CARD GUARD
Scientific Survival LTD.

CG-2211 SelfCheck ECG Transmitter
510(k) Summary of Safety and Effectiveness

K012223 p.1/4

SEP 1 0 2001

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Date Prepared: July 12, 2001

1. Definition and Intended Use

The CG-2211 SelfCheck is a personal single lead event ECG transtelephonic transmitter. The device is intended for self-testing by patients and records a limited period of heart activity. The recording is activated by patient, when symptom is experienced.

The CG-2211 SelfCheck transmits the recorded data to a receiving station, where data is displayed for analysis and evaluation by physician. The transmission includes the time, when the event recording was activated by patient.

The CG-2211 SelfCheck is compatible and intended for use with TM 2000, the Card Guard's Transtelephonic Receiving Center in its LAN as well as its standalone configuration.

The CG-2211 SelfCheck is classified as Class II medical device.

2. Applicable Standards, Regulations, Guidances

CG-2211 SelfCheck ECG Transmitter meets the requirements of the following Standards, Regulations and Guidances:

- CFR Title 21 Part 820 - Quality System Regulation, Medical Devices, published in Federal Register, 61 RF 52602 - October 7, 1996
- ANSI/AAMI EC38-D, "Ambulatory Electrocardiograph", 1994
- ANSI/AAMI EC13 Cardiac Monitors, HR Meters and Alarms, 2nd edition 1992
- ANSI/AAMI EC1-1993, "Safe Current Limits for Electromedical Apparatus" Dec 1993
- ANSI/AAMI EC11 Diagnostic Electrocardiographic Devices, 2nd edition 1991
- 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 801-1, 1984, "General Introduction"

- IEC 601-1, 1996, "Medical Electrical Equipment, Part I General Requirements for Safety"
- IEC 601-1-1, 1996, "Safety Requirements for Medical Electrical Systems"
- IEC 601-1-2, 1993, "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"
- 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
- 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/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.

3. Features

- Two control buttons: RECORD and SEND.
- Data storage capacity 32 Kbyte, sufficient for one ECG event.
- Transmission via acoustic transducer.
- Pacemaker detection and marking.
- The device is internally-powered with applied parts of type BF, suitable for continuous operation.
- Low Battery detection and audio warning

4. User Interface

The CG-2211 user interface incorporates the following controls and signals:

- RECORD control button
- SEND control button
- Fluctuating recording sound ending with a wavy tone (approximately 30 seconds).
- Fluctuating transmission sound (approximately 10 second).
- Low battery warning (three sequential beeps).

5. Substantial Equivalence

This document pertains to Card Guard's application for the FDA premarket clearance the CG-2211 SelfCheck ECG transmitter. Said clearance is hereby sought on the grounds that the CG-2211 is substantially equivalent to the following predicate devices:

1. CG-2206 ECG Transmitter K963725
2. HeartCard® Telephone Electrocardiograph Transmitter and Receiver K010945

The CG-2206 ECG Transmitter was cleared for sale in the US in September 10, 1997 as a prescription device (tracking number K963725).

The Card Guard's HeartCard® Telephone Electrocardiograph Transmitter and Receiver was cleared in June, 2001 as a non-prescription device (tracking number K010945). The non-prescription distribution includes:

- Direct-to-consumer (via direct advertising and promotion) and
- Over the counter (via traditional Retail Stores)

The CG-2211, subject of this application, is physically identical to the CG-2206 ECG Transmitter K963725, the difference is as follows:

1. The CG-2211 records one ECG event, while the CG-2206 records 6 events,
2. The duration of the ECG event recorded by the CG-2211 is 60 seconds, while the duration of the ECG event recorded by the CG-2206 is 60 seconds,
3. Method of distribution to customer: CG-2206 is a prescription device, while CG2211 is intended for the OTC distribution.

The CG-2211, subject of this application, is identical to the Card Guard's HeartCard® Telephone Electrocardiograph Transmitter and Receiver K010945 in the method of distribution to customer and the following common qualities:

- Intended use:

Both devices are intended for self-testing by patients whereas the recording is activated by patient when symptom is experienced. Both devices record a limited period of heart activity.

- Principles of operation, features and technological characteristics.

Both devices enable transmission of the ECG trace and recording time to a receiving station, where data is displayed for analysis by physician.

6. 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-2211 compliance with all the design specifications. This included:

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-2211 was characterized as a moderate level of concern system.

The System Safety and Risk analysis conducted for CG-2211 provided rigorous design and structural evaluation aimed at revealing potential failures or possible system flaws which could directly or indirectly effect the patient.

7. Conclusions

CG-2211 SelfCheck ECG Transmitter constitutes a safe and reliable means for recording and transmitting standard ECG for the purpose of cardiac condition diagnosis. 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

SEP 1 0 2001

Mr. Leonid Trachtenberg
Chief Engineer
Card Guard Scientific Survival, Ltd.
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Re: K012223
Trade Name: CG-2211 SelfCheck ECG Transmitter
Regulation Number: 21 CFR 870.2920
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: July 12, 2001
Received: July 16, 2001

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) 594-4646. 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,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use
CG-2211 SelfCheck ECG Transmitter and LifeWatch Heart Screening Service

510(k) Number (if known): **K012223**

The CG-2211 SelfCheck ECG Transmitter and LifeWatch Heart Screening Service are intended for self-testing by patients who are concerned about their heart rhythm (i.e. during or after exercise) or who experience the following symptoms that are suggestive of abnormal heart rhythms, and who would like to monitor these symptoms:

- Skipped Beats
- Pounding heart (Palpitations)
- Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

Contraindications for Use:

In order to use this service, the patient must be able to perform all of the following:

- Read and understand the User's Manual
- Place the HeartCard on his/her chest and hold it steadily for at least 30 seconds.
- Hear the "beeps" for low battery.
- Speak and understand English.
- Operate a telephone.
- Operate a simple, push-button device.

Due to the possible seriousness of the abnormal heart rhythms that can be associated with these conditions, persons who have been diagnosed with the following conditions should consult their physician before using this service:

- Blockage of the arteries of the heart
- Heart valve problems
- Heart transplant
- Congestive heart failure
- Loss of consciousness

If the patient has any of these conditions, LifeWatch will need to obtain authorization from their physician within 35 days of enrollment in the service.

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Warning:

This device is not designed to be used with pacemakers or defibrillators. If the patient has either of these, the patient will not be allowed to enroll in the service.

This device also cannot predict or diagnose a heart attack or be used for chest pain monitoring.

Need for Signed Physician Agreement:

Your agreement indicates you understand that LifeWatch (or affiliate) will contact your physician to verify in writing that you are their patient and that they are willing to be contacted in cases where there are clinically significant events involving your care.

Your agreement indicates you understand that if written verification is not received from your physician within 35 days of your enrollment, you will not be able to utilize any aspects of the LifeWatch (or affiliate) service until such verification is received by LifeWatch (or affiliate).

Your agreement certifies you understand that this service is not a substitute for physician care and that this is only a screening service.

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

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 of Cardiovascular & Respiratory Devices
510(k) Number K012223