January 23, 2026

Boston Scientific Cardiac Diagnostic Technologies, Inc.
Meghan Styles
Regulatory Affairs Specialist
2900 37th Street NW
Building 003
Rochester, Minnesota 55901

Re: K243349
Trade/Device Name: BodyGuardian Remote Monitoring System (BGRMS v3.0)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: DSI, QYX
Dated: October 25, 2024
Received: October 28, 2024

Dear Meghan Styles:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

JENNIFER W. SHIH -S

Jennifer Kozen
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243349

Device Name
BodyGuardian Remote Monitoring System (BGRMS v3.0)

Indications for Use *(Describe)*
The BodyGuardian™ Remote Monitoring System detects and monitors cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional.

The BodyGuardian Remote Monitoring System is intended for use with adult and pediatric patients who are at least 29 days old in clinical and non-clinical settings to collect and transmit electrocardiogram (ECG) and other health parameters to healthcare professionals for monitoring and evaluation. Health parameters, such as heart rate and ECG data, are collected from external devices such as ECG sensors.

The BodyGuardian Remote Monitoring System does not provide any diagnosis.

Contraindications:
The BodyGuardian Remote Monitoring System is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias. Not for use for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response.

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

1. Submitter

Boston Scientific Cardiac Diagnostic Technologies, Inc.
2900 37th Street NW
Building 003
Rochester, MN 55901

Contact: Meghan Styles
Regulatory Specialist
Phone: 651.582.5096
Email: meghan.styles@cdxbsci.com

Date Prepared: 21 January 2026

2. Device

Trade Names: BodyGuardian™ Remote Monitoring System
510(k) Number: K243349
Common Name: Arrythmia detector and alarm
Product Code/Panel: DSI, Cardiovascular and QYX, Outpatient Cardiac Telemetry
Device Class and Panel: Class II
Classification Regulation: 21 CFR 870.1025

3. Predicate Device

Trade Name: BodyGuardian™ Remote Monitoring System
Manufacturer: Boston Scientific Cardiac Diagnostic Technologies, Inc. (formerly Preventice Technologies, Inc.)
510(k) Number: K192732, 26 March 2020
Common Name: Arrythmia detector and alarm
Product Code/Panel: DSI, Cardiovascular
Device Class and Panel: Class II
Classification Regulation: 21 CFR 870.1025

Secondary Predicate: SmartCardia 7L
510(k) Number: K240653, 31 October 2024
Common Name: Arrythmia detector and alarm
Product Code/Panel: QYX Cardiovascular
Device Class and Panel: Class II
Classification Regulation: 21 CFR 870.1025

4. Indication for Use

The BodyGuardian™ Remote Monitoring System detects and monitors cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional.

The BodyGuardian Remote Monitoring System is intended for use with adult and pediatric patients who are at least 29 days old in clinical and non-clinical settings to collect and transmit electrocardiogram (ECG) and other health parameters to healthcare professionals for monitoring and evaluation. Health parameters, such as heart rate and ECG data, are collected from external devices such as ECG sensors.

The BodyGuardian Remote Monitoring System does not provide any diagnosis.

Contraindications

The BodyGuardian Remote Monitoring System is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias. Not for use for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response.

5. Device Description

The BodyGuardian Remote Monitoring System (BGRMS) is a system for recording and analyzing ECG data for cardiac arrhythmias to assist healthcare professionals, including ECG technicians at 24/7 attended analysis centers in evaluating a patient's cardiac health. Reports are generated for clinician review, that provide analysis and summary of the ECG data collected during a patient's monitoring study. Both the predicate and proposed devices, feature a modular design inclusive of outpatient cardiac telemetry (commonly called mobile cardiac telemetry (MCT)), cardiac event monitor and connected/non-connected Holter modalities. Components in the system external to the software include ECG monitors, electrodes, mobile phones and apps.

The BGRMS System includes the following main components:

- ECG monitor – a patient worn device for ECG waveform data collection and transmission, utilized with compatible electrodes
- Mobile App – applications that execute on an off-the-shelf (OTS) smartphone to communicate with the ECG monitor and the PatientCare Server for collection and transmission of data
- PatientCare – server software responsible for receiving, storing, analyzing, and displaying and reporting data gathered from the ECG monitors; includes the ECG analysis algorithm BeatLogic™
- AI-Based Device Software Functionality (AI-DSF) – Automated classification of continuous

ECG based on the proprietary BeatLogic™ AI algorithm. BeatLogic consists of an ensemble of deep neural networks (DNNs), trained on real-world patient data and post-processing logic that combines the DNN output to produce individual beat, rhythm, and waveform classifications. This output is intended to be reviewed and confirmed by healthcare professionals to assist in diagnosis.

