April 13, 2022

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

Re: K213181
Trade/Device Name: CARESCAPE B650, E-musb
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, MUD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT, QEM
Dated: March 11, 2022
Received: March 14, 2022

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. 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,

for

Jennifer Shih Kozen
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CARESCAPE B650

Indications for Use *(Describe)*

The CARESCAPE B650 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital 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, regional oxygen saturation, total hemoglobin concentration, 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 CARESCAPE B650:
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.

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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:	September 27, 2021
Owner/Submitter:	GE Healthcare Finland Oy. Kuortaneenkatu 2 00510 Helsinki FINLAND Phone: +358 10 39411
Primary Contact Person:	Joel Kent Senior Regulatory Affairs Manager GE Healthcare Phone: 617-851-0943 E-mail: joel.kent@ge.com
Secondary Contact Person:	Karin Mårtenson Regulatory Affairs Leader GE Healthcare Finland Oy Kuortaneenkatu 2 00510 Helsinki Finland Phone: + 358 50 384 6646 E-mail: karin.martenson@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 870.2700 Oximeter, Tissue Saturation
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
21 CFR 870.2700 Cerebral Oximeter

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, MUD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT, QEM
Predicate Device(s) (807.92(a)(3):	The primary predicate for this submission is K191149 CARESCAPE B650 Additional predicates / reference devices: K182868, INVOS PM7100 Patient Monitor, INVOS Adult rSO2 Sensor K110028, MASIMO RADICAL Y PULSE CO-OXIMETER
Device Description (807.92(a)(4)):	CARESCAPE B650 is a new version of a portable multi-parameter patient monitoring system. The CARESCAPE B650 includes the monitor with built-in CPU, power unit, a 15 inch touch display, the CARESCAPE Software and the battery. CARESCAPE B650 is equipped with two module slots where patient data acquisition modules (E-Module type) can be connected to perform patient monitoring. CARESCAPE B650 is equipped with the ePort interface that supports use of PDM or CARESCAPE ONE patient data acquisition devices. In addition to the ePort interface the PDM module can be also connected directly to the CARESCAPE B650 via special slide mount connector which is in the back of the monitor. The CARESCAPE B650 includes features and subsystems that are optional or configurable.
Intended Use: (807.92(a)(5):	**Indications *(from labeling)*** The CARESCAPE B650 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital 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, regional oxygen saturation, total hemoglobin concentration, 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.

Technology (807.92(a)(6)): CARESCAPE B650 incorporates updated software and minor modifications to the hardware.

The fundamental function and operation of the proposed CARESCAPE B650 monitor are unchanged compared to CARESCAPE B650 (K191149).

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 B650 (K191149)	Proposed CARESCAPE B650	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
Intrahospital transport	Intrahospital transport within a professional healthcare facility.	Intrahospital transport within a professional healthcare facility.	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
Module Housing	Two E-module slots for two single-width E-modules or one double-width E-module and optional recorder. One slide mount for acquisition module.	Two E-module slots for two single-width E-modules and optional recorder. One slide mount for acquisition module.	Equivalent Added mechanical block to E-module housing mechanics and removed related electronic components, to prevent use of double-width legacy modules, that are no longer supported. There is no change to functionality of the E-module frame itself, only preventing users from connecting legacy E-modules that CARESCAPE B650 does not support
Display/screen	15” TFT color LCD	15” TFT color 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-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	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	Identical

Optional system components	-Remote Control -CARESCAPE D19KT VER01 optional display -CARESCAPE RAD, Remote Alarm Device -Keyboard -Mouse -Barcode scanner -Laser Printer	-Remote Control -CARESCAPE D19KT VER01 optional display -CARESCAPE RAD, Remote Alarm Device -Keyboard -Mouse -Barcode scanner -Laser Printer -E-musb Interface module	Equivalent Added E-musb Interface module that provides a communication path for the OEM owned devices CARESCAPE rSO2 – INVOS and CARESCAPE CO2 – Microstream to the CARESCAPE Bx50 host monitors
Available measurement 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, regional oxygen saturation, total hemoglobin concentration, 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.	Equivalent Added hemodynamic parameters (in bold) that are previously cleared but are new to the monitor: regional oxygen saturation and total hemoglobin concentration, often referred to as rSO2 and SpHb. The Indications for Use were updated accordingly. The CARESCAPE B650 does not change the measurement or algorithm of these parameters but simply displays the values from the OEM owned CARESCAPE parameter devices CARESCAPE SpO2 –Masimo and CARESCAPE rSO2 –INVOS.
EK-Pro arrhythmia detection algorithm	EK-Pro V14	EK-Pro V14	Identical
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
Mounting options	Multiple GCX mounting systems, Roll Stand, Quick Mount	Multiple GCX mounting systems, Roll Stand	Equivalent Quick Mount is obsolete and not sold anymore.

Alarms	Alarm management core functionalities: Classification and notification of alarms Adjustment of alarm settings Possibility to set critical alarm limits Alarm On/Off functionality and audio silencing	Alarm management core functionalities: Classification and notification of alarms Adjustment of alarm settings Possibility to set critical alarm limits Alarm On/Off functionality and audio silencing	Identical
Battery operation	Rechargeable Lithium-Ion batteries	Rechargeable Lithium- Ion batteries	Identical
Networking capability	CARESCAPE Network LAN/VLAN Optional WLAN	CARESCAPE Network LAN/VLAN Optional WLAN	Identical
Network interface	10baseT, 100baseT, 802.11 abgn, IEEE 802.11r fast roaming is supported.	10baseT, 100baseT, 802.11 abgn, IEEE 802.11r fast roaming is supported.	Identical

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.

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

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 as safe, as effective, and the performance to be substantially equivalent to the predicate device.