MAR 2 4 2009

GE Healthcare
510(K) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 20, 2009
Submitter:	GE Medical Systems *Information Technologies* 8200 West Tower Avenue Milwaukee, Wisconsin 53223
Primary Contact Person:	Robert L Casarsa Regulatory Affairs Leader GE Healthcare Phone: 1-414-362-3063 Fax: 1-414-362-2585
Device Trade Name:	Capnostat / CapnoFlex CO2 System For Solar 8000M/i, Dash 3000/4000/5000
Common/Usual Name:	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
Classification Names:	21 CFR 870.1025
Product Code (Primary):	MHX
Product Code (Secondary) / Classification / Name:	CCK – Analyzer, Gas, Carbon Dioxide, Gaseous Phase DSI – Detector and Alarm, Arrhythmia DXN – System, Measurement, Blood Pressure, Noninvasive DQK – Programmable Diagnostic Computer DPS – Electrocardiograph DRT – Monitor, Cardiac (Incl. Cardiotachometer & rate alarm) DQA – Oximeter DSB – Plethysmograph, Impedance GWQ – Electroencephalograph
Predicate Device(s):	K073462 - Dash 3000/4000/5000 Patient Monitor K071073 – Solar 8000M/i K030431 – Dash 3000/4000/5000 Patient Monitor
Device Description:	The Capnostat / CapnoFlex CO2 System provides end-tidal CO2 monitoring which is continuous, noninvasive technique for determining the concentration of CO2 (carbon dioxide) in respiratory gas by measuring the adsorption of infrared light of specific wavelengths. The light generated in the analyzer bench

is passed through respiratory gas samples. The amount of adsorption by CO2 in the sample is measured and digitized by the photodetector. The module processes the electronic signal and displays the waveform (labeled *CO2*) and digital values for expired CO2 (*EXP*), inspired CO2 (*INSP*) and respiratory rate (*RR*). The Capnostat / CapnoFlex CO2 System consists of a Capnostat Mainstream CO2 module used for intubated patients and a CapnoFlex LF CO2 module used for intubated or non-intubated patients. The Capnostat / CapnoFlex CO2 System uses specially designed sampling cannulas and on-airway adaptor kits. The CapnoFlex LF CO2 module uses a CapnoFlex LF Adapter that connects the CapnoFlex LF CO2 module to the Capnostat Mainstream CO2 module.

Intended Use:

Dash 3000/4000/5000:

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.

Solar 8000M/i:

The Solar 8000M/i patient monitoring system is a multi-parameter physiological patient monitoring system intended for use on adult, pediatric and neonatal patients. It provides uninterrupted monitoring of physiological patient data. The Solar 8000M/i patient monitoring system is capable of monitoring and analyzing the following parameters for all patient populations: electrocardiogram, invasive pressure, non-invasive blood pressure, pulse, temperature, cardiac output, respiration, pulse oximetry, venous oxygen saturation, transcutaneous pO2 and pCO2, CO2 and respiratory mechanics. The Solar 8000M/i patient monitoring system is capable of monitoring the following parameters for adult and pediatric patient populations: anesthetic agent concentrations, O2, impedance cardiography, electroencephalography and bispectral index. The Solar 8000M/i patient monitoring system interfaces with a variety of third-party peripheral medical devices that support serial and/or analog data outputs. Information from these devices can be displayed, trended and stored in the monitoring system. The Solar 8000M/i patient monitoring system also provides physiological data over the UNITY NETWORK™.

Technology:

The Capnostat / CapnoFlex CO2 System employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Capnostat / CapnoFlex CO2 System and its applications comply with voluntary standards as detailed in Section 9 and 17 of this premarket 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 (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, Capnostat / CapnoFlex CO2 System, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Capnostat / CapnoFlex CO2 System to be as safe, as effective, and its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2009

Mr. Robert L. Casarsa
Regulatory Affairs Leader
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K083750
Trade/Device Name: Capnostat/CapnoFlex CO2 System for the Dash 3000/4000/5000 And Solar 8000M/i Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-segment Measurement and Alarm)
Regulatory Class: II
Product Code: MHX, CCK, DSI, DXN, DQK, DPS, DRT, DQA, DSB, GWQ
Dated: February 23, 2009
Received: February 25, 2009

Dear Mr. Casarsa:

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,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K083750

Device Name: Capnostat / CapnoFlex CO2 System for the Dash 3000/4000/5000 and Solar 8000M/i Monitors

Indications for Use:

Dash 3000/4000/5000:

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

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083750