FEB 19 2009

K090212

GE Healthcare

510(K) Premarket Notification Submission

MAC 800 Resting ECG Analysis System

510(k) Summary

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

Date: January 26, 2009

Submitter:
Larry Lepley
Regulatory Affairs – Diagnostic Cardiology
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Wauwatosa, WI 53226

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Device: Trade Name: MAC 800 Resting ECG Analysis System

Common/Usual Name: Electrocardiograph

Classification Names / Product Code:

21 CFR	Classification Name	Code
870.2340	Electrocardiograph	DPS
870.1425	Programmable Diagnostic Computer	DQK
870.2920	Transmitters and Receivers, Electrocardiographs, Telephone	DXH

Predicate Device(s): K081437, MAC 1600 ECG Analysis System

Device Description: The MAC 800 ECG acquisition, analysis and recording system can print and display multiple leads of ECG data. The MAC 800 will provide, in resting ECG mode, ECG quality information using the hookup advisor. The hookup advisor advises users of poor lead quality based on noise measurement. It can be upgraded to provide options such as ECG measurement and interpretation with 12SL. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is also optional. Multiple QT correction formulas including Bazett, Framingham and Fridericia will be available as a user selectable option. Clinical Trials Data Guard and audit trail options are also available to support electronic record requirements.

The MAC 800 delivers multiple leads of ECG on full-size reports and includes an SMS/text message telephone keypad for patient demographics and other data entry with T9 input method, an integrated 7" color display, and an integrated thermal writer. The thermal writer will print real time continuous waveform, alphanumeric data and non real time reports. The device can print the resting ECG report via the external laser printer. The device will have optional internal memory and removable storage to store resting ECG records. The device also can export the resting ECG record to PDF file on SD card as an optional function. An optional barcode reader and magnetic card scanner to enter patient information is available. The MAC 800 can be used as a portable unit.

Intended Use:

The MAC 800 is a portable ECG acquisition, analysis and recording system.

The MAC 800 is intended to acquire, analyze, display and record information from adult and pediatric populations. Pediatric population is defined as patients between the ages of 0 and 15 years.

The MAC 800 is intended to be used by trained operators in a hospital or medical professional's facility environment to record ECG signals from surface electrodes.

The basic system shall provide 2 modes of operation: (1) Resting ECG mode and (2) Arrhythmia mode.

The basic systems shall print 3, 6-leads of ECG. The device shall be upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis.

Transmission and reception of ECG data to and from a central ECG cardiovascular information system shall be optional.

The arrhythmia detection portion of the MAC 800 is provided to the customer for the convenience of automatic documentation.

The MAC 800 is used under the direct supervision of a licensed healthcare practitioner.

Contraindications:

The MAC 800 is not designed to provide alarms for arrhythmia detection.

The device is not suitable for intra cardiac application.

It is not intended for use:

- As a vital signs physiological monitor; or
- For use during patient transport.

Technology: The MAC 800 Resting ECG Analysis System employs the same functional scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MAC 800 Resting ECG Analysis System and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, MAC 800 Resting ECG Analysis System, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the MAC 800 Resting ECG Analysis System 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
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2009

GE Medical Systems Information Technologies
c/o Mr. Larry Lepley
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K090212
Trade Name: MAC 800 Resting ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS and DQK
Dated: January 26, 2009
Received: January 28, 2009

Dear Mr. Lepley:

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.

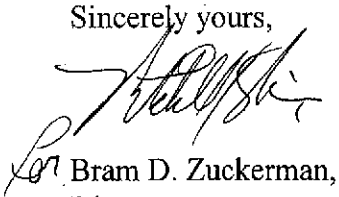
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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): K090212

Device Name: **MAC 800 Resting ECG Analysis System**

Indications for Use:

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- As a vital signs physiological monitor; or
- For use during patient transport.

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)

Peter B Zuckerman

(Division Sign-Off) 2/20/09
Division of Cardiovascular Devices
510(k) Number K090212