April 26, 2022

GE Medical Systems Information Technologies, Inc.
Joel Kent
Sr. Manager Regulatory Affairs
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K213234
Trade/Device Name: CARESCAPE ONE and CARESCAPE DOCK F0, Model Numbers MBZ323 and MFA101, CARESCAPE ECG, Model Number MKE101,CARESCAPE TEMP, Model Number MKT101, CARESCAPE PRES, Model Number MKP101, CARESCAPE SPO2, Model Numbers MKS101 and MKS201
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

Dear Joel Kent:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 12, 2022. Specifically, FDA is updating this SE Letter to add a missing product code as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Shih, OHT2: Office of Cardiovascular Devices, Jennifer.Shih@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

Jennifer Shih
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

April 12, 2022

GE Medical Systems Information Technologies, Inc.
Joel Kent
Sr. Manager Regulatory Affairs
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K213234
Trade/Device Name: CARESCAPE ONE
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, DRT, DSI, DSJ, DSK, DXN, FLL, MLD, MUD, QEM
Dated: March 16, 2022
Received: March 17, 2022

Dear Joel Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Shih
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.

510(k) Number *(if known)*
K213234

Device Name
CARESCAPE ONE

Indications for Use *(Describe)*

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.
CARESCAPE ONE is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.
Regional oxygen saturation (rSO2) is an adjunct parameter for noninvasive monitoring of cerebral/somatic regional oximetry of blood in the brain or other tissue beneath the sensor. It is intended to be used on patients greater than 40 kg (88 lbs) at risk for reduced-flow or no-flow ischemic states.
CARESCAPE ONE is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the 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.

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.

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GE Medical Systems Information
Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226, USA

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: April 7, 2022

Owner/Submitter: GE Medical Systems Information Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226, USA

Primary Contact Person: Joel Kent
Director, Regulatory Affairs Strategy
GE Healthcare
Phone: 617-851-0943
E-mail: joel.kent@ge.com

Secondary Contact Person: Monica Morrison
Regulatory Affairs Executive
GE Healthcare
Phone: 608-515-3077
E-mail: monica.morrison@ge.com

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

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

Classification Names:	21 CFR 870.1025 monitor, physiological, patient (with arrhythmia detection or alarms) 21 CFR 868.2375 monitor, breathing frequency 21 CFR 868.1400 Carbon dioxide gas analyzer 21 CFR 870.2340 Electrocardiograph 21 CFR 870.2710 oximeter, ear 21 CFR 870.2700 oximeter 21 CFR 870.1425 Programmable diagnostic computer 21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm) 21 CFR 870.1025 detector and alarm, arrhythmia 21 CFR 870.1100 alarm, blood-pressure 21 CFR 870.1110 computers, blood-pressure 21 CFR 870.1130 system, measurement, blood-pressure, non-invasive 21 CFR 880.2910 Clinical electronic thermometer 21 CFR 870.1025 monitor, St Segment with alarm 21 CFR 870.2700 Oximeter, Tissue Saturation 21 CFR 870.2700 Cerebral Oximeter
Product Code:	MHX
Subsequent Product Codes:	BZQ CCK DPS DPZ DQA DQK DRT DSI DSJ DSK DXN FLL MLD MUD QEM

