

M 1200

Summary of Safety and Effectiveness Tapered Distal Segment Modification (510(k) #K972500)

This premarket notification describes a manufacturing modification to the distal end of BIOTRONIK TIR/TIJ and POLYROX bipolar endocardial leads. Through design functionality, simplicity and material biocompatibility, the parts proposed in this submission (parts 124132 and 124133) are designed to be safe, chronically implantable components of the devices within which they are used. The safety and effectiveness of TIR/TIJ and POLYROX bipolar endocardial leads is addressed within their respective 510(k) applications. The proposed use of these pre-formed tapered silicone parts is for manufacturability and quality control only and will not affect any aspect of lead performance or utility, including but not limited to indications for use, lead size, material biocompatibility, handling characteristics, sterilization procedures or labeling.

Parts 124132 and 124133 have undergone the following testing:

- Visual control of the single distal tip pieces (also sampled during manufacture)
- Visual control of leads manufactured using new distal tip pieces (also sampled during manufacture)
- Insulation testing according to prEN 45502:2 1996, Section 23.3, for the leads within each of the two lead families (TIR, TIJ, PX, PX-J)
- Representative strength tests of adhesive connections using NuSil Med 1511 and NuSil Med 1137 (these adhesives are used interchangeably in the manufacture of BIOTRONIK leads):
 - a) Adhesive connection of the passive fixation tines (LSR-4070) and distal end piece (LSR-4070)
 - b) Adhesive connection of the distal end piece (LSR-4070) and the ring electrode (90% Pt / 10% Ir)

All test results were within specifications; therefore, when the proposed parts are in use, the patient will be exposed to no risks in excess of those experienced by patients using existing TIR/TIJ or POLYROX leads, or other equivalent market-released leads.

Possible side effects of lead implantation include, but are not limited to, body rejection phenomena, thrombosis, muscle and nerve stimulation, infection and erosion through skin. BIOTRONIK is not aware of any other adverse safety and effectiveness data on endocardial leads.

Since the beginning of non-US distribution in 1994, 29,820 TIR/TIJ bipolar endocardial leads have been distributed within Japan and the EEC. For these devices, adverse events (incident reports) are reported as required under the European Vigilance System. No incident reports have been filed; four complaints have been filed. Of the four complaints filed, one lead was a TIJ 53-BP and the remaining were TIR 60-BP leads. The TIJ lead was analyzed by the manufacturer and found to be operating within specifications (complaint related to "unacceptable" bipolar thresholds). Of the

three complaints relating to TIR leads, one lead was found to perform within manufacturer's specifications (complaint related to "no capture"), one was seen to have a "lead puncture" (complaint related to no pacing and high impedance), and one was found to have a short circuit between the tip and the ring electrodes (complaint related to "unacceptable" bipolar thresholds).

The distribution of bipolar POLYROX leads in non-US countries began in February, 1996; as of submittal date of this document, 4,268 leads have been distributed within Japan and the EEC. Adverse events also are reported for these devices as required under the European Vigilance System. There are no reported adverse events or complaints associated with this lead.

Within the United States, numbers of bipolar TIR/TIJ and POLYROX leads distributed to date are 110 and 529, respectively. There are no reported adverse events associated with the use of these leads in the United States. There have been no returns of TIR/TIJ leads in the United States; two device returns are recorded for POLYROX leads - one because of physician preference (decided to use another lead), and one because the lead was dropped in the operating room at time of implant.



MAR 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lauren L. Foote Christensen
Regulatory Affairs Manager, Bradycardia
Biotronik, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369

Re: K972500
Biotronik POLYROX and TIR/TIJ Pacing Leads
Regulatory Class: III (three)
Product Code: 74 DTB
Dated: January 28, 1998
Received: January 30, 1998

Dear Ms. Christensen:

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 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 registration, listing of devices, good manufacturing practices, and 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, 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 regulation.

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Under Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under Section 522(a)(1)(A) the device cleared for marketing by this letter as requiring postmarket surveillance.

Within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you are required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is attached.

Submit five (5) copies to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Room 3083 (HFZ-544)
1350 Piccard Drive
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. You should not begin your postmarket surveillance study of this device until the protocol has been approved. Data generated under an unapproved protocol may not satisfy your obligation under section 522. Please note that you must continue to collect and report data needed to maintain compliance with Medical Device Reporting regulations (21 CFR 803).

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 U.S.C. 331 (q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

If you have questions specifically concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

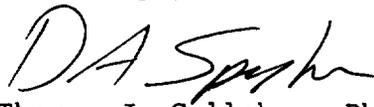
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In addition, on August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has 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 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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,

for 

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

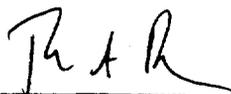
Enclosures

Indications for Use
BIOTRONIK POLYROX Leads

The POLYROX PX and PX-JBP endocardial leads are designed for use with implantable pulse generators which require pacing leads with a bipolar (BP) 3.2 mm IS-1 connector configuration. The leads are indicated for use in any patient for whom single or dual chamber pacemaker therapy is medically indicated.

BIOTRONIK TIR/TIJ Leads

The BIOTRONIK transvenous TIR 60/53 UP/BP and TIJ 53/45 UP/BP leads are indicated for pacing and sensing in the ventricle or atrium, respectively. The leads are designed for use with implantable pulse generators which require pacing leads with an unipolar (UP) or bipolar (BP) IS-1 connector configuration. The leads may be used with single or dual chamber pacing systems.



(Division Sign)
Division of Cardiovascular, Respiratory
and Neurological Devices
510(k) Number K972500