Attachment A. 510(k) Summary

JUL 2 8 2010

PBI

Pulse Biomedical, Inc.
1305 Catfish Lane, Norristown, PA 19403, USA
Tel: 610-666-5510 Fax: 610-666-5630

Pulse Biomedical GmbH
Wilhelm Bihler Str 4, 72474 Winterlingen, GERMANY
Tel: +49-7434-316038 Fax:+49-7434-316039

Special 510(k) - QRS Card™ S-T Segment Analysis Patient Monitoring System Modification

Section 6

510(k) Summary – 807.92

Applicant Name and Address
Pulse Biomedical Inc.
1305 Catfish Lane
Norristown, PA 19403

Manufacturer Name and Address
Pulse Biomedical Inc.
1305 Catfish Lane
Norristown PA 19403

Contact Person
Saleem Hasan – President
Tel. No. - 610-660-5510
Fax No. – 610-666-5630

Establishment Registration Number
2529508
Device Name:

Device Trade Name	Common Classification / Name	Regulation Number	Classification Code	Device Class	Classification Name
QRS Card BT	Physiological Monitor	N/A	DPS	II	Electrocardiograph

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Legally Marketed Devices to Which Substantial Equivalence is Claimed

510(k) Number	Trade Name	Company
K972255	QRS CARD™ S-T Segment Analysis Patient Monitoring System	Pulse Bio Medical Inc.
K080141	PC ECG 1200W System	Norav Medical LTD
K061977	Plex 04 Wireless Electrocardiograph with Software Accessories	PinMed, Inc.
K082077	BR3/6, BR12	Coscience GmbH & Co KG

Device Description:
The QRS CARD™ S-T Segment Analysis Patient Monitoring System converts a commercially available personal computer (PC) into an ECG monitor with ST segment measurement capability. Physicians can initiate ST evaluations on patients and the data are transmitted, using Bluetooth wireless technology, to a computer screen. Test results can also be printed at any time during the testing, or saved in computer memory for future review or additional report generation.

The QRS CARD™ S-T Segment Analysis Patient Monitoring System consists of the following components:

- The QRS CARD™ Office ECG Device
- ECG Patient Cable and Lead Wires
- Product Software on CD
- User Manual

Intended Use:
This device is intended for use as a patient monitor for any patient undergoing ECG S-T Segment Analysis and/or ECG stress analysis during rest or exercise. Exercise can be performed treadmill or bicycle ergometer use. The intended use locations are either in a physician's office, hospital or rehabilitation facilities, or similar use areas. It is intended to be used by or on the order of a physician or similarly qualified health care professional. This device is intended for use in a hospital environment, physician's office, or similar settings. This device is not intended for home use.

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Conclusion:
The technological characteristics of the QRS CARD™ S-T Segment Analysis Patient Monitoring System are safe and effective and substantially equivalent to the legally marketed predicate devices.

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

Pulse Biomedical, Inc.
c/o Mr. Saleem Hasan
President
1305 Catfish Lane
Norristown, PA 19403

JUL 23 2010

Re: K100813
Trade/Device Name: QRS Card™ ST-Segment Analysis Patient Monitoring System
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: June 22, 2010
Received: June 23, 2010

Dear Mr. Hasan:

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

PBI

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Section 4

Indications for Use Statement

510(k) Number: K 100813
(if known)

Device Name:
QRS Card™ S-T Segment Analysis Patient Monitoring System

Indications for Use:
This device is intended for use as a patient monitor for any patient undergoing ECG S-T Segment Analysis and/or ECG stress analysis during rest or exercise. Exercise can be performed treadmill or bicycle ergometer use. The intended use locations are either in a physician's office, hospital or rehabilitation facilities, or similar use areas. It is intended to be used by or on the order of a physician or similarly qualified health care professional. This device is intended for use in a hospital environment, physician's office, or similar settings. This device is not intended for home use.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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

Prescription Use __X__ OR Over the Counter Use ______

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100813