Predicate Device(s) (807.92(a)(3)):	The primary predicate for this submission is K200494, CARESCAPE ONE Additional reference devices: K191149, CARESCAPE B650 K191323, CARESCAPE B850 K191249, CARESCAPE B450 K182868, INVOS PM7100 Patient Monitor, INVOS Adult rSO2 Sensor K110028, MASIMO RADICAL Y PULSE CO-OXIMETER
Device Description (807.92(a)(4)):	CARESCAPE ONE belongs to the CARESCAPE patient monitor family. The concept of the CARESCAPE ONE is to provide a flexible bedside monitor that can also be used during intra-hospital transport. The flexibility of the CARESCAPE ONE allows the user to configure the monitor's vital sign acquisition for only the parameters they require. This is achieved using plug and play Active Cable Modules (ACM) that connect via medical grade USB ports on the CARESCAPE ONE monitor. Note that the USB ports are not compatible with commercial USB items on the market due to a custom connector design. Each ACM is dedicated to measuring a particular vital sign, currently there are 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). The only exception is the Non-Invasive Blood Pressure (NIBP) measurement which does not require a separate ACM since the capability to measure NIBP is built-in to the CARESCAPE ONE monitor itself. CARESCAPE ONE provides the users the acquired display values, waveforms, alarms and status messages in compact footprint monitor that runs on an internal battery as well as AC power when connected to the docking station. When connected to a compatible host monitor, CARESCAPE ONE operates as an acquisition device. In this mode, CARESCAPE ONE screen and user interface is effectively disabled and it transmits data received form the Active Cable Modules to the host monitor, which is responsible for managing clinical configuration settings, and displaying values, waveforms, alarms, and status messages.

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

Indications

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.

CARESCAPE ONE is intended for use on adult, pediatric, and

neonatal patients and on one patient at a time.

Regional oxygen saturation (rSO2) is an adjunct parameter for noninvasive monitoring of cerebral/somatic regional oximetry of blood in the brain or other tissue beneath the sensor. It is intended to be used on patients greater than 40 kg (88 lbs) at risk for reduced-flow or no-flow ischemic states.

CARESCAPE ONE is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the 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.

Technology (807.92(a)(6)): The CARESCAPE ONE uses the same fundamental technology and functionality as the predicate CARESCAPE ONE (K200494).

The main differences with respect to the predicate discussed throughout the submission are summarized below:

- Compatibility with CARESCAPE Bx50 host monitors running the latest version of software
- Compatibility with new OEM CARESCAPE Parameter Modules
- Extended support for Masimo parameters
- Updates to the Indications for Use (We have revised the Indications for Use statement from the predicate to reflect the changes that have been made for clarity and to reflect the inclusion of the acquisition of OEM parameter rSO2 with the CARESCAPE rSO2 – INVOS™ Parameter module and extended functionality with CARESCAPE SpO2 - Masimo measurement device
- Continuous improvements in Cybersecurity
- Workflow enhancements in the clinical software
- Workflow enhancements in the monitor service and installation features
- Updates to the list of accessories
- Updates to the user documentation

The CARESCAPE ONE remains substantially equivalent to the predicates and the device itself (software and hardware) remains nearly identical to the version cleared under K200494. There are no significant changes to the CARESCAPE ONE monitored parameters, and all measurement algorithms are identical to those that were included in K200494.

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

Product Comparison versus Predicate Main features

Specification	PREDICATE CARESCAPE ONE (K190008)	CARESCAPE ONE	Discussion of Differences
Indications for Use	The 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. The CARESCAPE ONE is indicated for the monitoring of hemodynamic (including ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, and temperature), and respiratory (impedance respiration and CO2 airway gas) physiological parameters. The CARESCAPE ONE can be used as a standalone monitor. In this mode of operation, the CARESCAPE ONE provides ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter acquisition and monitoring. The CARESCAPE ONE can be connected as an accessory to a compatible CARESCAPE monitor. In this mode of operation, the CARESCAPE ONE provides ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter acquisition. Visual and audible alarms, user controls, and user interface on the CARESCAPE ONE are not active in this mode.	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**	Equivalent Added functionality to pass total hemoglobin concentration [SpHb] from CARESCAPE SpO2 – Masimo (previously cleared K110028) and regional oxygen saturation (rSO2) from CARESCAPE rSO2 – INVOS (previously cleared K182868) through to a host monitor. These parameters are not displayed on the CARESCAPE ONE. There were some minor text edits made to improve clarity. This change is substantially equivalent to the predicate device.

