September 1, 2026

GE Healthcare Finland Oy
Anssi Ruokonen
Program Manager, Regulatory Affairs, Monitoring Solutions
Contact Address

Re: K260656
Trade/Device Name: Carescape ONE; Carescape Dock F0; TruSignal ECG MM; TruSignal PRES MM; TruSignal TEMP MM; TruSignal SpO2 MM 1.8M; TruSignal SpO2 MM 3.0M
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, DXN, FLL, MLD, MUD, QEM
Dated: February 27, 2026
Received: July 27, 2026

Dear Anssi Ruokonen:

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,

JENNIFER W. SHIH -S

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260656 ?

Please provide the device trade name(s). ?

Carescape ONE;
Carescape Dock F0;
TruSignal ECG MM;
TruSignal PRES MM;
TruSignal TEMP MM;
TruSignal SpO2 MM 1.8M;
TruSignal SpO2 MM 3.0M

Please provide your Indications for Use below. ?

Carescape ONE:

Carescape ONE is both a multi-parameter physiological patient monitor and an accessory to a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility.

Carescape ONE is indicated for the monitoring of hemodynamic and respiratory physiological parameters.

When the Carescape ONE is operated as a standalone multi-parameter physiological patient monitor, it provides the following physiological parameters:

• ECG (heart rate, ST segment, and arrhythmia detection)
• Pulse oximetry (pulse rate, functional oxygen saturation [SpO2])
• Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)
• Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)
• Temperature
• Respiratory carbon dioxide (EtCO2, FiCO2, and respiration rate)
• Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible Host Monitor, it provides the following physiological parameters to the Host Monitor:

• ECG (heart rate, ST segment, and arrhythmia detection)
• Pulse oximetry (pulse rate, functional oxygen saturation [SpO2], and total hemoglobin concentration [SpHb])
• Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)
• Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)
• Regional oxygen saturation (rSO2)
• Temperature
• Respiratory carbon dioxide (EtCO2, FiCO2, and respiration rate)
• Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible host monitor, visual and audible alarms, user controls, and user interface are provided on the compatible host monitor and not on Carescape ONE.

When Carescape ONE is operated as a transportable monitor, it can interface with a compatible host monitor to provide data for remote viewing and data management software devices via a network.

Carescape ONE is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

Carescape ONE is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Contraindications for using Carescape ONE:

The Carescape ONE is not intended for use within a controlled MR environment.

Carescape Dock F0:

Carescape Dock F0 is intended for providing a DC power source to a docked Carescape ONE, which also charges the Carescape ONE battery. Carescape Dock F0 is intended to provide a docked Carescape ONE with communication to the host monitor.

The Carescape Dock F0 is indicated for use in multiple areas within a professional healthcare facility.

The Carescape Dock F0 is indicated 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 Carescape Dock F0 is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time.

Contraindications for using Carescape Dock F0:

The Carescape Dock F0 is not intended for use within a controlled MR environment.

TruSignal ECG MM

The TruSignal ECG MM is intended for monitoring of electrocardiogram and impedance respiration. TruSignal ECG MM is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal ECG MM Device

The TruSignal ECG MM is not intended for use within a controlled MR environment.

TruSignal PRES MM

The TruSignal PRES MM is intended for monitoring of invasive pressure and pulse rate. TruSignal PRES MM is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal PRES MM Device

The TruSignal PRES MM is not intended for use within a controlled MR environment.

TruSignal TEMP MM

The TruSignal TEMP MM is intended for monitoring of temperature. TruSignal TEMP MM is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal TEMP MM Device

The TruSignal TEMP MM is not intended for use within a controlled MR environment.

TruSignal SpO2 MM 1.8M

The TruSignal SpO2 MM 1.8M is intended for monitoring arterial oxygen saturation and pulse rate. TruSignal SpO2 MM 1.8M is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal SpO2 MM 1.8M Device

The TruSignal SpO2 MM 1.8M is not intended for use within a controlled MR environment.

TruSignal SpO2 MM 3.0M

The TruSignal SpO2 MM 3.0M is intended for monitoring arterial oxygen saturation and pulse rate. TruSignal SpO2 MM 3.0M is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal SpO2 MM 3.0M Device

The TruSignal SpO2 MM 3.0M is not intended for use within a controlled MR 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)	?
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

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510(k) Summary (K260656)

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

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

Date: August 31, 2026
Owner/Submitter: GE Healthcare Finland Oy
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00510 Helsinki
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Phone: +358 10 39411

Primary Contact Person: Anssi Ruokonen
Program Manager, Regulatory Affairs, Monitoring Solutions
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Device names (807.92(a)(2)):

