

K012467

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FEB 11 2002

Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:

July 31, 2001

Submitter:

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

Contact Person:

Karen Webb
Sr. Regulatory Affairs Specialist
GE Medical Systems Information Technologies
Phone: (414) 362-3329
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Device: Trade Name:

Solar 8000M System

Common/Usual Name:

Physiological Patient Monitor

Classification Names:

Physiological Patient Monitor

Predicate Devices:

K993757 Solar 7/8000 System

Device Description:

The Solar 8000M System includes the following basic components:

- Solar 8000M processing unit
- a display
- TRAM-rac housing
- acquisition module(s)
- keypad and/or remote control

Additional, optional components include:

- Clinical Information Center (central station)
- Remote display
- digital writer or printer
- TRAM-Net interface adapter(s)
- Octanet connectivity device
- Remote Alarm Box

Intended Use:

The Solar 8000M System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in the use of the equipment. The Solar 8000M is a multiparameter physiological patient monitoring system intended for use on adult, pediatric and neonatal patients, within a hospital or facility environment.

The Solar 8000M System is capable of monitoring electrocardiogram, invasive blood pressure, non-invasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, venous O₂ saturation, Transcutaneous O₂ and CO₂ respiratory mechanics, and/or (for adult and/or pediatric patients) anesthetic agent concentrations, impedance cardiography, electroencephalography and bispectral index. O₂ and CO₂ 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 8000M System is also intended to provide physiologic data over the UNITY™ network.

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

Technology:

The Solar 8000M System employs the same functional scientific technology as its predicate devices.

Test Summary:

The Solar 8000M System and its host patient monitoring system comply 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 8000M System:

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

Conclusion:

The results of these measurements demonstrated that the Solar 8000M System are as safe, as effective, and perform as well as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2002

Ms. Karen M. Webb
Senior Regulatory Affairs Specialist
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K012467
Trade Name: Solar 8000M System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: November 9, 2001
Received: November 13, 2001

Dear Ms. Webb:

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

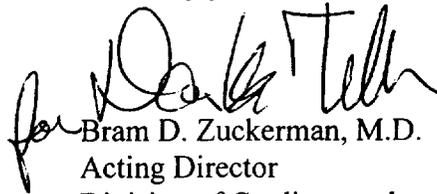
Page 2 - Ms. Karen M. Webb

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style with a large initial "B".

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

Enclosure

510(k) Number (if known): K012467; 510(k) filed on July 31, 2001

Device Name: Solar 8000M System

Indications for Use:

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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
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)


Division of Cardiovascular & Respiratory Devices
510(k) Number K012467