Specification	PREDICATE CARESCAPE ONE (K190008)	CARESCAPE ONE	Discussion of Differences
	The CARESCAPE ONE is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE ONE is indicated for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the 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.	**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.** CARESCAPE ONE is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time. **Regional oxygen saturation (rSO2) is an adjunct parameter for noninvasive monitoring of cerebral/somatic regional oximetry of blood in the brain or other tissue beneath the sensor. It is**	

Specification	PREDICATE CARESCAPE ONE (K190008)	CARESCAPE ONE	Discussion of Differences
		intended to be used on patients greater than 40 kg (88 lbs) at risk for reduced-flow or no-flow ischemic states. CARESCAPE ONE is **intended** for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the 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.	
Patient type	Adult, pediatric & neonatal	Adult, pediatric & neonatal	Identical
Use environments	Within a professional healthcare facility (Not intended for MRI)	Within a professional healthcare facility (Not intended for MRI)	Identical
Intrahospital transport within a professional healthcare facility.	Yes	Yes	Identical
Acquisition Mode (accessory to a compatible host monitor)	Connects to a compatible "host" CARESCAPE Patient Monitor. The CARESCAPE ONE provides parameter acquisition for the host patient Monitor. Visual and audible alarms, user controls, and user interface functions are not active on the CARESCAPE ONE and instead those functions are provided by the host CARESCAPE Patient Monitor.	Connects to a compatible "host" CARESCAPE Patient Monitor. The CARESCAPE ONE provides parameter acquisition for the host patient Monitor. Visual and audible alarms, user controls, and user interface functions are not active on the CARESCAPE ONE and instead those functions are provided by the host CARESCAPE Patient Monitor. CARESCAPE ONE is compatible with host monitors running the latest software versions.	Equivalent The basic functionality, data transfer mechanisms, and physical connection mechanism between the CARESCAPE ONE and compatible host monitors is identical to the predicate CARESCAPE ONE (K200494). However, due to enhancements in functionality (i.e., compatibility with new CARESCAPE Parameters) that are not available in older versions of host monitors, CARESCAPE ONE is compatible with host monitors running the latest software versions. This change is substantially equivalent to the predicate device.

Specification	PREDICATE CARESCAPE ONE (K190008)	CARESCAPE ONE	Discussion of Differences
Monitored Parameters	Parameters monitored by CARESCAPE ONE include: - hemodynamic (ECG, ST segment, arrhythmia detection, invasive pressures, NIBP, temperature, and pulse oximetry) - respiratory (impedance respiration, CO2)	Parameters monitored by CARESCAPE ONE include: - hemodynamic (ECG, ST segment, arrhythmia detection, invasive pressures, NIBP, temperature, and pulse oximetry) - respiratory (impedance respiration, CO2)	Identical
Medical Standards	IEC 60601-1:2005 + C1:2006 + C2:2007 + A1:2012 IEC 60601-1-2:2007 IEC 60601-1-2:2014-02 / EN 60601-1-2:2015 IEC 60601-1-6:2010 + A1:2013 IEC 60601-1-8:2006 + A1:2012 IEC 60601-2-27:2011 IEC 80601-2-30:2018 IEC 60601-2-34:2011 IEC 80601-2-49:2018 ISO 80601-2-55:2018 ISO 80601-2-56:2017 + A1:2018 ISO 80601-2-61:2017 IEC 62304:2006 + A1:2015 IEC 62366:2007+ A1:2014 IEC 62366-1:2015 ISO 10993-1:2009 IEC 62133-2:2017 UL 2054:2004 UL 1642:2012 AIM 7351731:2017	IEC 60601-1:2005 + C1:2006 + C2:2007 + A1:2012 IEC 60601-1-2:2014-02 / EN 60601-1-2:2015 IEC 60601-1-6:2010 + A1:2013 IEC 60601-1-8:2006 + A1:2012 IEC 60601-2-27:2011 IEC 80601-2-30:2018 IEC 60601-2-34:2011 IEC 80601-2-49:2018 ISO 80601-2-55:2018 ISO 80601-2-56:2017 + A1:2018 ISO 80601-2-61:2017 IEC 62304:2006 + A1:2015 IEC 62366:2007+ A1:2014 IEC 62366-1:2015 ISO 10993-1:2009 IEC 62133-2:2017 UL 2054:2004 UL 1642:2012 AIM 7351731:2017	Equivalent CARESCAPE ONE no longer claims compliance to IEC 60601-1-2:2007 because it has been superseded by IEC 60601-1-2:2014-02 / EN 60601-1-2:2015. CARESCAPE ONE complies with the FDA recognized standards in scope of the device and its intended use. This change is substantially equivalent to the predicate device.

