1. GENERAL

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Submitter **Card Guard Scientific Survival Ltd.,**
Address 2 Pekeris St. P.O.B. 527 Rehovot 76100, Israel
Contact: **Alex Gonorovsky, RA Manager**
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DEC 17 2009

Device

Trade Name: HealthePod
Classification: Transmitters and receivers, electrocardiograph, telephone
Product Code: DXH Cardiovascular transmitters and receivers, FLL Thermometer electronic, clinical electrocardiograph, telephone
Regulation No: 21 CFR 870.2920
Class: II

2. DEVICE DEFINITION

The Card Guard® CG-1411USB HealthePod is a medical and non-medical monitor designed for self-testing by patients. It contains 4 sensors designed to execute the following features:

- ECG 1-lead
- Heart rate
- Ambient temperature
- Body temperature
- Pedometer - walking steps and walking distance,
- Calorie Meter
- Stopwatch, Count down, Alarm clock
- Date/Time

Note: The following HealthePod non-medical functions are not subject to FDA clearance: Ambient temperature, Pedometer, Calorie Meter, Stopwatch, Count down, Alarm clock and Date/Time.

HealthePod can communicate measured data and patient information to a PC with a receiving medical Application such as PMP[4]. Two dry electrodes are assembled on the device PCB. It features an LCD, three buttons and a USB connector for communication with PC.

3. REFERENCED STANDARDS

The HealthePod meets the requirements of the following standards:

EN ISO 9001: Quality management systems - Requirements; December 2000

EN ISO 13485: Quality systems – Medical devices; August 2000

EN ISO 14971: Medical devices – application of risk management to medical devices; March 2001

EN 60601-1: Medical electrical equipment; Part 1: General requirements for safety; Sept. 2002

EN 60601-1-2: Medical electrical equipment; Part 1: 2. Collateral Std: EMC; requirements and tests; 2001

EN 60601-1-4: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable el. medical systems; 2001

EN 980: Graphical symbols for use in the labeling of medical devices; August 2003

EN 1041: Terminology, Symbols and Information provided with Medical Devices; Information supplied by the manufacturer with medical devices; April 1998

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4. SUBSTANTIAL EQUIVALENCE

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

1. Card Guard's CG-2206 K963725 for the one lead feature and similarity in electronic design.
2. Card Guard's PMP[4] SelfCheck ECG K042254 for the over-the-counter distribution business method when the PMP[4] SelfCheck ECG is set to its one lead configuration.
3. TaiDoc Technology Corporation Clever TD-1112 IR thermometer K061800

5. CONCLUSIONS

The HealthePod constitutes a safe and reliable device. 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 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

Card Guard Scientific Survival, Ltd.
c/o Mr. Alex Gonorovsky
Manager, Regulatory Affairs
2 Pekeris St, Science Park
Rehovot
Israel 76100

DEC 17 2009

Re: K083174
Trade Name: Health-ePod
Dated: August 5, 2009
Received: August 10, 2009

Dear Mr. Gonorovsky:
Re: K083174
Trade/Device Name: Health-ePod
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone electrocardiograph transmitter and receiver
Regulatory Class: Class II
Product Code: DXH, FLL
Dated: November 9, 2009
Received: November 12, 2009

Dear Mr. Gonorovsky:

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): K083174
Device Name: **HealthePod**
Indications for Use:

The HealthePod is a medical device designed for self-testing. It comprises the following medical features:

- ECG 1-lead
- Heart rate
- Body temperature

Prescription Use _____ AND/OR Over-The-Counter Use [X]
(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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083174

(Posted November 13, 2003)