CARD GUARD® Scientific Survival LTD.

TM2005 Personal Medical Phone™ Center
Special 510(k) Premarket Notification *510(k) Summary of Safety and Effectiveness*

**Submitter:** Card Guard Scientific Survival Ltd.,
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JAN 1 5 2003

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**Date Prepared:** December 02, 2002

## 1. Definition and Intended Use

The TM2005 Personal Medical Phone™ software system is designed to manage data from remote patients and physicians. The system users are patients, physicians and administrators. Each user has a unique access to database according to his permissions in the system.

The system enables the user to connect to the Internet Server, view and update data according to the user permissions, download data via PDA or PC. This includes ECG, and other patient related data, (such as demographics, doctors, medical history and status, diagnoses, etc.).

An external means (CGTTM) is provided for displaying, measuring, and printing the downloaded ECG.

The system includes a DB Management application and a means to receive data via Internet. It also provides auxiliary tools to enable the administrator to add users, set user permissions, link between users (patients/doctors and a Backup utility).

## 2. Device Class

The TM2005 Receiving Center system is classified as Class II medical device (21 C.F.R. Par. 870.2920 (1992)).

## 3. Applicable Standards

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Act for telephone ECG and Spirometric transmitter devices.

TM2005 meets the requirements of the following standards and guidances:

- EN1441: 1997 Medical Devices – Risk Analysis
- IEC 1025: 1990 Fault tree analysis (FTA)
- IEC/TR 513: 1994 Fundamental aspects of safety standards for medical electrical equipment
- IEC 601-1, 1996, Medical Electrical Equipment, General Requirements for Safety
- IEC 601-1-1, 1996, Safety Requirements for Medical Electrical Systems
- IEC 601-1-4, 1996, Part 1-4, Programmable Electrical Medical Systems
- IEC 812: 1985 Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)

- IEC 300-3-9: 1995 Dependability management, Part 3: Application guide, Section 9, Risk analysis of technological systems
- Reviewer Guidance for Computer Controlled Medical Devices, FDA Aug 29, 1991
- ISO/IEC Guide 51: 1990 Guidelines for the inclusion of safety aspects in standards
- ISO 9002 guidelines
- EN-46002
- IEEE Standard for Software Quality Assurance Plan
- FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998
- FDA's New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial equivalence in Premarket Notifications - Final Guidance, CDRH, March 20, 1998.

## 4. Features

- Runs on Windows 2000 Server; XP Server operating system
- Manual entry of patient and physician detail
- Data processing capabilities
- ECG event recording
- Receiving, storing medical data

## 5. User Interface

The TM2005 GUI enables access to all categories of data through 3 built-in interfaces:

- Administrator interface
- Physician interface
- Patient interface

## 6. Substantial Equivalence

The basis of this special 510(k) premarket notification is Card Guard's belief that TM2005 is substantially equivalent to the predicate system: the TM2000 Receiving Center K992164: it has the same intended use and main principles of operation.

The main difference between the systems is that in the TM2000 is essentially a DB server while TM2000 is a web server that supports JSP files. The differences between the systems have no effect on safety, and are intended to improve the system effectiveness.

## 7. Design Controls and Quality System Regulations

The Card Guard manufacturing facility is in conformance the with design control procedure requirements specified in 21 CFR 20.61, the records are available for review.

The Card Guard's product design procedure, and quality assurance and control policy, formalize the design and production process and assure that all respective requirements are met.

The Pre-Production design control for the original development and subsequent modifications is properly established according to the Quality System Regulation (21 CFR 820.30 Subpart C Design Controls of the Quality System Regulation).

## 8. Level of Concern and Hazard Analysis

The device Level of Concern criteria were evaluated and the system was determined to be *a moderate level of concern system.*

The rigorous design evaluation and the System Safety and Risk analysis expose potential failures or possible system flaws which could directly or indirectly effect the patient.

## 9. Conclusions

The system constitutes a safe and reliable means for receiving, storing, displaying, updating, and re-transmitting of patient ECG and other patient related data. Its 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

JAN 1 5 2003

Card Guard Scientific Survival Ltd.
c/o Mr. Alex Gonorovsky
Regulatory Affairs Officer
2 Pekeris Street
Rehovot 76100
Israel

Re: K024365
Trade Name: TM2005 Personal Medical Phone™ Center
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: December 1, 2002
Received: December 31, 2002

Dear Mr. Gonorovsky:

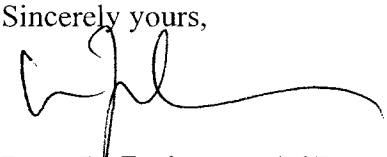
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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 may be obtained 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,



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

Enclosure

K024365

CARD GUARD® Scientific Survival LTD.™

# Indications For Use
# TM2005 Personal Medical Phone™ Center

510(k) Number (if known):

The Personal Medical Phone™ Center is intended for supporting transtelephonic monitoring of Electrocardiography (ECG) parameters of cardiac patients.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovas...

510(k) Number K024365