May 1, 2026

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

Re: K261074
Trade/Device Name: Biomonitor IV (471155)
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 31, 2026
Received: April 1, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALEXANDRA K. MANARAS -S

For Hetal Odobasic
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

Please provide the device trade name(s).

BIOMONITOR IV (471155)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) #: K261074

510(k) Summary

Prepared on: 2026-03-31

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BIOTRONIK, Inc.
Applicant Address	6024 Jean Road Lake Oswego OR 97035 United States
Applicant Contact Telephone	(503) 970-7014
Applicant Contact	Mr. Jon Brumbaugh
Applicant Contact Email	jon.brumbaugh@biotronik.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BIOMONITOR IV (471155)
Common Name	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Classification Name	Recorder, Event, Implantable Cardiac, (With Arrhythmia Detection)
Regulation Number	870.1025
Product Code(s)	MXD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230375	BIOMONITOR IV	MXD

Device Description Summary

21 CFR 807.92(a)(4)

BIOMONITOR IV is a programmable, subcutaneous injectable 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 to record cardiac rhythm during symptomatic episodes.
NOTE:
The BIOMONITOR IV subcutaneous ECG may differ from a surface ECG due to differences in electrode separation and device placement in the body.

BIOMONITOR IV detects a subcutaneous ECG from a pair of electrodes. These signals are filtered in two different ways. For detection of QRS complexes, the signals are filtered with a passband of 10-40 Hz in order to suppress T-waves, artifacts, and baseline drift at low frequencies, and myopotentials and EMI at high frequencies. The resulting signal is appropriate for QRS detection as other components of the signal have been suppressed. This signal naturally does not have a typical ECG morphology due to the bandpass. For waveform display (real-time streaming sECG with the physician's programmer and snapshots for review by the physician), a different passband is utilized to retain signal features that may have diagnostic value. This passband is 0.5 – 40 Hz, which is designed to retain morphological features of a typical ECG while still rejecting large low frequency artifacts and baseline drift.

The BIOMONITOR IV system consists of three main components:

1. BIOMONITOR IV insertable cardiac monitor – The BIOMONITOR IV is a small, leadless device that is typically inserted under the skin, in the chest. The device uses two electrodes on the body of the device to continuously monitor the patient's subcutaneous ECG. BIOMONITOR IV can store up to 96 minutes (67 min minimum) of subcutaneous ECG (sECG) recordings from both automatically detected arrhythmias and from manually triggered symptom episodes. When a patient experiences symptoms, the sECG recordings can be manually triggered by placing the Remote Assistant III over the BIOMONITOR IV. The injectable cardiac monitor is provided preloaded in an insertion tool. An incision tool is also provided.
2. BIOTRONIK Renamic / Renamic Neo Programmer – The programmer is used to set up the BIOMONITOR IV to detect arrhythmias. It also allows one to view, save, or print the stored information.
3. BIOTRONIK CardioMessenger® Smart is a telemetry patient device that forwards the data from the BIOMONITOR IV to BIOTRONIK's Home Monitoring Service Center.

BIOMONITOR IV may be used with BIOTRONIK Home Monitoring® technology, which is an automatic, wireless, remote monitoring system for management of patients with insertable cardiac monitors. When active, Home Monitoring enables the exchange of information about a patient's cardiac status from the implant to the Home Monitoring Service Center (HMSC) where the physician may log in to view the data. The HMSC can be used to provide the physician with advanced reports from the implanted device and process them into a graphical and tabular format that is accessible via the internet platform HMSC. This information may help the physician optimize the therapy process, possibly providing earlier notification of clinically relevant events to help guide future therapy.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed updated BIOMONITOR IV Implantable Cardiac Monitors (ICMs) are substantially equivalent to the predicate device, BIOTRONIK's BIOMONITOR IV (K230375, cleared May 19, 2023).
The proposed device and the predicate device BIOTRONIK's BIOMONITOR IV ICMs were compared with respect to indications for use, principle of operation, product labeling, intended use, technological characteristics, and safety characteristics. Based on this comparison, BIOTRONIK believes that the proposed BIOMONITOR IV is substantially equivalent to the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed updated BIOMONITOR IV Implantable Cardiac Monitors (ICMs) are substantially equivalent to the predicate device, BIOTRONIK's BIOMONITOR IV (K230375, cleared May 19, 2023).
The proposed device and the predicate device BIOTRONIK's BIOMONITOR IV ICMs were compared with respect to indications for use, principle of operation, product labeling, intended use, technological characteristics, and safety characteristics. Based on this comparison, BIOTRONIK believes that the proposed BIOMONITOR IV is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

All necessary performance testing was conducted on the updated BIOMONITOR IV to ensure that the device conforms to the design specification and to support a determination of substantial equivalence to the predicate device.
The collective results of the performed testing demonstrated that the firmware updates meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the proposed device does not introduce new issues of safety or effectiveness when compared to the predicate device.
This submission does not contain any animal testing or human clinical data.