

CG-2100 ECG Transmitter
 510(k) Summary of Safety and Effectiveness

Submitter:

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Date Prepared:

November 22, 1999

1. Definition and Intended Use

CG-2100 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.

CG-2100 enables transmission of 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.

CG-2100 is compatible and intended for use with Telemedicine 2000, the Card Guard's Transtelephonic Receiving Center in its LAN as well as its standalone configuration.

CG-2100 is classified as Class II medical device.

2. Applicable Standards, Regulations, Guidances

CG-2100 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
- ANSI/AAMI EC53-1995 "ECG Cables and Leadwires".
- 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"



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- 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/SEND and RESET/CLEAR.
- Data storage capacity 32 Kbyte, sufficient for one ECG event.
- Transmission via acoustic transducer.
- Pacemaker detection and marking.
- The device shall be internally-powered with applied parts of type BF, suitable for continuous operation.
- Low Battery detection and audio warning

4. User Interface

The CG-2100 user interface incorporates the following controls and signals:

- RECORD/SEND control button
- RESET/CLEAR 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).



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5. Substantial Equivalence

The CG-2100 single lead event ECG transtelephonic transmitter, the subject of this submission, is a simplified version of the CG-2206 personal ECG transmitter (K963725). Therefore the CG-2100 is equivalent to its predicate device: the CG-2206.

CG-2100 and its predicate device, CG-2206, have the following qualities in common:

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

6. Material differences

- CG-2606 has a Common input whereas CG-2100 has none.
- CG-2100 has a 32 Kbyte Memory, as compared to CG-2606 128 Kbyte.

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 the laboratory testing was conducted to verify and validate the CG-2100 compliance with all the design specifications. This included:

- | Validation tests | Environmental Tests |
|------------------------------|--|
| • Common Mode Rejection Test | • High and Low Temperature and Humidity Test |
| • Frequency Response Test | • Surface temperature Test |
| • Input Dynamic Range Test | • Leakage Current Test |
| • Overall System Error Test | • Dielectric Strength Test |
| • Step Response Test | • Mechanical Vibration Shock Test |
| • System Noise Test | • Ingress of Liquids Test |
| • Safe Current Test | • EMC Test |

The device biocompatibility was evaluated and found to be satisfactory.

The device Level of Concern criteria were evaluated and CG-2100 was characterized as a moderate level of concern system.

The System Safety and Risk analysis conducted for CG-2100 provided rigorous design and structural evaluation aimed at revealing potential failures or possible system flaws which could directly or indirectly effect the patient.

8. Conclusions

CG-2100 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 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-2100 demonstrate that the device is as safe, as effective and performs as well as or better than the legally marketed predicate device, CG-2206 personal ECG transmitter (K963725).



DEC 21 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994009
CG-5100 ECG Transmitter
Regulatory Class: II (two)
Product Code: DXH
Dated: November 17, 1999
Received: November 26, 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.

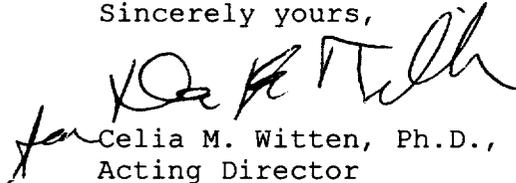
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Leonid Trachtenberg

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.

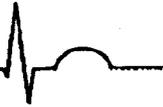
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the 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,



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



The device is intended for self-testing by patients who experience transient symptoms that may suggest cardiac arrhythmia.

The device is not intended for simultaneous recording and transmitting of the patient ECG signals.

(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 Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K994009