Trade Name:	Carescape ONE Carescape Dock F0 TruSignal ECG MM TruSignal PRES MM TruSignal TEMP MM TruSignal SpO2 MM 1.8M TruSignal SpO2 MM 3.0M
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) BZQ - 21 CFR 868.2375 monitor, breathing frequency 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 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 FLL - 21 CFR 880.2910 Clinical electronic thermometer
Product Code:	MHX
Subsequent Product Codes:	BZQ, CCK, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXN, FLL, MLD, MUD, QEM

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Predicate Device(s) (807.92(a)(3)):	Primary predicate: K213234 CARESCAPE ONE and CARESCAPE DOCK F0, CARESCAPE ECG, CARESCAPE TEMP, CARESCAPE PRES and CARESCAPE SPO2 Reference devices: K213363 CARESCAPE B450, E-musb K234130 Portrait™ Mobile Monitoring Solution. K211561 INVOS PM7100 Patient Monitor, INVOS Pediatric rSO2 Sensor, INVOS Infant Regional Saturation Sensor
Device Description (807.92(a)(4)):	Carescape ONE, with Carescape Software version 4.0 provides a flexible bedside monitor that can also be used during intrahospital transport. The flexibility of Carescape ONE allows the user to configure the monitor's vital sign acquisition for only the parameters they require. This is achieved by using plug and play Active Cable Modules (ACM) called micro-modules that connect via medical grade USB ports on the Carescape ONE monitor. The GE HealthCare micro-modules included in this submission are TruSignal ECG MM, TruSignal PRES MM, TruSignal TEMP MM, TruSignal SpO2 MM 1.8M and TruSignal SpO2 MM 3.0M. Each micro-module is dedicated to measuring a particular vital sign. Currently there are micro-modules for ECG/Respiration, Invasive Blood Pressure, Temperature, SpO2, CO2, and rSO2. rSO2 monitoring is only supported when Carescape ONE is operating as an acquisition device. rSO2 values are not displayed on Carescape ONE. Non-Invasive Blood Pressure (NIBP) measurement is an exception from the uses of the micro-modules, as the capability to measure NIBP is built-in to the Carescape ONE monitor itself. Carescape ONE provides the users with the acquired display values, waveforms, alarms, and status messages in a compact footprint monitor that runs on an internal battery as well as AC power when connected to the Carescape Dock F0 docking station. When connected to a compatible host monitor, Carescape ONE operates as an acquisition device. In this mode, Carescape ONE screen and the user interface is effectively disabled, and it transmits data received from the micro-modules to the host monitor, which is responsible for managing clinical configuration settings, and displaying values, waveforms, alarms, and status messages.

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

Indications (from labeling)

Carescape ONE

Carescape ONE is both a multi-parameter physiological patient monitor and an accessory to a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility.

Carescape ONE is indicated for the monitoring of hemodynamic and respiratory physiological parameters.

When the Carescape ONE is operated as a standalone multi-parameter physiological patient monitor, it provides the following physiological parameters:

• ECG (heart rate, ST segment, and arrhythmia detection)

• Pulse oximetry (pulse rate, functional oxygen saturation [SpO2])

• Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)

• Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)

• Temperature

• Respiratory carbon dioxide (EtCO2, FiCO2, and respiration rate)

• Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible Host Monitor, it provides the following physiological parameters to the Host Monitor:

• ECG (heart rate, ST segment, and arrhythmia detection)

• Pulse oximetry (pulse rate, functional oxygen saturation [SpO2], and total hemoglobin concentration [SpHb])

• Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures)

• Invasive pressure (pulse rate and systolic, diastolic, and mean pressures)

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• Regional oxygen saturation (rSO2)

• Temperature

• Respiratory carbon dioxide (EtCO2, FiCO2, and respiration rate)

• Impedance respiration

When the Carescape ONE is connected as an accessory to a compatible host monitor, visual and audible alarms, user controls, and user interface are provided on the compatible host monitor and not on Carescape ONE.

When Carescape ONE is operated as a transportable monitor, it can interface with a compatible host monitor to provide data for remote viewing and data management software devices via a network.

Carescape ONE is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.

Carescape ONE is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Contraindications for using Carescape ONE

The Carescape ONE is not intended for use within a controlled MR environment.

Carescape Dock F0

Carescape Dock F0 is intended for providing a DC power source to a docked Carescape ONE, which also charges the Carescape ONE battery. Carescape Dock F0 is intended to provide a docked Carescape ONE with communication to the host monitor.

The Carescape Dock F0 is indicated for use in multiple areas within a professional healthcare facility.

The Carescape Dock F0 is indicated 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 Carescape Dock F0 is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time.

