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K051026

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Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:

April 20, 2005

Submitter:

GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

Lisa M. Baumhardt
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: (262) 293-1699
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Device: Trade Name:

MARS Holter Analysis Workstation

Common/Usual Name:

Holter Analysis Workstation

Classification Names:

21 CFR 870.1425 *Programmable Diagnostic Computer*

Predicate Devices:

K991786 GEMS-*IT* MARS Unity Workstation
K010949 Agilent Technologies 2010 Plus Holter for Windows

Device Description:

The MARS Holter Analysis Workstation system is a software-system that runs on PC based hardware. The MARS Holter Analysis Workstation supports a number of software applications including analysis, user editing and final report processing.

The MARS Holter Analysis Workstation analyzes ambulatory ECG data, to detect and label beats, and then presents it in a variety of screens to the user for review and data editing purposes. The MARS Holter Analysis Workstation system stores and prints final reports and allows reports to be sent to the MUSE Cardiology Information Management System for long- term archive. The MARS Holter Analysis Workstation supports acquisition from ambulatory ECG Recorders. A variety of different final report formats can be stored and printed. The final report is used by trained medical personal to diagnosis a patient's cardiac abnormalities.

Intended Use:

MARS Holter Analysis Workstation is designed for acquisition, analysis, edit, review, report and storage of ambulatory ECG data. Results of the automated analysis are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data. The MARS Holter Analysis Workstation is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric (greater than 10Kg) human patients. The MARS Holter Analysis Workstation provides the user arrhythmia studies and holter analysis capabilities.

Data acquired may be use for the following indications:

- Evaluation of symptoms that may be caused by cardiac arrhythmia and/or conduction disturbances
- Evaluation of symptoms that may be due to myocardial ischemia
- Detection of ECG events that alter prognosis in certain forms of heart disease
- Detection and analysis of pacemaker function and failure
- Determination of cardiac response to lifestyle
- Evaluation of therapeutic interventions
- Investigations in epidemiology and clinical trials

Technology: The proposed MARS Holter Analysis Workstation employs the same functional scientific technology as the predicate devices MARS Unity (K991786) and 2010 Plus Holter for Windows (K010949)

Test Summary: The MARS complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the device:

- Requirements specification review
- Risk analysis
- Software and hardware testing
- Performance testing
- Safety testing
- Environmental testing
- Clinical use evaluation
- Final validation

Conclusion:

The results of these measurements demonstrated that the MARS Holter Analysis Workstation is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

General Electric Medical Systems Information Technologies
c/o Lisa Baumhardt
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K051026
Trade Name: MARS Holter Analysis Workstation
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: April 20, 2005
Received: April 22, 2005

Dear Ms. Baumhardt:

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 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,

B Zimmerman for

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

Enclosure

Indications for Use

510(k) Number (if known): K051026

Device Name: **MARS® Holter Analysis Workstation**

Indications for Use:

MARS Holter Analysis Workstation is designed for acquisition, analysis, edit, review, report and storage of ambulatory ECG data. Results of the automated analysis are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data. The MARS Holter Analysis Workstation is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric (greater than 10Kg) human patients. The MARS Holter Analysis Workstation provides the user arrhythmia studies and holter analysis capabilities.

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- Evaluation of therapeutic interventions
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051026