K093303

ScoutPro 7F Long Guiding Catheters
Special 510(k) Premarket Notification

NOV 20 2009

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:	ScoutPro 7F Sheath Hook L
	ScoutPro 7F Sheath Multipurpose Hook L
	ScoutPro 7F Sheath Amplatz 6.0 L
	ScoutPro 7F Sheath BIO2 L
	ScoutPro 7F Sheath MPEP L
	ScoutPro 7F Sheath Extended Hook L
	ScoutPro 7F Sheath Extended Hook Right L
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Guide, Catheters, Percutaneous
Product Code:	DQY, DRE

General Description:

ScoutPro 7F is a delivery system for 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. The system contains guiding catheters with seven distal arc shapes and accessories to facilitate the lead implantation. This Special 510(k) introduces additional catheters as shown below, which have the same distal arc shapes but are 5 cm longer in length:

ScoutPro 7F Sheath Hook L

ScoutPro 7F Sheath Multipurpose Hook L

ScoutPro 7F Sheath Amplatz 6.0 L

ScoutPro 7F Sheath BIO2 L

ScoutPro 7F Sheath MPEP L

ScoutPro 7F Sheath Extended Hook L

ScoutPro 7F Sheath Extended Hook Right L

Each of these catheters is separately available from the ScoutPro 7F kit and contains the following components:

- 1 guiding catheter
- 1 (long) dilator for the guiding catheter

Device Modification:

The main difference between the predicate device ScoutPro 7F catheters and the ScoutPro 7F long catheters described in this documentation is the length. The long catheters also utilize a modified X-ray marker which is described in this document; however the patient contacting materials remain identical to the predicate. Additionally, a new dilator which is identical to the predicate but differs in length is also described.

Predicate Device:

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

- ScoutPro 7F Sheath Amplatz 6.0
- ScoutPro 7F Sheath Hook
- ScoutPro 7F Sheath Multipurpose Hook

BIOTRONIK's ScoutPro 7F (#K072329, 25-Mar-2008)

- ScoutPro 7F Sheath BIO2
- ScoutPro 7F Sheath Extended Hook
- ScoutPro 7F Sheath Extended Hook Right
- ScoutPro 7F Sheath MPEP

Indication for Use:

The ScoutPro 7F long catheters are used in conjunction with the ScoutPro 7F CS Lead Introducer System to facilitate lead implantation in the left side of the heart via the coronary sinus.

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

Contact Person(s) 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.
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

NOV 2 0 2009

Re: K093303
Trade/Device Name: ScoutPro 7F Long Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY, DRE
Dated: October 20, 2009
Received: October 21, 2009

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.

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

Indications for Use

510(k) Number (if known): K093303

Device Name: ScoutPro 7F Long Catheters

Indications For Use:

The ScoutPro CS lead introducer system and its separately available accessories are used to facilitate lead implantation in the left side of the heart via the coronary sinus.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K093303