Contraindications for using the Carescape Dock F0

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The Carescape Dock F0 is not intended for use within a controlled MR environment.

TruSignal ECG MM

The TruSignal ECG MM is intended for monitoring of electrocardiogram and impedance respiration. TruSignal ECG MM is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal ECG MM Device

The TruSignal ECG MM is not intended for use within a controlled MR environment.

TruSignal PRES MM

The TruSignal PRES MM is intended for monitoring of invasive pressure and pulse rate. TruSignal PRES MM is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal PRES MM Device

The TruSignal PRES MM is not intended for use within a controlled MR environment.

TruSignal TEMP MM

The TruSignal TEMP MM is intended for monitoring of temperature. TruSignal TEMP MM is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal TEMP MM Device

The TruSignal TEMP MM is not intended for use within a controlled MR environment.

TruSignal SpO2 MM 1.8M

The TruSignal SpO2 MM 1.8M is intended for monitoring arterial oxygen saturation and pulse rate. TruSignal SpO2 MM 1.8M is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal SpO2 MM 1.8M Device

The TruSignal SpO2 MM 1.8M is not intended for use within a

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controlled MR environment.

TruSignal SpO2 MM 3.0M

The TruSignal SpO2 MM 3.0M is intended for monitoring arterial oxygen saturation and pulse rate. TruSignal SpO2 MM 3.0M is indicated for all hospital patients. The device is indicated for use by licensed healthcare practitioner.

Contraindications for using the TruSignal SpO2 MM 3.0M Device

The TruSignal SpO2 MM 3.0M is not intended for use within a controlled MR environment.

Technology (807.92(a)(6)): The Carescape ONE hardware was modified to incorporate updated CPU carrier board module and CPU module. The display and touchscreen currently available in predicate have been integrated into Carescape ONE. The NIBP subsystem has been rearchitected. The SuperSTAT algorithm and core NIBP determination algorithm logic hasn't changed and remains identical to predicate.

Wireless local area network capability was integrated into the Carescape ONE hardware through incorporation of a standards-compliant WLAN module. Front panel graphics were updated to include indicators for newly introduced WLAN connectivity.

A passive radio frequency identification (RFID) tag was integrated into the device enclosure to enable asset tracking and inventory management capabilities.

Software modifications carried out on the legally marketed predicate CARESCAPE ONE software version 3.2, resulted in the new product Carescape ONE which is the subject of this submission.

The update introduces no technical changes to the Indications for Use but adds compatibility with 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, and calculation updates. 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) and temperature. In addition, the update incorporates continuous

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improvements in cybersecurity.

The Carescape ONE monitor includes Platform Software that has been updated from version 3.2 to version 4.0.

Carescape ONE monitor indications for use were updated, regarding rSO2 expanded patient population and updated transport scenarios with wireless connectivity. The indications for use for Carescape ONE are equivalent to the predicate.

The micro-modules previously named CARESCAPE ECG, CARESCAPE PRES, CARESCAPE TEMP, and CARESCAPE SpO_2 (1.8 m and 3.0 m) have been renamed as TruSignal ECG MM, TruSignal PRES MM, TruSignal TEMP MM, and TruSignal SpO_2 MM (1.8 m and 3.0 m). Micro-module and Carescape Dock F0 specific Indications for Use statements have been developed for clarity of labeling. The renaming and labeling refinements do not reflect any changes to the Form, Fit, or Function of the micro-modules or docking station compared with those cleared in the predicate CARESCAPE ONE (K213234).

The fundamental function and operation of the proposed Carescape ONE monitor are unchanged compared to the predicate CARESCAPE ONE (K213234).

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

Subject Device and Predicate Device Comparison

Specification	Proposed Carescape ONE	The legally marketed predicate K213234 CARESCAPE ONE	Differences
Patient type	Adult, pediatric & neonatal	Adult, pediatric & neonatal	Identical
Use environments	Within a professional healthcare facility (Not intended for controlled MRI)	Within a professional healthcare facility (Not intended for controlled MRI)	Identical
Stand-alone monitor functionality	Yes	Yes	Identical
Acquisition module for hosts	Yes Can be used as an acquisition device for hosts: Canvas 1000 and Smart Display with v4.0 software	Yes Can be used as an acquisition device for hosts: Canvas 1000, Canvas Smart Display with v3.3 software	Equivalent

