APR 2 0 2011

Selectra Lead Introducer System

Additional Information for Special 510(k) #K110461

1. 510(K) SUMMARY

Name and Address of Applicant:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	Selectra
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Wire, Guide, Catheters, Percutaneous
Product Code:	DQY, DRE, DQX

General Description:

The Selectra CS lead introducer system is a family of guiding catheters specifically used for the placement of coronary sinus leads. It is designed to assist with introducing leads into the veins of the left side of the heart via the coronary sinus. The system also facilitates access to the coronary sinus venous system as well as probing the coronary sinus. The following Selectra guiding catheters are the subject of this Special 510(k):

- Selectra Amplatz 6.0-45
- Selectra Amplatz 6.0-55
- Selectra Straight-45
- Selectra Straight-55
- Selectra BIO2-45
- Selectra BIO2-55
- Selectra Extended Hook-45
- Selectra Extended Hook-55
- Selectra Hook-45
- Selectra Hook-55
- Selectra MPEP-45
- Selectra MPEP-55
- Selectra MPH-45
- Selectra MPH-55
- Selectra Right-45
- Selectra Right-55

The **Selectra Guiding Catheter** is packaged with the following components:

- 1 Selectra CS guiding catheter (sterile)
- 1 dilator for the guiding catheter (sterile)
- 1 technical manual or web-card (non-sterile)

Device Modification:
The changes made to the Selectra compared to the previously cleared ScoutPro ACS are mainly minor changes in design.
The usage of the Selectra remains unchanged and the product characteristics such as indications for use, contraindications, and functions are identical to the previously cleared ScoutPro ACS guiding catheters in submission K101776, cleared on July 23, 2010. Therefore, this previously cleared version will serve as the predicate device for the modified product family included in this Special 510(k).

Predicate Device:
BIOTRONIK's ScoutPro ACS Catheters (K101776, 23-Jul-2010)

- ScoutPro ACS Amplatz 6.0 (45cm)
- ScoutPro ACS Amplatz 6.0 L (50cm)
- ScoutPro ACS Straight (45cm)
- ScoutPro ACS Straight L (50cm)
- ScoutPro ACS BIO2 (45cm)
- ScoutPro ACS BIO2 L (50cm)
- ScoutPro ACS Extended Hook (45cm)
- ScoutPro ACS Extended Hook L (50cm)

- ScoutPro ACS Hook (45cm)
- ScoutPro ACS Hook L (50cm)
- ScoutPro ACS MPEP (45cm)
- ScoutPro ACS MPEP L (50cm)
- ScoutPro ACS MPH (45cm)
- ScoutPro ACS MPH L (50cm)
- ScoutPro ACS Right (45cm)
- ScoutPro ACS Right L (50cm)

Indication 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.

Name and Address of Manufacturing Site:

BIOTRONIK SE & Co. KG (reg. no. 9610139)
Woermannkehre 1,
12359 Berlin, Germany
011-49-30-689-05-1210

Name and Address of Manufacturing Site:

BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland
011-41-44-864-5169

Name and Address of Contract Sterilizer:
Sterigenics Germany GmbH
(reg. no. 3002807090)
Kasteler Straße 45
(Rheingaustrasse 190 – 196)
D-65203 Wiesbaden, Germany

510(k) Contact Person and Phone Number:

Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Phone (888) 345-0374
Fax (503) 635-9936
jon.brumbaugh@biotronik.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

APR 2 0 2011

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

Re: K110461
Trade/Device Name: Selectra Lead Introducer System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: February 17, 2011
Received: April 13, 2011

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. 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110461

Indications for Use

510(k) Number (if known): TBD

Device Name: Selectra CS Lead Introducer System
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 ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110461