K061212

Packaging Changes for Endocardial Pacing Leads

Special 510(k) Premarket Notification

1. 510(k) SUMMARY

Name and Address of Sponsor:

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

JUL 10 2006

Establishment Registration Number: 1028232

Device Name:

Product	Proprietary Name (Multiple)	FDA Product Code	Classification Name	Device Classification
Arox	Arox 53-BP	DTB	Electrode, Pacemaker, Permanent	III (21 CFR 870.3680)
	Arox 60-BP			
	Arox 45-JBP			
	Arox 53-JBP			
Synox	Synox-SX 45-JBP	DTB	Electrode, Pacemaker, Permanent	III (21 CFR 870.3680)
	Synox-SX 53-JBP			
	Synox SX 53-BP			
	Synox SX 60-BP			
Synox with 15 mm tip to ring spacing	Synox SX 53/15-BP	DTB	Electrode, Pacemaker, Permanent	III (21 CFR 870.3680)
	Synox SX 60/15-BP			
Polyrox w/ 15 mm Spacing	PX 53/15-BP	DTB	Electrode, Pacemaker, Permanent	III (21 CFR 870.3680)
	PX 60/15-BP			
Polyrox	PX 45-JBP	DTB	Electrode, Pacemaker, Permanent	III (21 CFR 870.3680)
	PX 53-BP			
	PX 53-JBP			
	PX 60-BP			
YP	YP 45/15-BP	DTB	Electrode, Pacemaker, Permanent	III (21 CFR 870.3680)
	YP 53/15-BP			
	YP 60/15-BP			

General Description and Predicate Devices:

BIOTRONIK proposes modifications to the packaging process and containers for bradycardia pacing leads, at BIOTRONIK's manufacturing and sterilization facility (BIOTRONIK GmbH & Co. KG) in Berlin, Germany and contract manufacturing facility (BIOTRONIK AG) in Bülach Switzerland. BIOTRONIK believes that the previously approved products cleared through 510(k) notifications and manufactured and sterilized at BIOTRONIK GmbH & Co. KG in Berlin, Germany or BIOTRONIK AG in Bülach Switzerland are appropriate as predicate devices for the products affected by the aforementioned packaging modifications. The above table provides a list of the products that are manufactured and/or sterilized at BIOTRONIK GmbH & Co. KG in Berlin, Germany or BIOTRONIK AG in Bülach Switzerland and the 510(k) notifications under which the products were cleared.

Indication for Use:
BIOTRONIK's endocardial leads are designed for use with implantable pulse generators that require pacing leads with a bipolar IS-1 connector configuration; they may be used with single or dual chamber pacing systems. The leads are designed for use in patients for whom single or dual chamber pulse generator therapy is medically indicated. This indication follows that recommended in the Class I definition of the ACC/AHA/NASPE Task Force Report, entitled "ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee on Pacemaker Implantation)" (Gregoratos et al. 2002).

The straight lead models are intended for placement in either the right atrium or right ventricle. The JBP lead models have a pre-formed J-shaped distal end to facilitate lead placement in the right atrial appendage.

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

JUL 10 2006

Biotronik, Inc.
C/O Jon Brumbaugh
6024 Jean Rd.
Lake Oswego, OR 97035

Re: K061212
Trade/Device Name: Biotronik Endocardial Pacing Leads
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular permanent or temporary pacemaker electrode.
Regulatory Class: Class III
Product Code: DTB
Dated: June 21, 2006
Received: June 22, 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K061212

Device Name: Bradycardia Pacing Leads, (see attached list)

Indications for Use:

Pacing Leads –
BIOTRONIK's endocardial leads are designed for use with implantable pulse generators that require pacing leads with a bipolar IS-1 connector configuration; they may be used with single or dual chamber pacing systems. The leads are designed for use in patients for whom single or dual chamber pulse generator therapy is medically indicated. This indication follows that recommended in the Class I definition of the ACC/AHA/NASPE Task Force Report, entitled "ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee on Pacemaker Implantation)" (Gregoratos et al. 2002).

The straight lead models are intended for placement in either the right atrium or right ventricle. The JBP lead models have a pre-formed J-shaped distal end to facilitate lead placement in the right atrial appendage.

Prescription Use ✓ 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)

Ashley B. Boam

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061212