K073462

JAN 11 2008

Premarket Notification 510(k) Summary
As required by section 807.92
Dash 3000, Dash 4000 and Dash 5000 Monitor and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

November 19, 2007

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Dash 3000, Dash 4000 and Dash 5000 Monitor and accessories

COMMON NAME:

Patient Monitor

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
MHX	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)	870.1025
CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase	868.1400
BZQ	Breathing Frequency Monitor	868.2375
DXN	Noninvasive Blood Pressure Measurement System	870.1130
DSJ	Blood Pressure Alarm	870.1100
DQK	Programmable Diagnostic Computer	870.1425
DPS	Electrocardiograph	870.2340
DSK	computer, blood-pressure	870.1110

DXG	computer, diagnostic, pre-programmed, single-function	870.1435
FLL	Temperature, Electronic Clinical	880.2910
DRT	Monitor, Cardiac (Incl. Cardiotachometer & rate alarm)	870.2300
DQA	Oximeter, Pulse	870.2700
DSB	Plethysmograph, Impedance	870.2770
GWQ	Electroencephalograph	882.1400

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Dash 3000, Dash 4000 and Dash 5000 Monitor and accessories is substantially equivalent to the predicate DASH 3000/4000/5000 V6 Monitor (K051367).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The DASH 3000/4000/5000 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, end- tidal carbon dioxide, oxygen, nitrous oxide and anesthetic agents. The DASH 3000/4000/5000 Patient Monitor is a portable patient monitor manufactured in various fixed configurations. 3/5/10-leadwire ECG, impedance respiration, pulse oximetry, noninvasive blood pressure (NBP), four invasive pressures, two temperatures, thermal dilution cardiac output, and CO2 parameters can be monitored in a stand alone configuration (BP, CO, and CO2 are software enabled options). The DASH 3000/4000/5000is designed to monitor and present patient data on a color display. Three screen sizes are available: 8.4, 10.4, and 12.1 inches. The screen displays patient information, and the Trim Knob control and remote control provides single control operations of virtually all monitor functions. The operator can adjust parameter alarm settings that give audible and visual indication when a violation occurs. It also provides an option for printing information by a paper recorder. The software comes in a base feature set. Additional software options are provided in the following packages: 12SL ECG analysis, Acute Cardiac Ischemia - Time Insensitive Predictive Instrument (ACI-TIPI), high-resolution CRG trends, network connectivity, cardiac package, and cardio-pulmonary package. The IntelliRate feature is an optional feature that uses the most accurate of the three existing heart rate calculations (ECG, invasive blood pressure, and pulse oximetry) as the primary estimate of patient heart rate.
The Atrial Fibrillation algorithm is an optional feature of the EKPro ECG analysis program. It is an update to the existing Irregular arrhythmia call. The Dash 3000/4000/5000 interfaces with patients through accessories (cables / sensors). Each parameter on the Dash receives signals from the patient through the accessories. The Dash 3000/4000/5000 is compatible with GE Healthcare's Unity Network. An optional wireless LAN radio connection to the Unity Network can be built into the monitor. The Dash 3000/4000/5000 also includes auxiliary communication and defibrillator synchronization/analog output interfaces. The auxiliary communication interface can be connected to a Rac 2A Module Housing, providing interface to a SAM Module or ICG Module. The SAM Module provides the display features required to monitor anesthetic agents, O2, N2O, and CO2, and the ICG Module provides impedance cardiography. The auxiliary communication interface can also be connected to an external Aspect Medical BISx Bi-Spectral Index monitor, a remote alarm interface to a nurse call system, used for software updates, or as an interface to an information system. The DASH 3000/4000/5000 was developed to interface with other manufacturer's peripheral bedside devices via a networked, multi-serial port data accessory unit. The DASH 3000/4000/5000 monitor displays information sent from the peripheral devices. These connected devices may consist of, but are not limited to, ventilators, anesthesia machines, urimeters, and infusion pumps. The DASH 3000/4000/5000 can interface to a Nellcor 395 pulse oximeter without using the networked, multi-serial port data accessory unit.
Other optional components that interface to the DASH 3000/4000/5000 Patient Monitor include a central station, thermal printer and alarm light.

