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AUG 1 2 2002

# Summary of Safety and Effectiveness

*TM2000 FetalTrace Receiving Center Software*



| | Name | Title | Signature | Date |
|---|---|---|---|---|
| Written by | A. Gonorovsky | Deputy Chief Engineer | | March 26, 2002 |
| Approved by | Amnon Shur | Project Manager | | March 26, 2002 |
| | | | | |

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**Date Prepared:** 18 April 2002

## Table of Contents

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## 1. Definition and Intended Use

The TM2000 FetalTrace Transtelephonic Receiving Center is a software system designed and intended for supporting a remote (transtelephonic) monitoring of patient Fetal/Maternal parameters. The System enables receiving, storing, displaying, updating, printing and re-transmitting of patient Fetal/Maternal parameters and other patient related data, (such as demographics, doctors, medical history and status, diagnoses, etc.).

## 2. Device Class

The TM2000 FetalTrace Transtelephonic Receiving Center system is classified as Class II medical device (21 C.F.R. Par. 870.2920 (1992)).

## 3. Applicable Regulatory Documents and Card Guard Procedures

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

The complete list of the Applicable Documents referenced and/or incorporated in this project is provided in the FDA submission package: *Chapter 18, Applicable Normative Documents: Standards, Regulations, Guidances, Procedures; Publications*

Chapter 18 includes the following sections:

- Applicable FDA Documents
- American National Standards Institute (ANSI), Association for the Advancement of Medical Instrumentation (AAMI)
- International Electrotechnical Commission (IEC/CEI), International Organization for Standardization (ISO), European Norm (EN)
- Code of Federal Regulations
- International Special Committee On Radio Interference (CISPR)
- Institute of Electrical and Electronics Engineers (IEEE)
- Card Guard Ltd: Applicable Procedures
- Card Guard Ltd: Product Definitive Reference
- Articles, Publications

## 4. Operational Characteristics, Features and Functions

1. Runs on any MS Windows operating system
2. Maximum database file size of 2 GB,
   Storage of up to 10 - 40 thousand transmissions (depending on transmitter type)
3. Accessing and updating the receiving center DB.
   Manual entry of patient and physician detail
4. Receiving and processing patients' transmitted signals and medical data
5. Graphic representation of FM signals
6. Intuitive, user friendly HMI
7. Capability for signal/data transmission over Web (Planned for implementation in future)
8. Localization
9. Reports generation

10. Reports previewing and printing
11. Manageable security, fail-safe protection against unauthorized access. Discretionary access control, restrictions based on privileges (Not yet implemented)

## 5. User Interface

The TM2000 Graphic User Interface (GUI) features pull down menus and dialog boxes for representation and updating of data. Generation of GUI and implementation of the related DB connectivity mechanism utilizes the C/C++ native methods in conjunction with the Windows API functions.

## 6. Substantial Equivalence

The TM2000 FetalTrace is substantially equivalent to its predicate TM2000 K013879 Receiving Center, cleared on Nov 23, 2001.

The TM2000 FetalTrace has the Fetal/Maternal service, with the user interface forms totally identical to those of TM2000 K013879.

The TM2000 FetalTrace differs from the TM2000 K013879 in two aspects:

1. Unlike the TM2000 K013879, the TM2000 FetalTrace has no ECG and Spiro services.
2. The TM2000 FetalTrace uses the Access DB engine while the TM2000 K013879 uses the Oracle DB engine. This aspect will be discussed in further detail *Substantial Equivalence 2* TM2000 FetalTrace vs. TM2000 EasyTrace since the latter also uses Access.

The proof of substantial equivalence in all that concerns the intended use, principles of operation, features and technological characteristics is provided in Chapter 7. *Substantial Equivalence to Cleared Devices.*

## 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 the respective requirements are met. In the framework of the Design Controls the testing was conducted to verify the system compliance with all its design specifications.

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.

## 8. Conclusions

The system constitutes a safe and reliable means for receiving, storing, displaying, analyzing, updating, printing and re-transmitting of patient Fetal/Maternal parameters 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

AUG 12 2002

Mr. Alex Gonorovsky
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Regulatory Affairs
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2 Pekeris St. P.O.B. 527
Rehovot 76100
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Re: K021574
Trade/Device Name: TM2000 Fetal Trace Transtelephonic Receiving Center Software
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: May 8, 2002
Received: May 14, 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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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" (21 CFR Part 807.97). 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

CARD GUARD
Scientific Survival LTD.

# Indications For Use

*TM2000 Fetal Trace Receiving Center Software*

The TM2000 FetalTrace Telemedicine Receiving Center is intended for supporting transtelephonic monitoring of the Fetal/Maternal parameters of 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)

David G. Feigal

**(Division Sign-Off)**
**Division of Reproductive, Abdominal,**
**and Radiological Devices**
**510(k) Number** K021574