APR 2 4 2003

K023205



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

**Date Prepared:** September 24, 2002

**General Description:**
Elox P leads are straight, bipolar endocardial pacing leads that utilize 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 distal tip of the fixation helix is additionally coated with Parylene C. The non-insulating distal sleeve, consisting of an inner and outer sleeve, is composed of Polyurethane (Pellethane 2363-75D). The leads contain two conductors composed of quadrifilar MP35N wire in coaxial configurations and are insulated with silicone tubing. A 3.2 mm IS-1 bipolar connector attaches the lead to the pulse generator. The Elox P lead is available in lead lengths of 45 cm, 53 cm, and 60 cm.

**Device Modification:**
The proposed Elox P leads in this Special 510(k) notification are modified versions of BIOTRONIK's currently marketed Elox leads (K994240, cleared 04-13-00 and K001413, cleared 06-02-00). The modification to the Elox P lead involves the addition of a Parylene C coating to the proximal portion of the fixation helix in order to decrease the electrically active surface of the helix and therefore increase the electrical impedance of the lead.

**Predicate Devices:**
BIOTRONIK proposes the following leads cleared through 510(k) notifications as predicate devices for the Elox P leads:

- BIOTRONIK's Elox bipolar, active fixation, endocardial leads (#K994240, cleared 04-13-00)
- BIOTRONIK's Elox 45-BP bipolar, active fixation, endocardial leads (#K001416, cleared 06-02-00)
- BIOTRONIK's Synox bipolar, passive fixation endocardial leads with 31 mm spacing (#K980869, cleared 09-10-98)
- Intermedics's Quantum implantable pulse generator (#K911122, cleared 05-16-91)

**Indications for Use:**
BIOTRONIK's ELOX P 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 P 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:**
Jon Brumbaugh
Director, Regulatory Affairs
Phone (888) 345-0374
Fax (503) 635-9936

**Name and Address of Contract Manufacturing Site:**
BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland
011-41-1-864-5169

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2003

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

Re: K023205
Trade Name: Elox P
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular permanent or temporary pacemaker electrode
Regulatory Class: III (three)
Product Code: DTB
Dated: January 24, 2003
Received: January 27, 2003

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K023205

Device Name: Elox P Active-Fixation, Bipolar Pacemaker Lead

Indications For Use:

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**The ELOX P lead models are intended for placement in either the right atrium or right ventricle.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Prescription Use Only**

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023205