January 29, 2020

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

Re: K191323
Trade/Device Name: CARESCAPE B850
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 23, 2019
Received: December 26, 2019

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,

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)*
K191323

Device Name
CARESCAPE B850

Indications for Use *(Describe)*
The CARESCAPE B850 is a multi-parameter patient monitor intended for use in multiple areas within a professional healthcare facility.
The CARESCAPE B850 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.
The CARESCAPE B850 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 B850 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 B850 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 B850 also shows alarms from other ECG sources.
The CARESCAPE B850 also provides other alarms, trends, snapshots and events, and calculations, and can be connected to displays, printers and recording devices.
The CARESCAPE B850 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 B850 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:	January 21, 2020
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:	Anssi Ruokonen Regulatory Affairs Leader GE Healthcare Finland Oy Kuortaneenkatu 2 00510 Helsinki Finland Phone: + 358 10 394 3686 E-mail: Anssi.ruokonen@ge.com

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

Trade Name:	CARESCAPE B850
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):	K131414 CARESCAPE Monitor B850
Device Description (807.92(a)(4)):	CARESCAPE B850 V3 is a new version of a modular multi-parameter patient monitoring system. The monitor includes a separate 19-inch touchscreen display, the central processing unit (also called CPU) and the module frame F5 or F7. CARESCAPE B850 V3 is equipped with an "ePort" interface that supports use of PDM or CARESCAPE ONE patient data acquisition modules for patient monitoring. In addition, the F5 module frame has five module slots, and the F7 module frame has seven module slots where patient data acquisition modules (E-Module type), can be connected to perform patient monitoring. The CARESCAPE B850 V3 includes features and subsystems that are optional or configurable.
Intended Use: (807.92(a)(5):	Indications *(from labeling)* The CARESCAPE B850 is a multi-parameter patient monitor intended for use in multiple areas within a professional healthcare facility. The CARESCAPE B850 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE B850 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 B850 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 B850 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 B850 also shows alarms from other ECG sources.

The CARESCAPE B850 also provides other alarms, trends, snapshots and events, and calculations, and can be connected to displays, printers and recording devices.

The CARESCAPE B850 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 B850 is not intended for use in a controlled MR environment.

Technology (807.92(a)(6)): CARESCAPE B850 with CARESCAPE Software version 3 incorporates updated hardware and a new software platform.

The fundamental function and operation of the proposed CARESCAPE B850 V3 monitor are unchanged compared to CARESCAPE Monitor B850 with ESP V2 software (K131414). There are no new types of monitored parameters introduced compared to the predicate B850 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 B850 with ESP V2 software (K131414)	CARESCAPE B850 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	91 x 401 x 340 mm (3.6 x 15.8 x 13.5 in) and weight 7.5 kg (16.5 lbs)	91 x 401 x 340 mm (3.6 x 15.8 x 13.5 in) and weight 7.5 kg (16.5 lbs)	Identical
Processor	Intel Celeron-M 423 ULV 1.06GHz	Freescale ARM Cortex-A9	Equivalent The CARESCAPE Bx50 V3 monitors have an updated common CPU platform.
Module Housing	Up to 12 optional E-module slots with F5 and F7 Frames. One slide mount for acquisition module	Up to 12 optional E-module slots with F5 and F7 Frames. One slide mount for acquisition module	Identical
Display/screen	19" Active matrix color TFT LCD	19" Active matrix color TFT LCD	Identical
Waveforms and parameter windows	Standard view: Up to 8 individual waveforms and up to 20, if horizontal parameter area turned on.	Standard view: Up to 8 individual waveforms and up to 20, 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, TRAM	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-sCAiOE, E-sCAiOV, E-sCAiOVX, E-sCAiOVE, E-sCO, E-sCOV, E-sCOVX, PDM, CARESCAPE ONE	Equivalent Removed support for several legacy E/M multiparameter hemodynamic acquisition modules as many newer acquisition modules are included, covering the same parameters. Added support for CARESCAPE ONE and E-EEGX acquisition modules. Added support for E-sCAiOVX and E-sCOVX modules (K150245).

Specification	CARESCAPE Monitor B850 with ESP V2 software (K131414)	CARESCAPE B850 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 B850 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 Version 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	Local recorder/printer and networked laser printer. Printings for waveforms, alarms waveforms, numeric trends	Local recorder/printer and networked laser printer. Printings for waveforms, alarms waveforms, numeric trends	Identical

Specification	CARESCAPE Monitor B850 with ESP V2 software (K131414)	CARESCAPE B850 with CSP software version V3	Differences
Mounting options	Multiple GCX mounting systems	Multiple GCX mounting systems	Identical
Alarms	Alarm management core functionalities: Classification and notification of alarms Adjustment of alarm settings 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	Equivalent 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. In general, options for tailored/specific alarm management schemes have been added supporting clinicians in their goals of reducing alarm fatigue while maintaining safety. Default setting are according to IEC 60601-1-8.
Specification	**CARESCAPE Monitor B850 with ESP V2 software**	**CARESCAPE B850 with CSP software version V3**	**Differences**

	(K131414)		
Remote Alarm Device	Alarm Interface to the Remote Alarm Box with Remote Light (RAB RL).	Alarm Interface to the Remote Alarm Device, CARESCAPE RAD	Equivalent CARESCAPE RAD replaces the Remote Alarm Box with Remote Light (RAB RL) device. The CARESCAPE RAD is the new accessory for use with the CARESCAPE Bx50 V3. The proposed accessory communicates with the CARESCAPE Bx50 V3 via a standard USB connection. 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 Bx50 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.
Networking capability	CARESCAPE Network LAN/VLAN	CARESCAPE Network LAN/VLAN Single wire network configuration supported for CARESCAPE Networks	Equivalent The single wire network configuration simplifies the installation and maintenance of CARESCAPE Bx50 V3 patient monitors. The single wire network configuration has no impact on clinical monitoring.
Network interface	10baseT, 100baseT	10baseT, 100baseT	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 B850, demonstrating the design meets the specifications.

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

The CARESCAPE B850 has been found to substantially equivalent to the predicate device(s) for the intended users, uses and use environments. Extensive usability work has been completed for CARESCAPE B850 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 B850 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 B850 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 B850 did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE Healthcare considers the CARESCAPE B850 to be substantially equivalent to the predicate device(s).