K021366 JUL 3 2002 1/3

510(k) Summary of Safety and Effectiveness

Date: June 26, 2002

Submitter: GE Medical Systems Information Technologies
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Milwaukee, WI 53223 USA

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GE Medical Systems Information Technologies
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Trade/Proprietary Name: MAC-LAB/CardioLab EP/ComboLab System

Common/Usual Name: Cardiac Catheterization Laboratory System

Classification Names & Citations:

870.1425 Programmable Diagnostic Computer (DQK, Class II, 74 CV)
870.2050 Biopotential Amplifier and Signal Conditioner (DRR, Class II, 74 CV)
870.2340 Electrocardiograph (DPS, Class II, 74 CV)
870.1110 Blood Pressure Computer (DSK, Class II, 74 CV)

Predicate Device: MAC-LAB System and CardioLab EP System K#001305 and CardioTree®Coronary Tree Diagrams K#912829.

Device Description:

The MAC-LAB System:

The MAC-LAB System is a microprocessor based data acquisition system used during cardiac catheterization procedures. The MAC-LAB system, via various models of the GE Medical Systems Information Technologies TRAM module (K921669) and amplifier module, acquires patient data which may include surface ECG, invasive and non-invasive blood pressure, blood oxygen saturation via pulse oximetry, respiration, and temperature. The TRAM module is housed in a dedicated front end chassis called the remote acquisition case (RAC). The MAC-LAB System joins together the TRAM module and amplifier module with computer processors, software, high resolution display monitors, power supply, laser printer, keyboard and mouse. Digital data is transmitted, via cable, from the TRAM module and/or amplifier module to the computer for processing. Major functions of the software include data acquisition and display, data storage, reporting of data, and transmission of data to other information systems via LAN.

The CardioLab EP System:

The CardioLab EP System is a microprocessor based data acquisition system used during electrophysiology procedures to acquire ECG, intracardiac signals, and pressure signals via amplifier module. Digital data is also acquired from other devices such as RF generators, fluoro video systems and the GE Medical Systems Information Technologies TRAM module. The ECG, intracardiac and pressure data are acquired by an amplifier that is connected to the patient by third-party devices such as ECG leadwires and catheters. The amplifier filters, amplifies, digitizes and transmits the data to the computer via fiber optic cable. The computer stores the data on optical disks, displays the data on the video monitors, allows the user to perform basic signal measurements, and prints out waveforms on a laser printer or continuous paper recorder. Major functions of the software include data acquisition and display, data storage, reporting of data, and transmission of data to other information systems via LAN.

The ComboLab System

The product will be available in three configurations: CardioLab EP application only, MAC-LAB application only, or combination of both CardioLab EP and MAC-LAB applications. The 'CardioLab EP only'

configuration only allows the user to run the CardioLab EP mode. The 'MAC-LAB only' configuration only allows the user to run the MAC-LAB mode. The combination of both CardioLab EP and MAC-LAB allows the user to run the CardioLab EP and MAC-LAB modes, though only one mode may be used at a time (CardioLab EP for electrophysiology lab cases and MAC-LAB for catheterization lab cases).

Intended Use:

MAC-LAB System:
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 Medical Systems Information Technologies 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). This information can be displayed, trended, stored, printed and/or transmitted to other networked hospital information systems. The system does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.

CardioLab EP System:
The CardioLab EP System is intended for use under the direct supervision of a licensed healthcare practitioner to acquire, filter, digitize, amplify, display, and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. Signal types acquired include ECG signals, direct cardiac signals, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. Additionally, the system may acquire, amplify, display, and record data received from other medical devices typically used during these procedures, such as imaging devices and RF generators. The system does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.

The ComboLab System
The ComboLab is the combination of both CardioLab EP and MAC-LAB allowing the user to run the CardioLab EP and MAC-LAB modes, though only one mode may be used at a time (CardioLab EP for electrophysiology lab cases and MAC-LAB for catheterization lab cases). The system does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.

The MAC-LAB / CardioLab EP and ComboLab systems do not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze physiological data or other data acquired during procedure.

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

Intended for use in catheterization and related cardiovascular specialty labs.

Technology: The proposed MAC-LAB/CardioLab EP/ComboLab System employs the same functional technology as the predicate device.

Test Summary: The MAC-LAB System and CardioLab EP System comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures are applied to the development of the Systems:

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

Conclusion: The results of these measurements demonstrate that the MAC-LAB/CardioLab EP/ComboLab System are as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

GE Medical Systems Information Technologies
c/o Mr. David Wahlig
Senior Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K021366
Device Name: MAC-LAB/CardioLab EP/ComboLab System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: June 5, 2002
Received: June 6, 2002

Dear Mr. Wahlig:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: MAC-LAB/CardioLab EP/ComboLab System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K021366

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

(Optional Format 1-2-96)

510(k) Number (if known): K021366
Device Name: MAC-LAB/CardioLab EP/ComboLab System

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(Per 21 CFR 801.109)