INTENDED USE as required by 807.92(a)(5)

Indications for use:

The Dash 3000/4000/5000 patient monitor 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 Dash3000/4000/5000 patient monitor is designed as a bedside, portable, and intra-hospital transport monitor that can operate in all professional medical facilities 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, free-standing surgical centers, and other alternate care facilities. Physiologic data includes but is not restricted to: electrocardiogram, invasive blood pressure, noninvasive blood pressure, heart rate, temperature, cardiac output, respiration, pulse oximetry, carbon dioxide, bi-spectral index, impedance cardiography, oxygen, and anesthetic agents as summarized in the operator's manual. The Dash 3000/4000/5000 patient monitor is also intended to provide physiologic data over the UNITY NETWORK™ indirectly to clinical information systems (via our Enterprise Gateway) and allow the user to access hospital data at the point-of-care.The information can be displayed, trended, stored, and printed. The Dash 3000/4000/5000 patient monitor was developed to interface with nonproprietary third party peripheral devices that support serial data outputs.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The intended use and the indications for use for the device, Dash 3000/4000/5000 monitor and accessories is basically the same (with clarification) as compared to the predicate Dash 3000/4000/5000 V6 (K051367).

There has been no change to the fundamental scientific technology from the predicate.

We have clarified the indications for use statement to indicate that only intra-hospital transport mode is supported for the monitors and clarification to the list of physiologic data included
A detailed analysis in this submission analyzes the changes to the Dash 3000/4000/5000 monitor and accessories with V6.6 software and compares the specifications to the predicate Dash 3000/4000/5000 V6 (K051367). It demonstrates the functional equivalence of the products and shows the device does not raise new issues of safety and effectiveness. Verification and validation testing demonstrate that no adverse effects have been introduced by these differences. The DASH 3000/4000/5000 monitor with V6.6 software is as safe and effective, and is substantially equivalent to the predicate DASH 3000/4000/5000 V6 Monitor (K051367).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Dash 3000, Dash 4000 and Dash 5000 Monitor and accessories has been assessed against the standards below and details of conformity are presented in the attached 510(k) notification. The device has been thoroughly tested through validation and verification of specifications.

- FDA 21 CFR Part 898, § 898.12
- IEC 60601-1-1:1988/A:1991/A:
- IEC 60601-1-2:2007
- IEC 60601-1-4:1996/A:1999
- IC 60601-2-27:1994
- IEC 60601-2-30:1999
- ANSI/AAMI SP10
- IEC 60601-2-34:2000
- EN 12470-4:2000
- EN ISO 9919:2005
- IEC 60601-2-49:2001
- EN ISO 14971:2001/A1:2003
- EN 60601-1:1990/A1:1993/A2:1995/A13:1996
- UL 60601-1:2003
- CAN/CSA C22.2 No. 601.1-M90·
- EN ISO 21647:2004
- FDA /ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices, May 11, 2005
- ANSI/AAMI EC57:1998 (R)2003
- ANSI/AAMI EC11:1991/(R)2001
- ANSI/AAMI EC13:2002

CONCLUSION:

The summary above shows that the Dash 3000, Dash 4000 and Dash 5000 Monitor and accessories is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Dash 3000/4000/5000 V6 (K051367).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

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

Re: K073462
Trade/Device Name: Dash 3000/4000/5000 monitor with V6.6 software
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: November 27, 2007
Received: December 10, 2007

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Indications for Use

510(k) Number (if known): K073462

Device Name: Dash 3000, Dash 4000 and Dash 5000 Monitor and accessories.

Indications for use:

The Dash™ 3000/4000/5000 patient monitor 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™ 3000/4000/5000 patient monitor is designed as a bedside, portable, and intra-hospital transport monitor that can operate in all professional medical facilities 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, free-standing surgical centers, and other alternate care facilities.

Physiologic data includes but is not restricted to: electrocardiogram, invasive blood pressure, noninvasive blood pressure, heart rate, temperature, cardiac output, respiration, pulse oximetry, carbon dioxide, bi-spectral index, impedance cardiography, oxygen, and anesthetic agents as summarized in the operator' s manual.

The Dash™ 3000/4000/5000 patient monitor is also intended to provide physiologic data over the UNITY NETWORK™ indirectly to clinical information systems (via our Enterprise Gateway) and allow the user to access hospital data at the point-of-care. The information can be displayed, trended, stored, and printed. The Dash™ 3000/4000/5000 patient monitor was developed to interface with nonproprietary third party peripheral devices that support serial data outputs.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073462