

510(k) Summary

1.4.1 -- 510(k) Owner

Proteus Biomedical
2600 Bridge Parkway, Suite 101
Redwood City, CA 94065
(650) 632-4031 (tel)
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MAR 25 2010

1.4.2 -- Contact Person

Gregory Moon, MD

1.4.3 -- Date Summary Prepared

February 10, 2010

1.4.4 -- Name of Device

Trade name: Raisin™ Personal Monitor
Common name: Physiological Data and Event Logging Device
Classification name: Cardiovascular Transmitter and Receiver (Product Code DXH)

1.4.5 -- Predicate Devices

HealthePod™ (K083174)
Actiheart® (K052489)
Actiwatch-Score® (K991033)

1.4.6 -- Device Description and Technologic Characteristics

The Raisin™ Personal Monitor (RPM) is a miniaturized, ambulatory, battery-operated data-logging device that is worn on the torso to record heart rate, activity, and patient-logged events.

Patient-logged events can be extrinsic (e.g., dosing of a medication) or intrinsic (e.g., a symptom) and are time-stamped using a manual button on the device, in order to contextualize the physiologic measures. Subjective meaning of these events is assigned by the user. In addition to quantification of physical motion, signals from the device's accelerometer are used to determine body position relative to gravity. Electrode-to-electrode impedance is also measured to assess whether the device is attached properly to the user. RPM recorded data are transferred via Bluetooth telemetry to a general computing device for display and conversion for export to other programs. The RPM is available in two form factors to accommodate individual comfort preferences: one-piece and two-piece. The functionality, intended use, duration and location of wear, and fundamental scientific technologies are exactly the same between the two RPM form factors.

1.4.6.1 -- Basic technologies

Parameter	Sensor Technology	Method
<i>Heart rate</i>	Biopotential low-frequency amplifier	Digitized R wave
<i>Activity</i>	Accelerometer	Digitized accelerometer output
<i>Body angle</i>	Accelerometer	Double integration of accelerometer output
<i>Patient event logging</i>	Patient activated button	Digital pulse
<i>Inter-electrode impedance</i>	Biopotential high-frequency amplifier	Digitized impedance from small auxiliary current

1.4.6.2 -- Physical Characteristics

Parameter	Value
Shape	One-piece: ovoid
	Two-piece: triangular
Size	One-piece: 115 x 54 x 12 mm
	Two-piece: 95 x 84 x 10 mm
Weight	50 g
	20 g
Battery type	Rechargeable lithium ion
Moisture susceptibility	Waterproof
Memory	4 MB
Storage temperature	-25 °C to +75 °C
Relative humidity	10% to 90%, not condensing

1.4.6.3 -- Theory of Operation

The Raisin™ Personal Monitor acquires, time-stamps and logs digital data corresponding to physiologic signals and patient-marked events. Heart rate, quantified using R-wave frequency, is sensed via three adhesive skin electrodes on the base of the data recorder. Activity data are provided by a 3-axis accelerometer integrated into the RPM. Subjects can mark subjectively defined, personally relevant events by depressing a button on the data recorder. Raisin™ Personal Monitor data are periodically uploaded to a general computing device via Bluetooth telemetry for display and export.

