



December 08, 2020

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

Re: K201865

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: October 21, 2020
Received: October 22, 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,

Jennifer Shih
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

Indications for Use

510(k) Number (if known)
K201865

Device Name
BIOMONITOR III
BIOMONITOR IIIIm

Indications for Use (Describe)

The BIOMONITOR III/BIOMONITOR IIIIm is indicated to detect the following cardiac arrhythmias:

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

The BIOMONITOR III/BIOMONITOR IIIIm 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.

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510(k) Summary**BIOMONITOR III and BIOMONITOR IIIIm, Implantable Cardiac Monitors****Traditional 510(k) Premarket Notification****1. Submission Information**

Date prepared September 2, 2020

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Registration number 9610139

2. Subject Devices

Trade Name BIOMONITOR III and BIOMONITOR IIIIm

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 IIIIm, K200444, cleared April 23, 2020

4. Device Descriptions

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

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

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

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

The BIOMONITOR III/BIOMONITOR IIIIm 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 devices is supported by the information included in the premarket notification. This includes the following information:

- Description of the subject and predicate devices including the addition of temperature change alerts and display through BIOTRONIK's Home Monitoring System
- 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

K201865

Table 1. Comparison of the Predicate and Subject Devices

Technical Data	Predicate BIOMONITOR III and BIOMONITOR III m	BIOMONITOR III and BIOMONITOR III m
FDA Clearance	K200444, 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 III m 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 III m sends recorded SECG and statistics to the Home Monitoring Service Center.	
Temperature Sensor Data	Transmission of temperature sensor data from the subject device to the Home Monitoring System	Transmission of temperature sensor data from the subject device to the Home Monitoring System, implementation of associated alerts and display of historical trends and temperature changes
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 newly available feature included in this 510(k) is the ability to measure core body temperature and the effect on determination of substantial equivalence was minimal as there was no associated change to intended use, indications for use, or hardware and no additional questions regarding safety or effectiveness.

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

- Verification Testing for BIOMONITOR III and BIOMONITOR IIIIm Temperature Sensor

7.2 Animal Testing:

Performance of the temperature sensor was validated in swine for detection of fever to a measurement accuracy of within 0.1°C when compared to a clinical reference

8. Clinical Performance Data

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

9. Conclusion

The subject BIOMONITOR III/BIOMONITOR IIIIm devices and predicate BIOMONITOR III/BIOMONITOR IIIIm devices are identical. They have the same principle of operation and identical physical device characteristics as well as software features and functionality. The enabling of the temperature sensor for data transmission introduces no new issues of safety or effectiveness. Additionally, the hardware design remains unchanged. These aspects of equivalence are confirmed by testing provided within the application.

Therefore, the BIOMONITOR III/BIOMONITOR IIIIm were determined to be substantially equivalent to the primary predicate devices.