Synox Passive 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:	Synox Leads
Classification:	Class III (21 CFR 870.3680(b))
Classification Name:	Cardiovascular Permanent Pacemaker Electrode
Product Code:	DTB

Date Prepared: April 2, 1999

General Description and Predicate Devices:

The Synox 53/15-BP and 60/15-BP leads introduced in this 510(k) notification are modified versions of BIOTRONIK's currently marketed straight Synox leads (SX 53-BP and SX 60-BP) approved September 10, 1998 under 510(k) #K980869. The modification is a reduction of the distance between the ring and tip electrodes from 31 mm to 15 mm. Because of this change, the silicone insulation between the tip and ring electrodes was shortened and the prior tapered design was changed to one with a consistent thickness. The new 15 mm spacing distance between the ring and tip electrodes is identical to the electrode spacing of the "J" shaped Synox leads (SX 45-JBP and SX 53-JBP) also approved September 10, 1998 under 510(k) #K980869. The SX xx/15-BP straight leads with 15 mm spacing will not replace the existing straight leads, but will be distributed in conjunction with the currently marketed Synox leads.

Synox xx/15-BP leads are bipolar, passive fixation endocardial leads that feature three silicone tines for fixation in the heart's trabeculae. The tip electrode is made of a titanium base material with a surface treatment of fractal iridium and a surface area of 1.3 mm^2. The ring electrode is made of a platinum/iridium base material with a surface treatment of fractal iridium and a surface area of 34 mm^2. The lead conductor is quadrifilar MP35N wire in a coaxial configuration, insulated with silicone rubber tubing. All Synox leads utilize a 3.2 mm IS-1 connector.

The predicate devices are BIOTRONIK's Synox passive fixation endocardial leads (straight and "J" configurations) cleared for commercial distribution on September 10, 1998 under 510(k) #K980869.

Indications for Use:
Synox leads are designed for use with implantable pulse generators that require pacing leads with a bipolar 3.2 mm 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 Task Force Report, entitled "Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmic Devices" (JACC, Vol. 18, No. 1, July 1991:1 - 13).

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
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

JUL -1 1999

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

Re: K991169
Trade Name: Synox SX 53/15-BP and SX 60/15-BP Endocardial Pacing Leads
Regulatory Class: III
Product Code: DTB
Dated: April 2, 1999
Received: April 7, 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

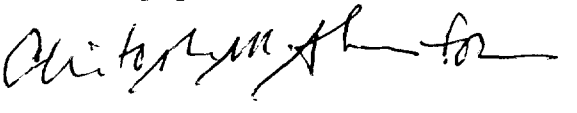
under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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

Enclosures

2. INDICATIONS FOR USE

Synox leads are designed for use with implantable pulse generators that require pacing leads with a bipolar 3.2 mm 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 Task Force Report, entitled "Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmic Devices" (JACC, Vol. 18, No. 1, July 1991:1 - 13).

for Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991169

Mike,
prescription device