1.4.7 -- Intended Use

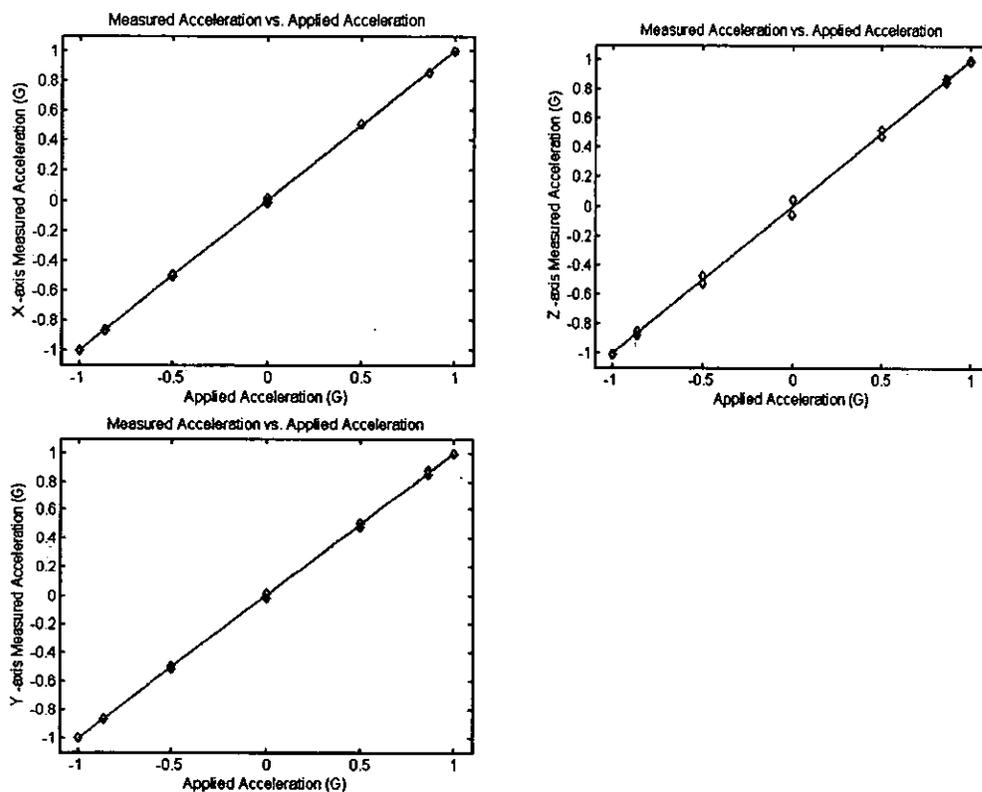
The Raisin™ Personal Monitor is a miniaturized, wearable data-logger for ambulatory recording of heart rate, activity, body angle relatively to gravity, and time-stamped, patient-logged events. The Raisin™ Personal Monitor enables unattended data collection for clinical and research

applications. The Raisin™ Personal Monitor may be used in any instance where quantifiable analysis of event-associated heart rate, activity, and body position is desirable.

1.4.8 -- Summary of Non-Clinical Performance Data

The three-axis accelerometer provides motion and position data and is validated against a known acceleration applied against each of its three axes.

The figure below shows bench validation of the accelerometer in all three of its axes.



The biopotential low-frequency amplifier is used to quantify heart rate by measuring R-wave frequency. The table below shows R-wave detection validation results, based upon a modified Hamilton-Tompkins algorithm, tested using guidelines set forth in the ANSI/AAMI EC 13 standard.

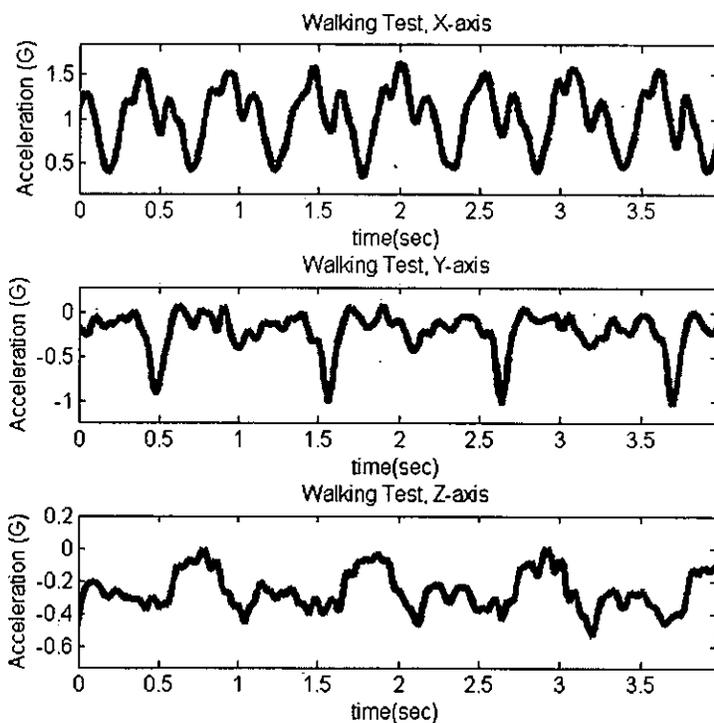
Test Description	Expected Results (bpm)	Algorithm Results (bpm)
Default ECG waveform	80	80.0
T-wave rejection R-wave amplitude of 1 mV T-wave amplitude of 0.4 mV	80	80.0
Ventricular bigeminy	80	79.9
Slow alternating ventricular bigeminy	60	60.5
Rapid alternating ventricular bigeminy	120	119.8
Bidirectional systoles	90	90.1
Default ECG waveform Pacing pulse with 2 mV amplitude, 2 ms width	80	80.0

The table below shows validation testing results of R-wave detection during arrhythmia. Raisin™ Personal Monitor-reported R-wave locations were compared with annotated R-wave locations in all 48 test files from the MIT-BIH arrhythmia database.

