April 6, 2023

GE Healthcare Finland Oy
Joel Kent
Director Regulatory Affairs Strategy
Kuortaneenkatu 2
Helsinki, FI-00510
Finland

Re: K223531
Trade/Device Name: CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, F2 Frame (F2-01)
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, BZQ, CCK, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXG, DXN, FLL, KRB, MLD, MUD, QEM, BZK, BZL, CAP, CBQ, CBR, CBS, CCL, GWJ, GWQ, KOI, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
Dated: November 23, 2022
Received: March 8, 2023

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 Shruti N. Mistry -S

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.

Submission Number *(if known)*

K223531

Device Name

CARESCAPE Canvas 1000;
CARESCAPE Canvas Smart Display;
CARESCAPE Canvas D19;
F2 Frame (F2-01)

Indications for Use *(Describe)*

Indications for Use for CARESCAPE Canvas 1000:
CARESCAPE Canvas 1000 is a multi-parameter patient monitor intended for use in multiple areas within a professional healthcare facility.
CARESCAPE Canvas 1000 is intended for use on adult, pediatric, and neonatal patients one patient at a time.
CARESCAPE Canvas 1000 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).
CARESCAPE Canvas 1000 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. CARESCAPE Canvas 1000 also shows alarms from other ECG sources.
CARESCAPE Canvas 1000 also provides other alarms, trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices.
CARESCAPE Canvas 1000 can interface to other devices. It can also be connected to other monitors for remote viewing and to data management software devices via a network.
CARESCAPE Canvas 1000 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.
CARESCAPE Canvas 1000 is not intended for use in an MRI environment.

Indications for Use for CARESCAPE Canvas Smart Display:
CARESCAPE Canvas Smart Display is a multi-parameter patient monitor intended for use in multiple areas within a professional healthcare facility.
CARESCAPE Canvas Smart Display is intended for use on adult, pediatric, and neonatal patients one patient at a time.
CARESCAPE Canvas Smart Display 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 temperature, and
• respiratory (impedance respiration, airway gases (CO2)

CARESCAPE Canvas Smart Display 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. CARESCAPE Canvas Smart Display also shows alarms from other ECG sources.
CARESCAPE Canvas Smart Display also provides other alarms, trends, snapshots and events.
CARESCAPE Canvas Smart Display can use CARESCAPE ONE or CARESCAPE Patient Data Module (PDM) as patient data acquisition devices. It can also be connected to other monitors for remote viewing and to data management software devices via a network.
CARESCAPE Canvas Smart Display 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.
CARESCAPE Canvas Smart Display is not intended for use in an MRI environment.

Indications for Use for CARESCAPE Canvas D19:
CARESCAPE Canvas D19 is intended for use as a secondary display with a compatible host device. It is intended for displaying measurement and parametric data from the host device and providing visual and audible alarms generated by the host device.
CARESCAPE Canvas D19 enables controlling the host device, including starting and discharging a patient case, changing parametric measurement settings, changing alarm limits and disabling alarms.
Using CARESCAPE Canvas D19 with a compatible host device enables real-time multi-parameter patient monitoring and continuous evaluation of the patient's ventilation, oxygenation, hemodynamic, circulation, temperature, and neurophysiological status.

Indications for Use for F2 Frame; F2-01:
The F2 Frame, module frame with two slots, is intended to be used with compatible GE multiparameter patient monitors to interface with two single width parameter modules, CARESCAPE ONE with a slide mount, and recorder.
The F2 Frame is intended for use in multiple areas within a professional healthcare facility. The F2 Frame is intended for use under the direct supervision of a licensed healthcare practitioner, or by person trained in proper use of the equipment in a professional healthcare facility.
The F2 Frame is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

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 for K223531

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

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

Date: November 23, 2022

Owner/Submitter: GE Healthcare Finland Oy.
Kuortaneenkatu 2
00510 Helsinki
FINLAND
Phone: +358 10 39411

Primary Contact Person: Joel Kent
Director, Regulatory Affairs Strategy
GE Healthcare

Phone: 617-851-0943

E-mail: joel.kent@ge.com

Secondary Contact Person:

Päivi Roiha
Regulatory Affairs Manager
GE Healthcare Finland Oy
Kuortaneenkatu 2
00510 Helsinki
Finland

Phone: + 358 40 768 4664

E-mail: paivi.roiha@ge.com

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

Trade Name: CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display CARESCAPE Canvas D19, and F2 Frame (F2-01)

Common/Usual Name: Multiparameter patient monitor (monitor, physiological, patient (with arrhythmia detection or alarms)

