K990483

JUN 3

Retrox Active Fixation Endocardial Lead

510(K) SUMMARY

Name and Address of Sponsor:

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

Establishment Registration Number:

1028232

Device Name:

Proprietary Names: RX-45-JBP, RX 53-BP, RX 53-BP, and RX 60-BP
Classification: Class III (21 CFR 870.3680(b))
Classification Name: Cardiovascular permanent pacemaker electrode

Date Prepared:

May 17, 1999

General Description and Predicate Devices:
BIOTRONIK's Retrox leads are transvenous, bipolar, active fixation, endocardial pacing leads. The predicate device for the Retrox Endocardial Lead with Elgiloy Active-Fixation is the Retrox Active-Fixation Endocardial Lead. BIOTRONIK obtained clearance to commercially distribute the Retrox Active-Fixation Endocardial Lead on July 22, 1998 after determination of substantial equivalence under 510(k) #K981083. The Retrox lead being introduced in this 510(k) notification is identical to the Retrox lead already cleared for distribution with the exception that the material used to construct the fixation helix has changed to Elgiloy. Currently, the fixation helix in the Retrox is manufactured with an alloy containing 70% platinum/30% iridium.

With regard to the Retrox lead's new active fixation material, the VascoTwist 9/60 series of endocardial leads (#K920662, dated 11/24/93) is the predicate device to which the Retrox lead with Elgiloy is substantially equivalent.

Indications for Use:

The BIOTRONIK **RETROX** RX 53/60-BP and **RETROX** RX 45/53-JBP transvenous, active-fixation endocardial leads are indicated for permanent pacing and sensing. Active-fixation pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators. The leads may be used with single- or dual-chamber pacing systems.

RETROX RX-BP and RX-JBP leads differ in the shape of the distal portion of the lead. The RX-BP models are intended for placement in the ventricle or atrium and have straight distal ends. The RX-JBP models have a pre-formed J-shaped distal end to facilitate lead placement in the right atrial appendage.

Name and Address of Manufacturing Site:
BIOTRONIK GmbH & Co.(reg. no. 7010992)
Woermannkehre 1, Berlin, Germany
011-49-30-689-05-304

Sponsor Contact Person and Phone Number:
Jon Brumbaugh, Regulatory Affairs Manager
Phone (888) 345-0374
Fax (503) 635-9936

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Mr. Jon Brumbaugh
Biotronik, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K990483
Trade Name: Retrox Active-Fixation Endocardial Pacing Leads
Models RX-BP amd RX-JBP
Regulatory Class: III
Product Code: 74 DTB
Dated: May 24, 1999
Received: May 25, 1999

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not

affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please not the regulation entitled, " Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities

under the Act, may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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* For Prescription Use Only

for TJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990483