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CARD GUARD Scientific Survival LTD.

CG-6108 Arrhythmia ECG Event Recorder 510(k) Summary of Safety and Effectiveness

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1. General

Submitter	**Card Guard Scientific Survival Ltd.,**	
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Device		
Trade Name:	CG-6108 Arrhythmia ECG Event Recorder	
Classification:	Transmitters and receivers, electrocardiograph, telephone	
Product Code:	DXH	
Regulation No:	21 CFR 870.2920	
Class:	II	

2. Definition and Intended Use

The CG-6108 system is an Arrhythmia ECG Event Recorder designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center. It comprises a chest-worn ECG sensor and a handheld device with a proprietary application, configured to process and transmit the ECG recordings.

The chest-worn unit includes 3 electrodes on a harness and it houses a battery, an ASIC and a Bluetooth transceiver for the acquisition, recording, and transmission of the ECG signal.

The ECG signals are transmitted via Bluetooth to the handheld device. When an event is detected it is wirelessly transmitted to the CG Monitoring Center for professional analysis. The handheld device is equipped with shared memory used to record the signal received from the sensor and to allow pre- and post processing options through the use of this memory in a dual memory loop configuration, both running in parallel. One loop is auto-triggered, with programmable thresholds, that starts recording based on specific rhythms and arrhythmias detected or manually activated by the patient. The second, and longer, recording loop is controlled remotely to provide the physician with more information, when requested by the CG Monitoring Center.

The handheld device automatically transmits the recorded ECG, via cellular link, to the Monitoring Center. When cellular service is unavailable the patient can transmit via landline telephone.

3. PMP^4 Medical Application

The PMP^4 Medical Application is designed for wireless mobile platforms, e.g. PDA, SmartPhone and for static platforms, i.e., PC. It is used to receive from the CG-6108 (and other Card Guard's devices), the test results and other medical data, to process and save these test results, and synchronize data and test results with the PMP^4 Medical Center. The Application is a part of a personal medical system solution. The PMP^4 Medical Application performs the following activities:

1. Receives medical test inputs from the external accessories
2. Collects medical test data and other related information as defined for each test
3. Accesses historical test and related data stored on the device
4. Transmits medical test data and additional information to Center for professional evaluation/backup
5. Receives data from Center
6. Enables configuring GPRS data connection (based on mobile phone GPRS/CDMA capabilities), changing user name and password.

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4. Referenced Standards

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Art for wireless ECG event recording devices. The CG-6108 meets the requirements of the following standards:

(1) MDD 93/42/EEC Medical Device Directive Council Directive 93/42/EEC; June 14, 1993
(2) EN 475: Medical devices - Electrically-generated alarm signals ; April 1995
(3) EN 980: Graphical symbols for use in the labeling of medical devices; August 2003
(4) EN 1041: Terminology, Symbols and Information provided with Medical Devices; Information supplied by the manufacturer with medical devices; April 1998
(5) EN ISO 9001: Quality management systems - Requirements; December 2000
(6) EN ISO 13485: Quality systems – Medical devices; August 2000
(7) EN ISO 14971: Medical devices – application of risk management to medical devices; March 2001
(8) EN ISO 10993 Biological evaluation of medical devices Part 1: Evaluation and testing; Dec. 1997
(9) EN 60601-1: Medical electrical equipment; Part 1: General requirements for safety; Sept. 2002
(10) EN 60601-1-2: Medical electrical equipment; Part 1: 2. Collateral Std: EMC; requirements and tests; 2001
(11) EN 60601-1-4: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems; Apr. 01

5. Indications for use

The CG-6108 Arrhythmia ECG Event Recorder is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.

6. Principles of operation

The CG-6108 Arrhythmia ECG Event Recorder comprises a chest-worn ECG sensor with three electrodes and a handheld device with a proprietary PMP^4 Medical Application, used to process and transmit the ECG recordings. The battery powered chest-worn unit has an ASIC and a transceiver for the acquisition, recording, and transmission of the ECG signal. The ECG signals are transmitted via Bluetooth to the handheld device equipped with the PMP^4 Medical Application, which incorporates an algorithm specially developed for detection of arrhythmia artifacts, e.g. AF. A detected artifact triggers transmission of the signal to the CG Monitoring Center for analysis.

7. Substantial Equivalence

The clearance for the CG-6108 is sought on the grounds of its claimed substantial equivalence (SE) to the following predicate devices:

1. Card Guard's CG-6106 K963811 for its memory loop monitoring principle of operation and the identity of the intended use.
2. Card Guard's CG-6550 K003220 Personal 3-lead ECG Transmitter - for its arrhythmia artifacts detection algorithm (e.g. AF)
3. Card Guard's PMP^4 SelfCheck ECG K042254 - for the BT transmission capability and for interfacing and including the PMP^4 Medical Application - the CG proprietary SW for storing, measuring, displaying and transmitting data gathered from medical sensors.

8. Conclusions

The CG-6108 Arrhythmia ECG Event Recorder constitutes a safe and reliable means for designed for self-testing by patients who experience transient symptoms that may suggest cardiac arrhythmia. Its material composition and operation present no adverse health effect or safety risks when used as intended.

The device is as safe, as effective and performs as well as or better than its cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2007

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ISRAEL

Re: K060911
Trade Name: CG-6108 Arrhythmia ECG Event Recorder
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: August 4, 2006
Received: August 4, 2006

Dear Mr. Gonorovsky:

This letter corrects our substantially equivalent letter of August 22, 2006 and the subsequent correction letter of March 27, 2007.

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

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): K060911

Device Name: **CG-6108 Arrhythmia ECG Event Recorder**

Indications for Use:

Intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Symmons

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060911

(Posted November 13, 2003)