Classification Names:

MHX - 21 CFR 870.1025 monitor, physiological, patient (with arrhythmia detection or alarms)
DSI - 21 CFR 870.1025 detector and alarm, arrhythmia
MLD - 21 CFR 870.1025 monitor, St Segment with alarm
DSJ - 21 CFR 870.1100 alarm, blood-pressure
DSK - 21 CFR 870.1110 computers, blood-pressure
DXN - 21 CFR 870.1130 system, measurement, blood-pressure, non-invasive
DQK - 21 CFR 870.1425 Programmable diagnostic computer
DXG - 21 CFR 870.1435 computer, diagnostic, pre-programmed, single-function
KRB - 21 CFR 870.1915 probe, thermodilution
DRT - 21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)
DPS - 21 CFR 870.2340 Electrocardiograph
DQA - 21 CFR 870.2700 oximeter
MUD - 21 CFR 870.2700 oximeter, tissue saturation
QEM - 21 CFR 870.2700 cerebral oximeter
DPZ - 21 CFR 870.2710 oximeter, ear
CCK - 21 CFR 868.1400 Carbon dioxide gas analyzer
BZQ - 21 CFR 868.2375 monitor, breathing frequency
FLL - 21 CFR 880.2910 Clinical electronic thermometer
BZK - 21 CFR 868.1850 spirometer, monitoring (w/wo alarm)
BZL - 21 CFR 868.1730 computer, oxygen-uptake
CAP - 21 CFR 868.2600 monitor, airway pressure (includes gauge and/or alarm)
CBQ - 21 CFR 868.1500 analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)
NHO - 21 CFR 868.1500 analyzer, gas, desflurane, gaseous-phase (anesthetic concentration)
NHP - 21 CFR 868.1500 analyzer, gas, sevoflurane, gaseous-phase (anesthetic concentration)
NHQ - 21 CFR 868.1500 analyzer, gas, isoflurane, gaseous-phase (anesthetic concentration)
CBS - 21 CFR 868.1620 analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
CBR - 21 CFR 868.1700 analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
CCL - 21 CFR 868.1720 analyzer, gas, oxygen, gaseous-phase
GWQ - 21 CFR 882.1400 full-montage standard electroencephalograph
OLT - 21 CFR 882.1400 non-normalizing quantitative electroencephalograph software
OLW - 21 CFR 882.1400 index-generating electroencephalograph software
OMC - 21 CFR 882.1400 reduced- montage standard electroencephalograph
ORT - 21 CFR 882.1400 burst suppression detection software for electroencephalograph
GWJ - 21 CFR 882.1900 stimulator, auditory, evoked response
KOI - 21 CFR 868.2775 stimulator, nerve, peripheral, electric

Product Code:	MHX
Subsequent Product Codes:	BZQ, CCK, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXG, DXN, FLL, KRB, MLD, MUD, QEM, BZK, BZL, CAP, CBQ, CBR, CBS, CCL, GWJ, GWQ, KOI, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
Predicate Device(s) (807.92(a)(3)):	The primary predicate for this submission is K213336 CARESCAPE B850 V3.2 Reference devices: K213490 Monitor B105M, Monitor B125M, Monitor B155M, Monitor B105P, Monitor B125P K211171 CARESCAPE Respiratory Modules E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories
Device Description (807.92(a)(4)):	Hardware and software modifications carried out on the legally marketed predicate device CARESCAPE B850 V3.2, resulted in new products CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display, along with the CARESCAPE Canvas D19 and F2 Frame (F2-01) all of which are the subject of this submission. CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display are new modular multi-parameter patient monitoring systems. In addition, the new devices CARESCAPE Canvas D19 and F2 Frame (F2-01) are a new secondary display and new module frame respectively. The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display patient monitors incorporates a 19-inch display with a capacitive touch screen and the screen content is user-configurable. They have an integrated alarm light and USB connectivity for other user input devices. The user interface is touchscreen-based and can be used also with a mouse and a keyboard or a remote controller. The system also includes the medical application software (CARESCAPE Software version 3.3). The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display include features and subsystems that are optional or configurable. The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display are compatible with the CARESCAPE Patient Data Module and CARESCAPE ONE acquisition device via F0 docking station (cleared separately). For the CARESCAPE Canvas 1000 patient monitor, the other type of acquisition modules, E-modules (cleared separately) can be chosen based on care requirements and patient needs. Interfacing subsystems that can be used to connect the E-modules to the CARESCAPE Canvas 1000 include

a new two-slot parameter module F2 frame (F2-01), a five-slot parameter module F5 frame (F5-01), and a seven-slot parameter module F7 frame (F7-01).

