GE Healthcare Finland Oy
Kuortaneenkatu 2, P.O. Box 900
FI-00031 GE
Finland
T: +358 10 39411
F: +358 9 1463310

510(k) Summary

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

Owner/Contact/Date (807.92(a)(1):

Date: August 20, 2013

Submitter: GE Healthcare Finland Oy.
Kuortaneenkatu 2
Helsinki, Finland
FIN-00510
Phone: + 358 10 394 11
Fax: +3589 2726532

DEC 0 4 2013

Primary Contact Person: Joel Kent
Manager, Quality and regulatory Affairs
GE Healthcare
Phone 781-449-8685
Fax 781-433-1344

E-mail: joel.kent@ge.com

Secondary Contact Person: Päivi Roiha
Regulatory Affairs Leader
GE Healthcare Finland Oy
Kuortaneenkatu 2
Helsinki, Finland
FIN-00510
Phone: + 358 10 394 3731
Fax: +358 9 2726532
E-mail: paivi.roiha@ge.com

Device names (807.92(a)(2):

Trade Name: CARESCAPE Monitor B450

Common/Usual Name: multi-parameter patient monitor

Classification Names: 21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Primary Product Code: MHX

Secondary Product Code: BZK, BZL, BZQ, CAP, CBQ, CBR, CBS, CCK, CCL, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXG, DXN, FLL, GWJ, GWQ, KOI, KRB, MLD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT

Predicate Device(s) (807.92(a)(3)):	K102239 CARESCAPE Monitor B650
Device Description (807.92(a)(4)):	The CARESCAPE Monitor B450, including both new and existing subsystems interconnected forms a low acuity, portable multi-parameter patient monitoring system. The CARESCAPE Monitor B450 includes the monitor itself with built-in CPU and power unit, the CARESCAPE Software Platform (ESP software version 2 in this submission) and one or two batteries. The CARESCAPE Monitor B450 has a 12 inch touch screen display, mounting for a PSM/PDM hemodynamic module and a frame for one additional parameter measurement module. A variety of options are available to the customer including additional displays, various input devices (keyboard, mouse, bar code reader and USB remote control), and additional modules. The CARESCAPE Monitor B450 supports a variety of existing physiological parameter measurement modules and also can connect to OEM medical devices via the existing network infrastructure. The CARESCAPE Monitor B450 interfaces to a variety of other patient monitoring systems via a cabled or wireless network interface. The CARESCAPE Monitor B450 includes features and subsystems that are optional or configurable.
Intended Use (807.92(a)(5)):	The CARESCAPE Monitor B450 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility. The CARESCAPE Monitor B450 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE Monitor B450 is indicated for monitoring of: ◆ hemodynamic (including ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, cardiac output (thermodilution and pulse contour), temperature, mixed venous oxygen saturation, and central venous oxygen saturation, ◆ respiratory (impedance respiration, airway gases (CO2, O2, N2O and anesthetic agents), and spirometry) ◆ neurophysiological status (including electroencephalography, Entropy, Bispectral Index (BIS), and neuromuscular transmission). The CARESCAPE Monitor B450 also provides alarms, trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices. The CARESCAPE Monitor B450 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 B450 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 B450 is not intended for use during MRI.

Technology (807.92(a)(6)): The CARESCAPE Monitor B450 is a new monitor where features and parameters are essentially same as in predicate monitor platform CARESCAPE Monitor B650 (K102239). The CARESCAPE Monitor B450 uses the CARESCAPE Software Platform (also called ESP software) version 2 whereas the predicate monitor CARESCAPE Monitor B650 (K102239) has software version 1.

The fundamental technology of the CARESCAPE Monitor B450 is the same as the predicate device.

The CARESCAPE Monitor B450 with ESP v2 software uses an improved arrhythmia and ST analysis algorithm called EK-Pro v13 in the Monitor Software. It is based on the previous algorithm version EK-Pro v12, which has been cleared as part of the predicate device CARESCAPE Monitor B650 with ESP V1 software (K102239).

The CARESCAPE Monitor B450 device is as safe and effective as the predicate device.

