including principles of operation and mechanism of action, of the subject device are identical to those of the predicate device, the Lunderquist Wire Guide (K061670). Differences in materials and technological characteristics between the subject and predicate devices do not raise new or different types of safety and effectiveness questions. The results of verification and validation activities provide support for substantial equivalence of the proposed Mechanical Guidewire to the predicate device.