December 13, 2018

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

Re: K183265
Trade/Device Name: Selectra Catheters, Selectra Accessory Kit
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 21, 2018
Received: November 23, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Hetal B. Patel -S
2018.12.13 14:54:42 -05'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

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.

Type of Use (Select one or both, as applicable)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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.*

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510(k) Summary
BIOTRONIK Selectra Lead Introducer System
Selectra Catheters, Selectra Accessory Kit and Selectra Slitter Tool

1. Submitter
BIOTRONIK
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97035 Phone: (888)
345-0374
Fax: 503-451-8519

Contact Person: Jon Brumbaugh
Date Prepared: November 13, 2018

2. Device
Name of Device Selectra Lead Introducer System, including Selectra 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

3. Predicate Devices
- BIOTRONIK Selectra 7F Catheters (K123324, cleared January 11, 2013)
- BIOTRONIK Selectra 5F Catheters (K151409, cleared August 7, 2015)
- BIOTRONIK Selectra Accessory Kit (K131978, cleared August 23, 2013)
- BIOTRONIK Selectra Slitter Tool (K112482, cleared September 26, 2011)

4. Reference Device
The reference device for this submission is:
- Medtronic’s C315 Delivery Catheter (K101885, cleared September 9, 2010)

5. 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 Selectra Accessory Kit includes the following components in a single sterile package:
- 1 Selectra Slitter Tool
- 1 guide wire
- 4 transvalvular insertion (TVI) tools
- 1 syringe
- 1 torque tool
- 2 check valves
- 2 stopcocks
- 2 sealing caps
510(k) Summary
BIOTRONIK Selectra Lead Introducer System
Selectra Catheters, Selectra Accessory Kit and Selectra Slitter Tool

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.

6. Indications for Use

The Indications for Use statements have been updated to reflect industry standard.

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.

Selectra Accessory Kit:
The Selectra accessory kit is used in conjunction with the lead introducer system to facilitate lead
implantation in the coronary veins via the coronary sinus or to facilitate lead implantation into the
heart chambers.

Selectra Slitter Tool:
Selectra accessories are used in conjunction with the lead introducer system to facilitate lead
implantation in the coronary veins via the coronary sinus or to facilitate lead implantation into the
heart chambers.

7. Comparison of Technological Characteristics with the
Predicate Device

The technological principles of the subject and predicate devices are identical because no design
changes have been made.

8. Performance Data
Performance data was not required to support this submission because no design change has been
made.

9. Conclusions
The subject devices result from minor labeling modifications to the predicate devices. The new
Indications for Use statements fall within the same Intended Use for all devices.