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CARD GUARD® Scientific Survival LTD.

PMP[4] Medical Web Center Special 510(k) Summary

1. System Definition

The **Card Guard® PMP[4] Medical Web Center** is a medical communication system using the latest cellular technologies, a mobile device (e.g. PDA, Cellular Phone), and personal medical monitors. It allows the patient to monitor his health and interact with the physician from anywhere and at anytime. As a web-based application, all the data is accessed through a common internet browser.

The PMP[4] Medical Web Center provides round-the-clock monitoring services from any location for healthcare providers and patients. The Center generates and manages electronic medical files for each patient who can be accessed from any handheld or PC browser. Patients receive a secure personal web page to send, view and store their health measurements, physician diagnosis, and disease-specific health trends. Physicians receive a secure patient database to host patient's medical files and test results. The Center also features educational content and health tips specific to the subscribers' health condition.

The Center enables receiving, storing, displaying, updating, printing and forwarding of patient health and other patient related data, (such as demographics, doctors, medical history, diagnoses, etc.).

Each user has a unique access to the Center. The system enables the administrator to add users, set user permissions and link between users.

After recording a test on PMP[4] monitors, the measurement can be sent wirelessly to the PMP[4] Center, and the healthcare provider is notified of new patient data. The PMP[4] system can help patients improve compliance and clinical outcomes, improve disease management and may reduce unnecessary hospitalizations, and emergency room visits.

The PMP[4] medical line of products include a 1/12-lead ECG event monitor, Spirometer, Pulse Oximeter, and monitors for measuring Blood Pressure, and Blood Glucose. Other monitors, such as Body Fat, Heart Rate, Body Temperature, and Weight Scale are proposed as future options.

2. Name: Classification and Trade

Trade name: PMP[4] Medical Web Center
Classification name: PMP[4] Center
Class II medical devices (21 C.F.R. Par. 870.2920 (1992)

3. Substantial Equivalence

The basis PMP[4] Medical Web Center is substantially equivalent the TM2005 Receiving Center K024365: it has similar intended use and main principles of operation. The main difference between the systems is that in PMP[4] Center is designed to monitor spirometric, blood pressure and pulse rate, glucometric, oximetric, *and cardiac data* (ECG), while TM2005 is a cardiac center only.

4. Proposed Labeling

1. The PMP[4] Medical Web Center is a medical communication system used to monitor patient's health parameters.
2. The PMP[4] Center is a web-based application used to access data through an internet browser.
3. The PMP[4] Center enables receiving, storing, displaying, updating, printing and forwarding of patient health and other related data, (e.g. demographics, doctors, medical history, diagnoses, etc.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Card Guard Scientific Survival Ltd.
c/o Mr. Alex Gonorovsky
Manager, Regulatory Affairs
2 Pekeris St. P.O.B. 527
Rehovot 76100
Israel

Re: K050940
Trade Name: PMP[4] Medical Web Center
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: June 9, 2005
Received: June 13, 2005

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 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) 276-0295. 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 (301) 443-6597 or at its Internet address.

Sincerely yours,

Donna R. Vachner

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

Enclosure

K050940/S

Indications for Use

The PMP[4] Medical Web Center is a Software application intended for supporting remote monitoring of Electrocardiographic (ECG), Spirometric, Fetal/Maternal, Blood Pressure, Heart Rate, Blood Glucose, Blood Oxygen Saturation, Body Weight and optionally other patients' vital signs and parameters.

The data is received from transducers/monitors, which are external to the system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Donna R. Vechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050940