DEC 10 1999

K993799

CARD GUARD
Scientific Survival LTD

CG-7000DX Recorder/Transmitter
510(k) Summary of Safety and Effectiveness

Submitter:

Card Guard Scientific Survival Ltd.,
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Chief Engineer,
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Date Prepared: October 31, 1999

1. Definition and Intended Use

CG-7000DX Recorder/Transmitter is a 12 Lead ambulatory electrocardiograph capable of recording and transmitting up to 40 standard ECGs for the purpose of cardiac monitoring and diagnosis, which incorporates a recording and transmitting circuitry, graphic LCD, a package of firmware tools and is intended for use by a medical professional:

a. The ECG is recorded and transmitted to a remote receiving station for consultation with a cardiologist.

b. The ECG is recorded and transferred to a PC for viewing and processing.

The CG-7000DX allows acoustic or optical transmission. The Universal IR Adapter conveys data to the remote receiving station or local PC.

CG-7000DX is compatible and intended for use with Telemedicine 2000, the Card Guard's standard Transtelephonic Receiving Center in its LAN as well as its standalone configuration.

CG-7000DX is classified as Class II medical device.

The CG-7000DX Recorder/Transmitter meets the requirements of the following standards:

(1) ANSI/AAMI EC38, "Ambulatory Electrocardiographs" 1994

(2) ANSI/AAMI EC13 Cardiac Monitors, Heart Rate Metersand Alarms, 2nd edition 1992

(3) ANSI/AAMI EC11 Diagnostic Electrocardiographic Devices, 2nd edition 1991

(4) IEC-601-1-4 Medical Electrical Equipment 1996.

2. Features and Functions

(1) Graphic display for ECG representation and device control.

(2) One screen shows 1,52 sec lead length. For viewing full length scrolling is used.

(3) Keypad with 17 keys for device control and data input.

(4) Simultaneous recording of ECG 12-leads, up to 40 ECG records.

(5) Menu selectable lead duration: 4, 8, 12, 16, and 20 seconds.

(6) All records include a mandatory minimum 12 seconds arrhythmia trace.

(7) Recorded ECG is transmitted acoustically or optically.

(8) Low battery detection.

(9) Self-test in BIT mode.

(10) Pacemaker artifact detection and marking.

(11) Patient Cable with 10 lead wires.

3. Substantial Equivalence

The CG-7000DX is an enhanced CG-7000D ECG Recorder/Transmitter (K942704). CG-7000DX is substantially equivalent to its predicate CG-7000D since both devices have:

- The same intended use, and
- The same principles of operation, features and technological characteristics.

4. Material differences

The most important innovations in CG-7000DX include:

(1) Keypad with 17 keys for device control and data input.

(2) Transmission of ECG along with its relational time and the following record IDs:

- Device ID
- Patient ID
- Doctor ID
- Clinic ID

(3) A selectable transmission speed: Real time/Rapid: ×2, 33600 bit/s

(4) 10 bit digital resolution.

(5) Self-test and calibration.

(6) Heart-rate display.

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 the laboratory testing was conducted to verify and validate the CG-7000DX compliance with all the design specifications. This included:

Verification Tests

- SW Unit/Module Testing (19 tests)
- User Interface Verification Test
- Reference Voltage Verification Test
- Clock Oscillator Verification Test
- Flash Memory Verification Test
- LPF Verification Test
- QRS Detection Test
- PM Pulse Detection Test
- Patient Cable Test

Validation tests

- Common Mode Rejection Test
- Frequency Response Test
- Input Dynamic Range Test
- Overall System Error Test
- Step Response Test
- System Noise Test
- Safe Current Test

Environmental Tests

- High and Low Temperature and Humidity Test
- Surface temperature Test
- Leakage Current Test
- Dielectric Strength Test
- Mechanical Vibration Shock Test
- Ingress of Liquids Test
- EMC Test

The device biocompatibility was evaluated and found to be satisfactory.

The device Level of Concern criteria were evaluated and CG-7000DX was characterized as a moderate level of concern system.

The System Safety and Risk analysis conducted for CG-7000DX provided rigorous design and structural evaluation aimed at revealing potential failures or possible system flaws which could directly or indirectly effect the patient.

6. Conclusions

CG-7000DX ECG Recorder/Transmitter, constitutes a safe and reliable means for recording and transmitting standard ECG for the purpose of cardiac condition diagnosis. Its material composition and of operation present no adverse health effect or safety risks to patients when used as intended.

The conclusions drawn from clinical and laboratory testing of CG-7000DX demonstrate that the device is as safe, as effective and performs as well as or better than the legally marketed predicate device, CG-7000D ECG Recorder/Transmitter (K942704).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

Mr. Leonid Trachtenberg
Chief Engineer
Card Guard Scientific Survival Ltd.
2 Pekeris St. P.O.B. 527
Rehobot 76100, Israel

Re: K993799
CG-7000DX ECG Recorder/Transmitter
Regulatory Class: II (two)
Product Code: DXH
Dated: November 2, 1999
Received: November 9, 1999

Dear Mr. Trachtenberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Nancy C Brogden for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CARD GUARD
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CG-7000DX Indications For Use

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a. The ECG is recorded and transmitted to a remote receiving station for consultation with a cardiologist.

b. The ECG is recorded and transferred to a PC for viewing and processing.

The Universal IR Adapter is used for conveying data to the remote receiving station or PC.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K993799

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)