DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 29, 2017

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

Re: K171514
Trade/Device Name: BioMonitor 2 Insertable Cardiac Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MXD
Dated: May 22, 2017
Received: May 24, 2017

Dear Jon Brumbaugh:

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 application (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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 Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171514

Device Name
BioMonitor 2 Insertable Cardiac Monitor

Indications for Use *(Describe)*
The BioMonitor 2 is indicated to detect the following cardiac arrhythmias:
• Atrial fibrillation,
• Bradycardia,
• Sudden rate drop,
• High ventricular rate (HVR),
• Asystole.

The BioMonitor 2 is indicated for:
• Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
• Patients who experience transient symptoms that may suggest a cardiac arrhythmia
• The device has not been tested for and it is not intended for pediatric use

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1. Submitter

BIOTRONIK
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Lake Oswego, OR 97035
Phone: (888) 345-0374
Fax: 503-451-8519

Contact Person: Jon Brumbaugh

Date Prepared: June 29, 2017

2. Device

Name of Device	BioMonitor 2 Insertable Cardiac Monitor
Common or Usual Name	Insertable Cardiac Monitor
Classification Name	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Classification	Class II (21 CFR 870.1025)
Product Code	MXD

3. Predicate Devices

BIOTRONIK BioMonitor 2 (K152995, cleared April 11, 2016)

4. Device Description

The BioMonitor 2 senses subcutaneous electrocardiograms (SECG) using two integrated electrodes and has the capability of detecting a number of arrhythmias. The BioMonitor 2 uses BIOTRONIK's Home Monitoring to send recorded SECG and statistics to the Home Monitoring Service Center (P950037/S66, dated November 21, 2008; and P950037/S69, dated March 23, 2009) for further analysis. BioMonitor 2 is intended to aid in the diagnosis of cardiac arrhythmias that might otherwise go undetected.

BioMonitor 2 is designed to detect and trigger automatic recording of certain cardiac arrhythmias; these arrhythmias can be classified as follows:

- atrial fibrillation
- bradycardia
- sudden rate drop
- high ventricular rate (HVR)
- asystole.

Patients can also manually trigger recording of the cardiac information by use of the Remote Assistant. The memory capacity of BioMonitor 2 is such that the device can record at least 66 minutes of subcutaneous electrocardiograms (SECG). The device automatically stores a maximum of 55 separately recorded SECG-episodes of 40 seconds each (60 seconds maximum), and a maximum of 4 patient triggered SECG-episodes of 7.5 minutes. The BioMonitor 2 reports the recorded episodes and related statistical data through the physician's programmer and BIOTRONIK's Home Monitoring®.

5. Indications for Use

The BioMonitor 2 Insertable Cardiac Monitor is indicated to detect the following cardiac arrhythmias:

- Atrial fibrillation,
- Bradycardia,
- Sudden rate drop,
- High ventricular rate (HVR),
- Asystole.

The BioMonitor 2 Insertable Cardiac Monitoris indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- The device has not been tested for and it is not intended for pediatric use.

6. Comparison of Technological Characteristics with the Predicate Device

The technological principles of the subject and predicate device are the same. The differences represent minor modifications to the currently marketed BioMonitor 2 as follows:

- Dimensional changes to the FIT accessories:
  - FIT1 assists to create the device pocket for insertion. Dimensions at the tip and handle of this accessory were modified for improved handling.
  - FIT2 supports the device during insertion. Dimensions of this accessory were modified for improved support during insertion.
- Packaging changes to the FIT accessories:
  - FIT1 and FIT2 were provided separately in double sterile pouches, and may now be provided together in a sterile blister package.
- A visual inspection was added to the receiving inspection of batteries. Subsequent testing and inspections, including acceptance criteria for device performance, are unchanged.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

To demonstrate that the modified BioMonitor 2 meets the same performance criteria, the following tests were conducted using the same test methods and acceptance criteria as for the predicate device.

- Mechanical system verification of FIT1 and FIT2
- Visual inspection and handling of FIT1 and FIT2
- Usability testing: system verification and validation
- Visual inspection of labeling
- Compatibility testing of BioMonitor 2 with FIT 2
- Procedure of implantation: Product Validation
- Bioburden
- Pyrogenicity
- Sterilization validation
- Biocompatibility
- Packaging validation, including seal integrity, environmental conditioning, sealing process, and label integrity

No clinical testing was deemed necessary or completed in the premarket notification submission for a determination of substantial equivalence.

8. Conclusions

The subject device results from minor modifications to the predicate device. The performance testing demonstrates that the subject device meet the same functional acceptance criteria for the same intended use.