January 28, 2020

GE Healthcare Finland Oy
Joel Kent
Senior Regulatory Affairs Manager
Kuortaneenkatu 2
00510 Helsinki
Finland

Re: K191149
Trade/Device Name: CARESCAPE B650
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
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: December 18, 2019
Received: December 20, 2019

Dear Joel Kent:

This letter corrects our substantially equivalent letter of January 21, 2020.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Shih
Assistant Director (Acting)
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191149

Device Name
CARESCAPE B650

Indications for Use *(Describe)*
The CARESCAPE B650 is a multi-parameter patient monitor intended for use in multiple areas and intra hospital transport within a professional healthcare facility.
The CARESCAPE B650 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.
The CARESCAPE B650 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), spirometry, gas exchange), and
● neurophysiological status (including electroencephalography, Entropy, Bispectral Index (BIS), and neuromuscular transmission).
The CARESCAPE 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 B650 is able to detect and generate alarms for ECG arrhythmias: atrial fibrillation, accelerated ventricular rhythm, asystole, bigeminy, bradycardia, ventricular couplet, irregular, missing beat, multifocal premature ventricular contractions (PVCs), pause, R on T, supra ventricular tachycardia, tachycardia, trigeminy, ventricular bradycardia, ventricular fibrillation/ventricular tachycardia, ventricular tachycardia, and VT>2. The CARESCAPE B650 also shows alarms from other ECG sources.
The CARESCAPE B650 also provides other alarms, trends, snapshots and events, and calculations, and can be connected to displays, printers and recording devices.
The CARESCAPE 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.

Contraindications for using the monitor
The CARESCAPE B650 is not intended for use in a controlled MR environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

GE Healthcare Finland Oy
Kuortaneenkatu 2
00510 Helsinki
Finland
T: +358 10 39411

## 510(k) Summary

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

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

| | |
|---|---|
| Date: | January 21, 2020 |
| Owner/Submitter: | GE Healthcare Finland Oy.<br>Kuortaneenkatu 2<br>00510 Helsinki<br>FINLAND<br>Phone: +358 10 39411 |
| Primary Contact Person: | Joel Kent<br>Senior Regulatory Affairs Manager<br>GE Healthcare<br>Phone: 617-851-0943<br><br>E-mail: joel.kent@ge.com |
| Secondary Contact Person: | Anssi Ruokonen<br>Regulatory Affairs Leader<br>GE Healthcare Finland Oy<br>Kuortaneenkatu 2<br>00510 Helsinki<br>Finland<br><br>Phone: + 358 10 394 3686<br><br>E-mail: Anssi.ruokonen@ge.com |

Device names (807.92(a)(2)):

| | |
|---|---|
| Trade Name: | CARESCAPE B650 |
| Common/Usual Name: | Multiparameter patient monitor (monitor, physiological, patient (with arrhythmia detection or alarms) |

Classification Names:

21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)
21 CFR 868.1850 spirometer, monitoring (w/wo alarm)
21 CFR 868.1730 computer, oxygen-uptake
21 CFR 868.2375 monitor, breathing frequency
21 CFR 868.2600 monitor, airway pressure (includes gauge and/or alarm)
21 CFR 868.1500 analyzer, gas, enflurane, gaseous-phase (anesthetic conc.)
21 CFR 868.1500 analyzer, gas, desflurane, gaseous-phase (anesthetic conc.)
21 CFR 868.1500 analyzer, gas, sevoflurane, gaseous-phase (anesthetic conc.)
21 CFR 868.1500 analyzer, gas, isoflurane, gaseous-phase (anesthetic conc.)
21 CFR 868.1700 analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
21 CFR 868.1620 analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
21 CFR 868.1400 analyzer, gas, carbon-dioxide, gaseous-phase
21 CFR 868.1720 analyzer, gas, oxygen, gaseous-phase
21 CFR 870.2340 electrocardiograph
21 CFR 870.2710 oximeter, ear
21 CFR 870.2700 oximeter
21 CFR 870.1425 computer, diagnostic, programmable
21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)
21 CFR 870.1025 detector and alarm, arrhythmia
21 CFR 870.1100 alarm, blood-pressure
21 CFR 870.1110 computer, blood-pressure
21 CFR 870.1435 computer, diagnostic, pre-programmed, single-function
21 CFR 870.1130 system, measurement, blood-pressure, non-invasive
21 CFR 870.2910 thermometer, electronic, clinical
21 CFR 882.1900 stimulator, auditory, evoked response
21 CFR 882.1400 full-montage standard electroencephalograph
21 CFR 868.2775 stimulator, nerve, peripheral, electric
21 CFR 870.1915 probe, thermodilution
21 CFR 870.1025 monitor, st segment with alarm
21 CFR 882.1400 non-normalizing quantitative electroencephalograph software
21 CFR 882.1400 index-generating electroencephalograph software
21 CFR 882.1400 reduced- montage standard electroencephalograph

