K050853

MAY - 4 2005

CARD GUARD
Scientific Survival LTD.

PMP4 Spiro Pro
510(k) Summary of Safety and Effectiveness

Submitter: Card Guard Scientific Survival Ltd.,

2 Pekeris St. P.O.B. 527
Rehovot 76100, Israel

Tel: 972-8-9484000

Fax: 972-8-9484044

Contact Person: Alex Gonorovsky

RA Manager
Tel: 972-8-9484000
E-mail: galex@cardguard.com

Date Prepared: May 2, 2005

1. Definition

PMP4 Spiro Pro is a portable spirometer designed to accurately measure lung ventilatory functions during the Forced Vital Capacity (FVC) tests.

The system records the following:

- Volume-Time and Flow-Volume curves
- FVC
- Forced Expiratory Volume: FEV1, FEV3
- Peak Expiration Flow (PEF)
- Forced Expiratory Flow: FEF75%, FEF50%, FEF25%, FEF25/75

PMP^4 Spiro Pro operates in two modes: PDA and Stand-alone.
In the PDA mode the test data is transmitted through a Bluetooth or infrared link to a PDA. In this mode all necessary calculations are performed by the PDA's software.
In the stand-alone mode the Spiro Pro calculates all parameters and displays the results on its LCD. In conjunction with the pulmonary receiving station PMP^4 Spiro Pro provides an important tool for monitoring COPD patients.

2. Intended Use

The PMP4 Spiro Pro is intended for pulmonary function testing for use in hospital, clinic or home settings. It allows patients to display and transmit their pulmonary function data via a communication device to medical professionals in a remote server.

3. Applicable Standards, Regulations, Guidances

PMP4 Spiro Pro meets the requirements of the following Standards, Regulations and Guidances:

- ISO 14971:2000 , Medical devices - Application of risk management to medical devices
- American Thoracic Society, Standardization of Spirometry, 1994 update.
- IEC 1025: 1990 Fault tree analysis (FTA)
- IEC 801-1, 1984, General Introduction
- IEC 601-1-1, 1996, Safety Requirements for Medical Electrical Systems
- IEC 601-1-2, 2001, Part 2: Electromagnetic compatibility-Requirements and Tests
- IEC 601-1-4, 1996, Part 1-4, Programmable Electrical Medical Systems
- IEC 801-2, 1991, Electrostatic Discharge Requirements'
- IEC 801-3, 1992, Immunity to Radiated Radiofrequency electromagnetic fields
- IEC 801-4, 1988, Electrical Fast Transient Burst Requirements
- CISPR 11 1990 Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio frequency Equipment 2nd Edition
- Reviewer Guidance for Computer Controlled Medical Devices, FDA Aug 29, 1991
- ISO 13485 (2003), Medical Devices – Quality Management Systems
- ISO 9001:2000, Quality Management Systems – Requirements
- ISO 10993:2003, part 5 Biological evaluation of medical devices. Evaluation and testing
- MIL-STD 810E, product environmental testing
- FDA's New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial equivalence in Premarket Notifications Final Guidance, CDRH, March 20, 1998.
- 21 CFR part 820 subchapter H – medical devices , quality system regulations

4. Substantial Equivalence

The substantially equivalence to the following predicate devices is claimed:

Card Guard	CG-303 , Spirophone	K934795	Decision Date 04/14/1995
Card Guard	SelfCheck™ ECG	K042254	Decision Date01/13/2005

The correlation between the comparable parameters and features of the devices, for the purpose of proving their substantial equivalency is herby provided in the comparison table on chapter 7.

5. Design Controls and Hazard Analysis

The Card Guard's product design procedure, and QA and QC policy, formalize the design and production process and assure that all respective requirements are met. In the framework of the Design Controls and as required by the Risk Analysis, laboratory testing were conducted to verify and validate the PMP^4 Spiro Pro compliance with all design specifications. Safety and EMC tests as well as performance tests according to the Thoracic society standardization were performed and assured the safety and efficacy of the device.

The device biocompatibility was evaluated and found to be satisfactory.

The device Level of Concern criteria were evaluated and PMP4 Spiro Pro was characterized as a moderate level of concern system.

The system safety and risk analysis conducted for PMP4 Spiro Pro provided rigorous design and structural evaluation aimed at revealing potential failures or possible system flaws which could directly or indirectly affect the patient.

6. Conclusions

PMP^4 Spiro Pro constitutes a safe and reliable means for pulmonary function testing. Its material composition and operation present no adverse health effect or safety risks to patients when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Mr. Alex Gonorovsky
Regulatory Affairs Manager
Card Guard Scientific Survival Limited
2 Pekeris Street P.O.B 527
Rehovot 76100
ISRAEL

Re: K050853
Trade/Device Name: PMP4 Spiro Pro
Regulation Number: 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: March 31, 2005
Received: April 4, 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.

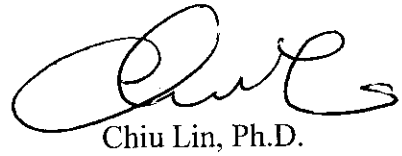
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device name: PMP4 Spiro Pro

The PMP4 Spiro Pro is intended for pulmonary function testing for use in hospital, clinic or home settings. It allows patients to display and transmit their pulmonary function data via a communication device to medical professionals in a remote server.

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)

for Ann Graham

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K050553