K993757

MAR 2 3 2000

Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:
November 1, 1999

Submitter:

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

Contact Person:

Karen Webb
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems
Phone: (414) 362-3329
Fax: (414) 362-2420

Device: Trade Name:
Solar 7/8000 System

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. cardiotachometer & rate alarm)
21 CFR 870.2700 Oximeter, Pulse

Predicate Devices:

K900598 Marquette Tramscope System
K921669 Marquette SL Series Transport Remote Acquisition Module

Device Description: The Solar 8000 System includes four basic components:

- Solar 8000 processing unit
- a display (monochrome or color)
- TRAM-rac housing
- acquisition module(s)

The Solar 7000 System includes three basic components:

- Solar 7000 monitor (integrated display and processing unit) (monochrome or color)
- TRAM-rac housing
- acquisition module(s)

Optional Solar 7/8000 components include:

- central station (K901072)
- remote display
- remote control
- writer (Direct Digital Writer/ PRN 50 Thermal Recorder / Laser Printer)
- TRAM-Net hub
- TRAM-Net interface adapter(s)
- SolarView Remote Display Controller
- Octanet connectivity device
- Trend Memory Storage System

Intended Use: The Solar 7/8000 System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The intended use of the system is to monitor physiologic parameter data on adult, pediatric and neonatal patients within a hospital or facility providing patient care.

Physiologic parameter data includes: electrocardiogram, invasive blood pressure, noninvasive blood pressure, pulse, temperature, cardiac output, respiration, end tidal CO_2, pulse oximetry, venous O_2 saturation, Transcutaneous O_2 and/or CO_2, respiratory mechanics, and/or (for adult and/or pediatric patients) anesthetic agent concentrations. O_2 and/or CO_2 concentrations are available for neonates not under anesthesia. Information can be displayed, trended and stored in the monitor from a variety of peripheral devices.

The Solar 7/8000 System is also intended to provide physiologic data over the UNITY™ network.

The Solar 7/8000 System was developed to interface with third party peripheral devices that support serial and/or analog data outputs.

Technology:

The Solar 7/8000 employs the same functional technology as its predicate devices.

Test Summary:

The Solar 7/8000 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 7/8000:

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

Conclusion:

The results of these measurements demonstrated that the Solar 7/8000 is 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

MAR 23 2000

Ms. Karen Webb
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K993757
Trade Name: Solar 7/8000 System
Regulatory Class: III
Product Code: 74 DSI
Dated: February 1, 2000
Received: February 2, 2000

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 (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) 594-4586. 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 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,

for James E. Dillard III
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 November 1, 1999

Device Name: Solar 7/8000 System

Indications for Use:

The Solar 7/8000 System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The intended use of the system is to monitor physiologic parameter data on adult, pediatric and neonatal patients within a hospital or facility providing patient care.

Physiologic parameter data includes: electrocardiogram, invasive blood pressure, noninvasive blood pressure, pulse, temperature, cardiac output, respiration, end tidal CO_2, pulse oximetry, venous O_2 saturation, Transcutaneous O_2 and/or CO_2, respiratory mechanics, and/or (for adult and/or pediatric patients) anesthetic agent concentrations. O_2 and/or CO_2 concentrations are available for neonates not under anesthesia. Information can be displayed, trended and stored in the monitor from a variety of peripheral devices.

The Solar 7/8000 System is also intended to provide physiologic data over the UNITY™ network.

The Solar 7/8000 System was developed to interface with third party peripheral devices that support serial and/or analog data outputs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Jim Dillard

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993757

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

(Optional Format 1-2-96)