| | |
|---|---|
| | 21 CFR 882.1400 burst suppression detection software for electroencephalograph |
| Product Code: | MHX |
| Subsequent Product Codes: | 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): | K131223 CARESCAPE Monitor B650 |
| Device Description (807.92(a)(4)): | CARESCAPE B650 V3 is a new version of a portable multi-parameter patient monitoring system. The CARESCAPE B650 V3 includes the monitor with built-in CPU, power unit, a 15 inch touch display, the CARESCAPE Software version 3 and the battery. CARESCAPE B650 V3 is equipped with so called ePort interface that supports use of PDM or CARESCAPE ONE patient data acquisition modules for patient monitoring. CARESCAPE B650 V3 is also equipped with two module slots where patient data acquisition modules (E-Modules), can be connected to perform patient monitoring. The CARESCAPE B650 V3 includes features and subsystems that are optional or configurable. |
| Intended Use: (807.92(a)(5): | Indications *(from labeling)*<br>The CARESCAPE B650 is a multi-parameter patient monitor intended for use in multiple areas and intra hospital transport within a professional healthcare facility.<br>The CARESCAPE B650 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.<br>The CARESCAPE B650 is indicated for monitoring of:<br>● 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),<br>● respiratory (impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), spirometry, gas exchange), and<br>● neurophysiological status (including electroencephalography, Entropy, Bispectral Index (BIS), and neuromuscular transmission). |

The CARESCAPE 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 B650 is able to detect and generate alarms for ECG arrhythmias: atrial fibrillation, accelerated ventricular rhythm, asystole, bigeminy, bradycardia, ventricular couplet, irregular, missing beat, multifocal premature ventricular contractions (PVCs), pause, R on T, supra ventricular tachycardia, tachycardia, trigeminy, ventricular bradycardia, ventricular fibrillation/ventricular tachycardia, ventricular tachycardia, and VT>2. The CARESCAPE B650 also shows alarms from other ECG sources.

The CARESCAPE B650 also provides other alarms, trends, snapshots and events, and calculations, and can be connected to displays, printers and recording devices.

The CARESCAPE 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.

**Contraindications for using the monitor**

The CARESCAPE B650 is not intended for use in a controlled MR environment.

Technology (807.92(a)(6)): CARESCAPE B650 with CARESCAPE Software version 3 incorporates updated hardware and a new software platform.

The fundamental function and operation of the proposed CARESCAPE B650 V3 monitor are unchanged compared to CARESCAPE Monitor B650 with ESP V2 software (K131223). There are no new types of monitored parameters introduced compared to the predicate B650 monitor.

A summary of the main changes compared to the predicate are listed below in the comparison table.

