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Section 2 Summary

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510(k) Summary of Safety and Effectiveness

Date: January 7, 2005

Submitter: GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Ronald N. Blaski
Regulatory Affairs Specialist
GE Medical Systems Information Technologies
Phone: (414) 362-2348
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Device: Trade Name: Mac-Lab/CardioLab EP/ComboLab System
Common/Usual Name: Cardiac Catheterization Laboratory System

Classification Names: 21 CFR 870.1425 *Programmable Diagnostic Computer*

Predicate Device: Mac-Lab/CardioLab EP/ComboLab System Version 6.0 (K032577)

Device Description:

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The Mac-Lab System:

The Mac-Lab System is a microprocessor based data acquisition system used during cath procedures to monitor, calculate and record physiological data from pediatric or adult patients. Data may be entered manually or acquired via an interfaced GE Medical Systems Information Technologies acquisition device, such as: TRAM module (K011000), EtCO2 module (K904789), CardioLab Amplifier Module (K910307), DASH 3000/4000 Monitor (K001359), Solar 8000M Monitor (K993757), MUSE cardiovascular system (K992637) or other peripheral interface. Data includes: ECG, pressure, respiration intracardiac electrocardiograms (IECG), and SpO2 waveforms, heart rate, pulse oximetry (SpO2), respiration rate, valve gradients and areas, cardiac output, EtCO2, hemodynamic measurements, invasive and noninvasive blood pressure, temperature, and procedural information. The Mac-Lab joins together the acquisition devices with computer processors, software, high-resolution display monitors, power supply, printers, keyboard and mouse. Digital data is transmitted, via cable, from the acquisition devices 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 the CardioLink INW server and other networked hospital information systems.

The CardioLab EP System:

The CardioLab EP System is a microprocessor based data acquisition system used during electrophysiology procedures to monitor, calculate and record physiological data from pediatric or adult patients. Data may be entered manually or acquired via an interfaced GE Medical Systems Information Technologies acquisition device, such as: CardioLab Amplifier Module (K910307), TRAM module (K011000), EtCO2 module (K904789), DASH 3000/4000 Monitor (K001359), Solar 8000M Monitor (K993757), MUSE cardiovascular system (K992637) or other peripheral interface, such as RF generators and fluoro video Data includes: ECG, intracardiac electrocardiograms (IECG), and pressure waveforms, heart rate, pulse oximetry (SpO2), respiration rate, EtCO2, invasive and noninvasive blood pressure, temperature, and procedural information. 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 CardioLab joins together the acquisition devices with computer processors, software, high-resolution display monitors, power supply, printers, keyboard and mouse. Digital data is transmitted, via cable, from the acquisition devices 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 the CardioLink INW server and other networked hospital information systems.

The ComboLab System:

The product will be available in three configurations: CardioLab EP application only, Mac-Lab application only, or a 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 ComboLab configuration is the combination of both CardioLab EP and Mac-Lab modes, though only one mode may be used at a time (CardioLab EP for electrophysiological lab cases and Mac-Lab for catheterization lab cases).

Intended Use:

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Mac-Lab System:

The Mac-Lab System is intended for use in a catheterization and related cardiovascular specialty laboratories under the direct supervision of a licensed healthcare practitioner. It is intended to monitor, calculate and/or record cardiovascular data from adult and pediatric patients undergoing cardiac catheterization procedures. The data may be manually entered or acquired via interfaced devices. Data includes: ECG, heart rate, pulse oximetry (SpO2), respiration rate, EtCO2, temperature, valve gradients and areas, cardiac output, hemondynamic measurements, invasive and noninvasive blood pressure and procedural information and optional intracardiac electrocardiogram (IECG). 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, and generate reports on the data. Additionally, the system may acquire, amplify, display and record data received from other interfaced medical devices typically used during these procedures, such as imaging devices. The Mac-Lab System does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze data acquired during procedure. The Mac-Lab 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 in an electrophysiological laboratory and related specialty laboratories under the direct supervision of a licensed healthcare practitioner. It is intended to monitor, calculate and/or record electrophysiological data from adult and pediatric patients under going electrophysiological studies. Data includes: ECG, pressure, and intracardiac electrocardiogram (IECG) waveforms, heart rate, pulse oximetry (SpO2), respiration rate, EtCO2, temperature, invasive and noninvasive blood pressure, and procedural information. 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, and generate reports on the data. Additionally, the system may acquire, amplify, display and record data received from other interfaced medical devices typically used during these procedures, such as imaging devices and RF generators. The CardioLab EP System does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze data acquired during the procedure. The CardioLab EP System does not transmit alarms or arrhythmias and does not have arrhythmia detection capabilities.

ComboLab System

The ComboLab System is the combination of the both the Mac-Lab and CardioLab EP systems. The ComboLab System is intended for use in either a catheterization laboratory or electrophysiological laboratory and related speciality laboratories under the direct supervision of a licensed healthcare practitioner. The ComboLab System allows the user to run either the Mac-Lab System or the CardioLab EP System, although only one may be used at a time.

Technology: The proposed Mac-Lab/CardioLab EP/ComboLab System employs the same functional scientific technology as the predicate device Mac-Lab/CardioLab EP/ComboLab System (K032577).

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Test Summary: The Mac-Lab/CardioLab EP/ComboLab System 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 device:

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

Conclusion: The results of these measurements demonstrated that the Mac-Lab/CardioLab EP/ComboLab System is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

GE Medical Systems Information Technologies
c/o Mr. Ronald N. Blaski
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee WI 53223

Re: K050093
Trade Name: Mac-Lab / CardioLab EP / ComboLab Systems
Regulation Number: 21 CFR 870.1245
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: April 11, 2005
Received: April 12, 2005

Dear Mr. Blaski:

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 Office of Compliance at (240) 276-0120.. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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): K050093

Device Name: **Mac-Lab/CardioLab EP/ComboLab System**

Indications For Use:

Mac-Lab System:

The Mac-Lab System is intended for use in a catheterization and related cardiovascular specialty laboratories under the direct supervision of a licensed healthcare practitioner. It is intended to monitor, calculate and/or record cardiovascular data from adult and pediatric patients undergoing cardiac catheterization procedures. The data may be manually entered or acquired via interfaced devices. Data includes: ECG, heart rate, pulse oximetry (SpO2), respiration rate, EtCO2, temperature, valve gradients and areas, cardiac output, hemondynamic measurements, invasive and noninvasive blood pressure and procedural information and optional intracardiac electrocardiogram (IECG). 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, and generate reports on the data. Additionally, the system may acquire, amplify, display and record data received from other interfaced medical devices typically used during these procedures, such as imaging devices. The Mac-Lab System does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze data acquired during procedure. The Mac-Lab System does not transmit alarms or arrhythmias and does not have arrhythmia detection capabilities.

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Prescription Use__X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (Per 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 K050093