

1.4 Safety and Effectiveness Summary

The RETROX endocardial lead is a safe and effective bipolar sense/pace lead used with implantable cardiac pacemakers when an active-fixation endocardial lead is preferred. The lead body insulation is NuSil MED-4750 silicone rubber tubing, with a conductor of quadrafil 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. This is the same material used for the active-fixation helix of the BIOTRONIK ELC lead, a unipolar epicardial active-fixation lead (ELC xx-UP Epicardial Lead, 510(k) #K965106, cleared January 27, 1998).

The patient-contact materials used to manufacture RETROX leads are commonly used in market-released leads. Additionally, corrosion studies were completed to address both long-term toxicity and durability of the physical vapor deposition (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 validation testing results validate the safety and effectiveness of the lead design and materials used. RETROX leads undergo extensive device and component evaluations, including IS-1 BP connector testing, Si tube abrasion testing, lead tip and ring testing, complete lead mechanical, electrical and environmental testing, stylet testing, silicone adhesive testing, suture sleeve testing and sterile package testing. All test results were within specifications.

Based on the similarity of RETROX lead design to other market-released active fixation retractable endocardial leads, *in-vitro* and other validation testing performed by the manufacturer, non-U.S. and limited U.S. clinical experience, the risk to the patient in using these leads is the same as that of any implantable endocardial lead.

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

Table 3 below summarizes some of the potential symptoms indicating a complication and possible corrective actions:

**Table 3
Lead Complications**

SYMPTOM	POTENTIAL COMPLICATION	POTENTIAL CORRECTIVE ACTION
Loss of pacing or sensing	<ul style="list-style-type: none"> • Electrode dislodgement • Lead fracture • Setscrew penetration of lead insulation • Improper lead to pacemaker connection 	<ul style="list-style-type: none"> • Reposition lead • Replace lead • Replace lead • Reconnect lead to pacemaker
Increase or decrease in threshold	<ul style="list-style-type: none"> • Fibrotic tissue formation 	<ul style="list-style-type: none"> • Adjust pulse generator output; • Reposition lead

1.5 Summary of Studies

1.5.1 NONCLINICAL STUDIES

Validation testing was performed to evaluate the final device as well as various manufacturing processes. All applicable national and international standards and/or criteria were evaluated. In all cases, test specifications were met. Tests were performed in the following categories:

- IS-1 BP connector testing
- Si tube abrasion testing
- lead tip and ring testing
- complete lead mechanical, electrical and environmental testing
- stylet testing
- silicone adhesive testing
- suture sleeve testing
- sterile package testing

1.5.2 CLINICAL STUDIES

The Interim Clinical Investigation Summary is presented within **Appendix 3**. A total of 31 leads were implanted in a total of 19 patients prior to discontinuation of the study; 14 RETROX leads and 17 control (Oscor) leads were implanted. The Interim Clinical Investigation Summary presents data received between the date of study initiation (November 26, 1997) and March 15, 1998. Data from implant documentation, patient follow-up visits and out-of-service case report forms are included.

Three anticipated adverse events have been recorded associated with the 14 study leads implanted to date; four anticipated adverse events have been recorded associated with the 17 control leads implanted to date. There have been no unanticipated adverse device effects experienced with the RETROX pacing leads as defined in 21 CFR 812.3(s); there have been no reported patient complaints regarding RETROX pacing leads.

There was one patient death reported during the clinical investigation. The patient had been randomized to control leads in both the atrium and the ventricle. This death was evaluated by the investigator and determined to be unrelated to the pacing system; relevant information is presented within the Interim Clinical Investigation Summary.



Food and Drug Administration
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Ms. Lauren L. Foote Christensen
Manager, Regulatory Affairs Bradycardia
Biotronik, Inc.
6024 Jean Road
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Re: K981083
Trade Name: Retrox RX 53-BP, Retrox RX 60-BP, Retrox RX
45-JBP, and Retrox 53-JBP Active Fixation Endocardial Leads
Regulatory Class: III
Product Code: DTB
Dated: June 17, 1998
Received: June 19, 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 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) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of

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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 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

Indications for Use

The BIOTRONIK **RETROX RX 53/60-BP** and **RETROX RX 45/53-JBP** transvenous, active fixation endocardial leads are indicated for permanent pacing and sensing. Active fixation pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators. The leads may be used with single- or dual-chamber pacing systems.

RETROX RX-BP and **RX-JBP** leads differ in the shape of the distal portion of the lead. The **RX-BP** models are intended for placement in the ventricle or atrium and have straight distal ends. The **RX-JBP** models have a pre-formed J-shaped distal end to facilitate lead placement in the right atrial appendage.

The indications for use of a **RETROX** lead in combination with a connected cardiac pacemaker follow those 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.)