Determination of Substantial Equivalence (807.92(b)(1)):

Summary of Non-Clinical Tests:

The CARESCAPE Monitor B450 and its applications comply with voluntary standards as detailed below. The following quality assurance measures were applied in 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)

The CARESCAPE Monitor B450 was designed and tested for compliance to the following standards:

1. IEC 60601-1:1988, A1:1991, A2:1995, Corr1:1995, Medical Electrical Equipment Part 1: General Requirements for Safety - Second Edition
2. IEC 60601-1-1:2000, Medical Electrical Equipment - Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems-Edition 2.0
3. IEC 60601-1-2:2001 + A.2004, Medical electrical equipment – Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests – Edition 2
4. IEC 60601-1-4: 2000, Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
5. IEC60601-1-6:2006, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – collateral Standard: Usability – Edition 2
6. IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices

7. IEC 60601-1-8:2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems, Second Edition
8. IEC 60601-2-10:1987 + A1:2001, Medical Electrical Equipment Part 2-10: Particular Requirements for the Safety of Nerve and Muscle Stimulators-First Edition
9. IEC 60601-2-25:1993 + A1:1999, Medical electrical equipment Part 2-25- Particular requirements for the safety of electrocardiographs – First Edition
10. IEC 60601-2-26:2002, Medical electrical equipment - Particular requirements for the safety of electroencephalographs
11. IEC 60601-2-27:2005, Medical electrical equipment Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
12. IEC 60601-2-30:1999, Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment-Second Edition
13. IEC 60601-2-34:2000, Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment-Edition 2
14. IEC 60601-2-40:1998, Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
15. IEC 60601-2-49:2001, Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment-Edition 1
16. IEC 60601-2-51:2003, Medical electrical equipment Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs-Edition 1
17. AAMI EC11:1991/(R)2001/(R)2007, Diagnostic Electrocardiographic Devices
18. AAMI EC13: 2002/(R)2007, Cardiac monitors, heart rate meters, and alarms,
19. AAMI EC57:1998, A1:2008, Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
20. AAMI SP10:2002 + A1:2003 + A2:2006, Manual, electronic, or automated sphygmomanometers.
21. EN1060-1:1995 +A1:2002, Non-invasive sphygmomanometers- Part 1: General requirements
22. EN1060-3:1997 +A1:2005, Non-invasive sphygmomanometers- Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

Except for the following clause:

- 7.9: Testing performed in accordance with EN 1060-4 failed by PDM module

23. EN 12470-4:2000, A1:2009, Clinical Thermometers – Part 4: Performance of Electrical Thermometers for Continuous Measurement

    Except for the following clauses:

- 6.3 b) Temperature measurement error with single use probes exceeded maximum permissible error.
- 6.4: The response time of the Esophageal stethoscope with temperature probe exceeds 150s for the probe sizes 18F and 24F.

24. ISO 21647:2004 + C1:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors
25. ISO9919:2005, Medical electrical equipment Particular requirements for the safety and essential performance of pulse oximeter equipment for medical use - Second Edition
26. EN 1041: 2008, Information supplied by the manufacturer of medical devices
27. IEC 62304:2006, Medical device software – Software life cycle processes

Clinical (807.92(b)(2)): Summary of Clinical Tests:

The subject of this premarket submission, CARESCAPE Monitor B450 did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE Healthcare considers the CARESCAPE Monitor B450 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 4, 2013

Ge Healthcare Finland Oy
Joel Kent
Manager, Quality and Regulatory Affairs
Kuortaneenkatu 2
Helsinki, FIN-00510 FI

Re: K132533
Trade/Device Name: Carescape Monitor B450
Regulation Number: 21 CFR 870.1025
Regulation Name: Multiparameter Patient Monitor (Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MHX, BZK, BZL, BZQ, CAP, CBQ, CBR, CBS, CCK, CCL, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXG, DXN, FLL, GWJ, GWQ, KOI, KRB, MLD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
Dated: November 1, 2013
Received: November 4, 2013

Dear Joel 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. 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Owen P. Faris -S

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):

Device Name: **CARESCAPE Monitor B450**

Indications for Use:

The CARESCAPE Monitor B450 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility.

The CARESCAPE Monitor B450 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

The CARESCAPE Monitor B450 is indicated for monitoring of:

- hemodynamic (including ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, cardiac output (thermodilution and pulse contour), temperature, mixed venous oxygen saturation, and central venous oxygen saturation,
- respiratory (impedance respiration, airway gases (CO2, O2, N2O and anesthetic agents), and spirometry)
- neurophysiological status (including electroencephalography, Entropy, Bispectral Index (BIS), and neuromuscular transmission).

The CARESCAPE Monitor B450 also provides alarms, trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices.

The CARESCAPE Monitor B450 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 B450 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 B450 is not intended for use during MRI.

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)

Digitally signed by Owen L. Faris -S
Date: 2013.12.04 10:29:21 -05'00'