NOV 29 1999

K992948

# Section 2: 510(k) Summary of Safety and Effectiveness

Date: August 28, 1999

Submitter: GE Marquette Medical Systems
100 Marquette Drive
Jupiter, FL USA

Contact Person: Maria Vitug Fouts
Sr. Regulatory Compliance Specialist
GE Marquette Medical Systems
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Device: Trade Name: MAC-LAB System

Common/Usual Name: MAC-LAB, MAC-LAB System EX

Classification Names: 21 CFR 870.1425 Programmable Diagnostic Computer

Predicate Devices: MAC-LAB Cardiac System,
k895801, SE date: 04 April 1990

MAC-LAB Electrophysiology (IECG)Option,
K935394, SE date: 20 October 1994

Device Description: The MAC-LAB Systems join together the TRAM module which is housed in a Remote Acquisition Unit (RAU) with computer processors, software, high resolution display monitors, power supply, thermal printer and a keyboard. Data acquisition modules, depending upon application, are inserted into the RAU and then digital data is transmitted, via cable, to the computers for processing. An optional IECG module (K935394) enables electrophysiological investigations of the heart to be performed. The IECG module consists of electronic amplifiers and other signal processing devices. An IECG cable connects an intracardiac catheter (not covered by this submission) to the IECG system.

Intended Use: The MAC-LAB Systems are intended for use under the direct supervision of a licensed healthcare practitioner. The device is intended to monitor and/or calculate and/or record cardiovascular data from patients as they undergo catheterization of the heart and circulatory system. Data includes: ECG waveforms, heart rate, pulse oximetry, respiration rate, valve gradients and areas, cardiac output, hemodynamic measurements, invasive and noninvasive blood pressure, procedural information, and optional intracardiac electrocardiogram (IECG). This information can be displayed, trended, stored, printed and/or transmitted to other networked hospital information systems.

Applicable to pediatric/adult patients requiring cardiac/circulatory system catheterization

Intended for use in catheterization and related cardiovascular specialty labs.

## Section 2: 510(k) Summary of Safety and Effectiveness, continued

Technology: The proposed MAC-LAB Cardiac Catheterization Laboratory System employs the same functional technology as the predicate devices.

Test Summary: The MAC-LAB complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the MAC-LAB System:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the MAC-LAB system is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 29 1999

Ms. Maria Vitug Fouts
Senior Regulatory Compliance Specialist
GE Marquette Medical Systems
A GE Medical Systems Company
200 Harry S. Truman Parkway, Suite 220
Annapolis, Maryland 21401

Re: K992948
Trade Name: MAC-LAB System Version 18A
Regulatory Class: 2
Product Code: 74-DQK
Dated: August 28, 1999
Received: August 31, 1999

Dear Ms. Fouts:

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.

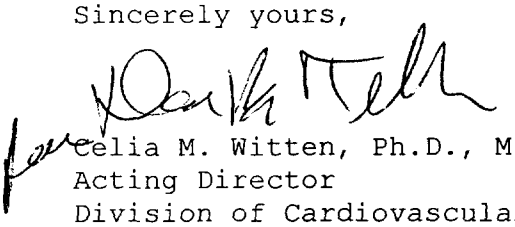
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 premarket 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.

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) 594-4645. 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992948*

Device Name: MAC-LAB System

Indications For Use:

The MAC-LAB System is intended for use under the direct supervision of a licensed healthcare practitioner to monitor and/or calculate and/or record cardiovascular data from patients as they undergo cardiac catheterization. Cardiovascular data may be manually entered or acquired via an interfaced GE Marquette TRAM modules (k921669), MUSE cardiovascular system and other interfaced information systems. Data includes: ECG waveforms, heart rate, pulse oximetry ($SpO_2$), respiration rate, valve gradients and areas, cardiac output, hemodynamic measurements, invasive and noninvasive blood pressure, procedural information, and optional intracardiac electrocardiogram (IECG).

Applicable to pediatric/adult patients requiring cardiac/circulatory system catheterization

Intended for use in catheterization and related cardiovascular specialty labs

*Note:* Catheterization devices are *not* provided or offered for use with the MAC-LAB system.

*To be assigned by FDA upon receipt of 510(k) submission

(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 K992948

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)