## Subject Device and Predicate Device Comparison

| Specification | CARESCAPE Monitor B650 with ESP V2 software (K131223) | CARESCAPE B650 with CSP software version V3 | Differences |
|---|---|---|---|
| **Patient type** | Adult, pediatric & neonatal | Adult, pediatric & neonatal | Identical |
| **Use environments** | Within a professional healthcare facility (Not intended for MRI) | Within a professional healthcare facility (Not intended for MRI) | Identical |
| **Size (H x W x D) & Weight** | 360 x 370 x 220 mm (14.2 x 14.6 x 8.7 in) and weight 9.2 kg (20.3 lbs) with battery but without modules | 360 x 370 x 220 mm (14.2 x 14.6 x 8.7 in) and weight 9.2 kg (20.3lbs) with battery but without modules. | Identical |
| **Processor** | Freescale PowerPC MPC8270 | Freescale ARM Cortex-A9 | Equivalent<br>The CARESCAPE Bx50 V3 monitors have an updated common CPU platform. |
| **Module Housing** | Two optional E-module slots and optional recorder. One slide mount for acquisition module | Two optional E-module slots and optional recorder. One slide mount for acquisition module | Identical |
| **Display/screen** | 15” Active matrix color TFT LCD | 15” Active matrix color TFT LCD | Identical |
| **Waveforms and parameter windows** | Standard view: Up to 8 individual waveforms and up to 20 parameter windows, if horizontal parameter area turned on. | Standard view: Up to 8 individual waveforms and up to 20 parameter windows, if horizontal parameter area turned on. | Identical |
| **Modules** | E-PSM; E-PSMP, E-PRESTN, E-PRETN, E-RESTN, M-PRESTN, M-PRETN, M-RESTN, E-miniC, E-CO, E-CAiO, E-CAiOV, E-CAiOVX, E-COVX, E-COV, E-P, E-PP, E-PT, E-COP, E-COPSv, E-EEG, E-Entropy, E-NMT, E-BIS, E-NSAT, E-NSATX, E-Masimo, E-sCO, E-sCAiO, E-sCOV, and E-sCAiOV, E-PiCCO, PDM | E-BIS, E-COP, E-COPSv, E-PiCCO, E-EEGX, E-Entropy, E-Masimo, E-miniC, E-NMT, E-NSATX, E-PP, E-PT, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCO, E-sCOV, E-sCOVX, PDM, CARESCAPE ONE | Equivalent<br>Removed support for several legacy E/M multiparameter hemodynamic acquisition modules as many newer acquisition modules are included, covering the same parameters.<br>Added support for CARESCAPE ONE and E-EEGX acquisition modules.<br><br>Added support for E-sCAiOVX and E-sCOVX modules (K150245). |

| Specification | CARESCAPE Monitor B650 with ESP V2 software (K131223) | CARESCAPE B650 with CSP software version V3 | Differences |
|---|---|---|---|
| **Available parameters** | 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, impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), spirometry, gas exchange, electroencephalography, Entropy, Bispectral Index (BIS), neuromuscular transmission. | 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, impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), spirometry, gas exchange, electroencephalography, Entropy, Bispectral Index (BIS), neuromuscular transmission. | Identical |
| **EK-Pro arrhythmia detection algorithm** | EK-Pro V13 | EK-Pro V14 | Equivalent CARESCAPE B650 V3 uses an EK-ProV14 arrhythmia analysis algorithm compared to the EK-Pro V13 used in the predicate monitors. |
| **Graphical user interface** | GE Healthcare Common User Interface (CUI) Requirements and Style Versio 6 | GE Healthcare HDX | A new color scheme for the display and slight visual adjustments have been incorporated, in line with a GE Healthcare wide user interface design guideline. The overall user interface layout, structure, operations, and workflow remains the same as the predicate. |
| **Printing** | Built–in or central and networked laser printer Printings for waveforms, alarms waveforms, numeric trends | Built–in or central and networked laser printer Printings for waveforms, alarms waveforms, numeric trends | Identical |

| Specification | CARESCAPE Monitor B650 with ESP V2 software (K131223) | CARESCAPE B650 with CSP software version V3 | Differences |
|---|---|---|---|
| **Mounting options** | Multiple GCX mounting systems, Roll Stand, Quick Mount | Multiple GCX mounting systems, Roll Stand, Quick Mount | Identical |
| **Alarms** | Alarm management core functionalities:<br>Classification and notification of alarms<br>Adjustment of alarm settings<br>Alarm On/Off functionality and audio silencing | Alarm management core functionalities:<br>Classification and notification of alarms<br>Adjustment of alarm settings<br>Possibility to set critical alarm limits<br>Alarm On/Off functionality and audio silencing | Equivalent<br>The predicate already included the options to configure some alarm settings. In V3, more flexibility was added for the user to adjust alarm priorities and alarm criteria for additional parameter alarms, including additional alarm delay options, critical alarm options, alarm acknowledgement and latched alarm indicators, and a pause monitoring & central function.<br>In general, options for tailored/specific alarm management schemes have been added supporting clinicians in their goals of reducing alarm fatigue while maintaining safety.<br>Default setting are according to IEC 60601-1-8. |

