Modifications to theScoutPro Hemostatic Valve Special 510(k) Premarket Notification

1. 510(K) SUMMARY

Name and Address of Applicant:

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

JUL 2 1 2010

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	ScoutPro 7F
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Wire, Guide, Catheters, Percutaneous
Product Code:	DQY, DRE, DQX

Date Prepared: June 18, 2010

General Description:

The ScoutPro family of introducer systems and accessories is specifically used for the placement of coronary sinus leads. It is designed to assist with introducing leads into the vessels 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. This submission is in regard to a modification in a hemostatic valve, which is an accessory component of the ScoutPro family. The following ScoutPro 7F kit contains the hemostatic valve which is the subject of this Special 510(k):

The ScoutPro 7F kit (with accessories) were cleared under 510(k) #K060807 on April 24, 2006:

The basic set **ScoutPro 7F** contains the following components:

- 1 hemostatic valve (which is also separately available)
- 2 guiding catheters "MPEP" and "BIO2"
- 1 dilator for the guiding catheter
- 1 peel-away sheath 10F with dilator
- 1 guide wire
- 1 needle
- 1 syringe
- 2 slitter tools 4.9 F and 6.3 F for different lead sizes

Device Modification:

The hemostatic valve is included with the ScoutPro 7F kit and is also separately available. The hemostatic valve will be modified to include a 2-way spigot instead of a 3-way spigot, from a new supplier, Qosina. All patient contacting materials have already been used in other US legally marketed devices and the modified hemostatic valves have successfully undergone a full battery of biocompatibility testing. As a result of these modifications, updates will be made to the labeling. No changes have been made to the functionality of the hemostatic valve or any other accessories included within the kit. The change is being made to ensure continued supply of the hemostatic valves.

The usage of the ScoutPro hemostatic valve and ScoutPro 7F kit remains unchanged and the product characteristics such as indications for use, contraindications, and functions are identical to the previously cleared ScoutPro accessories in submission #K060807, cleared on April 24, 2006. Therefore, the previously cleared versions will serve as predicate devices for the modified products included in this Special 510(k).

Predicate Device:

BIOTRONIK's ScoutPro 7F (#K060807, 24-Apr-2006)

Indications for Use:

The ScoutPro CS Lead Introducer System facilitates lead implantation in the left of the heart via the coronary sinus.

The ScoutPro accessories are used in conjunction with the ScoutPro CS Lead Introducer System to facilitate lead implantation in the left of the heart via the coronary sinus.

Name and Address of Manufacturing Site:

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12359 Berlin, Germany
011-49-30-689-05-1210

Name and Address of Manufacturing Site:

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

510(k) Contact Person and Phone Number:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

JUL 21 2010

Re: K101282
Trade/Device Name: ScoutPro Hemostatic Valve
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: June 18, 2010
Received: June 21, 2010

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.

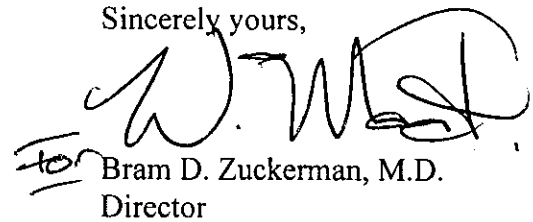
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

K101282

Indications for Use

510(k) Number (if known): TBD

Device Name: ScoutPro Hemostatic Valve (Part of the ScoutPro 7F Kit)

Indications for Use:

The ScoutPro CS Lead Introducer System facilitates lead implantation in the left of the heart via the coronary sinus.

The ScoutPro accessories are used in conjunction with the ScoutPro CS Lead Introducer System 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_____