



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2015

Biotronik, Inc.
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs And Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K151409

Trade/Device Name: Selectra CS Lead Introducer System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II
Product Code: DQY
Dated: July 7, 2015
Received: July 8, 2015

Dear Mr. 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

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

Indications for Use

510(k) Number (if known): K151409

Device Name: Selectra Catheters and Selectra Accessory Kit

Indications For Use:

The Selectra CS lead introducer system is used to facilitate lead implantation in the left side of the heart via the coronary sinus.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

BIOTRONIK Selectra CS Lead Introducer System
Selectra Catheters and Selectra Accessory Kit

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: May 14, 2015

2. Device

Name of Device	Selectra CS Lead Introducer System, including Selectra Catheters and Selectra Accessory Kit
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 (K111154, cleared May 23, 2011)
- BIOTRONIK Selectra Accessory Kit (K131978, cleared August 23, 2013)

No reference devices were used in this submission.

4. Device Description

BIOTRONIK's Selectra CS lead introducer system is a combination of guiding catheters and implantation accessories used to facilitate access to the coronary venous system for suitable leads and catheters. The Selectra CS 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 CS Lead Introducer System
Selectra Catheters and Selectra Accessory Kit

The catheters are available as inner (5F) and outer (7F) catheters which jointly form a telescope system, and allow probing of the ostium of the coronary sinus, access to the coronary sinus, introduction of contrast media for angiography, and positioning of left ventricular leads, also called coronary sinus (CS) leads.

The Selectra catheters are compatible with one another as well as the Selectra Accessory Kit.

5. Indications for Use

The Selectra CS lead introducer system is used to facilitate lead implantation in the left side of the heart via the coronary sinus.

The Indications for Use statement for the Selectra system is identical to the predicate device.

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 catheters as follows:

- Additional models with a shorter overall working length and the same diameter
- A modified blister package
- A longer shelf life
- Manufacturing changes with no effect on performance criteria
- Stopcock produced from a different polycarbonate material

In addition to the longer shelf life, labeling was updated to facilitate internal inventory management, to comply with UDI requirements (CFR 801.20 and 801.40) and to comply with international standards.

7. Performance Data

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

A biocompatibility evaluation for the Selectra Catheters and Selectra Accessory Kit was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Selectra CS lead introducer system is classified as an external communicating device with direct contact to blood path and limited contact duration (< 24 h). The testing included:

- Cytotoxicity
- Hemocompatibility

In addition, the subject devices were tested for the following:

- Particulate matter
- Endotoxin
- Bioburden

510(k) Summary

BIOTRONIK Selectra CS Lead Introducer System
Selectra Catheters and Selectra Accessory Kit

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

- Visual inspection
- Simulated use testing (handling,)
- Leak testing
- Kink testing
- Tensile strength
- Friction characteristics
- X-ray visibility
- Package integrity
- Process validation for manufacturing changes.

When appropriate, test samples were subjected to environmental preconditioning and accelerated aging prior to testing.

8. Conclusions

The subject devices result from minor modifications to the predicate devices. The performance testing demonstrates that the subject devices meet the same functional acceptance criteria for the same intended use. In addition, testing conducted after accelerated aging support the longer labeled shelf life of the catheters.