| Specification | CARESCAPE Monitor B650 with ESP V2 software (K131223) | CARESCAPE B650 with CSP software version V3 | Differences |
|---|---|---|---|
| **Remote Alarm Device** | Alarm Interface of ESP V2 SW was not utilized | Alarm Interface to the Remote Alarm Device, CARESCAPE RAD | Equivalent<br>The predicate device did not support the connector type of the Remote Alarm Box with Remote Light (RAB RL). Therefore, the Alarm Interface of ESP V2 could not be utilized.<br>The CARESCAPE RAD is the new USB accessory for use with the CARESCAPE B650 V3.<br>As the proposed CARESCAPE B650 V3 provides USB connection, now the Alarm Interface of the CARESCAPE B650 V3 is utilized for remote alarming.<br>The CARESCAPE RAD is intended for relaying primary alarm signals from the host device to an external distributed alarm system, i.e. a nurse call system or a remote alarm light. The CARESCAPE B650 V3 alarm functionality is unaffected when using the CARESCAPE RAD as the new accessory simply receives data from the monitor (one-way communication) to indicate when an alarm is active or not. |
| **Intrahospital transport within a professional healthcare facility.** | Yes | Yes | Identical |
| **Battery operation** | Rechargeable Lithium-Ion batteries | Rechargeable Lithium-Ion batteries | Identical |

| Specification | CARESCAPE Monitor B650 with ESP V2 software (K131223) | CARESCAPE B650 with CSP software version V3 | Differences |
|---|---|---|---|
| **Networking capability** | CARESCAPE Network<br>LAN/VLAN<br>Optional WLAN | CARESCAPE Network<br>LAN/VLAN<br>Single wire network configuration supported for CARESCAPE Networks<br>Optional WLAN | Equivalent<br><br>The single wire network configuration simplifies the installation and maintenance of CARESCAPE B650 V3 patient monitors. The single wire network configuration has no impact on clinical monitoring. |
| **Network interface** | 10baseT, 100baseT, 802.11 abg<br>IEEE 802.11r fast roaming is not supported. | 10baseT, 100baseT, 802.11 abgn<br>IEEE 802.11r fast roaming supported. | Equivalent<br>V3 supports wireless data transfer with support for WPA2-Enterprise security mechanisms for enhanced security, and support the IEEE 802.11n protocol for faster wireless data transfer, and the IEEE 802.11r fast roaming standard for fast and secure handoffs from one access point to another during intra-hospital transport. |

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

Summary of Non-Clinical Tests:

Bench testing related to software, hardware and performance including applicable consensus standards was conducted on the CARESCAPE B650, demonstrating the design meets the specifications.

The hardware bench testing included electromagnetic compatibility, electrical safety, environmental, WLAN, and usability.

The CARESCAPE B650 has been found to substantially equivalent to the predicate device(s) for the intended users, uses and use environment. Extensive usability work has been completed for CARESCAPE B650 and the predicate devices including critical task identification through use-based hazard analysis, multiple rounds of formative usability testing and summative testing, among other activities.

Software testing included software design, development, verification, validation and traceability.

Patient safety, security, and privacy risks have been addressed in the design and development of CARESCAPE B650 including a Security Risk Assessment and Threat model. This includes system integrity controls, access controls, audit controls, network controls, and remote service controls which map to the General Principles and Security Capabilities outlined in the FDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document issued on October 2, 2014.

Testing was completed on CARESCAPE B650 to show the device can withstand network storm, i.e. continue to monitor patients without rebooting when connected by wire to either MC, IX, or both networks which suffer broadcast storm traffic.

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

The subject of this premarket submission, CARESCAPE B650 did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE Healthcare considers the CARESCAPE B650 to be substantially equivalent to the predicate device(s).