510(k) Summary: Modified CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Introduction

This document contains the 510(k) summary for the modified CG-6108 1L Continuous ECG Monitor and Arrhythmia Detector. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Submitter	Card Guard Scientific Survival Ltd.,	
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Date Prepared:	June 8, 2010	
Predicate device	Unmodified version of CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector, cleared in K081257 on May 29, 2008.	
Trade Name:	CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector	
Classification:	Detector and alarm, arrhythmia / Transmitters and receivers, electrocardiograph, telephone	
Product Code:	DSI, DXH	
Regulation No:	870.1025, 870.2920	
Class:	II	

Device Description

CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center.

The chest-worn sensor is used for the acquisition, recording, and transmission of the ECG signal. The device is equipped with 4 electrodes on a harness and it houses a 3.6V AA battery, a Bluetooth transceiver and a buzzer.

The ECG signals are transmitted via Bluetooth to a handheld device with a proprietary interactive application, configured to process and transmit the ECG recordings. The handheld device is a mobile computing device with a display and a touch input such as a cell-phone. It has sufficient memory and processing capability to run the proprietary application.

When an arrhythmia event is detected the handheld device transmits the recorded ECG information automatically via cellular link, to the Monitoring Center or professional analysis. When cellular service is unavailable the patient has an option to transmit via a landline telephone.

Indications for Use:

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Summary of the Technological Characteristics / Principles of Operation

The technological characteristics and principles of operation of the modified device are the same as the predicate device. The chest-worn ECG sensor transmits signals via Bluetooth to the handheld device equipped with the Medical Application, which incorporates an algorithm for detection of cardiac events: Atrial Fibrillation, Tachycardia, Bradycardia and Pause. A detected artifact triggers transmission of the signal to the Monitoring Center for analysis.

Non-clinical performance data for the CG-6108 ACT-3L:

The modified version CG-6108 has been subjected to extensive verification / validation testing. Final testing of the system included various performance tests and software validation tests designed to ensure that the device meet all of its functional and performance requirements and is fit for its intended use. The following list summarizes the testing performed on the device;

- Software Verification and Validation
  - Software Functional Unit Verification
  - System Level Software Validation
  - Arrhythmia Detection Algorithm Performance Validation
- Hardware Verification and Validation
- Verification of Conformance with Special Controls Guidance Document

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003" and the device conforms to the applicable performance requirements contained in and referenced in this document. In addition, this submission was prepared in accordance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005". The design of the CG-6108 ACT-1L conforms to the following voluntary standards:

- ANSI/AAMI/ISO EC57:1998 (R) 2008: Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- ANSI/AAMI EC38:1998 Ambulatory Electrocardiograph
- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- IEC 60601-1:1988, 2nd edition, Part 1, plus A1:1991 and A2:1995: Medical electrical equipment; Part 1: General requirements for safety
- IEC 60601-1-2: 2001, plus am. 1:2004, Part 1: Medical electrical equipment, Part 1-2; Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:2000, plus Amendment 1:2004: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems
- IEC 62304:2006: Medical device software – Software life cycle processes
- ISO 15223:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Substantial Equivalence:

The modified CG-6108 ACT-3L device is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 13 2010

Card Guard Scientific Survival Ltd.,
c/o Clay Anselmo
President and CEO,
Reglera LLC.
555 Zang Street Suite 100
Lakewood, Colorado 80228

Re: K101703
Trade/Device Name: CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm.
Regulatory Class: Class II (two)
Product Code: DSI, DXH
Dated: June 14, 2010
Received: June 17, 2010

Dear Mr. Anselmo:

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,

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): K101703

Device Name: CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Indications for Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101703