K030575
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510(k) Summary of Safety and Effectiveness

Date: February 21, 2003

MAR 21 2003

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

Contact Person: Andrew Kluessendorf
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 414-362-3063
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Device: Trade Name: Solar 9500 Information Monitor

Common/Usual Name: Patient monitor

Classification Names:

21 CFR 870.1025	Monitor, Physiological Patient (with Arrhythmia Detection or Alarms)	74MHX
21 CFR 868.1400	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase	73CCK
21 CFR 868.1500	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Conc.)	73CBQ
21 CFR 868.1620	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Conc.)	73CBS
21 CFR 868.1690	Analyzer, Gas, Nitrogen, Gaseous-Phase (Anesthetic Conc.)	73CCI
21 CFR 868.1700	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase, (Anesthetic Conc.)	73CBR
21 CFR 868.1720	Analyzer, Gas, Oxygen, Gaseous-Phase	73CCL
21 CFR 868.2375	Breathing Frequency Monitor	73FLS
21 CFR 870.1025	Detector and Alarm, Arrhythmia	74DSI
21 CFR 870.1100	Monitor, Blood Pressure, Indwelling	74CAA
21 CFR 870.1130	Noninvasive Blood Pressure Measurement System	74BXD
21 CFR 870.1100	Blood Pressure Alarm	74DSJ
21 CFR 870.1425	Programmable Diagnostic Computer	74DQK
21 CFR 870.2340	Electrocardiograph	74FYW
21 CFR 870.1435	Monitor, Cardiac Output, Thermal (Balloon Type Catheter)	74KFN
21 CFR 880.2910	Monitor, Temperature (with probe)	80BWX
21 CFR 870.2300	Monitor, Cardiac (Incl. Cardiotachometer & rate alarm)	74DRT
21 CFR 870.2700	Oximeter, Pulse	74DQA

Predicate Device: K990068 Solar 9500 Information Monitor

Device Description: The Solar 9500 is a patient monitoring system that is designed to display patient physiological data that is received from the GE 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 Medical System'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-GE platforms via the Enterprise network.

The Solar 9500 system was developed to interface with third party peripheral devices that support serial and/or analog data outputs.

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 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 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 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

MAR 21 2003

GE Medical Systems Information Technologies
c/o Mr. Andrew Kluessendorf
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K030575
Trade Name: Solar 9500 Information Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: 74 MHX
Dated: February 21, 2003
Received: February 24, 2003

Dear Mr. Kluessendorf:

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 (301) 594-4646. 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

K030575

510(k) Number (if known): 510(k) filed on February 20, 2003

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.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030575