



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 11, 2016

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

Re: K152995

Trade/Device Name: BioMonitor 2

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: March 10, 2016

Received: March 11, 2016

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 yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored FDA logo watermark.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K152995 - Page 1 of 1

Device Name  
BioMonitor 2

### Indications for Use (Describe)

The BioMonitor 2 indicated to detect the following cardiac arrhythmias:

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

The BioMonitor 2 is indicated for use in:

- 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 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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# BioMonitor 2

## Implantable Cardiac Monitor

### Traditional 510(k) Premarket Notification

#### 1. SUBMISSION INFORMATION

**Date 510(k) Summary Prepared:** October 9, 2015

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

**Establishment Registration Number:** 1028232

**Name and Address of Manufacturer:** BIOTRONIK SE & Co. KG (reg. no. 9610139)  
Woermannkehre 1,  
12359 Berlin, Germany  
011-49-30-689-05-1210

Sterigenics Germany GmbH  
Kasteler Straße 45  
D- 65203 Wiesbaden, Germany

**Contact Person(s) and Phone Number:** Jon Brumbaugh  
VP, Regulatory Affairs and Compliance  
Phone (888) 345-0374  
Fax (800) 913-6993  
[jon.brumbaugh@biotronik.com](mailto:jon.brumbaugh@biotronik.com)

**Device Name:** Trade Name: BioMonitor 2  
Common Name: Implantable Cardiac Monitor  
Classification Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm).  
Classification: Class II (21 CFR 870.1025)  
Product Code: MXD

#### General Description:

The BioMonitor 2 is a small, leadless, implantable device that uses two electrodes on the body of the device to monitor continuously the patient's subcutaneous ECG. The BioMonitor 2 is designed to record automatically the occurrence of arrhythmias in a patient. Recordings can also be triggered by use of the associated Remote Assistant. Arrhythmia may be classified as atrial fibrillation, bradycardia, asystole, or high ventricular rate. The device memory can automatically store a maximum of 55 separately recorded SECG-episodes of 40 seconds each, and 4 patient triggered SECG-episodes of 7.5 minutes.

**Predicate Devices:**

- BIOTRONIK BioMonitor with AF Detection (K143503, cleared March 19, 2015)

**Indication for Use:**

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 use in:

- 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

**Technological Characteristics and Substantial Equivalence:**

The substantial equivalence claim between the subject and the predicate device is supported by the information included in this premarket notification. This includes the following information:

- Description of the subject and predicate devices
- Intended use of the subject and predicate devices
- Performance of the subject and predicate devices
- Technological characteristics of the subject and predicate devices
- Validation testing

**Table 1: BioMonitor 2 Compared to Predicate Device (changes are highlighted)**

Technical Data	BioMonitor	BioMonitor 2
<b>FDA Clearance</b>	<b>K143503</b>	<b>Subject</b>
Dimensions (mm) Length x Width x Height	53.3 x 42.7 x 7.1	88.4 x 15.2 x 6.2 Rigid portion 55.5 x 15.2 x 6.2
Volume	12.5 cc	5 cc
Weight	26 g	10.1 g
Longevity	48 months (+ 12 months pre-implant shelf life + 2 months ERI life)	
Subcutaneous ECG Recording	Yes	
Pre and Post Event Storage	Yes	
sECG Storage	35.8 min 22.5 min for patient triggered events 13.3 min for auto-activated events Longest/oldest/newest	>66 min 30 min for patient triggered events 36.7 min for auto-activated events Longest/oldest/newest
Patient Activation	7.5 min per event 7 min prior to activation 0.5 min following activation	
Asystole Brady/rate drop VT-FVT	40 s/episode 30 s prior auto activation 10 s post auto activation	
AF	40 s/episode 30 s prior auto activation 10 s post auto activation	
Vector Mapping Required	No	
Sampling Rate	128 Hz	
Auto Activation Triggers	Yes	
Manual (Patient) Activation Trigger	Yes - via magnet	Yes – via Remote Assistant
High Rate Trigger	Yes	
Programmable High Rate Count	Yes	
Low Rate Trigger	Yes	
Asystole Trigger	Yes	
Remote Monitoring	Home Monitoring daily transmissions, up to 1 episode per day	Home Monitoring daily transmissions, up to 6 episodes (at least one per triggered event type) per day
QRS Detection	Combination signal out of 3 vectors	Single vector
MR Conditional	1.5T, full body scan	1.5T and 3.0T, fully body scan

**Performance Data:**

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

### Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" in a separate submission. The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

### 3.0T MRI Scan Testing

BIOTRONIK conducted validation testing according to the Joint Working Group's International Technical Specification for ISO/TS 10974: 2012 (E). The following tests were performed:

- Gradient Induced Heating
- Vibration
- Static Malfunction
- Gradient Radiated Malfunction
- Vibration Malfunction

### Clinical Study

The objective of this study was to provide clinical data of the implantation procedure and the sensing quality of BIOTRONIK's second generation of Implantable Cardiac Monitor (ICM) BioMonitor 2. Data from 30 patients at 5 Australian clinical sites from December 18, 2014 through July 06, 2015 is included to support the substantial equivalence of BioMonitor 2 when compared to the predicate device. Additional implantations have commenced recently in Europe as part of a controlled Post Market Observation (PMO), as of October 9, 2015 there have been 15 implantations.

### List of Applied Standards

The BioMonitor 2 was tested in accordance with the following standards:

- EN 45502-1 (1997) Section 21
- EN 45502-2-1 (2003) Section 6.1.3
- ISO 11135-1 (2007)
- ISO 14708-1 (2014)
- ISO/TS 10974 (2012)

### **Conclusion:**

BIOTRONIK considers the BioMonitor 2 implantable cardiac monitor to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.