August 28, 2026

GE Healthcare Finland Oy
Päivi Roiha
Regulatory affairs manager
Kuortaneenkatu 2
Helsinki, FI-00510
Finland

Re: K260343
Trade/Device Name: Carescape Canvas 1000; Carescape Canvas Smart Display
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: February 2, 2026
Received: July 27, 2026

Dear Päivi Roiha:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

KIMBERLY N. CROWLEY -S

For: Jennifer Kozen
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260343	?

Please provide the device trade name(s). ?

Carescape Canvas 1000;
Carescape Canvas Smart Display

Please provide your Indications for Use below. ?

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 a controlled 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 a controlled MRI environment.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

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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: February 2, 2026

Owner/Submitter:
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Primary Contact Person:
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Device names (807.92(a)(2)):

Trade Name: Carescape Canvas 1000, Carescape Canvas Smart Display

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

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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

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Product Code:	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 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)):	Primary predicate: The predicate for this submission is K223531 CARESCAPE Canvas 1000 with CARESCAPE software version 3.3, and CARESCAPE Canvas Smart Display with CARESCAPE software version 3.3 patient monitors Reference device: The reference device for this submission is K211561 INVOS PM7100 Patient Monitor, INVOS Pediatric rSO2 Sensor, INVOS Infant Regional Saturation Sensor (also referred to as OxyAlert NIRSensor)
Device Description (807.92(a)(4)):	Carescape Canvas 1000 and Carescape Canvas Smart Display are new versions of a modular multi-parameter patient monitors. 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 4.0). The Carescape Canvas 1000 with Carescape software version 4.0 (referred to as Canvas 1000 V4.0) and Carescape Canvas Smart Display with Carescape software version 4.0. (referred to as Canvas Smart V4.0) 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 or Carescape ONE acquisition device via F0 docking station. For the Carescape Canvas 1000 patient monitor, the other type of acquisition modules, E-modules can be chosen based on care requirements

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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 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)):

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

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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 a controlled 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.

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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 a controlled MRI environment.

Technology (807.92(a)(6)): Software modifications carried out on the legally marketed predicates CARESCAPE Canvas 1000 with CARESCAPE software version 3.3, and CARESCAPE Canvas Smart Display with CARESCAPE software version 3.3 patient monitors, resulted in the new products Carescape Canvas 1000 and Carescape Canvas Smart Display which are the subject of this submission. Proposed Carescape Canvas 1000 and Carescape Canvas Smart Display have nearly identical hardware as predicate devices except for a few minor updates to hardware components.

The update introduces no technical changes to the Indications for Use, but adds compatibility with Carescape ONE v4.0 (CS ONE v4.0), re-branded micro-modules, and a revised OEM INVOS rSO_2 micro-module, while ensuring compliance with newly revised standards. It includes updates to user documentation, an updated user interface, enhanced alarm terminology, support for an updated Unity network protocol, updated printing capabilities, and calculation updates. The release also delivers enhancements to patient case management and intra-hospital transport monitoring support. Although the fundamental technology remains the same minor updates and/or improvements were implemented across multiple monitoring parameters, including ECG, invasive pressure, non-invasive blood pressure (NIBP), regional cerebral oxygen saturation (rSO_2), impedance respiration, carbon dioxide (CO_2), temperature, spirometry and gas exchange, electroencephalography (EEG), entropy, and neuromuscular transmission (NMT). In addition, the update incorporates continuous improvements in cybersecurity.

The Carescape Canvas 1000 and Carescape Canvas Smart Display monitors include Platform Software that has been updated from version 3.3 to version 4.0.

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

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The indications for use for Carescape Canvas 1000 and Carescape Canvas Smart Display are equivalent to the predicate.

The fundamental function and operation of the proposed Carescape Canvas 1000 and Carescape Canvas Smart Display monitors are unchanged compared to the predicate CARESCAPE Canvas 1000 with CARESCAPE software version 3.3, and CARESCAPE Canvas Smart Display with CARESCAPE software version 3.3 patient monitors (K223531).

