March 1, 2023

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

Re: K213898
Trade/Device Name: ProTrack Pigtail Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 1, 2023
Received: February 1, 2023

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,

Jennifer Bastijanic -S

for Jaime Raben
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213898

Device Name
ProTrack™ Pigtail Wire

Indications for Use *(Describe)*
The ProTrack™ Pigtail Wires are intended for use to introduce and position catheters and other interventional devices within the chambers of the heart, including those used within transcatheter aortic valve procedures (TAVR).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
D.	*Company Facsimile:*	+1 (905) 602-5671
E.	*Contact Person:*	May Tsai Director, Regulatory Affairs
F.	*Summary Prepared on:*	23-Feb-2023

Device Identification

A.	*Device Trade Name:*	ProTrack™ Pigtail Wire
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:*	Medtronic Confida™ Brecker Curve™ Guidewire
B.	*Manufacturer:*	Medtronic
C.	*510(k)*	K132623
D.	*Indications for Use*	The Medtronic Confida™ Brecker Curve™ Guidewire is intended for use to introduce and position catheters during diagnostic and-interventional procedures within the chambers of the heart, including, transcatheter aortic valve implantation (TAVI).

Intended Use

The ProTrack™ Pigtail Wires are intended to facilitate the placement of devices during diagnostic and interventional procedures.

Indications for Use

The ProTrack™ Pigtail Wires are intended for use to introduce and position catheters and other interventional devices within the chambers of the heart, including those used within transcatheter aortic valve procedures (TAVR).

Device Description

The ProTrack™ Pigtail Wire is a single use device used for the patients requiring diagnostic and interventional procedures like transcatheter aortic valve replacement (TAVR). It is used to facilitate the introduction and placement of devices in catheterization procedures primarily by Electrophysiologists and Interventional Cardiologists. Procedures using the devices are performed in fully equipped catheter labs with imaging equipment, including fluoroscopy and echocardiography under sterile technique.

The device consists of a stainless-steel core wire with a flexible, spiral shaped stainless steel distal coil. A green PTFE coating is present on the entire length of the device and provides a lubricious surface for smooth tracking through accessory devices and vasculature. The Wire has a radiopaque coil (304V Stainless Steel) around the distal curve to allow visualization under appropriate imaging guidance during procedures. The device is offered in multiple models with two different lengths (230 cm and 275 cm), diameters (0.032" and 0.035"), and distal curve shapes (regular and small). The device is provided sterile (EO sterilized).

The wire is classified as an external communicating device, contacting circulating blood, with limited exposure and contact up to a maximum of 24 hours. The patient contacting materials are PTFE coating, stainless steel and adhesive.

Comparison of Technological Characteristic with Predicate Device

The subject ProTrack™ Pigtail Wire and predicate device Confida™ Brecker Curve™ Guidewire have the same intended use, fundamental scientific technology, sterility and principle of operation. Differences in design and technological characteristics between the subject and predicate device do not raise any new types of questions of safety and effectiveness. The results of verification and validation testing provide reasonable assurance of the safe and

effective use of the ProTrack™ Pigtail Wire to establish substantial equivalence for its intended use to the predicate device. **Table 1** below shows technological comparison of subject device with predicate device.

Table 1: **Comparison of Technological Characteristics with Predicate Device**

Characteristic	Comparison Result	Comment
Intended Use	Identical	The subject and predicate device are both intended to facilitate the placement of devices during diagnostic and interventional procedures.
Indications for Use	Similar	The indications for use of the subject device is similar to that of the predicate device, with minor wording differences to clarify the devices that can be positioned. The terms TAVI (used in predicate device labelling) and TAVR (used in subject device labelling) are considered equivalent.
Fundamental Scientific Technology	Identical	Both subject and predicate device rely on user controlled mechanical manipulation to percutaneously gain access to vasculature and chambers of heart.
Operating Principles	Identical	Both subject and predicate device facilitate the introduction and positioning of one catheter and/or interventional device for another, while maintaining guidewire position in the chambers of the heart.
Mechanism of Action	Identical	The mechanism of action for both subject and predicate device is mechanical force.
Environment of Use	Identical	Both subject and predicate device are used in facilities equipped and staffed to

		perform diagnostic and interventional procedures.
Materials	Similar	The subject and predicate device are both comprised of the following materials: • Stainless steel • PTFE coating The following material is different: • Adhesive
Technological characteristics	Similar	Both subject and predicate device share the same characteristic: • Distal tip configuration The following characteristics are different: • Device usable Length • Outer diameter • Distal tip spiral diameter • Compatibility with accessory device
Packaging	Similar	The subject and predicate device packaging system differ in: • Packaging material • Packaging configuration
Sterilization	Identical	Both subject and predicate device are Single Use, Ethylene Oxide sterilized

Performance Testing Summary

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

Mechanical Testing

Mechanical verification testing was conducted for the ProTrack™ Pigtail Wire to ensure compliance with the requirements per FDA guidance and ISO 11070:2014/Amd:2018. The following mechanical tests were performed for the device:

Per 11070:2014/Amd:2018:

- Corrosion Resistance
- Flex Test
- Fracture test
- Peak tensile force
- Tensile strength
- Tip Pull

Per FDA guidance Coronary, Peripheral, and Neurovascular Guidewires –Performance Tests and Recommended Labeling:

- Dimensional verification
- Visual inspection
- Repeated Simulated Use
- Peak tensile force/Tensile strength
- Tip pull
- Torque Strength
- Coating integrity
- Particulate testing
- Lubricity/Friction testing
- Corrosion resistance
- Kink resistance
- Tip flexibility
- Radiopacity

General Physical Testing

General physical verification testing was conducted for the ProTrack™ Pigtail Wire to ensure compliance with Baylis Medical Company Inc. self-enforced requirements. The following tests were performed:

- Curve Retention
- Flexural rigidity

Biocompatibility Verification

The biological safety of the ProTrack™ Pigtail Wire 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:

- ISO Cytotoxicity study
- ISO Maximization Sensitization Study
- ISO Intracutaneous Reactivity Study
- ISO/USP Material Mediated Pyrogenicity
- ISO Hemocompatibility Study
- ISO Acute Systemic Toxicity Study

Sterilization Verification

Sterilization verification was completed for the ProTrack™ Pigtail Wire to the requirements of ISO 11134-1:2014. Sterilization is performed with Ethylene Oxide to a Sterility Assurance Level (SAL) of 10^{-6}. Residual limits are in accordance with ISO 10993-7:2008.

Pyrogen Testing

The ProTrack™ Pigtail Wire 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 and ISO 11607-2:2017 over the proposed intended shelf life of the subject device.

Bench-top Validation

User needs for ProTrack™ Pigtail Wire were validated through benchtop validation activities. Users drawn from populations familiar with catheter-based interventional procedures were presented with a sequence of actions to perform with a benchtop model representative of a clinical workflow involving the device. Observations regarding ease of use and errors made were recorded and evaluated to conclude if customer requirements were met. The validation testing demonstrated that the ProTrack™ Pigtail Wire meets the intended use to support substantial equivalence.

Conclusion

The intended use and fundamental scientific technology, including principles of operation and mechanism of action, of the subject ProTrack™ Pigtail Wire are identical to those of the predicate Medtronic Confida™ Brecker Curve™ Guidewire (K132623). Differences in design and technological characteristics do not raise any different questions of safety and effectiveness. The results of verification and validation activities support the substantial equivalence of the subject and the predicate device.