k121197

AUG 10 2012

8 510(k) Summary

Submitter:	Preventice, Inc. 2765 Commerce Drive NW Suite 220 Rochester, MN 55901
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Date Prepared:	April 18, 2012
Trade Names:	BodyGuardian System [Preventice BodyGuardian Device (BodyGuardian Control Unit and BodyGuardian SnapStrip), Preventice BodyGuardian Connect, BodyGuardian Application, Preventice PatientCare, PatientCare Portal for the Web, and PatientCare for iPad
Classification:	21 CFR 870.1025 • Patient Physiological Monitor (with arrhythmia detection) • Arrhythmia Detector and Alarm
Product Codes:	MHX, DSI
Predicate Device:	AVIVO Mobile Patient Management System (k083287)
Device Description:	The BodyGuardian System is an ambulatory cardiac monitoring system prescribed by healthcare providers. It monitors and records a patient's electrocardiographic (ECG) data, heart rate, respiration rate and activity level. The complete system consists of components that collect data, send the data to a remote Preventice computer server, store the data in secure databases, and present the data for review by healthcare professionals.

510(k) Summary (Continued)

Intended Use:	The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time: • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity
Comparison of Technological Characteristics:	Both the predicate system and the BodyGuardian System are small, ambulatory cardiac monitors that measure ECG, heart rate, respiration rate and activity levels. Both transmit their data to an external device which, in turn, broadcasts the data to a remote computer server that allows healthcare professionals to access and review the data. There are no fundamental differences between their technological characteristics.
Non-Clinical Testing:	The following bench testing was conducted on the BodyGuardian System: • EMC and electrical safety testing • ECG performance testing • Activity level measurement validation • Respiration rate measurement validation • Software verification and validation • Biocompatibility testing
Clinical Testing	Not applicable.
Conclusion:	We conclude that the results of testing show the BodyGuardian System to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Preventice, Inc
c/o Drew Palin, M.D.
Medical Innovation Officer
2765 Commerce Drive NW, Suite 220
Rochester, MN 55901

Re: K121197
Trade Name: Preventice BodyGuardian System
Regulatory Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
(including ST-segment measurement and alarm)
Regulatory Class: II (two)
Product Code: DSI
Dated: August 2, 2012
Received: August 3, 2012

Dear Mr. Palin:

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. 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.

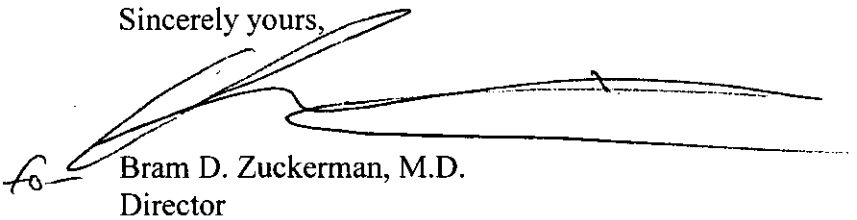
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 Indications for Use Statement

510(k) Number (if known):

Device Name: BodyGuardian System

Indications for Use:

The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:

- ECG
- Heart rate (including HR variability and HR reliability)
- Respiration rate
- Activity

Prescription Use ___ X ____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121197