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: August 1, 2013

Submitter: GE Medical Systems *Information Technologies*
9900 Innovation Drive
Wauwatosa, WI 53226

DEC 0 4 2013

Primary Contact Person: Kristin Pabst
Regulatory Affairs Manager
GE Medical Systems *Information Technologies*
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Regulatory Affairs
GE Medical Systems *Information Technologies*
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Device: Trade Name: MARS Holter Analysis Workstation

Common/Usual Name: ECG Analysis Computer

Classification Names: Programmable Diagnostic Computer (21 CFR 870.1425)

Product Code: DQK

Predicate Device(s): MARS Holter Analysis Workstation K#093141

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 proposed MARS Holter Analysis Workstation is a software device that runs on IT hardware employing the same functional scientific technology as the predicate device MARS Holter Analysis Workstation (K093141).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MARS Holter Analysis Workstation complies with voluntary standards:

- IEC 60601-1-1:2000 2nd edition Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, Edition 3
- IEC 60601-1-4:1996, +A1:1999 (AKA IEC 60601-1-4:2000) Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
- AAMI EC-57: 1998 (R2008) Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

The following quality assurance measures are applied to the development of the system:

- Requirements Definition
- Risk Analysis
- Requirements Reviews
- Design Reviews
- Code Inspection
- Testing on unit level (Module verification)
- Integration testing (Module and System verification)

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- Performance testing (Verification)
- Final Acceptance testing (Validation)
- Safety testing (Verification)

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 4, 2013

GE Medical Systems Information Technologies, Inc.
Kristin Pabst
9900 West Innovation Drive
Wauwatosa, WI 53226 US

Re: K132437
Trade/Device Name: MARS HOLTER analysis workstation
Regulation Number: 21 CFR 870.14257
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: November 5, 2013
Received: November 5, 2013

Dear Kristin Pabst:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); 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 Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen D. Faris -S

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

Enclosure

GE Healthcare

510(k) Premarket Notification Submission

510(k) Number: K132437

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. Data acquired may be used for the following indications:

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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)

Digitally signed by Owen R. Faris -S
Date: 2013.12.04 10:22:30 -05'00'