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
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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, DSK, DXG, DXN, FLL, GWJ, GWQ, KOI, KRB, MLD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
Predicate Device(s)
K102239 CARESCAPE Monitor B650

Device Description
(807.92(a)(3)):
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)): 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:

6. IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices

Summary of Non-Clinical Tests:
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
2-10: Particular Requirements for the Safety of Nerve and Muscle
Stimulators-First Edition
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
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
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
Devices:
18. AAMI EC13: 2002/(R)2007, Cardiac monitors, heart rate meters, and
alarms,
results of cardiac rhythm and ST segment measurement algorithms
automated sphygmomanometers.
1: General requirements
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

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.


26. EN 1041: 2008, Information supplied by the manufacturer of medical devices

27. IEC 62304:2006, Medical device software – Software life cycle processes

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**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.
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 I
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

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:

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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)

Digitally signed by Owen

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