K964190
July 10, 1997

A. 510(k) Summary of Safety and Effectiveness

1. General Information

Device Name	
Proprietary Name	ERA 300 Dual Chamber Pacing System Analyzer
Classification Name	External Pacemaker Pulse Generator Pacemaker Electrode Function Tester Pacemaker Generator Function Analyzer
Manufacturer	BIOTRONIK GmbH & Co. Woermannkehre 1 D-12359 Berlin Germany
Manufacturer's Registration Number	7010992
Applicant's Name & Address	BIOTRONIK, Inc. 6024 Jean Road Lake Oswego, OR 97035
Establishment Registration Number	1028232
Performance Standards	No applicable performance standards have been promulgated for these devices.

2. Device Description

The ERA 300 is a portable, dual-chamber pacing system analyzer (non-implantable) designed to test the electrical performance of the pulse generator and the pacing lead system at the time of pacemaker implantation and during invasive pacemaker troubleshooting or evaluation procedures. It can also operate as an external programmable pulse generator.

3. Substantial Equivalence

The ERA 300 is substantially equivalent to the FDA-cleared SeaMED Model 3300 Dual-Chamber Pacing System Analyzer, approved 8/19/86 (K883930), and the Medtronic Model 5311B A-V Pacing System Analyzer, approved (K884331). Data to support this statement are provided in the premarket notification.

4. Intended Use

The ERA 300 is intended for use in the following conditions:

- **Temporary External Pacing Function.** Provides temporary stimulation under DDD, DDI, VDD, DOO, VVI, VOO, AAI, or AOO

modalities during implantable pacemaker procedures or physician evaluations.

- **Lead Test Function.** Determines *in situ* lead characteristics of impedance, capture threshold, P/R wave amplitude and P/R wave slew rate. Determines the *in vivo* retrograde conduction time.
- **Pacemaker Test Function.** Tests and analyzes the *in vitro* operation of external or implantable pulse generators. Determines the parameters: modality, pulse amplitude and width, sensitivity, refractory period, A/V delay, and rate/interval.

5. Qualification Testing

Qualification testing for the ERA 300 is provided in this submission for the tests described in Table III, pages 14–33. Table III is organized into six main categories: ERA 300 Main Unit (System Checks); ERA 300 Main Unit (Electromagnetic Compatibility and Circuit Design); ERA 300 Main Unit (Firmware); ERA 300 Battery; Battery Recharger (ACD 300); and Pacemaker Test Cable (EK-4-E). Internal standards and specifications were used when relevant international standards were not available.

6. Labeling

Proposed labeling for the ERA 300 is included in the premarket notification. The product labeling includes instructions for use adequate to assure safe and effective operation of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 1997

Mr. Taras Tatarko, M.S.
Biotronik, Inc.
6024 Jean Road
Lake Oswego, Oregon 97035-5369

Re: K964190
ERA 300 Dual Chamber Pacing System Analyzer
Regulatory Class: III (three)
Product Code: 74 DTE
Dated: May 20, 1997
Received: May 21, 1997

Dear Mr. Tatarko:

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, 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 (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, 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 premarket 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.

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" (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/dsmamain.html".

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

The ERA 300 is indicated for use during invasive pacing system procedures in the following activities:

- **TEMPORARY EXTERNAL PACING**
  To provide temporary stimulation under DDD, DDI, DOO, VVI, VDD, VOO, AAI, or AOO modalities during implantable pacemaker procedures or physician evaluations.
- **LEAD THRESHOLD DETERMINATION**
  To determine in situ lead characteristics of impedance, capture threshold, P/R wave amplitude and P/R wave slew rate. To determine the in vivo retrograde conduction time.
- **PACEMAKER FUNCTION TEST**
  To test and analyze the in vitro operation of external or implantable pulse generators. To determine the following parameters: pulse amplitude and width, sensitivity, refractory period, A/V delay, and rate/interval.

for _____
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964190

Prescription Use ✓
(Per 21 CFR 801.109)