May 19, 2023

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

Re: K230375
Trade/Device Name: BIOMONITOR IV
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: April 20, 2023
Received: April 20, 2023

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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2023.05.19 20:38:13 -04'00'

for

Hetal Odobasic
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230375

Device Name
BIOMONITOR IV

Indications for Use *(Describe)*
The BIOMONITOR IV is indicated to detect the following cardiac arrhythmias:
• Atrial fibrillation
• Bradycardia
• Sudden rate drop
• Tachycardia
• Pause

The BIOMONITOR IV 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."

510(k) Summary:
BIOMONITOR IV, Implantable Cardiac Monitors
Traditional 510(k) Premarket Notification

1. Submission Information

Date prepared	April 20, 2023
Contact	Jon Brumbaugh VP, Regulatory Affairs and New Product Development 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 Devices

Trade Name	BIOMONITOR IV
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 and BIOMONITOR IIIm, K221856, cleared July 27, 2022

4. Device Descriptions

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

The BIOMONITOR IV is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial fibrillation (AF), bradyarrhythmia, pause, sudden rate drop, or tachycardia. In addition, the BIOMONITOR IV can be activated by the patient using the Remote Assistant III to record cardiac rhythm during symptomatic episodes. BIOMONITOR IV 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

While the indications for use for the BIOMONITOR IV are identical to the predicate device, the nomenclature has been slightly modified to align with the current ICM market expectations.

The BIOMONITOR IV is indicated to detect the following cardiac arrhythmias:

- atrial fibrillation
- bradycardia
- sudden rate drop
- tachycardia
- pause

The BIOMONITOR IV 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 BIOMONITOR IV and Predicate, BIOMONITOR III and BIOMONITOR IIIm

Technical Data	Predicate BIOMONITOR III, BIOMONITOR IIIm	BIOMONITOR IV
FDA Clearance	**K221856, Predicate**	**Subject of this 510(k)**
Indicated for use	The BIOMONITOR III/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.	The BIOMONITOR IV is indicated to detect the following cardiac arrhythmias: • Atrial fibrillation • Bradycardia • Sudden rate drop • Tachycardia • Pause The BIOMONITOR IV 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.
Principle of Operation	The BIOMONITOR IV senses subcutaneous electrocardiograms (sECG) using two integrated electrodes and has the capability of detecting a number of arrhythmias. Like the predicate device, BIOMONITOR IV 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	

The following technological differences exist between the subject and predicate devices:

- Minor wording updates to harmonize the 'Indication for Use' verbiage with the US ICM market
- An update of the electronic chipset
- On-demand transmission of patient triggered episode (up to 2) recordings of at least 7.5 min per day
- Improved pause sensitivity
- PVC and PAC counts included with daily burden trends

7. Non-Clinical Performance Data

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

7.1 Validation and Verification Testing:

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

• Mechanical and Electrical Verification Testing for BIOMONITOR IV

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 IV is substantially equivalent to BIOTRONIK's predicate BIOMONITOR III and BIOMONITOR IIIm. The subject devices and predicate devices have the same principle of operation and physical device characteristics as well as software features and functionality and there are no new issues of safety or effectiveness.