

K 994240

APR 13 2000

Elox Active Fixation Endocardial Lead 510(k) 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: Elox Leads
Classification: Class III (21 CFR 870.3680(b))
Classification Name: Cardiovascular Permanent
Pacemaker Electrode
Product Code: DTB

Date Prepared:

December 15, 1999

General Description and Predicate Devices:

Elox (EX xx-BP) is a straight, bipolar endocardial pacing lead utilizing an electrically active extendable/retractable fixation helix. The extendable/retractable fixation helix is comprised of a 70% Pt / 30% Ir alloy with a fractal Iridium coating. The non-insulating distal sleeve, consisting of an inner and outer sleeve, is composed of Polyurethane (Pellethane 2363-75D). The lead contains two conductors composed of quadrifilar MP35N wire in coaxial configurations and is insulated with silicone tubing. A 3.2 mm IS-1 bipolar connector attaches the lead to the pulse generator. The Elox lead is available in lead lengths of 45 cm, 53 cm, and 60 cm.

BIOTRONIK proposes the following leads cleared through 510(k) notifications as predicate devices for the Elox lead:

- BIOTRONIK's Retrox bipolar, active fixation, endocardial lead (#K981083, cleared 07/22/98)
- Medtronic's Model 6957J-58 unipolar, active fixation, endocardial lead (#K843707, cleared 01/08/85)
- BIOTRONIK's FH bipolar, active fixation, endocardial lead (#K910608, cleared 07/30/91)
- BIOTRONIK's Synox bipolar, passive fixation, endocardial lead (#K980869, cleared 09/10/98)

Indications for Use:

BIOTRONIK's **ELOX** (EX xx-BP) 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 with IS-1 headers. The leads may be used with single or dual chamber pacing systems.

The **ELOX** (EX xx-BP) lead models are intended for placement in either the right atrium or right ventricle.

Name and Address of Manufacturing Site:

BIOTRONIK GmbH & Co. (reg. no. 7010992)
Woermannkehre 1, 12359 Berlin, Germany
011-49-30-689-05-304

Contact Person(s) and Phone Number:

Jon Brumbaugh
Director, Regulatory Affairs
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2000

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

Re: K994240
Elox Active-Fixation Endocardial Pacing Lead, Model EX 45-BP,
EX 53-BP, and EX 60-BP
Regulatory Class: III (three)
Product Code: DTB
Dated: March 22, 2000
Received: March 23, 2000

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.

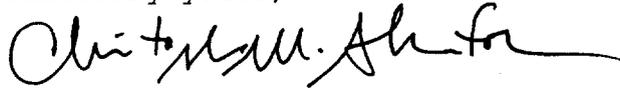
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

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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) 594-4648. 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" (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,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

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Clifton M. Ah for Dillard.

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K99A240