

AUG 19 1999

510(k) Summary of Safety and Effectiveness

Exhibit A

K991735

Date: May 21, 1999**Submitter:** GE Marquette Medical Systems, Inc.
8200 W. Tower Ave.
Milwaukee, WI 53223 USA**Contact Person:** David Wahlig
Corporate Regulatory Affairs
GE Marquette Medical Systems
Phone: (414) 362-2090
Fax: (414) 355-3790**Trade/Proprietary Name:** MAC Series electrocardiographs including MAC 5000, MAC PC, MAC 6,
MAC VU, MAC 8**Common/Usual Name:** Electrocardiograph**Classification Names & Citations:**

21 CFR 870.1425	Programmable diagnostic computer	74DQK
21 CFR 870.2920	Transmitters and Receivers, Electrocardiograph, Telephone	74DXH
21 CFR 870.2340	Electrocardiograph	74DPS
21 CFR 870.2340	System, ECG Analysis	74LOS

Predicate Devices: Marquette Option II ECG Analysis Computer for MAC I Electrocardiograph
(MAC II) – K820885

Marquette 12SL Analysis Program – K964750

Device Description: The Mac Series consists of electrocardiograph models designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes. The devices consist of two basic components: the processing unit and patient acquisition module. Models provide rechargeable battery operation and/or optional trolley for transporting the equipment.

The MAC 5000 can deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, 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. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

Intended Use: The MAC Series is intended to be used under the direct supervision of a licensed healthcare practitioner. The MAC Series 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 devices are intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations.**Technology:** The technological characteristics of the MAC 5000 and related MAC Series devices have been updated to reflect use of current technology and to incorporate user-requested features. Data in this submission demonstrate that these technological characteristics do not raise new questions of safety or effectiveness.**Test Summary:** The MAC Series complies with the voluntary standards as detailed in Section 9

E X T R A

Responsibility of the Manufacturer

GE Marquette Medical Systems, Inc. is responsible for the effects of safety, reliability, and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE Marquette.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.

General Information

Intended Use

The intended use of this device is to record ECG signals from surface ECG electrodes. This device can analyze, record, and store electrocardiographic information from adult and pediatric populations. This data can then be computer analyzed with various algorithms such as interpretive ECG and signal averaging for presentation to the user.

This device is intended for use under the direct supervision of a licensed health care practitioner.

This device is not intended for use with high frequency surgical units. Disconnect the patient from the device before using the high frequency surgical unit.

Caution:

This equipment uses a computerized ECG analysis program which can be used as a tool in ECG tracing interpretation. This computerized interpretation is only significant when used in conjunction with clinical findings. All computer-generated tracings should be overread by a qualified physician.

Bold →

Preliminary

000057



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1999

Mr. David Wahlig
-GE Marquette Medical Systems
8200 W. Tower Avenue
Milwaukee, WI 53223

Re: K991735
MAC 5000 and Related MAC Series Resting ECG Analysis Systems
Regulatory Class: III (three)
Product Code: 74 LOS, DQK, DPS, and DXH
Dated: May 21, 1999
Received: May 21, 1999

Dear Mr. Wahlig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. David Wahlig

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown; 510(k) filed on 21 May, 1999

Device Name: MAC Series Resting ECG Analysis System

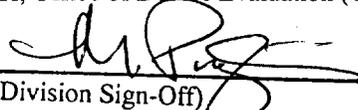
Indications For Use:

The MAC Series Resting ECG Analysis Systems (Includes the MAC PC, MAC 6, MAC VU, MAC 8, and MAC 5000) are 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, 12 lead interpretive analysis, 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. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC Series 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.

(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, Respiratory,
and Neurological Devices
510(k) Number K991735

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)