

K053121

1/3

Premarket Notification 510(k) Summary

As required by section 807.92

Date:

February 1, 2006

APR 5 2006

Submitter:

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

Contact Person:

Joel Kent
GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Phone: (781) 449-8685
Fax: (781) 433-1344

Device: Trade Name:

TRAM Module

Common/Usual Name:

Physiological Patient Monitor (Multi-parameter Module)

Classification Names:

The following Class II classifications appear applicable:

- 21 CFR 870.1025 Detector and Alarm, Arrhythmia
- 21 CFR 870.1025 Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
- 21 CFR 868.2375 Breathing Frequency Monitor
- 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 870.1915 Probe, Thermodilution
- 21 CFR 870.2340 Electrocardiograph
- 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:

K011000 GEMS-IT Transport Remote Acquisition Module (TRAM)

Device Description:

The TRAM Module is part of a multi-parameter modular system that measures and processes a patient's physiologic parameters. The TRAM Module works as a component of GE Medical Systems Information Technologies host monitoring systems and does not function on its own. The TRAM Module collects a patient's physiological data and sends it to a GEMS IT bedside monitor for display. TRAM modules incorporate different monitoring capabilities based on their configuration. The TRAM Module can also be used as a transport monitor when used with the Transport Remote Acquisition Module Patient Monitoring System.

Intended Use:

The TRAM Module is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in its proper use. The TRAM Module is intended to provide uninterrupted monitoring of physiologic parameter data on adult, pediatric and neonatal patients during transport from one area of the hospital or facility, and monitoring system, to another. During non-transport monitoring, the TRAM Module functions in the bedside monitoring system. Physiological parameter data includes ECG, invasive blood pressure, non-invasive blood pressure, pulse oximetry, cardiac output, temperature, and respiration. The TRAM Module acquires, processes and stores information regarding these parameters. The device is intended for use in a professional medical facility, such as hospital, clinic, surgical center or doctor's office. The TRAM System can be used in multiple 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. The device is intended for use as part of a transport monitoring system for intra-hospital transport.

Technology:

The TRAM Module employs the same functional scientific technology as its predicate devices.

Test Summary:

The TRAM Module 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 TRAM Module:

- 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

Conclusion:

The results of these measurements demonstrated that the TRAM Module are as safe, as effective, and perform as well as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2006

GE Medical Systems Information Technologies
c/o Mr. Joel Kent
GE Healthcare
86 Pilgrim Road
Needham, MA 02492

Re: K053121
Trade Name: TRAM Module
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-segment Measurement
and Alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 10, 2006
Received: February 13, 2006

Dear Mr. Kent:

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.

Page 2 – Mr. Joel Kent

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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman" followed by a flourish.

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

Enclosure

Indications for Use

510(k) Number (if known): K053121

Device Name: TRAM Module

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Special Agent in Charge
Division of Cardiovascular Devices
510(k) Number K053121