



March 26, 2020

Preventice Technologies, Inc.
Charles Rector
VP of Quality, Regulatory & Logistics
3052 Hwy52 N, Building 003-2
Rochester, Minnesota 55901

Re: K192732

Trade/Device Name: BodyGuardian Remote Monitoring System
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
Dated: February 20, 2020
Received: February 24, 2020

Dear Charles Rector:

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/pmnmn.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 (Acting)
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)

K192732

Device Name

BodyGuardian Remote Monitoring System

Indications for Use (Describe)

The BodyGuardian 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, and parameters such as ECG, heart rate, body weight, temperature, respiration rate, blood pressure, and SpO2.

The Preventice BodyGuardian Remote Monitoring System does not provide any diagnosis.

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

510(k) Summary (As required by section 21 CFR 807.92(c))	
Submitter:	Preventice Technologies, Inc. 3605 Hwy 52N, Building 003-2 Rochester, MN 55122
Contact Person:	Charles Rector Vice-President, Quality/Regulatory Telephone: 763-225-4977 Email: crector@preventice.com Preventice Technologies, Inc. 3605 Hwy 52N, Building 003-2 Rochester, MN 55122
Date Prepared:	September 25, 2019
Trade Name:	BodyGuardian Remote Monitoring System
Common/Usual Name:	Remote Monitoring System
Classification:	21 CFR 870.1025 Patient Physiological Monitor (with arrhythmia detection)
Product Code:	DSI
Manufacturer:	Preventice Technologies, Inc. 3605 Hwy 52N, Building 003-2 Rochester, MN 55122
Establishment Registration:	3009883402
Predicate Device:	BodyGuardian Remote Monitoring System, K151188
Device Description:	Arrhythmia Detector and Alarm; Patient Physiological Monitor (with arrhythmia detection)

510(k) Summary (As required by section 21 CFR 807.92(c))	
Intended Use	<p>The BodyGuardian 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.</p> <p>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, and parameters such as ECG, heart rate, body weight, temperature, respiration rate, blood pressure, and SpO2.</p> <p>The Preventice BodyGuardian Remote Monitoring System does not provide any diagnosis.</p>
Comparison of Technological Characteristics:	<p>The predicate device's ECG Unit is a small, ambulatory cardiac monitor that records and transmits ECG data. The subject device's ECG Unit is also a small, ambulatory cardiac monitor that records and transmits ECG data.</p> <p>Both products, the predicate and subject devices, provide a data hub function that connects to commercially available devices such as weight scales, blood pressure monitors, pulse oximeters, ECG Units and other plug-in devices.</p> <p>For both devices, the predicate and subject devices, data is transmitted to an external device or server, depending model. If not a server, this device sends the data to a remote computer server that allows healthcare professionals to access and review the data.</p> <p>There are no fundamental differences between their technological characteristics.</p>

510(k) Summary (As required by section 21 CFR 807.92(c))	
Non-Clinical Testing:	<p>The following bench testing was conducted on the Preventice BG RMS:</p> <ul style="list-style-type: none"> • EMC and electrical safety testing • Electrical and mechanical safety testing • System safety testing <ul style="list-style-type: none"> ○ Software verification and validation • Performance testing • Predicate device comparison tests • Usability Testing <p>The following testing has been performed to support substantial equivalence:</p> <ul style="list-style-type: none"> • Biocompatibility for patient contact materials. <p>The following quality assurance measures were applied during development of this device:</p> <ul style="list-style-type: none"> • Failure Mode Effects Analysis/Hazard Analysis (FMEA) • Design FMEAs for mechanical and RF designs • Performance Requirements Testing including Final System Verification and Validation Testing, ISO 60601 Testing, Edition 3.1.
Clinical Testing:	<p>This technology is not new, therefore a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.</p>

510(k) Summary (As required by section 21 CFR 807.92(c))	
Conclusion:	<p>We conclude that the results of testing show the Preventice BG RMS to be substantially equivalent to the predicate device.</p> <p>The Preventice BG RMS has the same technological characteristics as the predicate device in that all devices are intended to detect, transmit, and report digital data using similar computerized technology. The Preventice BG RMS has the same intended uses as the predicate device in that all devices are intended for ambulatory monitoring. A pediatric usability study has shown no new hazards or risk associated with pediatric use.</p> <p>It has been shown in this 510(k) submission that the differences between the Preventice BG RMS and the predicate do not raise any questions regarding safety and effectiveness. The Preventice BG RMS, as designed and manufactured, is substantially equivalent to, and as safe and effective as, the referenced predicate device.</p>