



April 13, 2022

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

Re: K213363

Trade/Device Name: CARESCAPE B450, 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, QEM, DQA, DQK,
DRT, DSI, DSJ, DSK, DXG, DXN, FLL, GWJ, GWQ, KOI, KRB, MLD, MUD, DPZ,
NHO, NHP, NHQ, OLT, OLW, ORT, OMC

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

Indications for Use

510(k) Number (if known)
K213363

Device Name
CARESCAPE B450

Indications for Use (Describe)

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

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

The CARESCAPE 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, 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 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 B450 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 B450 also shows alarms from other ECG sources.

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

The CARESCAPE 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

Contraindications for using the monitor

The CARESCAPE B450 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.

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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: October 12, 2021
Owner/Submitter: GE Healthcare Finland Oy.
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00510 Helsinki
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00510 Helsinki
Finland

Phone: + 358 50 384 6646

E-mail: karin.martenson@ge.com

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

Trade Name: CARESCAPE B450
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. cardiometer & 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) The primary predicate for this submission is K191249
(807.92(a)(3)): CARESCAPE B450

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 B450 is a new version of a portable multi-parameter patient monitoring system. The CARESCAPE B450 includes the monitor itself with built-in CPU, power unit, a 12 inch touch display, the CARESCAPE Software and one or two batteries. CARESCAPE B450 is equipped with an ePort interface that supports use of PDM or CARESCAPE ONE patient data acquisition modules for patient monitoring. CARESCAPE B450 is also equipped with one module slot where patient data acquisition modules (E-Modules), can be connected to perform patient monitoring. The CARESCAPE B450 includes features and subsystems that are optional or configurable.

Intended Use:
(807.92(a)(5)):

Indications for Use (from labeling)

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

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

The CARESCAPE 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, 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 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.

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

The CARESCAPE 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.

Contraindications for using the monitor

The CARESCAPE B450 is not intended for use in a controlled MR environment.

Technology (807.92(a)(6)): The CARESCAPE B450 incorporates updated software and minor modifications to the hardware.

The fundamental function and operation of the proposed CARESCAPE B450 monitor are unchanged compared to CARESCAPE B450 (K191249).

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 B450 (K191249)	Proposed CARESCAPE B450	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	290 x 310 x 160 mm (11.4 x 12.2 x 6.3 in) (H x W x D) and weight 4.7 kg (10.4 lbs) with two batteries inserted but without modules inserted.	290 x 310 x 160 mm (11.4 x 12.2 x 6.3 in) (H x W x D) and weight 4.7 kg (10.4 lbs) with two batteries inserted but without modules inserted.	Identical
Module Housing	One E-module slot and optional recorder. One slide mount for acquisition module.	One E-module slot and optional recorder. One slide mount for acquisition module.	Identical
Display/screen	Integrated 12" TFTcolor LCD Display	Integrated 12" TFTcolor LCD Display	Identical
Waveforms and parameter windows	Standard view: Up to 6 individual waveforms and up to 16 parameter windows, if horizontal parameter area turned on.	Standard view: Up to 6 individual waveforms and up to 16 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 B450 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, Bed Rail Hook, BRH	Multiple GCX mounting systems, roll stand, Bed Rail Hook, BRH	Equivalent Quick Mount is obsolete.
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
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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 B450, 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 B450 did not require clinical studies to support substantial equivalence.

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