K080157

Section 5: 510(k) Summary or 510(k) Statement

MAR 24 2008

510(k) Summary of Safety and Effectiveness

Date: January 21, 2008

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Contact Person: Sharon Untz
Quality and Regulatory Affairs Manager
GE Medical Systems *Information Technologies*
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Device: Trade Name: Dash 2500 Patient Monitor

Common/Usual Name: Physiological Patient Monitor (Multi-parameter Module)

Classification Names: 21 CFR 870.1025 Physiologic Patient Monitor (with arrhythmia detection or alarms)

Predicate Device: K031376 DINAMAP PRO 1000 V3 MONITOR

Device Description: The Dash 2500 Patient Monitor is a portable (intra-hospital) multi-parameter monitor designed for monitoring adult, pediatric, and neonate patient vital signs.
The Dash 2500 Patient Monitor is self-contained and can be powered by batteries or AC. The Monitor has a carrying handle and can be operated on a shelf or table. It can also be mounted in a variety of ways (e.g., wall, pole, bed rail, or head/foot board) using a mounting plate located on the bottom of the Monitor. The Monitor can be used as a stand-alone monitor with the capability to interface to a central station, a server or any other device capable of receiving data using the host communications protocol.

Intended Use: The Dash 2500 Patient Monitor is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of this device is a portable (intra-hospital) multiparameter unit designed for monitoring adult, pediatric, and neonate patient vital signs in a hospital subacute care environments, such as same-day surgery, emergency rooms, recovery/PACU, progressive care, interventional radiology, special care units, and GI/endoscopy.

The Dash 2500 Patient Monitor monitors and displays oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, oxygen saturation (SpO2) by non-invasive pulse oximetry, and temperature with an reusable electronic thermometer (predictive mode for oral and rectal temperature measurement, monitor mode for axillary temperature measurement).

The Dash 2500 also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

Technology: The Dash 2500 employs the same functional technology as the predicate devices.

Test Summary: The Dash 2500 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 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

Conclusion: The results of these measurements demonstrated that the Dash 2500 is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GE Medical Systems *Information Technologies*
c/o Ms. Sharon Untz
Quality Assurance and Regulatory Affairs Manager
8200 West Tower Avenue
Milwaukee, WI 53223

MAR 2 4 2008

Re: K080157
Dash 2500 Patient Monitor
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: January 21, 2008
Received: January 23, 2008

Dear Ms. Untz:

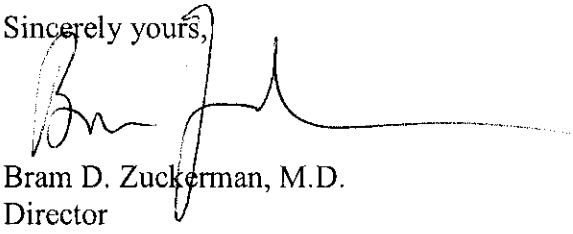
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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

Enclosure

K080157

Section 4: Indications for Use Statement

Indications for Use

510(k) Number (if known):
Device Name: Dash 2500 Patient Monitor

Indications for Use:

The Dash 2500 Patient Monitor is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of this device is a portable (intra-hospital) multiparameter unit designed for monitoring adult, pediatric, and neonate patient vital signs in a hospital subacute care environments, such as same-day surgery, emergency rooms, recovery/PACU, progressive care, interventional radiology, special care units, and GI/endoscopy.

The Dash 2500 Patient Monitor monitors and displays oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, temperature with an reusable electronic thermometer (predictive mode for oral and rectal temperature measurement, monitor mode for axillary temperature measurement), and functional oxygen saturation (SpO2) and pulse rate via spot checking and continuous monitoring, including monitoring during conditions of clinical patient motion or low perfusion.

The Dash 2500 also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

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 K080157