

AUG 14 1997

K971930

1.2 Safety and Effectiveness Summary

BIOTRONIK BK-N Sealing Caps are single-component silicone devices, designed to be safe and effective through design functionality, simplicity and material biocompatibility.

BK-N Sealing Caps are designed to be chronically implantable. The material of construction is Silopren LSR-4070, which has been extensively used by BIOTRONIK in cardiac pacing lead designs. FDA has reviewed and cleared this material in the following submissions:

BK Series Sealing Caps

510(k) #K970204

Cleared April 29, 1997

Dromos DR and SR Pulse Generators

PMA #P950037

Approved October 11, 1996

TIR and TIJ Endocardial Leads

510(k) #K953044

Cleared September 27, 1996

Physios CTM 01 Pulse Generator and ELC XX-UP Epicardial Lead

IDE #G960045

Approved August 22, 1996.

Silopren LSR-4070 has been thoroughly tested for biocompatibility, and is commonly used in many market-released Class III products, including pacemaker and defibrillator leads and their accessories. Acute and chronic biocompatibility tests have been performed, as well as long-term implantation studies.

BK-N Sealing Caps are tested for ease of use, ability to withstand temperature change, required extraction force of lead (following ligature application), electrical insulation following storage in warmed, aerated saline (in-vitro testing), and ETO residues. Packaging and transportation durability as well as sterilization validation have been performed to ensure the quality and sterility of the delivered product.

All production and biocompatibility test results were within specifications; therefore, when the currently proposed BK-N Sealing Caps are in use, the patient will be exposed to no risks in excess of those experienced by patients using comparable competitor sealing caps distributed in the United States, or older model BIOTRONIK sealing caps. Complications arising from usage may include body rejection phenomena, fibrosis, displacement, infection, and erosion. BIOTRONIK is not aware of any other adverse safety and effectiveness data on these accessories.

In accordance with the Safe Medical Device Act of 1990, a thorough literature search for adverse safety and effectiveness data on pacemaker lead sealing caps was performed. The search yielded no articles related to the safety of pacemaker lead sealing caps.

1.3 Previous 510(k) Submittals

In a letter dated August 9, 1991 (#K911142), FDA provided notification it had determined the BK Series Sealing Caps were Class III devices substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. The BK-N Sealing Caps addressed in that 510(k) document were constructed of HTV silicone.

1.4 Summary of Proposed Changes

1.4.1 DEVICE CHANGES

BIOTRONIK is proposing the following changes to the BK-N Sealing Cap:

- MOC will be Silopren LSR-4070
- MOC change requires slight changes in sealing cap design



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

AUG 14 1997

Re: K971930
BK-N Sealing Cap
Regulatory Class: III (three)
Product Code: DTD
Dated: May 23, 1997
Received: May 27, 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 requirement, 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

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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 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

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the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

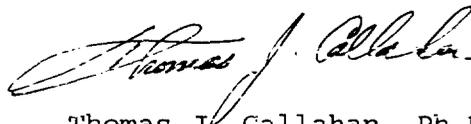
If you have questions specifically concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

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

1.1.1 INDICATIONS FOR USE

BK-N Sealing Caps are intended for use as components of cardiac pacing systems. BK-N Sealing Caps provide a permanent barrier of silicone insulation between the electrical conductive elements of the implantable therapeutic device lead(s) or adapter(s) and the physiological environment. BK-N Sealing Caps are designed to accommodate lead diameters of 4F, 5F and 7F.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices K971930
510(k) Number