September 12, 2024

Biotronik, Inc.
Jon Brumbaugh
Vice President,
Regulatory Affairs and New Product Development
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K240787
Trade/Device Name: Selectra 3D Lead Delivery System (443624-443629, 451789-451791); Selectra Slitter Tool (383119); Selectra Accessory Kit (375518)

Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 12, 2024
Received: August 13, 2024

Dear Jon Brumbaugh:

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 Hetal B. Odobasic -S

Sara Royce
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

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)*

K240787

Device Name

Selectra 3D Lead Delivery System (443624-443629, 451789-451791);
Selectra Slitter Tool (383119);
Selectra Accessory Kit (375518)

Indications for Use *(Describe)*

The lead delivery system, consisting of Selectra catheters in conjunction with the Selectra Accessory Kit, is used to facilitate implantation of leads in the heart chambers or in the coronary veins via the coronary sinus.
Selectra 3D catheters are also indicated to facilitate Solia S lead implantation in the left bundle branch area to achieve left bundle area pacing (LBBAP).

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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BIOTRONIK Selectra 3D Lead Delivery System (K240787):
Selectra 3D Catheters, Accessory Kit and Slitter Tool
510(k) Summary

I. Submitter

BIOTRONIK
6024 SW Jean Road
Lake Oswego, OR 97035
Phone: (888) 345-0374
Fax: (503) 451-8519

Contact Person: Jon Brumbaugh
Date Prepared: August 12, 2024

II. Device

Name of Device	Selectra 3D Lead Delivery System, including Selectra 3D Catheters, Selectra Accessory Kit and Selectra Slitter Tool
Common or Usual Name	Lead Introducer System
Classification Name	Percutaneous Catheter (21 CFR 870.1250)
Regulatory Class	II
Product Code	DQY

III. Predicate Devices

BIOTRONIK's Selectra 3D Catheters, Selectra Accessory Kit and Selectra Slitter Tool (K222037 cleared July 19, 2022).

IV. Device Description

BIOTRONIK's Selectra 3D lead introducer system is a combination of guiding catheters and implantation accessories used to facilitate access to the heart for suitable leads and catheters. The Selectra 3D lead introducer system consists of several individually available guiding catheters with various curve shapes and the Selectra accessory kit.

The Selectra Accessory Kit includes the following components in a single sterile package:

- 1 Selectra Slitter Tool
- 1 guide wire
- 2 7F Transvalvular Insertion Tools (TVI)
- 1 syringe
- 1 torque tool
- 2 check valves
- 2 stopcocks
- 1 Tuohy Borst Adapter (TBA)

The catheters facilitate implantation of leads into the heart. The Selectra catheters are compatible with one another as well as the Selectra Accessory Kit.

V. Indications for Use

Based on the Clinical Study Data, the Indications for Use statement has been updated from prior clearance (K222037 cleared July 19, 2022).

The lead delivery system, consisting of Selectra catheters in conjunction with the Selectra Accessory Kit, is used to facilitate implantation of leads in the heart chambers or in the coronary veins via the coronary sinus.

Selectra 3D catheters are also indicated to facilitate Solia S lead implantation in the left bundle branch area to achieve left bundle area pacing (LBBAP).

VI. Comparison of Technological Characteristics with the Predicate Device

The technological principles of the subject and predicate devices remain unchanged.

VII. Performance Data

Clinical Study Report was provided in support of the additional LBBAP specific indication in the premarket notification submission for a determination of substantial equivalence.

VIII. BIO|MASTER Selectra 3D Clinical Study Overview

The BIO|MASTER Selectra 3D study (NCT04323670) was a multi-center, international, single-arm, prospective study designed to provide post-market data and supporting evidence for the clinical safety, performance, and handling of the Selectra 3D guiding catheter when used to support lead implant for conduction system pacing. Patients with a guideline-recommended indication for the implant of a permanent pacemaker or a CRT-P device were included and followed for one year.

Following enrollment, subjects were implanted with a pacemaker or CRT-P system. Use of Selectra 3D for His bundle or left bundle branch area implant with Solia S lead was mandated in the protocol. The implant procedure followed standard clinical practice according to the applicable instructions for use. Successful His bundle or left bundle branch area pacing was determined by the implanting physician.

Assessment of the implanted system was conducted at 3-months, 6-months, and 12-months post implant. Subjects were exited after the 12-month follow-up visit.

Primary Endpoint: Selectra 3D-Related SADE-Free Rate

The primary endpoint evaluated the Selectra 3D-related serious adverse device effect (SADE)-free rate until 7 days after implantation. SADEs that were possibly, probably, or causally related to a Selectra 3D catheter during the initial implantation procedure were included in this primary endpoint. Pocket infection and pocket hematoma were considered procedure related and were not counted toward the endpoint. The assessment of relatedness to the Selectra 3D catheter was determined by the Endpoint Adjudication Committee.

Secondary Endpoint 1: Successful Implantation Rate
Secondary endpoint 1 evaluated the success of the lead implantation with the Selectra 3D catheter. The implantation success was assessed by the implanting investigator at the end of the procedure, where the investigator assessed the stability and suitability for long-term pacing an intended target lead position within the cardiac conduction system.

Study Status
Between October 8, 2020, and November 18, 2021, 157 patients were enrolled in ten investigational sites across Europe, Asia, and Australia. The last patient exited the study on December 20, 2022.

Safety Results
The primary endpoint of SADE-free rate was tested against a pre-defined performance goal of 90%. With an expected SADE-free rate of 97%, significance level alpha of 0.025, and power set to 90%, a sample size of 157 patients was sufficient to test the primary endpoint hypothesis. The primary endpoint was assessed by binomial test to identify the SADE-free rate and corresponding 95% confidence interval.

No SADEs related to the Selectra 3D catheter occurred through 7 days post-implant. The primary endpoint was met with a freedom from SADEs related to the Selectra 3D catheter through 7 days post-implant of 100% (95% CI: 97.7, 100).

In addition, an extended observation out to 28 days post-implant did not identify any serious adverse device effects related to the Selectra 3D catheter.

Effectiveness Results
No hypotheses were defined for secondary endpoint 1. Secondary endpoint 1 results were described by calculating the 95% confidence interval for the successful implant rate.

Successful conduction system pacing implants with Selectra 3D were achieved in 147 out of 157 subjects with an implant attempt, for a successful implant rate of 93.6% (95% CI: 88.6, 96.9). Of the 147 successful conduction system pacing implants, 82 were in the left bundle branch area and 65 were in the His bundle.

Study Conclusions
The Selectra 3D catheter supports substantial equivalence of implant of pacing leads in the left bundle branch area.

IX. Conclusions

The subject device and the predicate device remain identical with LBBAP specific Indications of Use and minor Contraindications updates. Based on the Clinical Study Data, it can be concluded that the Selectra 3D Lead Introducer System is substantially equivalent to the predicate device.