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		CARESCAPE B450, B650, B850 with v3.0, v3.1, or v3.2 software	
Size (H x W x D) & Weight	15.5 cm x 27.0 cm x 6.5 cm (6.1 in x 10.6 in x 2.6 in) less than 1.90 kg (4.19 lbs.) with battery	15.5 cm x 27.0 cm x 6.5 cm (6.1 in x 10.6 in x 2.6 in) less than 1.85 kg (4.08 lbs.) with battery	Equivalent
Module attachment configuration	8 Medical USB ports for attachment of parameter micro-modules	8 Medical USB ports for attachment of parameter micro-modules	Identical
Display/screen	Integrated 7” diagonal active matrix color TFT LCD	Integrated 7” diagonal active matrix color TFT LCD	Identical
Waveforms	Up to 4 individual waveforms	Up to 4 individual waveforms	Identical
Specification	**Proposed Carescape ONE**	**The legally marketed predicate K213234 CARESCAPE ONE**	**Differences**
Available parameters	ECG (includes ST segment, arrhythmia detection), invasive pressure, non-invasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter acquisition and monitoring. When operating as an acquisition device, also supports INVOS rSO2 and Masimo SpHb, PI, and PVi	ECG (includes ST segment, arrhythmia detection), invasive pressure, non-invasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter acquisition and monitoring. When operating as an acquisition device, also supports INVOS rSO2 and Masimo SpHb, PI, and PVi	Identical
Mounting options	Multiple configurations when using a docking station using GCX mounting systems including wall mounts, pole mounts, bedrail mounts, and roll stand.	Multiple configurations when using a docking station using GCX mounting systems including wall mounts, pole mounts, bedrail mounts, and roll stand.	Identical
Direct Network Connectivity (wired or wireless)	**Yes, wireless**	**No**	Equivalent
Battery operation	Yes 1 Lithium-Ion battery	Yes 1 Lithium-Ion battery	Identical

Determination of Substantial Equivalence (807.92(b)(1):

Summary of Non-Clinical Tests:

Non-clinical bench testing related to software, hardware and performance including applicable consensus standards was

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conducted on the Carescape ONE monitoring system, demonstrating the design meets the specifications.

This section addresses the Non-clinical testing for Carescape ONE monitoring system relied on for a determination of substantial equivalence to the primary predicate K213234 CARESCAPE ONE monitoring system and other predicates.

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
- IEC 60601-1:2005 + AMD1:2012, IEC 60601-1:2005 + AMD2:2020
- IEC 60601-1-2:2014 + AMD1:2020
- 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 80601-2-49: 2018

The Carescape ONE monitoring system meets 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". In addition, Carescape ONE monitoring system shows 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 ONE 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 ILAC accredited and Certified Body Testing Laboratory (CBTL) under the IECEE

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CB Scheme.

Carescape ONE monitoring system was designed and tested for compliance to the FDA 21 CFR Part 898, § 898.12 (Performance standard for electrode lead wires and cables).

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

Environmental (Mechanical, and Thermal Safety) testing, based on the Carescape ONE monitoring system proposed uses and locations has been confirmed to meet the specifications listed in the requirements.

The Carescape ONE monitoring system follows the FDA Biocompatibility guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff- Document issued on: September 8, 2023” and ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process. Testing data for showing biocompatibility of patient contacting devices is provided in the submission.

Carescape ONE monitoring system follows 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”.

Carescape ONE monitoring system is labelled MR Unsafe in line with “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff, document issued on October 10, 2023”

Carescape ONE monitoring system follows the Applying

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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 was concluded with clinical users. The usability testing of the Carescape ONE monitoring system 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 ONE monitor battery pack and battery cells have been verified to be compliant with the following standards:

- UL 2054:2021 - UL Standard for Safety Household and Commercial Batteries - Third Edition; Reprint with Revisions Through and Including March 10, 2022
- IEC 62133-2:2021 – Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- UL 1642:2020 UL Standard for Safety Lithium Batteries - Sixth Edition

Carescape ONE v4.0 wireless radios are compliant with IEEE ANSI USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence and have been certified by the FCC.

The Carescape ONE follows the FDA software guidance

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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
- Computer Software Assurance for Production and Quality Management System Software Guidance for Industry and Food and Drug Administration Staff, February 3, 2026.
- 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 February 3, 2026
- 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.

Patient safety, security, and privacy risks have been addressed in the design and development of Carescape ONE 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 "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Document issued on February 3, 2026".

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Clinical (807.92(b)(2)):	Summary of Clinical Tests: The Carescape ONE monitoring system did not require clinical studies to support substantial equivalence.
Conclusion (807.92(b)(3)):	GE HealthCare considers the Carescape ONE, Carescape Dock F0, TruSignal ECG MM, TruSignal PRES MM, TruSignal TEMP MM, TruSignal SpO2 MM 1.8M, TruSignal SpO2 MM 3.0M to be substantially equivalent to the predicate device.