K071073

MAY 11 2007

510(k) Summary of Safety and Effectiveness

Date:

April 13, 2007

Submitter:

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

Contact Person:

Karen M. Lunde
Regulatory Affairs Program Manager
GE Medical Systems *Information Technologies*
Phone: (414) 362-3172
Fax: (414) 755-0655
E-mail: Karen.Lunde@ge.com

Secondary Contact Person:

Lisa M. Baumhardt
Regulatory Affairs Program Manager
GE Medical Systems *Information Technologies*
Phone: (414) 362-3242
Fax: (414) 362-2585
E-mail: Lisa.Baumhardt@med.ge.com

Device Trade Name:

Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module

Common /Usual Name:

Physiological Patient Monitor

Classification Names:

21 CFR 870.1025 Physiological Patient Monitor (with arrhythmia detection or alarms)

Predicate Devices:

K012467 Solar 8000M System
K042642 Aware Transport Monitor System

Device Description:

The Patient Data Module can be used with the Solar 8000i in a bedside configuration or with the Transport Pro in a transport configuration.

The Patient Data Module (PDM) acquisition device acquires, measures processes, and stores patient physiological parameters. Patient physiological parameter data acquired by the PDM includes 12-Lead ECG, up to four invasive blood pressures (as options), non-invasive blood pressure, Masimo pulse oximetry or Nellcor pulse oximetry, two temperatures, impedance respiration and cardiac output.

The Transport Pro is a host patient monitor that provides continuous patient monitoring capability when coupled with a compatible acquisition device. The Transport Pro is a lightweight, rugged patient monitor that can be used in a transport environment. The Transport Pro provides a means to view patient parameter information and to alert the clinician of parameter limit violations via visual and audible alarms. The Transport Pro must be coupled with the PDM acquisition

device with a PDM dock or the TRAM Module acquisition device (K053121) with a TRAM chute.

The Solar 8000i is a host patient monitor that provides continuous patient monitoring capability when coupled with compatible acquisition devices or when connected to the GEMS-IT UNITY network. The Solar 8000i is used in a bedside patient care environment. Like the Transport Pro host patient monitor, the Solar 8000i can be coupled with either the PDM acquisition device or the TRAM Module acquisition device (K053121). Patient physiologic data may also be received from the GEMS-IT Tram-net network and/or multi-parameter modules, or discrete modules located in a TRAM-rac (remote acquisition) housing.

Intended Use:

The Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional medical facility, such as hospital, clinic, surgical center or doctor's office. It can be used in multiple areas such as operating room (OR), post anesthesia care unit (PACU), emergency department (ED), chest pain clinic, general intensive care unit (ICU), critical care unit, surgical intensive care unit (SICU), respiratory intensive care unit, coronary care unit (CCU), medical intensive care unit (MICU), pediatric intensive care unit (PICU), or neonatal intensive care unit (NICU).

The Patient Data Module (PDM) is intended to provide uninterrupted acquisition of physiologic parameter data on adult, pediatric and neonatal patients during non-transport/bedside and transport patient care episodes. Physiological parameter data acquired by the PDM includes ECG, invasive pressure, non-invasive blood pressure, pulse oximetry, temperature, cardiac output and respiration. This device acquires, processes and stores information for all aforementioned parameters and transmits this information to a transport or bedside central processing unit for viewing and alarm surveillance purposes.

The Transport Pro patient monitor is intended for use as part of a transport monitoring system for intra-healthcare facility transport. When used with the Patient Data Module (PDM) or the TRAM acquisition module, this device is intended to provide uninterrupted monitoring of physiologic parameter data for adult, pediatric, and neonatal patients during transport from one area of the healthcare facility to another. Physiological parameter data includes ECG, invasive pressure, non-invasive blood pressure, pulse oximetry, temperature and respiration. Both the PDM and TRAM acquisition module acquire, process and store information for all aforementioned parameters.