Specification	PREDICATE CARESCAPE ONE (K190008)	CARESCAPE ONE	Discussion of Differences
Parameters Acquisition Method	The CARESCAPE ONE utilizes the Active Cable Modules (ACMs) or PARAMETERS, in which the parameter electronics are encapsulated into the respective patient cables, rather than inside the main frame of the monitor. Only the NIBP parameter is integrated into the CARESCAPE ONE monitor. Parameter/Active Cable Modules: CARESCAPE Temperature CARESCAPE Pressure CARESCAPE ECG (Includes impedance respiration) CARESCAPE SPO2 (TruSignal) OEM CARESCAPE SPO2 - Nellcor SPO2 OEM CARESCAPE SPO2 - Masimo SPO2 OEM CARESCAPE CO2 - LoFlo (Philips Respironics LoFlo CO2)	The CARESCAPE ONE utilizes the Active Cable Modules (ACMs) or PARAMETERS, in which the parameter electronics are encapsulated into the respective patient cables, rather than inside the main frame of the monitor. Only the NIBP parameter is integrated into the CARESCAPE ONE monitor. Parameter/Active Cable Modules: CARESCAPE Temperature CARESCAPE Pressure CARESCAPE ECG (Includes impedance respiration) CARESCAPE SPO2 (TruSignal) OEM CARESCAPE SPO2 - Nellcor SPO2 OEM CARESCAPE SPO2 - Masimo SPO2 OEM CARESCAPE CO2 - LoFlo (Philips Respironics LoFlo CO2) **OEM CARESCAPE CO2 – Microstream (Medtronic)** **OEM CARESCAPE rSO2 – INVOS (Medtronic)**	Equivalent Added OEM CARESCAPE CO2 – Microstream and OEM CARESCAPE rSO2 – INVOS parameters. These two parameter cables can be plugged into any of the eight parameter acquisition ports on the CARESCAPE ONE. This change is substantially equivalent to the predicate device.
EK-Pro arrhythmia detection algorithm	EK-Pro V14	EK-Pro V14	Identical
Size (H x W x D)	155 mm x 270 mm x 65 mm (6.1 in x 10.6 in x 2.6 in) excluding dock and excluding any host CARESCAPE Patient monitor.	155 mm x 270 mm x 65 mm (6.1 in x 10.6 in x 2.6 in) excluding dock and excluding any host CARESCAPE Patient monitor.	Identical
Weight	1.85 kg (4.1 lbs.) with battery and excluding dock and excluding any host CARESCAPE Patient monitor.	1.85 kg (4.1 lbs.) with battery and excluding dock and excluding any host CARESCAPE Patient monitor.	Identical
Battery Type	Lithium-Ion	Lithium-ion	Identical
Display size	7 inch	7 inch	Identical

