July 5, 2019

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

Re: K190548
Trade/Device Name: BIOMONITOR III, Remote Assistant III
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: June 4, 2019
Received: June 6, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Nicole Goodsell
External Heart Rhythm and Rate Team
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190548

Device Name
BIOMONITOR III

Indications for Use *(Describe)*
The BIOMONITOR III 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

BIOTRONIK
excellence for life

510(k) Summary
BIOMONITOR III, Implantable Cardiac Monitor
Traditional 510(k) Premarket Notification

1. Submission Information

Date prepared March 1, 2019

Contact

Jon Brumbaugh
VP, Regulatory Affairs and Compliance
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Phone (888) 345-0374
jon.brumbaugh@biotronik.com

Manufacturer

BIOTRONIK SE & Co. KG
Woermannkehre 1,
12359 Berlin, Germany

Registration number 9610139

2. Subject Device

Trade Name BIOMONITOR III

Common Name Implantable Cardiac Monitor

Classification Name Recorder, Event, Implantable Cardiac (With Arrhythmia Detection)

Classification Class II (21 CFR 870.1025)

Product Code MXD

3. Predicate Device

BIOTRONIK BioMonitor 2, K152995, cleared April 11, 2016

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Telephone 800-547-0394
Fax 800-291-0470
www.biotronik.com

4. Device Description

BIOMONITOR III is a programmable, subcutaneous insertable monitor able to record subcutaneous ECGs (sECGs) and other physiological parameters.

The BIOMONITOR III is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial fibrillation (AF), bradyarrhythmia, asystole, sudden rate drop, or high ventricular rate. In addition, the BIOMONITOR III can be activated by the patient to record cardiac rhythm during symptomatic episodes. BIOMONITOR III may be used with the current legally marketed BIOTRONIK Home Monitoring® technology, which is an automatic, wireless, remote monitoring system for management of patients with implantable cardiac monitors. The BIOMONITOR III is smaller than the predicate BioMonitor 2 while maintaining the same clinical functionality.

5. Indications for Use

The indications for use for the BIOMONITOR III are identical to the predicate device.

The BIOMONITOR III 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.

6. Technological Characteristics

The substantial equivalence claim between the subject and the predicate device is supported by the information included in the 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

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Telephone 800-547-0394
Fax 800-291-0470
www.biotronik.com

BIOTRONIK
excellence for life

Table 1. Comparison of BIOMONITOR III and Predicate, BioMonitor 2

Technical Data	BioMonitor 2	BIOMONITOR III
FDA Clearance	**K152995, Predicate**	**Subject of this 510(k)**
Indications	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	
Principle of Operation	The BIOMONITOR III senses subcutaneous electrocardiograms (SECG) using two integrated electrodes and has the capability of detecting a number of arrhythmias. Like the predicate device, BIOMONITOR III sends recorded SECG and statistics to the Home Monitoring Service Center.	
Dimensions (mm) Length x Width x Height	53.4 x 15 x 6 (can) 88.4 length w/ lead	47.5 x 8.3 x 4.3 (can) 77.5 x 8.6 x 4.6 w/ lead
Volume	5.0 cc	1.9 cc
Weight	10.1 g	4.0 g
AT/AF	40 s/episode 30 s prior auto activation 10 s post auto activation	
MR Conditional	Yes	

7. Non-Clinical Performance Data

The following performance data are provided in support of the substantial equivalence determination:

7.1 Pre-clinical Study:

A preclinical study was performed in accordance with 21 CFR Part 58. The study was designed to assess whether the BIOTRONIK BIOMONITOR III ICM is safe and additionally to provide a comparison to the predicate device, BioMonitor 2.

This study successfully demonstrated no safety issues related to the BIOMONITOR III incision tool, FIT OneStep insertion tool, or the implant itself. In addition, the study demonstrated equivalent QRS detection performance between BIOMONITOR III and the predicate device over the course of the implantation period.

7.2 Usability Testing:

Usability/human factors aspects of BIOMONITOR III have been assessed, designed and validated in conformance to IEC 62366-1, in the context of the FDA's Guidance for Industry and Food and Drug Administration Staff: *Applying Human Factors and Usability Engineering*

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Telephone 800-547-0394
Fax 800-291-0470
www.biotronik.com

to Medical Devices. Based on these tests, the BIOMONITOR III user interfaces were found to be safe and effective for the intended users, uses and use environments.

7.3 Validation and Verification Testing:

The BIOMONITOR III, delivery tools, and Remote Assistant III have undergone thorough validation and verification testing to ensure final device functionality. The following categories of tests were performed and passed:

- Particulate Matter Validation
- Mechanical Verification and Validation
- Electrical Verification and Validation
- Biocompatibility
- Sterilization Validation

7.4 1.5T and 3.0T MRI Testing:

BIOTRONIK conducted validation testing according to the Joint Working Group's International Technical Specification for ISO/TS 10974: 2018.

8. Clinical Performance Data

No clinical performance data was submitted or relied upon in support of the substantial equivalence determination.

9. Conclusion

BIOTRONIK concludes that the BIOMONITOR III is substantially equivalent to BIOTRONIK's BioMonitor 2. The subject and predicate devices use the same principles of operation, have similar device features. The BIOMONITOR III device keeps the core software features and functionality as the BioMonitor 2, the detection algorithms of BIOMONITOR III being unchanged from the predicate device. Hardware design is similarly adapted from the predicate with the only significant difference being that the BIOMONITOR III implant hardware-platform has been miniaturized with respect to BioMonitor 2. BIOMONITOR III has the same part-rigid part-flexible design and the same overall shape as the predicate device (BioMonitor 2). Usability has been enhanced with minor GUI changes and improvements to the implantation tools. These aspects of equivalence are confirmed by testing provided within the application.

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Telephone 800-547-0394
Fax 800-291-0470
www.biotronik.com