The Solar 8000i patient monitoring system is a multi-parameter physiological patient monitoring system intended for use on adult, pediatric and neonatal patients. It provides uninterrupted monitoring of physiological patient data. The Solar 8000i patient monitoring system is capable of monitoring and analyzing the following parameters for all patient populations: electrocardiogram, invasive pressure, non-invasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, venous oxygen saturation, transcutaneous pO2 and pCO2, CO2 and respiratory mechanics. The

5

Solar 8000i patient monitoring system is capable of monitoring the following parameters for adult and pediatric patient populations: anesthetic agent concentrations, O2, impedance cardiography, electroencephalography and bispectral index. The Solar 8000i patient monitoring system interfaces with a variety of third-party peripheral medical devices that support serial and/or analog data outputs. Information from these devices can be displayed, trended and stored in the monitoring system. The Solar 8000i patient monitoring system also provides physiological data over the UNITY NETWORK™.

Technology:

The Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module employs the same functional scientific technology as its predicate devices.

Test Summary:

The subject of this 510(k) is a design modification for the Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module. The Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module complies with the voluntary standards as detailed in Section 4.2 Specific Standards and Guidance of this submission. The following quality assurance measures were applied to the development of the Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Subsystem Verification
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module 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

MAY 11 2007

GE Medical Systems Information Technologies
c/o Karen M. Lunde
Program Manager
200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K071073
Trade/Device Name: Solar 8000i with Patient Data Module / Transport Pro Patient Module
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: April 13, 2007
Received: April 16, 2007

Dear Ms. Lunde:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071073

Indications for Use

510(k) Number (if known):

Device Name: Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module

Indications for Use:

The Solar 8000i with Patient Data Module / Transport Pro with Patient Data Module is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional medical facility, such as hospital, clinic, surgical center or doctor's office. It can be used in multiple areas such as operating room (OR), post anesthesia care unit (PACU), emergency department (ED), chest pain clinic, general intensive care unit (ICU), critical care unit, surgical intensive care unit (SICU), respiratory intensive care unit, coronary care unit (CCU), medical intensive care unit (MICU), pediatric intensive care unit (PICU), or neonatal intensive care unit (NICU).

The Patient Data Module (PDM) is intended to provide uninterrupted acquisition of physiologic parameter data on adult, pediatric and neonatal patients during non-transport/bedside and transport patient care episodes. Physiological parameter data acquired by the PDM includes ECG, invasive pressure, non-invasive blood pressure, pulse oximetry, temperature, cardiac output and respiration. This device acquires, processes and stores information for all aforementioned parameters and transmits this information to a transport or bedside central processing unit for viewing and alarm surveillance purposes.

The Transport Pro patient monitor is intended for use as part of a transport monitoring system for intra-healthcare facility transport. When used with the Patient Data Module (PDM) or the TRAM acquisition module, this device is intended to provide uninterrupted monitoring of physiologic parameter data for adult, pediatric, and neonatal patients during transport from one area of the healthcare facility to another. Physiological parameter data includes ECG, invasive pressure, non-invasive blood pressure, pulse oximetry, temperature and respiration. Both the PDM and TRAM acquisition module acquire, process and store information for all aforementioned parameters.

The Solar 8000i patient monitoring system is a multi-parameter physiological patient monitoring system intended for use on adult, pediatric and neonatal patients. It provides uninterrupted monitoring of physiological patient data. The Solar 8000i patient monitoring system is capable of monitoring and analyzing the following parameters for all patient populations: electrocardiogram, invasive pressure, non-invasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, venous oxygen saturation, transcutaneous pO2 and pCO2, CO2 and respiratory mechanics. The Solar 8000i patient monitoring system is capable of monitoring the following parameters for adult and pediatric patient populations: anesthetic agent concentrations, O2, impedance cardiography, electroencephalography and bispectral index. The Solar 8000i patient monitoring system interfaces with a variety of third-party peripheral medical devices that support serial and/or analog data outputs. Information from these devices can be displayed, trended and stored in the monitoring system. The Solar 8000i patient monitoring system also provides physiological data over the UNITY NETWORK™.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K071073