Specification	PREDICATE CARESCAPE ONE (K190008)	CARESCAPE ONE	Discussion of Differences
Display type	Active matrix color TFT LCD	Active matrix color TFT LCD	Identical
Number of traces (waveforms)	Up to 8 with 4 available on 2nd waveform page.	Up to **12** total with 4 available on 1st page, 4 available on 2nd page, **and 4 available on 3rd page**.	Equivalent Support for a third page with four additional parameter windows and waveforms was added in this release. The third page is used to display any parameter windows and waveforms that are available but haven't been configured to be shown on either the first or second page. This functionality guarantees that all possible parameter windows and waveforms can be displayed on the screen. This functionality was expanded from two pages to three pages, due to the two additional invasive pressure channels that can now be monitored in this release.This change is substantially equivalent to the predicate device.
Operating System	Linux Operating System	Linux operating system	Identical
Software packages	5 software packages: Emergency Care (ED), Critical Care (ICU), Operating Room (OR), Post-Anesthesia Care (PACU), Neonatal Care (NICU)	5 software packages: Emergency Care (ED), Critical Care (ICU), Operating Room (OR), Post-Anesthesia Care (PACU), Neonatal Care (NICU)	Identical.
Patient Network Ethernet port connector (RJ45-8-pin)	No One Ethernet port for service tools.	No One Ethernet port for service tools.	Identical
Defaults available	User selectable arrhythmia alarm levels, Parameter settings and alarm levels, default alarm limits, display layout, parameter priority defaults. Up to 8 different pre-configured or custom defaults available. Not all parameters have configurable alarm priorities.	User selectable arrhythmia alarm levels, Parameter settings and alarm levels, default alarm limits, display layout, parameter priority defaults. Up to 8 different pre-configured or custom defaults available. Not all parameters have configurable alarm priorities.	Identical
Alarm Classification (IEC)	Four levels — High, Medium, Low and Informational	Four levels — High, Medium, Low and Informational	Identical
Alarm Notification	Audible and visual	Audible and visual	Identical
Technical alarms	System generated alarms to notify the user of special conditions.	System generated alarms to notify the user of special conditions.	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 ONE, demonstrating the design meets the specifications.

This section addresses the Non-Clinical testing for CARESAPE ONE modifications with respect to the predicate CARESCAPE ONE (K200494) that are the subject of this 510(k) submission.

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:

- Compatibility with new OEM CARESCAPE Parameter Modules
- Extended support for Masimo parameters
- Updates to the list of accessories
- Updates to the user documentation

The CARESCAPE ONE hardware design and environmental requirements have not changed since CARESCAPE ONE (K200494) and none of the other design changes required any new environmental testing.

CARESCAPE ONE was tested and meets the EMC requirements described in IEC 60601-1-2 Edition 4.0 2014-02 "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 “Guidance for Industry and Food and Drug Administration Staff: Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, Issued July 11, 2016” and "Electromagnetic Compatibility (EMC) of Medical Devices, issued on November 17, 2020"

CARESCAPE ONE was tested and meets the electrical safety requirements of IEC 60601-1:2012 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Edition 3.1".

Due to the software changes and addition of compatibility with new OEM CARESCAPE Parameters and accessories that is included in this submission, CARESCAPE ONE received updated CB reports demonstrating compliance with the FDA recognized standards in scope for the product.

The usability testing of the CARESCAPE ONE patient monitor is in compliance with the FDA Guidance for Industry and Food and Drug Administration Staff "Applying Human Factors and Usability Engineering to Medical Devices" (Feb 3, 2016).

The main differences with respect to the predicate (related to software) are listed below:

• Compatibility with CARESCAPE Bx50 host monitors running the latest version of software

• Compatibility with new OEM CARESCAPE Parameter Modules

•Extended support for Masimo parameters

•Continuous improvements in Cybersecurity

•Workflow enhancements in the clinical software

•Workflow enhancements in the monitor service and installation features

There are no changes to algorithms within CARESCAPE ONE, or any changes to any of the software within the CARESCAPE Parameters created by GE other than correction of minor anomalies in the CARESCAPE ECG parameter device. 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.

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 FDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for

Industry and Food and Drug Administration Staff Document issued on October 2, 2014 (and is in-line with the draft Guidance issue October 2018).

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

Clinical studies of the CARESCAPE ONE device performance were not required to establish substantial equivalence.

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