K102239
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OCT 18 2010

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510(k) Summary

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

Date:	August 5, 2010
Submitter:	GE Healthcare Finland Oy. Kuortaneenkatu 2 Helsinki, Finland FIN-00510
Primary Contact Person:	Päivi Roiha Regulatory Affairs Leader GE Healthcare Finland Oy Kuortaneenkatu 2 Helsinki, Finland FIN-00510 Phone: + 358 10 394 3731 Fax: +358-92726532 E-mail: paivi.roiha@ge.com
Secondary Contact Person:	Joel Kent Manager, Quality and regulatory Affairs GE Healthcare Phone: 781-449-8685 Fax: 781-433-1344
Device: Trade Name:	CARESCAPE™ Monitor B650
Common/Usual Name:	multi-parameter patient monitor
Classification Names:	21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Product Code:	MHX

Predicate Device(s): K092027 CARESCAPE™ Monitor B850

K061185 DATEX-OHMEDA S/5 COMPACT ANESTHESIA MONITOR WITH L-CANE05(A) SOFTWARE

K031320 EK-PRO ARRHYTHMIA DETECTION ALGORITHM (EK-Pro V11)

K092680 DATEX-OHMEDA S/5 ANESTHESIA MONITOR WITH L-ANE07 AND L-ANE07A SOFTWARE, USING F-CU8 OR F-CU5(P) MONITOR FRAME OPTIONS AND E-EXT EXTENSION MODULE AND E-REC RECORDER MODULE

Device Description: The CARESCAPE Monitor B650 is a multi-parameter patient monitor including both new and existing subsystems. The CARESCAPE Monitor B650 includes the monitor itself, the CARESCAPE Software Platform (also called ESP software) and the battery. The CARESCAPE Monitor B650 itself has 15 inch display (optional touch screen) with integrated keypad and a frame for parameter measurement modules. A variety of options are available to the customer including additional displays, various input devices (keyboard, mouse, bar code reader, and corded remote control), and physiological parameter measurement modules, which are existing subsystems.. The CARESCAPE Monitor B650 communicates to a variety of existing OEM medical devices. The CARESCAPE Monitor B650 interfaces to a variety of other existing patient monitoring systems via a cabled or wireless network interface. The CARESCAPE Monitor B650 includes features and subsystems that are optional or configurable.

Intended Use: The CARESCAPE Monitor B650 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility.

The CARESCAPE Monitor B650 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

The CARESCAPE Monitor B650 is indicated for monitoring and recording of, and to generate alarms for, hemodynamic (including ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, cardiac output, temperature and mixed venous oxygen saturation), impedance respiration, airway gases (CO2, O2, N2O and anesthetic agents), spirometry, gas exchange, and neurophysiological (including electroencephalography, Entropy, Bispectral Index (BIS) and neuromuscular transmission) status.

The CARESCAPE Monitor B650 can be a stand-alone monitor or interfaced to other devices. It can also be connected to other monitors for remote viewing and to data management software devices via a network.

The CARESCAPE Monitor B650 is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The CARESCAPE Monitor B650 is not intended for use during MRI.

Technology: The CARESCAPE Monitor B650 is a new monitor that essentially is a combination of the features and parameters of two existing predicate monitor

platforms. The predicate monitors are CARESCAPE™ Monitor B850 (K092027) and the DATEX-OHMEDA S/5 COMPACT ANESTHESIA MONITOR WITH L-CANE05(A) SOFTWARE (K061185).

The CARESCAPE Monitor B650 has the EK-Pro Arrhythmia Detection Algorithm, EK- Pro V12 that employs the same functional technology as the predicate device(s) in the monitoring of ECG parameter data. The predicate algorithms are EK-PRO ARRHYTHMIA DETECTION ALGORITHM, EK-Pro V11 (K031320) and DATEX-OHMEDA S/5 ANESTHESIA MONITOR WITH L-ANE07 AND L-ANE07A SOFTWARE, USING F-CU8 OR F-CU5(P) MONITOR FRAME OPTIONS AND E-EXT EXTENSION MODULE AND E-REC RECORDER MODULE (K092680).

The fundamental technology of the CARESCAPE Monitor B650 is the same as the predicate devices.

The CARESCAPE Monitor B650 device is as safe and effective the predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The CARESCAPE™ Monitor B650 and its applications comply with voluntary standards as detailed in 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, CARESCAPE™ Monitor B650 did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the CARESCAPE™ Monitor B650 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare Finland Oy
c/o Ms. Paiva Roiha
Regulatory Affairs Leader
Kuortaneenkatu 2
Helsinki, Finland
FIN-00510

OCT 18 2010

Re: K102239
Trade/Device Name: CARESCAPE™ Monitor B650
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: August 5, 2010
Received: August 9, 2010

Dear Ms. Roiha:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K102239

Indications for Use

510(k) Number (if known): _____ OCT 18 2010

Device Name: **CARESCAPE™ Monitor B650**

Indications for use:

The CARESCAPE Monitor B650 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility.

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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 K102239