

510(k) Summary of Safety and Effectiveness

Date:

January 7, 1999

Submitter:

GE Marquette Medical Systems  
8200 West Tower Avenue  
Milwaukee, WI 53223 USA

Contact Person:

Karen Webb  
Regulatory Affairs Specialist  
GE Marquette Medical Systems  
Phone: (414) 362-3329  
Fax: (414) 355-3790

Device:    Trade Name:

Solar 9500 Information Monitor

Common/Usual Name:

Patient monitor

Classification Names:

- 21 CFR 868.1400 Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
- 21 CFR 868.1500 Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Conc.)
- 21 CFR 868.1620 Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Conc.)
- 21 CFR 868.1690 Analyzer, Gas, Nitrogen, Gaseous-Phase (Anesthetic Conc.)
- 21 CFR 868.1700 Analyzer, Gas, Nitrous Oxide, Gaseous-Phase, (Anesthetic Conc.)
- 21 CFR 868.1720 Analyzer, Gas, Oxygen, Gaseous-Phase
- 21 CFR 868.2375 Breathing Frequency Monitor
- 21 CFR 870.1025 Detector and Alarm, Arrhythmia
- 21 CFR 870.1100 Monitor, Blood Pressure, Indwelling
- 21 CFR 870.1130 Noninvasive Blood Pressure Measurement System
- 21 CFR 870.1100 Blood Pressure Alarm
- 21 CFR 870.1425 Programmable Diagnostic Computer
- 21 CFR 870.2340 Electrocardiograph
- 21 CFR 870.1435 Monitor, Cardiac Output, Thermal (Balloon Type Catheter)
- 21 CFR 880.2910 Monitor, Temperature (with probe)
- 21 CFR 870.2300 Monitor, Cardiac (Incl. cardiometer & rate alarm)
- 21 CFR 870.2700 Oximeter, Pulse

Predicate Devices:

K954852 Solar 9000 Anesthesia Information Monitor

K921669 Marquette SL Series Transport Remote Acquisition Module

Device Description:

The Solar 9500 is a patient monitoring system that is designed to display patient physiological data that is received from the GE Marquette Medical Systems' Tram-net network and individual and multi-parameter data acquisition modules.

The Solar 9500 Information Monitoring System is comprised of four basic components: the processing unit, color display, Tram modules(s), and Tram-rac housing. Optional components include a remote display.

The Solar 9500 utilizes the GE Marquette's Unity Ethernet LAN allowing communication with monitoring, clinical information and cardiology products. An additional Ethernet connection is provided for connection to the hospital Enterprise Network. The Enterprise network connection allows the user access to the hospital INTRANet, through an embedded Web Browser on the Solar 9500. This web browsing capability enables the user to log on to the hospital INTRANet directly from the monitor allowing access to information such as patient history, up-to-the-minute lab results and cath reports. Data can also be accessed from non-Marquette platforms via the Enterprise network.

Intended Use:

The Solar 9500 Information Monitoring System is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the system is to monitor physiologic parameter data on adult, pediatric and neonatal patients, in high acuity areas such as operating room (OR), post anesthesia recovery (PARR), critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care. Physiologic data includes electrocardiogram, invasive blood pressure, noninvasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, carbon dioxide, oxygen, anesthetic gas concentrations and mixed venous oxygen saturation, as summarized in the Solar 9500 Operator's Manual. The monitoring parameters are contained in Appendix B under Technical Specifications.

The Solar 9500 Information Monitoring System is also intended to provide physiologic data over the Unity network to clinical information systems and allow the user to access hospital INTRANet data via a Web Browser at the point-of-care.

This information can be displayed, trended, stored, and printed.

Technology:

The Solar 9500 employs the same functional technology as the predicate devices.

**Test Summary:**

The Solar 9500 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 Solar 9500:

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

**Conclusion:**

The results of these measurements demonstrated that the Solar 9500 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

JUL 14 1999

Ms. Karen Webb  
GE Marquette Medical Systems, Inc.  
8200 West Tower Avenue  
Milwaukee, WI 53223

Re: K990068  
Solar 9500 Information Monitor  
Regulatory Class: III (three)  
Product Code: 74 MHX  
Dated: January 7, 1999  
Received: January 8, 1999

Dear Ms. Webb:

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.

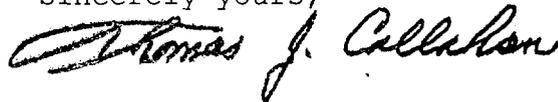
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, prominent initial 'T'.

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 January 7, 1999

Device Name: Solar® 9500 Information Monitor

Indications For Use:

The Solar® 9500 Information Monitoring System is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the system is to monitor physiologic parameter data on adult, pediatric and neonatal patients, in high acuity areas such as operating room (OR), post anesthesia recovery (PARR), critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care. Physiologic data includes electrocardiogram, invasive blood pressure, noninvasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, carbon dioxide, oxygen, anesthetic gas concentrations and mixed venous oxygen saturation, as summarized in the Solar® 9500 Operator's Manual. The monitoring parameters are contained in Appendix B under Technical Specifications.

The Solar® 9500 Information Monitoring System is also intended to provide physiologic data over the Unity network to clinical information systems and allow the user to access hospital INTRANet data via a Web Browser at the point-of-care.

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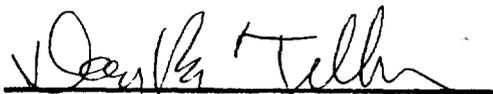
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K990068