K060655

APR 4 2006

ScoutPro 8F
Special 510(k) Premarket Notification

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 8F
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Catheters, Percutaneous
Product Code:	DQY, DRE, DQX

General Description:

ScoutPro 8F is a special delivery system for coronary sinus leads. It is designed to assist with introducing leads into the vessels of the left heart via the coronary sinus. It facilitates access to the coronary sinus venous system as well as probing the coronary sinus. It is a modified version of BIOTRONIK's currently legally marketed predicate device, ScoutPro (K033320, 11-19-2003). The following ScoutPro 8F accessories are subject to this 510(k)

The basic set **ScoutPro 8F** contains the following components:

1 hemostatic valve
2 guiding catheters BIO I and BIO 2
1 dilator for the guiding catheter
1 peel-away sheath 11F with dilator
1 guide wire
1 needle
1 syringe
2 slitter tools 4.9 F and 6.3 F for different lead sizes

ScoutPro 8F Sheath "Hook" contains the following components:

1 guiding catheter "Hook"
1 dilator for the guiding catheter

ScoutPro 8F Sheath "Multi-Purpose Hook" contains the following components:

1 guiding catheter "Multi-Purpose Hook"
1 dilator for the guiding catheter

ScoutPro 8F Sheath "Amplatz 6.0" contains the following components:

1 guiding catheter "Amplatz 6.0"
1 dilator for the guiding catheter

Additionally, the hemostatic valve and the slitter tools are available separately. These accessories have been cleared with the legally marketed predicate device ScoutPro (K033320, 11-19-2003).

Device Modification:

The main difference between the predicate device ScoutPro and the ScoutPro 8F described in this documentation are some modifications with the accessories included in the system. The changes to the accessories include the markings on the hemostatic valve, a bigger scaled syringe and a different plastic material and a different steel blade for slitter tools.

Predicate Device:

BIOTRONIK proposes the following delivery system cleared through 510(k) notification as a predicate device for the ScoutPro 8F:

- BIOTRONIK's ScoutPro (#K033320, 11-19-2003)

Indication for Use:

The intended use of the ScoutPro 8F is for introducing leads into the vessels of the left heart via the coronary sinus.

Name and Address of Manufacturer:

BIOTRONIK GmbH & 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:

Jon Brumbaugh
Director, Regulatory Affairs and Compliance
Phone (888) 345-0374
Fax (503) 635-9936
jon.brumbaugh@BIOTRONIK.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

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

Re: K060655
Trade Name: ScoutPro 8F Coronary Sinus Lead Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 10, 2006
Received: March 13, 2006

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ScoutPro 8F

Indications for Use:

The intended use of the ScoutPro 8F is for introducing leads into the vessels of the left 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 K060655