

1.2 Safety and Effectiveness Summary

BIOTRONIK A1 Series Lead Adapters and the PEH Adapter Sleeve are designed to be chronically implantable, safe and effective through design functionality, simplicity and material biocompatibility. Both devices were cleared for distribution pursuant to FDA review of the 1990 510(k).

For A1 Series Lead Adapters, the following changes are proposed:

- a titanium alloy (Ti4) will be used for the manufacture of the device set screw;
- the silicone of the lead connector receptacles and connectors will change from DOW Corning HTV silicones to Silopren LSR-4070;
- NuSil MED 1137 will be used as a silicone tube adhesive;
- slight design improvements and modifications related to the above described silicone material changes;
- blister packaging material will change from XT Polymer to PETG;
- the catalog number will change.

For the PEH Adapter Sleeve, the following changes are proposed:

- the main silicone-based MOC will change from DOW Corning HTV silicones to Silopren LSR-4070;
- the catalog number will change.

The proposed changes in PEH Adapter Sleeves and A1 Series Lead Adapters as described above will not adversely affect the overall safety and effectiveness of these devices.

Lead adapters undergo extensive testing and repeated inspections during device manufacturing, packaging and sterilization procedures.

A1 Series Lead Adapters are tested for

- IS-1 connector seal integrity testing,
- lead receptacle seal integrity testing,
- 500-hour and 2000-hour in-vitro tests,
- insertion/extraction forces of the IS-1 connector
- insertion/extraction forces of the lead connector(s) within the adapter's receptacle(s),
- connector port stop force,
- flex testing of the receptacle connection,
- device handling,
- deformation testing of the IS-1 connector upon set screw clamp-down,
- strength of the connector/receptacle connection,
- abrasion testing,
- tensile strength and micrographic examination of welded connections,
- destructive pressure testing of silicone tubing,

- ability of lead receptacle to withstand binding by ligature,
- ability of device to withstand temperature change during shipping, and
- various dimensional and visual inspections during device manufacture.

PEH Adapter Sleeves are tested for

- seal integrity testing,
- device handling,
- 500-hour and 2000-hour in-vitro tests,
- ability of device to withstand temperature change during shipping, and
- various dimensional and visual inspections during device manufacture.

Packaging and transportation durability as well as sterilization validation have been performed to ensure the quality and sterility of the delivered product. No changes to PEH packaging are proposed within the present 510(k) submittal. A1 packaging will change in that the material from which the packaging blisters are manufactured will change.

All production and biocompatibility test results were within specifications; therefore, when the currently proposed A1 Series Lead Connectors and PEH Adapter Sleeves are in use, the patient will be exposed to no risks in excess of those experienced by patients using comparable competitor adapters manufactured and distributed in the United States, or previous model BIOTRONIK adapters.

Possible side effects of lead adapter 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 these accessories.

In accordance with the Safe Medical Device Act of 1990, a thorough literature search for adverse safety and effectiveness data on lead adapters and adapter sleeves was performed. The search yielded several articles related to the safety of lead adapters, as well as information on device recalls. Lead adapters are safe and effective devices, when used in a manner consistent with manufacturer recommendations. The majority of adapter failures presented in the literature resulted from a loose device/adapter or adapter/lead connection. Some cases of wire or insulator breakage were reported, as were some instances where the adapter set screw, even when used in a manner consistent with manufacturer instructions, protruded from the side of the adapter, abrading and eroding the silicone insulation of both the adapter and the pacemaker device.

BIOTRONIK lead adapters are designed in a manner which avoids many of the aforementioned problems. Worldwide, there have been no voluntary or required recalls of the A1 Series Lead Adapters or PEH Adapter Sleeve. The only adverse event related to use of A1 Series Lead Adapters or PEH Adapter Sleeves worldwide occurred in September, 1996, and was related to the use of an A1-A lead adapter within the United States. In this instance a gradual deterioration in unipolar impedance following adapter implant was reported; this was remedied by removal of the adapter. An insulation break involving the adapter was suspected, but the observed impedance changes also could have resulted from the adapter set screw not being covered with medical adhesive at time of initial adapter implant. No record of a detailed structural examination of the

explanted device was provided to BIOTRONIK, nor was BIOTRONIK provided the opportunity to examine the explanted device.

1.3 Previous 510(k) Submittals

In a letter dated August 23, 1990 (#K902889), FDA provided notification it had determined the A1 Series Lead Adapters and PEH Adapter Sleeves were Class III devices substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976.

The following devices were submitted within the 1990 510(k):

- A1-A:** adapts one 5 mm unipolar connector to fit IS-1 connector receptacle
- A1-B:** adapts one 6 mm unipolar connector to fit IS-1 connector receptacle
- A1-ABP:** adapts two 5 mm unipolar connectors to fit IS-1 connector receptacle
- A1-MBP:** adapts one 3.2 mm "in line" bipolar connector to fit IS-1 connector receptacle; or, adapts one 3.2 mm unipolar connector to fit IS-1 connector receptacle.

- A1-Z:** adapts one unipolar connector without a connector to fit IS-1 connector receptacle

- A6-A:** adapts one unipolar connector without a connector to fit 5 mm unipolar connector receptacle
- A6-B:** adapts one unipolar connector without a connector to fit 6 mm unipolar connector receptacle

- PEH Sleeve:** adapts one unipolar lead with 5 mm connector to fit 6 mm connector receptacle.

** Note: the A1-Z, A6-A and A6-B adapters are no longer distributed by BIOTRONIK within the United States.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

AUG 14 1997

Re: K970388
A1-A, A1-B, A1-ABP, A1-MBP Adapters and PEH Adapter Sleeve
Regulatory Class: III (three)
Product Code: 74 DTD
Dated: May 29, 1997
Received: June 2, 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 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 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 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 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.

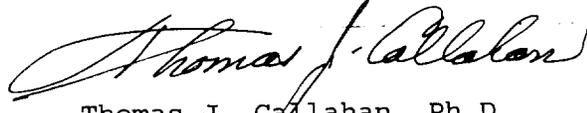
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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. Also, please note 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

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toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

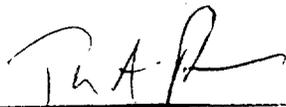
A handwritten signature in cursive script, appearing to read "Thomas J. Callahan".

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

Lead adapters, including silicone adapter sleeves, when used in conjunction with their accessories, provide a means of securely connecting pace/sense leads with otherwise mechanically incompatible pacemaker devices.



(Division Sign-Off)
Division of Cardiovascular, Respiration
and Neurological Devices
510(k) Number K970388