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

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Subject Device and Predicate Device Comparison

Specification	The legally marketed predicate CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display (K223531)	Proposed Carescape Canvas 1000, Carescape Canvas Smart Display	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	388 mm x 440 mm x 126 mm (15.3 x 17.3 x 5.0 in) and weight Canvas 1000 V3.3: 7.5 kg (16.6 lb) Canvas Smart V3.3: 7.2 kg (16.3 lb)	388 mm x 440 mm x 126 mm (15.3 x 17.3 x 5.0 in) and weight Canvas 1000 V4.0: 7.5 kg (16.6 lb) Canvas Smart V4.0: 7.2 kg (16.3 lb)	Identical
Module Housing	Canvas 1000 V3.3: Two/Five/Seven optional E-module slots in F2/F5/F7 Frame. One slide mount for acquisition module.	Canvas 1000 V4.0: Two/Five/Seven optional E-module slots in F2/F5/F7 Frame. 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	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	Canvas 1000 V4.0 & Canvas Smart V4.0: PDM, CARESCAPE ONE Canvas 1000 V4.0: 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	Identical
Specification	**The legally marketed predicate CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display (K223531)**	**Proposed Carescape Canvas 1000, Carescape Canvas Smart Display**	**Differences**

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Optional system components	Canvas 1000 V3.3 & Canvas Smart V3.3: -Remote Control -Keyboard -Mouse -Barcode scanner CARESCAPE RAD, Remote Alarm Device -Laser Printer Canvas 1000: E-musb Interface module Carescape Canvas D19 display	Canvas 1000 V4.0 & Canvas Smart V4.0: -Remote Control -Keyboard -Mouse -Barcode scanner CARESCAPE RAD, Remote Alarm Device -Laser Printer Canvas 1000: E-musb Interface module Carescape Canvas D19 display	Identical
Available measurement parameters	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: 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)	Canvas 1000 V4.0: 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: 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)	Identical
Specification	**The legally marketed predicate CARESCAPE Canvas 1000, CARESCAPE Canvas Smart Display (K223531)**	**Proposed Carescape Canvas 1000, Carescape Canvas Smart Display**	**Differences**

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Printing	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	Canvas 1000 V4.0 & Canvas Smart V4.0: Networked laser printer. Printings for waveforms, alarms waveforms, numeric trends Canvas 1000 V4.0: Local recorder/local printer	Identical
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 and Carescape Canvas Smart Display demonstrating the design meets the specifications.

This section addresses the Non-Clinical testing for Carescape Canvas 1000, and Carescape Canvas Smart Display relied on for a determination of substantial equivalence to the predicate K223531 CARESCAPE Canvas 1000 with CARESCAPE software version 3.3, and CARESCAPE Canvas Smart Display with CARESCAPE software version 3.3 patient monitors.

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

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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 + AMD1 2023
- ISO 80601-2-56: 2017+AMD1:2018
- ISO 80601-2-61: 2017 (corrected 2018
- IEC 80601-2-26:2019
- IEC 60601-2-40: 2024
- IEC 80601-2-49: 2018
- IEC 80601-2-49:2024, EMC only)
- IEC 80601-2-26:2024

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.

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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 Note: IEC 80601-2-49:2024 EMC only

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- ISO 80601-2-55: 2018 + AMD1 2023: 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 80601-2-26:2024: Medical electrical equipment Part 2-26: Particular requirements for the safety and essential performance of electroencephalographs
- IEC 60601-2-40: 20246: Medical Electrical Equipment Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Environmental (Mechanical, and Thermal Safety) testing, based on the Carescape Canvas 1000 and Carescape Canvas Smart Display, proposed uses and locations has been confirmed to meet the specifications listed in the requirements.

The Carescape Canvas 1000 and Carescape Canvas Smart Display 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”.

The Carescape Canvas 1000 and Carescape Canvas Smart Display 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

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Summative Usability testing has been concluded with 35 US Clinical users. The usability testing of the Carescape Canvas 1000 and Carescape Canvas Smart Display 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 and Carescape Canvas Smart Display follow the FDA software guidance documents as outlined in this submission.

- Guidance for Industry - Content of Premarket Submissions for Device Software Functions, issued June 14, 2023
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
- Guidance for Industry - Computer Software Assurance for Production and Quality System Software, issued September 24, 2025
- Guidance for Industry - Off-The-Shelf Software Use in Medical Devices, August 11, 2023
- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software January 14, 2005
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Document issued on June 27, 2025
- Guidance - Recommendations for Interoperable Medical Devices, Document issued on September 6, 2017

Software development and testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry - Content of Premarket Submissions for Device Software Functions, issued June 14, 2023. The software for this device follows Enhanced Documentation level. 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.

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Patient safety, security, and privacy risks have been addressed in the design and development of Carescape Canvas 1000 and Carescape Canvas Smart Display 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 Guidance for Industry and Food and Drug Administration Staff issued on June 27, 2025".

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

The subjects of this premarket submission, Carescape Canvas 1000 and Carescape Canvas Smart Display did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE HealthCare considers the Carescape Canvas 1000 and Carescape Canvas Smart Display to be substantially equivalent to the predicate device.