

Pikos Family of Pulse Generators Release of the NIPS Feature

1. SPECIAL 510(K) SUMMARY

Name and Address of Sponsor: BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name: Proprietary Names: Pikos
Device Class: Classification: Class III
Classification Name: Implantable Pacemaker Pulse Generator
Product Code: 74 WST; KRG

Date Prepared: October 7, 1999

General Description

BIOTRONIK requests clearance of the NIPS (Non-Invasive Programmed Stimulation) feature for BIOTRONIK's family of Pikos pulse generators. NIPS is provided as a feature in each of these pulse generators by allowing access to the NIPS software drivers that were previously locked out. Each of these pulse generators has been FDA approved for use with the EPR 1000^{PLUS} programmer (dated P950037/S8, dated 08-24-99). The affected members of the Pikos family are comprised of the following pulse generators.

Table 1

Pulse Generator Name	Cleared	Feature Set	Lead Port
Pikos 01	K914109A	Full	IS-1
Pikos E01	K914109A	Full	IS-1
Pikos 01-A	K923026C	Full	5-mm
Pikos E01-A	K923026C	Full	5-mm
Pikos 01-B	K9141937	Full	6-mm
Pikos E01-B	K9141937	Full	6-mm

Unlocking the NIPS feature within the programmer software allows a previously implanted pulse generator and lead system to invoke high rate pacing and perform a variety of cardiac electrophysiological (EP) studies.

The NIPS feature is generated entirely through the existing pulse generator and lead system. This feature is controlled by the programmer and activates the pulse generator only when the wand is placed directly over the device. There are no other external devices required for this system. The NIPS feature is approved for each pulse generator listed above outside the US, but has been blocked from the Pikos devices through BIOTRONIK's software lock. The NIPS feature will be unlocked for each member of the Pikos family with a release code to the B-HXX.0.U programmer software. BIOTRONIK will identify the software version as B-H02.0.U.

There are no hardware changes to any of the pulse generators or the EPR 1000^{PLUS} programmer system to allow this feature. The primary functions of these pulse generators, the EPR 1000^{PLUS} programmer system and the B-H02.0.U software remain the same.

Indications for Use:

The indications/contraindications for use of the PIKOS products are identical to those for all single chamber (AAI or VVI) pulse generators.

The use of multi-programmable, single chamber pacemakers is indicated as a therapeutic modality for control of heart rate, provided that implantation is preceded by an adequate diagnostic check, and no parameter values dangerous for the patient are programmed. The use of the pacemaker in the atrium is contraindicated in the case of AV conduction disorder, and if atrial fibrillation or atrial flutter are exhibited. Ventricular pacing is not indicated in patients who already showed a pacemaker syndrome especially if a dual chamber pacemaker can be used.

Name and Address of Manufacturing Site:

BIOTRONIK GmbH & Co. (reg. no. 7010992)
Woermannkehre 1, 12359 Berlin, Germany
011-49-30-689-05-304

Contact Person(s) and Phone Number:

Jon Brumbaugh
Director, Regulatory Affairs
Phone (888) 345-0374
Fax (503) 635-9936



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Mr. Jon Brumbaugh
Director, Regulatory Affairs
Biotronik, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K993434
Implantable Pacemaker Pulse Generator
Regulatory Class: III (three)
Product Codes: DXY
Dated: October 7, 1999
Received: October 12, 1999

Dear Mr. Brumbaugh:

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, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). 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.

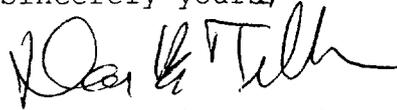
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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) 594-4648. 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" (21CFR 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,

for 

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K993434

Device Name: BIOTRONIK, Inc. Pikos single chamber pacemakers Models 01/01-A/E01/LP 01/LP E01/E01-B

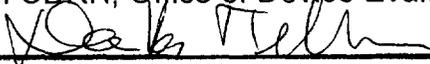
Indications For Use:

Pikos single chamber pacemakers, Models 01/01-A/E01/LP 01/LP E01/E01-B pacemakers are indicated for the following:

- Symptomatic paroxysmal or permanent second or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Vasovagal syndromes or hypersensitive carotid sinus syndromes

(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 Neurological Devices
510(k) Number K993434

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)