

YP xx/15-BP Active Fixation Endocardial Lead 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 Names: YP 45/15-BP, YP 53/15-BP, and YP 60/15-BP
Classification: Class III (21 CFR 870.3680(b))
Classification Name: Cardiovascular permanent pacemaker electrode

Date Prepared: September 17, 1999

General Description and Predicate Devices:

BIOTRONIK's YP xx/15-BP leads are transvenous, bipolar, active fixation, endocardial pacing leads. The lead conductor is quadrifilar MP35N wire in a coaxial configuration, insulated with silicone tubing, and electrodes surfaces with a fractal iridium surface treatment. The leads are available in 45, 53, and 60 cm lengths and have IS-1 connectors. The predicate devices upon which BIOTRONIK is basing its claim of substantial equivalence are the following:

- BIOTRONIK's Retrox family of bipolar, active fixation, endocardial leads with Elgiloy® (#K990483, cleared 06/03/99).
- BIOTRONIK's DY unipolar, active fixation, endocardial lead (#K841451/A, cleared 02/07/85).
- BIOTRONIK's FH bipolar, active fixation, endocardial lead (#K910608, cleared 07/30/91).
- Cardiac Pacemakers Inc. (CPI) Sweet Tip, bipolar, active fixation, endocardial lead (#K873888, cleared 05/17/88)

Indications for Use:

BIOTRONIK's YP xx/15-BP 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.

The YP xx/15-BP lead models are intended for placement in either the patient's right atrium or right ventricle.

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, Director of Regulatory Affairs
Phone (888) 345-0374
Fax (503) 635-9936



DEC 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jon Brumbaugh
Director of Regulatory Affairs
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K993139
Trade Name: Active-Fixation Endocardial Pacing Lead Model
YP 45/15-BP, YP 53/15-BP and YP 60/15-BP
Regulatory Class: III
Product Code: DTB
Dated: September 17, 1999
Received: September 20, 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, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). 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 (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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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

Page 2 - Mr. Jon Brumbaugh

you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

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Christopher M. Allen for Witte

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

K993139