The CARESCAPE Canvas 1000 can also be used together with the new secondary CARESCAPE Canvas D19 display. The CARESCAPE Canvas D19 display provides a capacitive touch screen, and the screen content is user configurable. The CARESCAPE Canvas D19 display integrates audible and visual alarms and provides USB connectivity for other user input devices.

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

The indications for use of the CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display have been updated compared to the predicate CARESCAPE B850 (K213336). The updates are related to clarity of labeling, and CARESCAPE Canvas Smart Display for changes of modified functionality due to reduced support of interfaces. We also include explicit indications for CARESCAPE Canvas D19 and F2 Frame (F2-01) where previously the secondary display and frame functionality was included as part of the main CARESCAPE B850 indications.

Indications (from labeling)

CARESCAPE Canvas 1000

CARESCAPE Canvas 1000 is a multi-parameter patient monitor intended for use in multiple areas within a professional healthcare facility. CARESCAPE Canvas 1000 is intended for use on adult, pediatric, and neonatal patients one patient at a time.

CARESCAPE Canvas 1000 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).

CARESCAPE Canvas 1000 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. CARESCAPE Canvas 1000 also shows alarms from other ECG sources.

CARESCAPE Canvas 1000 also provides other alarms, trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices.

CARESCAPE Canvas 1000 can interface to other devices. It can also be connected to other monitors for remote viewing and to data management software devices via a network.

CARESCAPE Canvas 1000 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.

CARESCAPE Canvas 1000 is not intended for use in an MRI environment.

CARESCAPE Canvas Smart Display

CARESCAPE Canvas Smart Display is a multi-parameter patient monitor intended for use in multiple areas within a professional healthcare facility.

CARESCAPE Canvas Smart Display is intended for use on adult, pediatric, and neonatal patients one patient at a time.

CARESCAPE Canvas Smart Display 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 temperature, and
• respiratory (impedance respiration, airway gases (CO2)

CARESCAPE Canvas Smart Display 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. CARESCAPE Canvas Smart Display also shows alarms from other ECG sources.

CARESCAPE Canvas Smart Display also provides other alarms, trends, snapshots and events.

CARESCAPE Canvas Smart Display can use CARESCAPE ONE or CARESCAPE Patient Data Module (PDM) as patient data acquisition devices. It can also be connected to other monitors for remote viewing and to data management software devices via a network.

CARESCAPE Canvas Smart Display 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.

CARESCAPE Canvas Smart Display is not intended for use in an MRI environment.

Indications for Use for CARESCAPE Canvas D19

CARESCAPE Canvas D19 is intended for use as a secondary display with a compatible host device. It is intended for displaying measurement and parametric data from the host device and providing visual and audible alarms generated by the host device.

CARESCAPE Canvas D19 enables controlling the host device, including starting and discharging a patient case, changing parametric measurement settings, changing alarm limits and disabling alarms.

Using CARESCAPE Canvas D19 with a compatible host device enables real-time multi-parameter patient monitoring and continuous evaluation of the patient's ventilation, oxygenation, hemodynamic, circulation, temperature, and neurophysiological status.

Indications for Use for F2 Frame; F2-01

The F2 Frame, module frame with two slots, is intended to be used with compatible GE multiparameter patient monitors to interface with two single width parameter modules, CARESCAPE ONE with a slide mount, and recorder.
The F2 Frame is intended for use in multiple areas within a professional healthcare facility. The F2 Frame is intended for use under the direct supervision of a licensed healthcare practitioner, or by person trained in proper use of the equipment in a professional healthcare facility.
The F2 Frame is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

Technology (807.92(a)(6)): The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display are new monitors where features and parameters are essentially same as in predicate monitor platform CARESCAPE B850 V3.2 (K213336). The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display monitors use the CARESCAPE Software Platform (also called CSP software) version 3.3 whereas the predicate monitor CARESCAPE B850 (K213336) has software version 3.2.

The CARESCAPE Canvas D19 is a new secondary display where the functionality is essentially same as in predicate D19KT Display of CARESCAPE B850 V3.2 (K213336).

The F2 Frame (F2-01) is a new parameter module frame for interfacing with acquisition devices with essentially same functionality as in predicate F5 Frame (F5-01) of CARESCAPE B850 V3.2 (K213336).

The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display with CSP v3.3 software has following changes at high level.

