K122184
P1/3

SECTION 5: 510(k) SUMMARY

FEB 1 4 2013

510(k) Summary

Date Prepared:	January 13, 2013
Submitter:	Cardiac Designs, LLC 3293 Niblick Drive Park City, UT 84098 Phone: 1 (512) 582-2453 Facsimile: 1 (713) 589-7964
Contact:	Karim Marrouche, Managing Director 1 (512) 582-2453
Trade/Proprietary Name of Device:	ECG CHECK
Common Name of Device:	Transmitters And Receivers, Electrocardiograph, Telephone
Classification:	Class II per 21 CFR 870.2920, Telephone electrocardiograph transmitter and receiver, Product Code DXH
Legally Marketed Predicate Device:	PMP4 SelfCheck™ ECG (K042254), manufactured by Card Guard Scientific Survival, Ltd.

Description of New ECG CHECK Device:

The ECG Check model ECG01-4S is a personal 1 lead ECG Event Monitor specifically designed to operate with an iPhone 4S handset and allows transmissions to the ECG Check web center. Future iterations will be designed for other handsets, but will not change the fundamental features and capabilities described herein. It will record a preselected amount of user ECG activity, as directed by the user. Typical configuration is to record 30 seconds of ECG per event.

The ECG Check is indicated for monitoring symptoms that may suggest irregular or abnormal heart rhythms. The ECG Check, when used in conjunction with the ECG Check web center, uses standard analysis of ECG by the web-based engine for objective assessment of the user in terms similar to a stoplight (Green, Yellow, Red). With a physician prescription, the user will be provided access to be able to trend their results and generate reports to provide to their physician or other caregivers. The symptoms may include: skipped beats, palpitations, racing

heart, fainting, lightheadedness, irregular rate, or history of other related heart abnormalities.

While performing the recording, the results are continuously sent to the iPhone by secure Bluetooth connection technology and, with a physician prescription, displayed for quality and observation purposes on the iPhone ECG Check application. Users without a physician prescription will not be able to view the waveform. The data can then be stored locally and/or transmitted to the ECG Check web center for analysis and assessment by qualified professionals. The ECG Check web center provides privacy and protection for user medical information and the ability to interact with Cardiac Designs, LLC technicians and engineers, as well as with their own caregivers.

The ECG Check Model ECG01-4S is intended for users that seek to manage their heart rate and rhythms over long periods of time. Additional features will be added to involve health care professionals in the service, with the intent to ensure that the device remains consumer focused and non-diagnostic.

Indications for Use of the New Device:

The ECG CHECK is intended for self-testing by patients at home. This 1-lead cardiac monitor allows remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the ECG CHECK is indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:

- Skipped Beats
- Pounding Heart (Palpatations)
- Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

Comparison of the Technological Features of the New (Modified) Device and Predicate Device:

The new ECG CHECK indications for use are equivalent to the predicate PMP4 SelfCheck™ ECG device. The new ECG CHECK and the predicate PMP4 SelfCheck™ ECG device have identical patient populations and places of use. In addition, the parameters that are measured by the new ECG CHECK device are identical to those measured by the predicate PMP4 SelfCheck™ ECG device.

There are few differences between the new ECG CHECK device and the predicate PMP4 SelfCheck™ ECG device. The main difference is as follows:

Leads:

The new ECG CHECK device operates with 1 lead. The predicate PMP4 SelfCheck™ ECG device can operate with 1 lead or with 12 leads. Cardiac Designs, LLC seeks substantial equivalence only to the 1 lead functionality of the predicate PMP4 SelfCheck™ ECG device. Comparisons, testing, and conclusions will be drawn based only on the 1 lead configuration.

Testing:

The ECG CHECK device successfully passed safety and essential performance testing as required by:
IEC 60601-1
IEC 60601-2-47 - Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.
ISO 10993-5:2009 Cytotoxicity – MEM Elution Test
ISO 10993-10:2010 Maximization Test for Delayed Hypersensitivity
ISO 10993-10:2010 Intracutaneous (Intradermal) Reactivity Test

Conclusion:

The conclusions drawn from the specifications and performance testing of the new ECG CHECK device demonstrate that the new ECG CHECK device is at least as safe and as effective and performs as well as or better than the Card Guard Scientific Survival, Ltd. predicate PMP4 SelfCheck™ ECG (K042254). For these reasons, we believe the new ECG CHECK device is substantially equivalent to the predicate device.

Signed,

Karim Marrouche

Karim Marrouche
Managing Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 14, 2013

Cardiac Designs, LLC
c/o Mr. Karim Marrouche
Managing Director
3293 Niblick Drive
Park City, UT 80498

Re: K122184
Trade/Device Name: ECG Check
Regulatory Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: January 18, 2013
Received: January 22, 2013

Dear Mr. Marrouche:

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,

Owen P. Faris -S

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

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K122184

Device Name: ECG CHECK

Indications for Use:

The ECG Check is intended for self-testing by patients at home. This 1-lead cardiac monitor allows remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the ECG Check is indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:

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- Lightheadedness or Faintness
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Prescription Use X (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S