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APR 4 2006

CARD GUARD Scientific Survival LTD

PMP^4 BP Pro Blood Pressure Monitor
510(k) Summary of Safety and Effectiveness

1. General

Submitter	**Card Guard Scientific Survival Ltd.,**
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Device	
Trade Name:	PMP^4 BP Pro Blood Pressure Monitor
Classification:	Noninvasive Blood Pressure Measurement System
Product Code:	DXN
Regulation No:	21 CFR 870.1130
Class:	II

2. Definition and Intended Use

The PMP^4 BP Pro is used for self-testing by patients and by healthcare professionals at home and at medical settings to monitor blood pressure (systolic and diastolic) and pulse rate from the upper arm. The device consists of a table top monitor and a receiving program - the PMP^4 Medical Application. The table top monitor obtains the blood pressure measurement through the oscillometric method, i.e. the blood movement through the artery in the upper arm are detected and converted into digital readings. For evaluation, the stored measurement results can be transmitted by Bluetooth interface to a wireless mobile platform, e.g. PDA or a static platform, i.e., PC with the PMP^4 Medical Application installed. The PMP^4 Medical Application interfaces to the table-top monitor and is used to receive from the BP Pro the test results and other medical data, to process and save these test results, and to synchronize data and test results with the PMP^4 Medical Center.
The PMP^4 Medical Application is also designed to receive ECG, spirometric, glucometric, and oximetric parameters from other Card Guard medical testing accessories in addition to BP+HR.
When the table top monitor is not used to measure blood pressure, it displays time and date.
The intended product users are Non-Medical Persons (NMP), i.e. persons expected to understand only basic medical data.

3. Referenced Standards

1. MDD 93/42/EEC Medical Device Directive Council Directive 93/42/EEC; June 14, 1993
2. MPG The Act on Medical Devices (Medizinproduktegesetz), rev 2; Germany; Dec 2001
3. EN 475: Medical devices - Electrically-generated alarm signals ; April 1995
4. EN 980: Graphical symbols for use in the labeling of medical devices; August 2003
5. EN 1041: Terminology, Symbols and Information provided with Medical Devices; Information supplied by the manufacturer with medical devices; April 1998
6. EN 1060: Non-invasive sphygmomanometers, Part 1: General requirements, Dec. 95 (EN 1060-1/A1: Changes; Sept. 02), Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems; Sept. 1997
7. EN ISO 9001: Quality management systems - Requirements; December 2000
8. EN ISO 13485: Quality systems – Medical devices; August 2000
9. EN ISO 14971: Medical devices – application of risk management to medical devices; March 2001
10. EN ISO 10993 Biological evaluation of medical devices Part 1: Evaluation and testing; Dec. 1997
11. EN 60601-1: Medical electrical equipment; Part 1: General requirements for safety; Sept. 2002
12. EN 60601-1-2: Medical electrical equipment; Part 1: 2. Collateral standard: EMC; requirements and tests; 2001
13. EN 60601-1-4: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems; Apr. 01
14. AAMI/ANSI SP10: Electronic or automated sphygmomanometers; October 1992

4. Method of Operation

Inflating the Cuff

To lessen patient discomfort, the cuff does not always inflate to a defined predetermined value, but by means of an approximation of the envelope curve during the inflation phase attempts to inflate only up to a value just above the systolic pressure. To do this the pressure is increased in defined predetermined pressure steps (85, 100, 120, 140, 160 ... mmHg) and a single pressure pulse is measured at each stage. An increase in pulse amplitude to a maximum and the subsequent decrease is determined during this type of inflation. The systolic pressure is then regarded as definitely attained and the inflation terminated when a pulse amplitude of <52% of the maximum is measured after exceeding the maximum.

Inflation with Auto Feedback Logic

After the first measurement, the device recognizes the systolic pressure. During the next inflation, the cuff inflates up to the most recent systolic value plus ≈15mmHg instead of inflating stepwise to a predefined value. The advantage is the reduced pumping time and therefore the reduced discomfort for the patient.

5. Substantial Equivalence

Substantial equivalence (SE) is claimed to the following predicate devices:

1. Card Guard's BP Pro *K053395* - for physical and functional identity and close similarity in IU.
2. Card Guard's CG-7000DX-BT *K052556* - for the remote communication functionality.
3. Card Guard's PMP⁴ Spiro Pro K050853 - for including the PMP⁴ Medical Application.
4. Card Guard's PMP⁴ Medical Web Center K050940 - for multiple-format medical data feature.

6. PMP⁴ Medical Application

The PMP⁴ Medical Application is designed for wireless mobile platforms, e.g. PDA and for static platforms, i.e., PC. It is used to receive from the BP Pro and other Card Guard's medical testing accessories, the test results and other medical data, to process and save these test results, and synchronize data and test results with the PMP⁴ Medical Center. The Application is a part of a personal medical system solution. The PMP⁴ 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 or backup.
5. Receives data from Center.
6. Enables configuring GPRS data connection (based on mobile phone GPRS/CDMA capabilities), changing user name and password.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Card Guard Scientific Survival Ltd.
c/o Mr. Alex Gonorovsky
Regulatory Affairs Manager
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P. O. Box 527
Rehevot 76100
ISRAEL

Re: K060703
Trade Name: PMP[4] BP Pro Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: February 21, 2006
Received: March 16, 2006

Dear Mr. Gonorovsky:

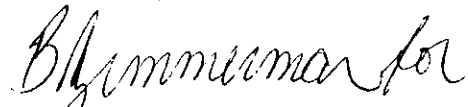
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K060703

Indications for Use

510(k) Number (if known):
Device Name: PMP[4] BP Pro Blood Pressure Monitor

Indications for Use:

The *PMP[4] BP Pro* Blood Pressure Monitor is intended to be used for monitoring Blood Pressure (BP) and Heart Rate (HR) from the upper arm. BP and HR can be recorded and transferred to a remote hand held device/PC for viewing and processing.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒
(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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060703