JAN 27 1998

1.4 Safety and Effectiveness Summary

The BIOTRONIK ELC xx-UP epicardial sutureless active fixation lead is a safe and effective unipolar lead used with implantable cardiac pacemakers when an epicardial lead is preferred, or when a transvenous lead cannot provide satisfactory results or is contraindicated. The lead body insulation of all ELC epicardial leads is NuSil MED-4750 silicone rubber tubing, with a conductor of quadrafilar MP35N wire.

These leads provide long-term safe and effective pacing through overall quality of design, manufacture and the surface structure of the active-fixation electrode tip. This tip is a single helically-wound fixation wire ("fixation screw") composed of 70% platinum and 30% iridium which has undergone a Physical Vapor Deposition (PVD) treatment, creating a fractal-surfaced, ball-like microstructure. The IS-1 (3.2 mm) connection system of the ELC lead complies with the International Standard ISO 5841.3:1992.

The materials used to manufacture the ELC leads which come into contact with the patient are commonly used in market-released leads, and have been tested for biocompatibility. Acute and chronic biocompatibility tests have been performed, as well as long-term implantation studies. In addition, corrosion studies were completed to address both long-term toxicity and durability of the PVD iridium treatment. The testing conducted for biocompatibility as well as extensive clinical experience confirms that iridium is safe for use as an implantable material, and analyses supporting this view have been published within technical journals. Long-term corrosion testing results substantiate that iridium is a non-toxic and durable material for use in implantable devices.

Additional qualification testing results validate the safety and effectiveness of the lead design and materials used. ELC leads are tested for weld strength of connections, fatigue strength, DC resistance, environmental resistance, adherence to IS-1 standards, packaging and transportation durability, electrical integrity, and sterilization validation. All test results were within specifications.

Field clinical experience as well as the *in-vitro* and qualification testing performed on the ELC lead show that the risk to the patient in using these leads is the same as that of any implantable epicardial lead.

Potential complications resulting from the use of epicardial leads include, but are not limited to: thombosis, embolism, body rejection phenomena, cardiac tamponade, muscle/nerve stimulation, fibrillation, and infection. Lead perforation through the myocardium has been rarely observed.

Table 2.0 below summarizes some of the potential symptoms indicating a complication and possible corrective actions:

Table 2.0
Lead Complications

SYMPTOM	POTENTIAL COMPLICATION	POTENTIAL CORRECTIVE ACTION
Loss of pacing or sensing	• Electrode dislodgement • Lead fracture • Setscrew penetration of lead insulation • Improper lead to pacemaker connection	• Reposition lead • Replace lead • Replace lead • Reconnect lead to pacemaker
Increase or decrease in threshold	• Fibrotic tissue formation	• Adjust pulse generator output; Reposition lead

The ELC lead received its CE mark in March, 1994, thereby clearing it for sale and distribution within the EEC. Since that date, over 2000 leads have been sold worldwide outside the United States, including 426 sold in 1996 (excluding December). There have been no reported device failures or complaints.

As of December 5, 1996, eighteen (18) leads have been implanted in the United States as part of a clinical trial with the Physios CTM 01 Cardiac Transplant Monitoring System (IDE #G960045; approved August 22, 1996).

All leads are functioning normally, with the exception of one which has been reported as an anticipated adverse event for the study - failing to yield consistent ventricular capture, potentially because of lead dislodgement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenneth Jensen
BIOTRONIK Regulatory Affairs
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369

JAN 27 1998

Re: K965106
Epicardial Pacing Leads, Models ELC 35 UP, ELC 54 UP
Regulatory Class: III (THREE)
Product Code: DTB
Dated: December 24, 1997
Received: December 29, 1997

Dear Mr. Jensen:

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 (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 regulation.

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 and 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.

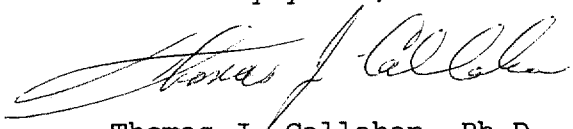
If you have questions specifically concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

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 requirement 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) 594-4648. 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/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

510(k) Number (if known): K965106

Device Name: ELC Epicardial Leads

Indications For Use:

The ELC xx-UP epicardial sutureless screw-in lead is indicated for unipolar pacing and sensing in the ventricle when an epicardial lead is preferred, or when a transvenous lead cannot provide satisfactory results or is contraindicated. Epicardial leads are well suited for situations where heart stimulation is necessary, for example, after open heart surgery, or based upon the patient's age or heart condition (e.g., in young patients who have not reached full physical maturity and risk potential lead dislodgement). Epicardial leads are also indicated in situations where transvenous access is not available or is contraindicated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurologic Devices
510(k) Number K965106

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)