October 16, 2020

BIOTRONIK, Inc
Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K193474
Trade/Device Name: Selectra 3D Outer Guiding Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 15, 2020
Received: September 16, 2020

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 (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,

for

Hetal Odobasic
Implantable Electrophysiology Devices Team
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

510(k) Number: K193474_____

Device Name: Selectra 3D Outer Guiding Catheters
Indications for Use:

In conjunction with the Selectra accessory kit, Selectra guiding catheters are used to facilitate lead implantation in the heart chambers or in the coronary veins via the coronary sinus.

Prescription Use __X___ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
BIOTRONIK Selectra 3D Outer Guiding Catheters

1. Submitter

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

Contact Person: Jon Brumbaugh
Date Prepared: December 11, 2019

2. Device

Name of Device	Selectra 3D Outer Guiding Catheters
Common or Usual Name	Lead Introducer System
Classification Name	Percutaneous Catheter (21 CFR 870.1250)
Regulatory Class	II
Product Code	DQY

3. Predicate Devices

- BIOTRONIK's Selectra 7F Guiding Outer Catheters, (K192996, cleared November 21, 2019)

4. Device Description

BIOTRONIK's Selectra 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 lead introducer system consists of several individually available guiding catheters with various different curve shapes and the Selectra accessory kit.

The catheters are available as inner (5F) and outer (7F) catheters which jointly form a telescopic system, and facilitate implantation of leads into the heart. The Selectra catheters are compatible with one another as well as the Selectra Accessory Kit.

5. Indications for Use

The Indications for Use statements are unchanged from prior submission (K192996, cleared November 21, 2019).

The Selectra lead introducer system is used to facilitate implantation of leads in the coronary veins via the coronary sinus or to facilitate lead implantation into the heart chambers.

Selectra Guiding Catheter:

In conjunction with the Selectra accessory kit, Selectra guiding catheters are used to facilitate implantation of leads in the coronary veins via the coronary sinus or to facilitate lead implantation into the heart chambers.

6. Comparison of Technological Characteristics with the Predicate Device

The technological principles of the subject and predicate devices are the same. The differences represent minor modifications to the currently marketed Selectra outer guiding catheters as follows:

- The Selectra 3D outer catheters provide additional curve shapes with updated working lengths compared to the currently marketed Selectra outer guiding catheters. Updated packaging was also required to support the new curve shapes.

The technological updates do not raise questions regarding safety and effectiveness based on the verification/validation testing that has been successfully performed and the conclusion that clinical benefit outweighs the residual risk according to the risk analysis. Quality control testing on the final products remains unchanged.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

To demonstrate that the modified Selectra outer catheters meet the same performance criteria, the following tests were conducted using the same test methods and acceptance criteria for the predicate devices.

- Compatibility Testing
- Functional Testing
- Biocompatibility
- Microbiology and sterilization
- Packaging Testing

No clinical testing was deemed necessary or completed in the premarket notification submission for a determination of substantial equivalence.

8. Conclusions

The subject devices result from minor modifications to the predicate devices. The performance testing demonstrates that the subject device meet the same functional acceptance criteria for the same intended use.