

APR 29 2011



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: 24-January-2011

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

Primary Contact Person: Patricia Taige
Regulatory Affairs Leader
GE Medical Systems Information Technologies, Inc.
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Secondary Contact Person: Joe Lucas
Regulatory Affairs Leader
GE Medical Systems Information Technologies, Inc.
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Device: Trade Name: MAC 5500 HD ECG Analysis System
MAC 3500 ECG Analysis System

Common/Usual Name: Electrocardiograph

<u>Classification Names:</u>	21 CFR 870.2340	Electrocardiograph	DPS
	21 CFR 870.1425	Programmable Diagnostic Computer	DQK
<u>Product Code:</u>	21 CFR 870.2920	Telephone Electrocardiograph	DXH
		Transmitter and Receiver	

Predicate Device(s): K073625 MAC 5500 ECG Analysis System

Device Description: The MAC 5500 HD and MAC 3500 ECG Analysis Systems are designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes. The devices consist of two basic components: the processing unit and the patient acquisition module. The MAC 5500 HD and MAC 3500 can deliver 3, 6, 12, or 15 lead ECG's, including interpretive analysis and 12 or 15 lead ECG's on full-size reports. In addition MAC 5500 HD can deliver vector loops and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram.

The MAC 5500 HD acquires ECG data using the external CAM HD patient data acquisition module. By placing the data acquisition device closer to the patient, signal fidelity is improved and noise is reduced. MAC 3500 has the patient data acquisition module integrated into the main device.

The MAC 5500 HD and MAC 3500 incorporate an alphanumeric keyboard for patient demographics and other data entry, a full VGA graphics and waveform display, an integrated thermal writer and



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removable data storage.

Models provide mains or, for customer convenience, rechargeable battery operation as well as optional transmission and reception of ECG data to and from a central ECG cardiovascular information system via communication links.

MAC 5500 HD and MAC 3500 are intended as mobile devices by offering an optional trolley for transporting the equipment but the main units can be separated from the trolley and used as desktop units.

Intended Use:

MAC 5500 HD: The MAC 5500 HD ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's; interpretive analysis; vector loops; and can be upgraded to provide software analysis options such as high resolutions signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional. The MAC 5500 HD is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

MAC 3500: The MAC 3500 ECG Analysis System is intended to acquire, analyze, display, and record resting electrocardiographic information from adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, including interpretive analysis. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional. The MAC 3500 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Technology:

The MAC 5500 HD and MAC 3500 employ the same fundamental scientific technology as their predicate device MAC 5500 ECG Analysis System (K073625).

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MAC 5500 HD and MAC 3500 and their 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 systems:

- Requirement Definition
- Risk Analysis
- Software Safety Classification
- Technical Review
- Formal Design Review
- Code Inspection



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- Integration Testing (Module and System verification)
- Final Acceptance Testing
- Performance Testing
- Safety testing

Summary of Clinical Tests:

The subject of this premarket submission, MAC 5500 HD and MAC 3500, did not require clinical studies to support substantial equivalence.

Conclusion: GE Medical Systems Information Technologies, Inc. considers the MAC 5500 HD / MAC 3500 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 Room -WO66-G609
Silver Spring, MD 20993-0002

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GE Medical Systems Information Technologies, Inc.
c/o Ms. Patricia Taige
Regulatory Affairs Leader
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K110266
Trade/Device Name: MAC 5500 HD and MAC 3500 ECG Analysis Systems
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Codes: DPS, DQK, DXH
Dated: January 24, 2011
Received: February 1, 2011

Dear Ms. Taige:

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.

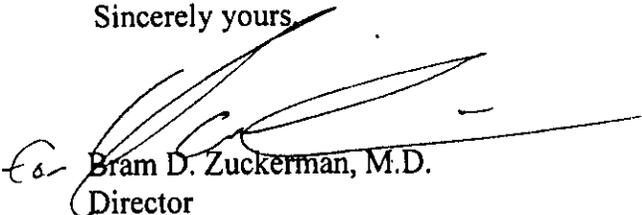
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



Bram D. Zuckerman, M.D.

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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510(k) Premarket Notification Submission

510(k) Number (if known): K110266

Device Name: MAC 5500 HD

Indications for Use:

The MAC 5500 HD ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolutions signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5500 HD is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(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

510(k) Number K110266



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510(k) Number (if known): K110266

Device Name: MAC 3500

Indications for Use:

The MAC 3500 ECG Analysis System is intended to acquire, analyze, display, and record resting electrocardiographic information from adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, including interpretive analysis. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 3500 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(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)

K110266 

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110266