Selectra 7F
Extended Shelf Life
Special 510(k) Premarket Notification

JAN 11 2013

1. 510(K) SUMMARY

Name and Address of Sponsor: BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	Selectra 7F Guiding Catheters
Classification:	Class II (21 CFR 870.1250)
Classification Name:	Percutaneous Catheter
Product Code:	DQY

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 legally marketed Selectra 7F guiding catheters (K110461, 20-Apr-2011) are the subjects 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)

Predicate Device:

BIOTRONIK's Selectra 7F Guiding Catheters (K110461, 20-Apr-2011)

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.

Device Modification:

The changes made to the Selectra 7F compared to the previously cleared Selectra 7F guiding catheters is a reduction in the concentration of Tungsten in the X-ray marker band (from 80% to 60%) and a shelf-life extension from 6 months to 12 months. The reason for the reduction in Tungsten concentration between the current and proposed catheters is to improve the mechanical properties of the X-ray marker after aging.

The usage of the Selectra 7F catheters remains unchanged and the product characteristics such as indications for use, contraindications, and functions are identical to the previously cleared Selectra 7F guiding catheters in submission K110461, cleared on April 20, 2011. Therefore, this previously cleared version will serve as the predicate device for the modified product family included in this Special 510(k).

Summary of Non-Clinical Testing:

The substantial equivalence claim between the subject and the predicate device is supported by the information included in this premarket notification. This includes the following:

- Comparison of attributes and specifications of the subject and predicate devices
- Subject device risk analysis
- Subject device validation testing which includes the following testing:
  - Mechanical
  - Packaging
  - Sterilization and Shelf life

Substantial Equivalence:

The substantial equivalence claim between the subject and the predicate device is supported by the information included in this premarket notification. This includes the following information:

- Description of the subject and predicate devices
- Intended use of the subject and predicate devices
- Material composition of the subject and predicate devices
- Validation testing

Name and Address of Manufacturer:	BIOTRONIK SE & Co. KG (reg. no. 9610139) Woermannkehre 1, 12359 Berlin, Germany 011-49-30-689-05-1210
Name and Address of Contract Manufacturer:	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
Contact Person(s) and Phone Number:	Jon Brumbaugh VP, Regulatory Affairs and Compliance Phone (888) 345-0374 Fax (800) 913-6993 jon.brumbaugh@biotronik.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Biotronik, Inc.
Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Rd.
Lake Oswego, OR 97035

JAN 11 2013

Re: K123324
Trade/Device Name: Selectra 7F Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 13, 2012
Received: December 14, 2012

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,

Matthew G. Hillebrenner

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

Enclosure

Indications for Use

510(k) Number (if known): TBD K123314

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 K123314