



January 18, 2026

Baylis Medical Technologies, Inc.
Barb Boyce
Senior Regulatory Affairs Specialist
2645 Matheson Blvd. E, Mississauga, On L4w 5m2
Mississauga, ON L4W 5S4
Canada

Re: K254114

Trade/Device Name: Baylis Connector Cable
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: December 18, 2025
Received: December 19, 2025

Dear Barb Boyce:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for **MARCO CANNELLA -S**

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254114

?

Please provide the device trade name(s).

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Baylis Connector Cable

Please provide your Indications for Use below.

?

The Baylis Connector Cable is intended to connect Baylis Radiofrequency (RF) Puncture Generators to separately cleared compatible RF devices.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

21 CFR 807.92

I. Submitter Information

Company Name: Baylis Medical Technologies Inc.

Address: 2645 Matheson Blvd. East, Mississauga, Ontario L4W 5S4, Canada

Phone: (905) 948-5800

Contact Person: Barb Boyce

Summary Prepared On: 16-Dec-2025

II. Device Identification

Device Trade Name: Baylis Connector Cable

Device Common Name: Cable, transducer and electrode, patient, including connector

Classification Name: 21 CFR 870.2900

Device Class: Class II

Product Code: DSA

III. Identification of Predicate Device

Predicate Device: RFP-100A Connector Cable (Single Use), cleared under 510(K) number K230571

Predicate Device Manufacturer: Baylis Medical Technologies Inc.

Recall Status: Predicate device has not been the subject of a design-related recall.

IV. Device Description

The Baylis Connector Cable is a sterile, single-use device designed to connect Baylis-approved Radiofrequency (RF) generators (including the PrecisePath RF Puncture Generator and RFP-100A Generator) to separately cleared compatible RF devices (e.g., RF guidewires).

The Baylis Connector Cable is 10 feet long with a multi-pin positive locking Generator Connector at one end and a spring-loaded wire connection connector at the other end which allows connection to the RF delivery device. Between the connector ends is a single insulated conductor cable.

Principle of Operation: Enables RF power transfer from generator to RF puncture device; no changes from predicate device.

V. Indications for Use

The Baylis Connector Cable is intended to connect Baylis Radiofrequency (RF) Puncture generators to separately cleared compatible RF devices.

VI. Comparison to Predicate Device

The Baylis Connector Cable and its predicate share the same intended use, principles of operation, and fundamental technology. Differences are minor and do not raise new questions of safety or effectiveness.

Detail	Equivalence	Comment
Legal Manufacturer	Identical	Baylis Medical Technologies Inc.
Indications for Use	Similar	Change in the name of the cable and updated list of compatible generators
Classification	Identical	21 CFR 870.2900
FDA Product Code	Identical	DSA
Sterility	Identical	Sterile, EO
Design	Similar	Both the predicate and subject device share the same fundamental design, the subject device differs as follows: - Minor design change to connector ends
Materials	Similar	Both the predicate and subject device share the same fundamental design, the subject device differs in materials as follows: - Minor change to insulation and connector material
Compatible Generators	Minor difference	Update to list of compatible generators to include PrecisePath Radiofrequency Puncture Generator (PRG-1)
Packaging	Identical	Tyvek/poly pouch in shelf box
Shelf-life	Identical	4 years

VII. Performance Data

Verification and validation activities confirm that the Baylis Connector Cable meets the same requirements as the predicate device. Testing included:

- Electrical Safety, EMC, and Generator Compatibility: IEC 60601-1 and IEC 60601-2-2 applicable requirements
- Mechanical Integrity: Connector strength, cable durability
- Sterilization & Packaging: EO sterilization validation, shelf-life testing (leveraged from predicate device's 510(K) since these parameters remain unchanged)

Results demonstrate that the subject device performs equivalently to the predicate device and does not introduce new risks.

VIII. Conclusions

The Baylis Connector Cable is substantially equivalent to the predicate device (RFP-100A Connector Cable (Single Use), K230571). Both devices share the same intended use, principles of operation, and fundamental technology. Verification and validation of design and material changes to the Baylis Connector Cable further support substantial equivalence to the legally marketed predicate device.