April 23, 2020

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

Re: K200444
Trade/Device Name: BIOMONITOR III, BIOMONITOR IIIm
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: February 21, 2020
Received: February 24, 2020

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

Jennifer Shih
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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)*
K200444

Device Name
BIOMONITOR III
BIOMONITOR IIIm

Indications for Use *(Describe)*
The BIOMONITOR III/BIOMONITOR IIIm is indicated to detect the following cardiac arrhythmias:
- atrial fibrillation
- bradycardia
- sudden rate drop
- high ventricular rate (HVR)
- asystole

The BIOMONITOR III/BIOMONITOR IIIm 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.

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510(k) Summary

BIOMONITOR III and BIOMONITOR IIIm, Implantable Cardiac Monitors

Traditional 510(k) Premarket Notification

1. Submission Information

Date prepared February 19, 2020

Contact

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Manufacturer

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

Registration number 9610139

2. Subject Devices

Trade Name	BIOMONITOR III and BIOMONITOR IIIm
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 III, K190548, cleared July 5, 2019

4. Device Descriptions

BIOMONITOR III and BIOMONITOR IIIm are programmable, subcutaneous insertable cardiac monitors able to record subcutaneous ECGs (sECGs) and other physiological parameters.

The BIOMONITOR III and BIOMONITOR IIIm are 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 and BIOMONITOR IIIm can be activated by the patient using the Remote Assistant III to record cardiac rhythm during symptomatic episodes. BIOMONITOR III and BIOMONITOR IIIm 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.

5. Indications for Use

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

The BIOMONITOR III/BIOMONITOR IIIm are indicated to detect the following cardiac arrhythmias:

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

The BIOMONITOR III/BIOMONITOR IIIm 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

Table 1. Comparison of Updated BIOMONITOR III, BIOMONITOR IIIm and Predicate, BIOMONITOR III

Technical Data	Predicate BIOMONITOR III	Updated BIOMONITOR III and BIOMONITOR IIIm
FDA Clearance	**K190548, Predicate**	**Subjects 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/BIOMONITOR IIIm senses subcutaneous electrocardiograms (SECG) using two integrated electrodes and has the capability of detecting a number of arrhythmias. Like the predicate device, BIOMONITOR III/BIOMONITOR IIIm sends recorded SECG and statistics to the Home Monitoring Service Center.	
Dimensions (mm) Length x Width x Height	47.5 x 8.3 x 4.3 (can) 77.5 x 8.6 x 4.6 w/ lead	
Volume	1.9 cc	
Weight	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 AF Detect Study:

The basic AF detection algorithm in BIOMONITOR IIIm remains unchanged compared to the predicate BIOMONITOR III. In the BIOMONITOR IIIm device, the AF detection algorithm has been extended with an additional parameter to identify and reject specific patterns associated with ectopy rhythms. An AF Detect study was conducted and the results of the study demonstrate the substantial equivalence of BIOMONITOR IIIm and BIOMONITOR III utilizing real-world clinical data while the additional ectopy rejection parameter resulted in further improvement of the performance in terms of reduction of false AF snapshots.

7.2 Validation and Verification Testing:

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

- Software Testing
- Electromagnetic Compatibility Testing
- Mechanical Testing
- Electrical Testing

7.3 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 Updated BIOMONITOR III and BIOMONITOR IIIm are substantially equivalent to BIOTRONIK's predicate BIOMONITOR III. The subject BIOMONITOR III and BIOMONITOR IIIm devices and the predicate BIOMONITOR III device use the same principles of operation, have similar device features, and there are no new issues of safety or effectiveness. The BIOMONITOR III and BIOMONITOR IIIm devices keep the core software features and functionality as the predicate BIOMONITOR III with only a minor update to the AF Detection Algorithm for BIOMONITOR IIIm. The hardware design is similarly adapted from the predicate with the only significant difference being that the updated BIOMONITOR III and BIOMONITOR IIIm have an updated electronic module. These aspects of equivalence are confirmed by testing provided within the application.