The devices that are subject of this 510(k) submission are the proposed new patient monitors CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display with the software CARESCAPE Software version 3.3. The new patient monitors CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display incorporate new hardware with modified software from the legally marketed device CARESCAPE B850 V3.2 (K213336).

The CARESCAPE Canvas 1000 V3.3 and CARESCAPE Canvas Smart Display V3.3 monitors incorporate new common hardware platform.

The CARESCAPE Canvas 1000 V3.3 and CARESCAPE Canvas Smart Display V3.3 monitors include Platform Software that has been updated from version 3.2 to version 3.3.

The CARESCAPE Canvas 1000 V3.3 and CARESCAPE Canvas Smart Display V3.3 monitors utilize the same type of measurement parameters as the predicate device.

The indications for use for CARESCAPE Canvas 1000 V3.3 and CARESCAPE Canvas Smart Display V3.3 are equivalent to the predicate device CARESCAPE B850 V3.2 (K213336) with changes mostly related to language clarity and text alignment with modified functionality.

The CARESCAPE Canvas 1000 V3.3 and CARESCAPE Canvas Smart Display V3.3 use the same fundamental technology, functions and operations as that of the predicate device CARESCAPE B850 V3.2 (K213336).

The detailed comparison between the proposed CARESCAPE Canvas 1000 V3.3, CARESCAPE Canvas Smart Display V3.3, CARESCAPE Canvas D19 and F2 Frame (F2-01) and the predicate is presented in Substantial Equivalence Comparison and a summary of the primary changes within this submission are listed below.
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 B850 (K213336)	Proposed CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display CARESCAPE Canvas D19, and F2 Frame (F2-01)	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 mm x 401 mm x 340 mm (3.6 in x 15.8 in x 13.4 in) and weight 7.5 kg (16.5 lbs)	388 mm x 440 mm x 126 mm (15.3 x 17.3 x 5.0 in) and weight Canvas 1000 V3.3: 7.6 kg (16.6 lb) Canvas Smart V3.3: 7.4 kg (16.3 lb)	Equivalent
Module Housing	Up to 12 optional E-module slots with F5 and F7 Frames. One slide mount for acquisition module	Canvas 1000 V3.3: Two/Five/Seven optional E-module slots in F2/F5/F7 Frame. One slide mount for acquisition module.	Equivalent
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	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	Canvas 1000 V3.3. & Canvas Smart V3.3.: PDM, CARESCAPE ONE Canvas 1000 V3.3: 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, E-sCAiOE and E-sCAiOVE	Equivalent
Specification	CARESCAPE B850 (K213336)	Proposed CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display CARESCAPE Canvas D19, and F2 Frame (F2-01)	Differences

Optional system components	-Remote Control -CARESCAPE D19KT VER01 display -CARESCAPE RAD, Remote Alarm Device -Keyboard -Mouse -Barcode scanner -Laser Printer	Canvas 1000 V3.3. & Canvas Smart V3.3.: -Remote Control -Keyboard -Mouse -Barcode scanner CARESCAPE RAD, Remote Alarm Device -Laser Printer Canvas 1000 V3.3: E-musb Interface module CARESCAPE Canvas D19 display	Equivalent
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.	Canvas 1000 V3.3: 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. Canvas Smart V3.3: 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), temperature, impedance respiration, airway gases (CO2)	Equivalent
Specification	CARESCAPE B850 (K213336)	Proposed CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display CARESCAPE Canvas D19, and F2 Frame (F2-01)	Differences

EK-Pro arrhythmia detection algorithm	EK-Pro V14	EK-Pro V14	Identical
Printing	Local recorder/printer and networked laser printer. Printings for waveforms, alarms waveforms, numeric trends.	Canvas 1000 V3.3. & Canvas Smart V3.3.: Networked laser printer. Printings for waveforms, alarms waveforms, numeric trends Canvas 1000 V3.3: Local recorder/local printer	Equivalent
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 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
Networking capability	CARESCAPE Network LAN/VLAN	CARESCAPE Network LAN/VLAN	Identical
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 Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19 and F2 Frame (F2-01) demonstrating the design meets the specifications.

This section addresses the non-Clinical testing for CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19 and F2 Frame (F2-01) relied on for a determination of substantial equivalence to the predicate K213336 CARESCAPE B850.