6. Substantial Equivalence

Characteristic	Predicate: BodyGuardian Remote Monitoring System K192732	Secondary Predicate Device for QYX SmartCardia 7L K240653	Proposed: BodyGuardian Remote Monitoring System K243349
Indications for use	The BodyGuardian Remote Monitoring System detects and monitors cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. Not for use with patients requiring attended, In-hospital monitoring for life-threatening arrhythmias. The Preventice BodyGuardian Remote Monitoring System is intended for use with adult and pediatric patients in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation. Health parameters are collected from a variety of commercially available, external plug-in devices such as ECG sensors, Weight Scales, Blood Pressure Meters and Pulse Oximeters. The Preventice BodyGuardian Remote Monitoring System does not provide any diagnosis.	The SmartCardia 7L Platform is intended for: 1. Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). 3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath). 4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring. 5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures. The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home. Contraindications 1. The SmartCardia 7L Platform is contraindicated for use for detection	The BodyGuardian Remote Monitoring System detects and monitors cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian Remote Monitoring System is intended for use with adult and pediatric patients who are at least 29 days old in clinical and non-clinical settings to collect and transmit electrocardiogram (ECG) and other health parameters to healthcare professionals for monitoring and evaluation. Health parameters, such as heart rate and ECG data, are collected from external devices such as ECG sensors. The BodyGuardian Remote Monitoring System does not provide any diagnosis. Contraindications The BodyGuardian Remote Monitoring System is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias. Not for use for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response.

Characteristic	Predicate: BodyGuardian Remote Monitoring System K192732	Secondary Predicate Device for QYX SmartCardia 7L K240653	Proposed: BodyGuardian Remote Monitoring System K243349
		or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response. It is not intended for monitoring patients during cardiac rehabilitation outside of healthcare facilities. 2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.	
Manufacturer	Preventice Technologies, Inc.	SmartCardia SA	Boston Scientific Cardiac Diagnostic Technologies, Inc.
Product Code	DSI	QYX (Subsequent pro codes: DRG, DSI)	DSI QYX
Prescription/OTC	Prescription	Prescription	Same
Compatible ECG Monitors	• BG Mini SL • BG Mini EL • BG Heart • BG One	• SmartCardia 7L	• BG Mini SL • BG Mini EL
Remote Monitoring	Yes	Yes	Same
Technological Characteristics	• Rechargeable Battery powered wearable ECG monitors • Mobile device with software apps • Server software with AI algorithm for ECG analysis and reporting	• SmartCardia 7L monitor • SmartCardia Phone • SmartCardia Web Browser application	Same as primary predicate
Functional Modalities	• Outpatient Cardiac Telemetry (OCT) • Cardiac Event Monitor (CEM) • Holter	• OCT • Event • Holter	Same as primary predicate
Monitoring Period	When using the rechargeable ECG monitor, monitoring period durations are as follows: • OCT up to 35 days • CEM up to 35 days • Holter up to 15 days	1. Holter Monitoring (up to 48 hours) and Extended Holter Monitoring (>48 hours and up to 14 days), 2. Event Monitoring (up to 48 hours, and >48 hours up to 14 days) 3. Cardiac Outpatient Telemetry (OCT) commonly called Mobile Cardiac Telemetry (MCT) (>48 hours up to 30 days when changing the 7L Patch)	Same as primary predicate
ECG Analysis	• Beat Detection • Rhythm Detection • Measurements: Heart Rate, Wave Intervals	• Electrocardiogram (ECG signal), • R-R interval, • Heart Rate	• Beat Detection • Rhythm Detection • Measurements: Heart Rate, Wave Intervals, HRV, QTc

Characteristic	Predicate: BodyGuardian Remote Monitoring System K192732	Secondary Predicate Device for QYX SmartCardia 7L K240653	Proposed: BodyGuardian Remote Monitoring System K243349
System Communication	Bluetooth Cellular Network Wi-Fi USB	Bluetooth Cellular Network	Same as primary predicate

7. Summary of Performance Testing

CDx Tech performed safety risk management activities, design verification and design validation to demonstrate that BodyGuardian Remote Monitoring System is substantially equivalence to the predicate devices. The system conforms to user needs and intended use and tested in accordance with ANSI/AAMI EC57.

Performance Testing:

- Biocompatibility
- Electromagnetic Compatibility
- Electrical Safety
- System Verification and Validation
- Software Verification and Validation
- Clinical Validations
- Cybersecurity Testing

7.1. Summary of Clinical Validation

Training and Validation Datasets

The training and validation data used for the BeatLogic algorithm consisted of real-world, randomly selected ECG records that ensured representation across algorithm outputs, compatible ECG device configurations and accessory types and demographic factors encompassing patient age, gender, geographic location, and indication for monitoring. The validation dataset consisted of 48.6% Female, 39.2% Male, 12.2% unknown gender and 50.1% < 65 years of age, 49.8% ≥65 years of age, 0.1% unknown age. No data from the training dataset was used for validation of the algorithm.

Performance Measurement

Performance of the algorithm was assessed by evaluating the Sensitivity and Positive Predictive value (PPV) for key rhythms across different patient subgroups. Performance numbers follow the EC57 standard for duration and episode measurements relative to ground truth annotations on real-world ECG data.

The clinical validation results met all predefined acceptance criteria and demonstrated substantially equivalent performance for BeatLogic. In addition, comprehensive analyses demonstrated consistent arrhythmia detection performance across various subgroups including compatible ECG device configurations and accessory types, gender, age, US geographic region, and indication for monitoring.

8. Conclusion

Based on the intended use, fundamental technological characteristics, performance testing and clinical validation, the proposed BodyGuardian Remote Monitoring System has been shown to be appropriate for the intended use and is considered to be substantially equivalent to the predicate devices.