

**V. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

K945627

**GENERAL INFORMATION**

**Device Name:**  
*Proprietary Name* Pikos LP 01, Pikos LP E01  
*Classification Name* Implantable Pacemaker Pulse Generators

**Device Classification:** Class III (21 CFR 870.3610)

**Manufacturer:** BIOTRONIK GmbH & Co.  
Woermannkehre 1  
D-12359 Berlin  
Germany

Registration No.: 7010992

**Applicant's Name & Address:** BIOTRONIK, Inc.  
6024 Jean Road  
Lake Oswego, OR 97035

**Establishment Registration No.:** 1028232

**Performance Standards:** No applicable performance standards have been promulgated for these devices.

**DESCRIPTION OF DEVICE**

The Pikos LP 01/LP E01 is a multi-programmable single chamber pulse generator which is designed and recommended for use with atrial or ventricular leads. The Pikos LP 01/LP E01 models offer a limited number of programmable options compared to those of the Pikos 01/E01 models.

**SUBSTANTIAL EQUIVALENCE**

The Pikos LP 01/LP E01 pulse generators are substantially equivalent to the currently marketed Pikos 01 and Pikos E01 respectively (K914109/A, approved February 26, 1992). Data to support this statement is provided in the premarket notification.

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## INTENDED USE

The Pikos LP 01/LP E01 models, like the Pikos 01/E01 models, are indicated for use in the following conditions:

- Sinus node arrest or bradycardia with or without AV conduction disorder.
- Intermittent or complete AV conduction block.
- Brady/tachy syndrome or other manifestation of sick sinus syndrome which results in symptomatic bradycardia.
- Atrial fibrillation and ventricular bradyarrhythmia.

## QUALIFICATION TESTING

Qualification testing for the Pikos LP 01/LP E01 models is provided in this submission with the exception of battery qualification data which is identical to that submitted in the Pikos 01/E01 premarket notification (K914109/A). Qualification reports describing the testing conducted for validation of the self-sealing header are included in this submission. The qualification of the self-sealing header included vibration, shock, temperature and transport tests; tests meeting the applicable IS-1 requirements; header leakage resistance tests. Sterilization of the self-sealing header was validated. Hybrid circuit modifications were qualified with complete electrical and mechanical testing.

## LABELING

Proposed labeling for the Pikos LP 01/LP E01 models is included in the premarket notification. The product labeling includes instructions for use adequate to assure safe and effective operation of the device.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

'APR 21 2009

Mr. Jon Brumbaugh  
Vice President, Regulatory Affairs and Compliance  
BIOTRONIK, Inc  
6024 Jean Road  
Lake Oswego, OR 97035

Re: K945627

Trade/Device Name: Pikos LP 01 and Pikos LP E 01 Pacemakers  
Regulation Number: 21 CFR 870.3610  
Regulation Name: Implantable pacemaker pulse generator  
Regulatory Class: III (three)  
Product Code: 74 DXY  
Dated: November 22, 1995  
Received: November 24, 1995

Dear Mr. Brumbaugh:

This letter corrects our substantially equivalent letter of March 5, 1995.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

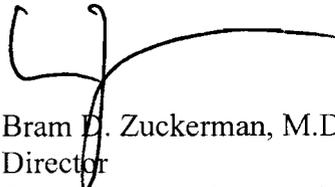
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health