Per the FDA guidance titled "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff, Document issued on December 20, 2019", the following was verified:

- Hardware Bench Testing
- Alarms Bench Testing

- IEC 60601-2-25:2011
- IEC 60601-2-27:2011
- IEC 80601-2-30: 2018
- IEC 60601-2-34: 2011
- ISO 80601-2-55: 2018
- ISO 80601-2-56: 2017+AMD1:2018
- ISO 80601-2-61: 2017 (corrected 2018
- IEC 80601-2-26:2019
- IEC 60601-2-40: 2016
- AAMI/ANSI EC57:2012
- IEC 80601-2-49: 2018

The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display monitoring systems meet the EMC requirements described in IEC 60601-1-2 Edition 4.1 2020 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests". Compliance according to the "Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff, issued on June 6, 2022" the CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display monitoring systems have been evaluated for electromagnetic compatibility and potential risks from common emitters in the CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display systems environment.

The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display monitoring systems meet the electrical safety requirements of IEC 60601-1:2020 "Medical electrical equipment

- Part 1: General requirements for basic safety and essential performance - Edition 3.2". This testing was performed by a recognized independent and Certified Body Testing Laboratory (CBTL) under the IECEE CB Scheme.

The CARESCAPE Canvas 1000 and CARESCAPE Canvas Smart Display systems were designed and tested for compliance to the FDA 21 CFR Part 898, § 898.12 (Performance standard for electrode lead wires and cables). The performance standard is fulfilled through compliance with IEC 60601-1:2020, Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance – Edition 3.2. clause 8.5.2.3 which is equivalent with clause 56.3 c in the IEC 60601-1:1988.

Additional data is provided for compliance to:

- IEC 60601-1-8: 2020 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
- IEC 60601-2-25:2011: Medical electrical equipment Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-2-27:2011: Medical electrical equipment Part 2-27: Particular Requirements for the Safety, Including Essential Performance of Electrocardiographic Monitoring Equipment
- IEC 80601-2-30: 2018: Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34: 2011: Medical electrical equipment Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
- IEC 80601-2-49: 2018: Medical electrical equipment Part 2-49: Particular requirements for the safety essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55: 2018: Medical electrical equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56: 2017+AMD1:2018: Medical electrical equipment Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 80601-2-61: 2017 (corrected 2018): Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

- IEC 80601-2-26:2019: Medical electrical equipment Part 2-26: Particular requirements for the safety and essential performance of electroencephalographs
- IEC 60601-2-40: 2016: Medical Electrical Equipment Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- ANSI/AAMI EC57:2012: Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

Environmental (Mechanical, and Thermal Safety) testing, based on the CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01) proposed uses and locations, was confirmed to meet the specifications listed in the requirements. The CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01) specifications verification evidence is included for the following:

- Operating temperature
- Operating humidity
- Operating pressure
- Storage and transport temperature
- Storage and transport humidity
- Storage and transport pressure
- Mechanical stress
- Fluid ingress
- Packaging Bench Testing

The CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01) follow the guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff. Document issued on: March 17, 2015”. Reprocessing efficacy validation has been conducted in accordance with the documented reprocessing instructions using worst-case devices/components of the CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01). The reprocessing efficacy validation met the acceptance criteria for the reprocessing efficacy validation tests.

The CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01) follows the Applying Human Factors and Usability Engineering to Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on: February 3, 2016 and the following standards:

- IEC 60601-1-6: 2020: Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1: 2020: Medical devices Part 1: Application of usability engineering to medical devices

Summative Usability testing has been concluded with 16 US Clinical, 16 US Technical and 15 US Cleaning users. The usability testing of the CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01) follows the FDA Guidance for Industry and Food and Drug Administration Staff "Applying Human Factors and Usability Engineering to Medical Devices" (Feb 3, 2016).

The CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01) follow the FDA software guidance documents as outlined in this submission.

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on May 11, 2005
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on January 11, 2002
- Off-The-Shelf Software Use in Medical Devices; Guidance for Industry and Food and Drug Administration Staff, Document issued on September 27, 2019
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff issued October 18, 2018
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, Document issued on September 6, 2017

Software testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered as a "Major" level of concern. Software standards IEC 62304: 2015 Medical device software - Software life cycle processes and risk management standard ISO 14971:2019 Medical devices - Application of risk management to medical devices were also applied to the design.

Patient safety, security, and privacy risks have been addressed in the design and development of CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D10 and F2 Frame (F2-01) including a Security Risk Assessment,

Threat model and Penetration testing. This includes system integrity controls, access controls, audit controls, network controls, and remote service controls which address the General Principles and Security Capabilities outlined in the "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff issued October 18, 2018".

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

The subjects of this premarket submission, CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19 and F2 Frame (F2-01) did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE Healthcare considers the CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display, CARESCAPE Canvas D19, and F2 Frame (F2-01) to be substantially equivalent to the predicate device.