October 28, 2025

Baylis Medical Technologies Inc.
Barb Boyce
Senior Regulatory Affairs Associate
2645 Matheson Blvd. East
Mississauga, ON L4W 5S4
Canada

Re: K250275
Trade/Device Name: PrecisePath™ Radiofrequency Puncture Generator and PrecisePath™ Footswitch
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 15, 2025
Received: October 16, 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.28 17:03:28 -04'00'

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250275

Device Name

PrecisePath™ Radiofrequency Puncture Generator and PrecisePath™ Footswitch

Indications for Use *(Describe)*

The PrecisePath Radiofrequency Puncture Generator and Footswitch (optional accessory) is indicated for use in general surgical procedures to cut and coagulate soft tissues.

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.

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14.0 510k Summary

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: 30-Jan-2025

II. Device Identification

Device Trade Name: PrecisePath™ Radiofrequency Puncture Generator and Footswitch

Device Common Name: Electrosurgical Generator

Classification Name: Electrosurgical cutting and coagulation device and accessories

Device Class: Class II per 21 CFR 878.4400

Device Code: GEI

III. Identification of Predicate Device

The predicate device is the BMC Radiofrequency Puncture Generator & Footswitch, which is cleared under 510(k) Premarket Notification Number K122278 (cleared 07-Nov-2012).
This predicate device has not been the subject of a design-related recall.

IV. Device Description

The PrecisePath Radiofrequency (RF) Puncture Generator is indicated for use in general surgical procedures to cut and coagulate soft tissue. It is designed to be used by trained medical professionals, to provide radiofrequency (RF) current for creating controlled punctures with compatible Baylis RF devices in a monopolar mode. This continuous or pulsed RF current is output at a fixed frequency within 450 kHz to 480 kHz.

The PrecisePath Footswitch (optional accessory) may be used as an alternative to the on/off button on the generator user interface by which the user can start and stop the delivery of RF energy.

The PrecisePath RF Puncture Generator is compatible with separately cleared Baylis radiofrequency devices and connector cables, off-the-shelf return (dispersive) electrodes that meet or exceed IEC 60601-2-2:2017, and the PrecisePath footswitch (optional accessory).

V. Indications for Use

The PrecisePath Radiofrequency Puncture Generator and Footswitch (optional accessory) is indicated for use in general surgical procedures to cut and coagulate soft tissues.

The indications for use are identical to those of the predicate device.

VII. Comparison to Predicate Device

The PrecisePath Radiofrequency Puncture Generator and Footswitch and its predicate device share the same intended use and technological characteristics.

Table 14.2: Comparison to Predicate Device

Characteristic	Proposed PrecisePath Radiofrequency Puncture Generator and Footswitch Compared to BMC Radiofrequency Puncture Generator & Footswitch
Intended Use	Identical
Indications for Use	Identical
Prescription Use Only	Identical
Target Population/conditions of use	Identical
Fundamental technology	Identical
Operating principles	Identical
Mechanism of action	Identical
Performance	Identical
Mode of Energy Delivery	Identical
Packaging configuration	Identical
Environment of Use	Identical

Performance Testing

Performance testing was conducted to evaluate the PrecisePath Radiofrequency Puncture Generator compared to the predicate device. The testing included assessments of electrical safety, electromagnetic compatibility (EMC), software validation, and performance. The results of this testing are summarized in this submission and demonstrate that the minor differences do not adversely affect the performance of PrecisePath Radiofrequency Puncture Generator. All testing was conducted in accordance with the following applicable standards and FDA guidances:

- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014+A1:2020 (Ed. 4.1) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-2:2017+A1:2023 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 62304:2006+A1:2015 - Medical device software - Software life cycle processes
- FDA Guidance, Content of Premarket Submissions Device Software Functions (June 2023)

The results of the testing support the substantial equivalence of PrecisePath Radiofrequency Puncture Generator to the predicate device.

VIII. Conclusions

The subject and predicate devices share the same intended use and technological characteristics. No significant changes have been made to the PrecisePath device's technology, engineering, performance or materials compared to the predicate device. Furthermore, the information provided in this submission, demonstrates that the PrecisePath Radiofrequency Puncture Generator and Footswitch does not raise new questions of safety or effectiveness compared to the predicate device, thereby supporting substantial equivalence.