K093141 P1/3

DEC 29 2009

GE Healthcare
510(K) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 30. 2009
Submitter:	GE Healthcare (GE Medical Systems *Information Technologies*) 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Joe Lucas Regulatory Affairs – Diagnostic Cardiology 9900 Innovation Drive Wauwatosa, WI 53226 T: (414) 721-2593 F: (414) 721-3863
Secondary Contact Person:	Kristin Pabst Regulatory Affairs – Diagnostic Cardiology 9900 Innovation Drive Wauwatosa, WI 53226 T: (414) 721-3104 F: (414) 721-3863
Device: Trade Name:	MARS Holter Analysis Workstation
Common/Usual Name:	Holter Analysis Workstation
Classification Names:	21 CFR 870.1425 Programmable Diagnostic Computer
Product Code:	DQK
Predicate Device(s):	K051026 MARS Holter Analysis Workstation K991786 GEMS-IT MARS Unity Workstation
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 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 and multi-parameter data from the CIC Pro Clinical Information Center. A variety of different final report formats can be stored and printed. The final report is used by trained medical personal to diagnose a patient's cardiac abnormalities.

Intended Use: MARS Holter Analysis Workstation is designed for acquisition, analysis, edit, review, report and storage of ambulatory ECG and multi-parameter 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 used 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 MARS Holter Analysis Workstation employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MARS Holter Analysis Workstation and its applications comply with voluntary standards as detailed in Section 9 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Requirement Definition
- Risk Analysis
- Technical Review
- Formal Design Review
- Code Inspection
- Integration testing (Module and System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing

Summary of Clinical Tests:

The subject of this premarket submission, MARS Holter Analysis Workstation, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the MARS Holter Analysis Workstation to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 9 2009

Mr. Joseph Lucas
Regulatory Affairs Leader
GE Medical Systems *Information Technologies*
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K093141
Trade/Device Name: MARS® Holter Analysis Workstation
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 19, 2009
Received: November 20, 2009

Dear Mr. Lucas:

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K093 4 1

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 and multi-parameter 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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Prescription Use__X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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