CARD GUARD
Scientific Survival Ltd.

K043162

Chapter 16

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: **Boris Aradovsky,**
VP QA and Regulatory Affairs
Tel: 972-8-9484000
E-mail: borisa@cardguard.com

Date Prepared: October 12, 2004

1. Definition

The PMP4 Oxy Pro is a photoelectric pulse oximeter device to be used for self testing upon prescription of an authorized health care provider. Specifically, it is designed for patients who wish to measure the oxygen saturation levels in the blood and pulse rate.

The PMP4 OxyPro is manually activated by the patient. It functions as a stand-alone device as patient can see "real time" data on its LCD. In addition, the PMP4 OxyPro enables transmission of real time data to the patient's PMP4 PDA or compatible generic PDA phone or personal computer supporting Bluetooth (BT) protocol.

2. Intended Use

The PMP4 Oxy Pro digital pulse oximeter system is intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients in different settings:

a) At hospitals, homes and alternate-sites as well as for EMS environment and for transport use.

b) At remote locations, where patients can obtain, display and transmit their pulse oximeter vital signs data to a medical expert via a communication device, such as a PDA or a remote server.

The PMP4 Oxy Pro is indicated for spot checking and/or continuous monitoring.

3. Applicable Standards, Regulations, Guidances

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

- ISO 14971:2000 , Medical devices - Application of risk management to medical devices
- 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, parts 1, 5, 10 - 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. Features

- Two control buttons
- Transmission via Bluetooth an IR (future optional)
- The device is internally-powered with applied parts of type CF, suitable for continuous operation.
- Low Battery detection.

5. User Interface

The PMP4 Oxy Pro user interface incorporates the following controls and signals:

- On/off control button
- Low battery warning

6. Substantial Equivalence

The substantially equivalence to the following predicate devices is claimed:

Nonin Avant® model 4000	Digital Pulse Oximetry System	K041156	Decision Date 06/09/2004

The Nonin Avant® 4000 was cleared as a prescription device on 06/09/04.

The PMP4 Oxy Pro, subject of this application, is substantially equivalent to the predicate device.

- Intended use:

Both devices are indicated for spot checking by patients and/or continuous monitoring. Both devices are digital pulse oximeter systems intended for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. They both intended for adults and pediatrics.

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.

7. 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 laboratory testing were conducted to verify and validate the PMP4 Oxy Pro compliance with all design specifications.

The device biocompatibility was evaluated and found to be satisfactory.

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

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

8. Conclusions

PMP4 Oxy Pro constitutes a safe and reliable means for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. 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

DEC 2 9 2004

Mr. Boris Aradovsky
Vice President Quality Assurance and Regulatory Affairs
Card Guard Scientific Survival, Limited
2 Pekeris Street
P.O.B 527
Rehovot, 76100
ISRAEL

Re: K043162
Trade/Device Name: PMP4 Oxy Pro
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 16, 2004
Received: November 16, 2004

Dear Mr. Aradovsky:

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/dsma/dsmamain.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: K043162

Device Name: PMP4 Oxy Pro

Indications For Use:

The PMP4 Oxy Pro digital pulse oximeter system is intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients in different settings:

a) At hospitals, homes and alternate-sites as well as for EMS environment and for transport use.

b) At remote locations, where patients can obtain, display and transmit their pulse oximeter vital signs data to a medical expert via a communication device, such as a PDA or a remote server.

Prescription Use ___✓____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON NOTHERPAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K043162