

NOV 26 1999

K992929

## 510(k) Summary of Safety and Effectiveness

Date:

August 24, 1999

Submitter:

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

Contact Person:

David Wahlig  
Sr. Regulatory Affairs Specialist  
GE Marquette Medical Systems  
Phone: (414) 362-2090  
Fax: (414) 355-3790

Device:    Trade Name:

Dash 3000 patient Monitor

Common/Usual Name:

Patient monitor

Classification Names:

- 21 CFR 868.1400 Analyzer, Gas, Carbon Dioxide, 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:

K964750 Eagle 4000 Patient Monitor

K921669 Marquette SL Series Transport Remote Acquisition Module

Device Description:

The Dash 3000 Patient Monitor is a device that is designed to be used to monitor, display, and print a patient's basic physiological parameters including: electrocardiography (ECG), invasive blood pressure, non-invasive blood pressure, oxygen saturation, temperature, impedance respiration, and end-tidal carbon dioxide. Other features include arrhythmia, cardiac output, cardiac and pulmonary calculations, dose calculations, PA wedge, ST analysis, and interpretive 12 lead ECG analysis (12SL). Additionally, the network interface allows for the display and transfer of network available patient data.

Intended Use:

The Dash 3000 Patient 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. The Dash is designed as a bedside, portable, and transport monitor that can operate in all professional

medical facilities and medical transport modes including but not limited to: emergency department, operating room, post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care areas located in hospitals, outpatient clinics, freestanding surgical centers, and other alternate care facilities, intra-hospital patient transport, inter-hospital patient transport via ground vehicles (i.e., ambulance, etc.) and fixed and rotary winged aircraft, and pre-hospital emergency response.

Physiologic data includes but is not restricted to: electrocardiogram, invasive blood pressure, noninvasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, and carbon dioxide as summarized in the operators manual.

The Dash 3000 Patient Monitoring System is also intended to provide physiologic data over the Unity network to clinical information systems and allow the user to access hospital data at the point-of-care.

This information can be displayed, trended, stored, and printed.

Technology:

The Dash 3000 employs the same functional technology as the predicate devices.

Test Summary:

The Dash 3000 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 Dash 3000:

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

Conclusion:

The results of these measurements demonstrated that the Dash 3000 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

NOV 26 1999

Mr. David Wahlig  
Corporate Regulatory Affairs  
GE Marquette Medical Systems  
8200 W. Tower Ave.  
Milwaukee, WI 53223

Re: K992929  
Dash 3000 Patient Monitor  
Regulatory Class: III (three)  
Product Code: MHK  
Dated: August 24, 1999  
Received: August 31, 1999

Dear Mr. Wahlig:

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.

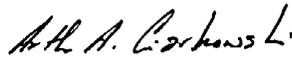
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4648. 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*   
Celia M. Witten, Ph.D., M.D.  
Acting 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 August 24, 1999

Device Name: Dash 3000 Patient Monitor

Indications For Use:

The Dash 3000 Patient 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.

The Dash is designed as a bedside, portable, and transport monitor that can operate in all professional medical facilities and medical transport modes including but not limited to: emergency department, operating room, post anesthesia recovery, critical care, surgical intensive care, respiratory intensive care, coronary care, medical intensive care, pediatric intensive care, or neonatal intensive care areas located in hospitals, outpatient clinics, freestanding surgical centers, and other alternate care facilities, intra-hospital patient transport, inter-hospital patient transport via ground vehicles (i.e., ambulance, etc.) and fixed and rotary winged aircraft, and pre-hospital emergency response.

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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)

A.H. A. Cochran  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K992929