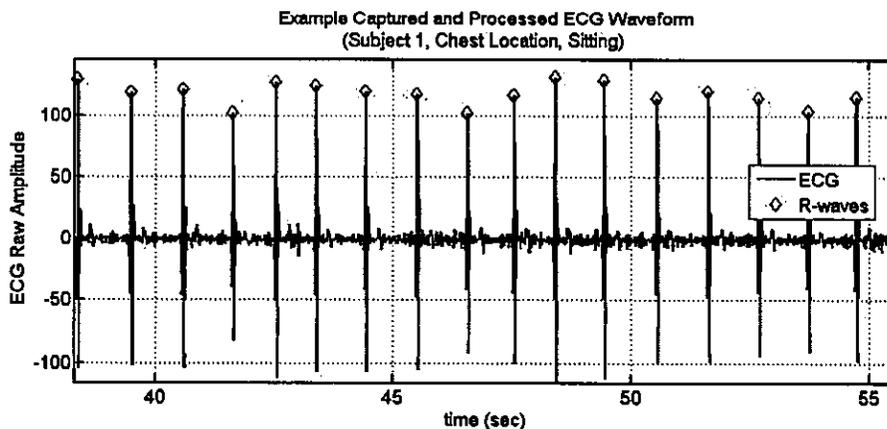
Metric	Median	Standard Deviation
Positive Detection Accuracy	99.7%	5.9%
False Positive Rate	0%	1.7%

1.4.9 -- Summary of Clinical Performance Data

The three-axis accelerometer was also validated clinically by assessing subject movement, in this case walking, to assess capture of expected features. The figure below demonstrates data from a representative walking test.



The figure below shows a representative subject ECG captured by the RPM, with the automatically identified R-waves highlighted.



The table below shows robust R-wave detection accuracy when heart rate data were collected from different body locations.

	Anterior Chest	Xyphoid	Stomach	Lateral Chest
Subject 1	100	99.72	-	-
Subject 2	99.30	99.00	99.24	99.61
Subject 4	99.14	98.58	99.31	98.05
Subject 5	99.14	99.37	98.66	98.81
Average R-wave detection accuracy	99.40	99.17	99.07	98.82

1.4.10 -- Conclusions

The Raisin™ Personal Monitor (RPM) is a small, ambulatory, battery-operated data-logging device that is worn on the chest surface to record heart rate, activity, body angle relative to gravity, and patient-logged events. Patient-logged events are used to contextualize the physiologic measures. The RPM's functionality has been validated in non-clinical and clinical testing as summarized above.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

MAR 25 2010

Proteus Biomedical, Inc.
c/o Gregory Moon, M.D.
Director of Clinical Affairs
2600 Bridge Parkway, Suite 101
Redwood City, CA 94065

Re: K093976
Trade/Device Name: Raisin™ Personal Monitor
Regulatory Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: February 26, 2010
Received: March 2, 2010

Dear Dr. Moon:

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.

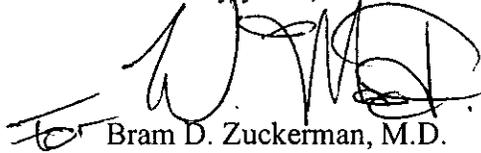
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indications for Use

510(k) Number (if known): K093976

Device Name: Raisin™ Personal Monitor

Indications for use:

The *Raisin™ Personal Monitor* is a miniaturized, wearable data-logger for ambulatory recording of heart rate, activity, body angle relatively to gravity, and time-stamped, patient-logged events. The *Raisin™ Personal Monitor* enables unattended data collection for clinical and research applications. The *Raisin™ Personal Monitor* may be used in any instance where quantifiable analysis of event-associated heart rate, activity, and body position is desirable.

Prescription Use
 (21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use
 (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093976