March 29, 2020

GE Healthcare
Joel Kent
Senior Regulatory Affairs Manager
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K200494
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, DQK, DRT, DSI, DSJ, DSK, DXN, FLL, MLD
Dated: February 25, 2020
Received: February 28, 2020

Dear Joel Kent:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200494

Device Name
CARESCAPE ONE

Indications for Use *(Describe)*

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.

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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GE Medical Systems Information
Technologies, Inc.
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

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:	March 10, 2020
Owner/Submitter:	GE Medical Systems Information Technologies, Inc. 8200 West Tower Avenue Milwaukee, Wisconsin 53223
Primary Contact Person:	Joel Kent Senior Regulatory Affairs Manager GE Healthcare Phone: 617-851-0943 E-mail: joel.kent@ge.com
Secondary Contact Person:	Monica Morrison Regulatory Affairs Director 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 Arrhythmia detector and alarm (including ST-segment measurement and alarm) 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
Product Code:	MHX
Subsequent Product Codes:	BZQ CCK DPS DPZ DQA DQK DRT DSI DSJ DSK DXN FLL MLD

Predicate Device(s) (807.92(a)(3)):	The primary predicate for this submission is K190008, CARESCAPE ONE Additional predicates/reference devices: K071073, Patient Data Module (PDM) K191249, CARESCAPE B450 K191149, CARESCAPE B650 K191323, CARESCAPE B850
Device Description (807.92(a)(4)):	CARESCAPE ONE, with CARESCAPE Software version 3 belongs to the CARESCAPE V3 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 we have ECG/Respiration, Invasive Blood Pressure, Temperature, SpO2, or CO2. 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, the 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. CARESCAPE ONE is compatible with the following 510(k) cleared host monitors: • CARESCAPE B450 (K191249) • CARESCAPE B650 (K191149) • CARESCAPE B850 (K191323)

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

Indications

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.

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.

Technology (807.92(a)(6)): The CARESCAPE ONE that is the subject of this submission is based on the primary predicate CARESCAPE ONE (K190008).

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

- Add the capability for CARESCAPE ONE to be utilized as an acquisition device when connected with host monitors (CARECSAPE Monitors). CARESCAPE ONE can be used as an acquisition module for compatible host devices, in addition to use as a stand-alone monitor. There are no changes to the device itself specifically to enable compatibility with the host monitors, as it was already built into the device design. The labeling and instructions have been updated to reflect the use with compatible host devices. Compatibility with CARESCAPE ONE was already cleared in the additional predicate devices CARESCAPE B650 K191149, CARESCAPE B450 K191249 and CARESCAPE B850 K191323. The acquisition module functionality in CARESCAPE ONE, as discussed in K190008, is substantially equivalent to the Patient Data Module (K071073).
- Minor software updates for maintenance/bug fixes only. No changes to function, operation, parameters monitored, or algorithms.
- Compliance demonstrated with newer versions of FDA recognized standards. No actual changes to the device were required to meet the updated standards, other than one update to the labeling for the water ingress protection level (IP44).
- Minor updates to the compatible accessories list.

The CARESCAPE ONE remains substantially equivalent to the predicates and the device itself (software and hardware) remains nearly identical to the version cleared under K190008. There are no changes to the monitored parameters or algorithms.

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 a multi-parameter physiological 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 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 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.	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. The CARESCAPE ONE is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time.	Equivalent. The predicate device is standalone Patient Monitor, which includes patient signal acquisition and processing, patient data display, alarm signal generation, and user input functions. The new device includes the standalone functionality and behavior, plus includes the ability to delegate alarm signal generation, patient data display, and user input functions to a connected "host" CARESCAPE Patient Monitor. The Patient Data Module (K071073) is a reference device which is similar to the CARESCAPE ONE used as an acquisition module since it connects to a CARESCAPE Monitor host and can also be used in patient transport and then reconnected to a host. The changes have been made to clarify that the CARESCAPE ONE can be used both as a standalone monitor and a compatible module/accessory for a host CARESCAPE Monitor. Verification of interoperability/ compatibility was completed. Compatibility of CARESCAPE ONE with the host monitors was also cleared in the following submissions: CARESCAPE B650 K191149, CARESCAPE B450 K191249 and CARESCAPE B850 K191323. 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 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)	N/A	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.	Equivalent. The predicate device is standalone Patient Monitor, which includes patient signal acquisition and processing, patient data display, alarm signal generation, and user input functions. The new device includes the standalone functionality and behavior, plus includes the ability to act as an acquisition device to a host monitor. This is equivalent to the reference device Patient Data Module (K071073) which acts as an acquisition module to a host device and was a predicate to K190008. This acquisition mode allows it to delegate alarm signal generation, patient data display, and user input functions to a connected "host" CARESCAPE Patient Monitor. The CARESCAPE ONE can be used both as a standalone and a compatible module for a host CARESCAPE Monitor. Verification of interoperability/compatibility was completed. Compatibility of CARESCAPE ONE with the host monitors was also cleared in the following submissions: CARESCAPE B650 K191149, CARESCAPE B450 K191249 and CARESCAPE B850 K191323. 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 80601-2-30:2013 IEC 60601-2-34:2011 IEC 60601-2-49:2011 ISO 80601-2-55:2011 ISO 80601-2-56:2009 ISO 80601-2-61:2011 IEC 62304:2006 + A1:2015 IEC 62366:2017 + A1:2014 ISO 10993-1:2009 IEC 62133:2012	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 62366:201 7+ A1:2014 ISO 10993-1:2009 IEC 62133-2:2017	Equivalent. Both the predicate and the new device comply with the same standards, except the new device complies with the more recent edition of the particulars for the following standards: IEC 80601-2-30:2018 IEC 80601-2-49:2018 ISO 80601-2-55:2018 ISO 80601-2-56:2017+A1 2018 ISO 80601-2-61:2017 The battery is identical to the predicate, but we now comply with the most recent battery standard IEC 62133-2:2017. Verification testing to show compliance with the updated standards are included in the submission. In order to meet the new standard requirements we did not require any software or hardware changes compared to the predicate CARESCAPE ONE (K190008). We have only changed our manuals to list the new standards and our IP41 water ingress specification and label has changed to a higher rating to comply with IEC 60601-2-61:2017. The new pulse oximetry standard requires IPx2 instead of IPX1, but we tested to IP44 for CARESCAPE ONE.

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 TEMP - Temperature CARESCAPE PRES – Invasive Pressure CARESCAPE ECG - ECG CARESCAPE SPO2 - Trusignal SPO2 CARESCAPE SPO2 Nellcor - Nellcor SPO2 CARESCAPE SPO2 Masimo - Masimo SPO2 CARESCAPE CO_2 - LoFlo	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 TEMP - Temperature CARESCAPE PRES – Invasive Pressure CARESCAPE ECG - ECG CARESCAPE SPO2 - Trusignal SPO2 CARESCAPE SPO2 Nellcor - Nellcor SPO2 CARESCAPE SPO2 Masimo - Masimo SPO2 CARESCAPE CO_2 - LoFlo	Identical
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) Note: Excludes dock	155 mm x 270 mm x 65 mm (6.1 in x 10.6 in x 2.6 in) Note: Excludes dock	Identical
Weight	1.85 kg (4.1 lbs) with battery	1.85 kg (4.1 lbs) with battery	Identical
Battery Type	Lithium-Ion	Lithium-ion	Identical
Display size	7 inch	7 inch	Identical
Display type	Active matrix color TFT LCD	Active matrix color TFT LCD	Identical

Specification	PREDICATE CARESCAPE ONE (K190008)	CARESCAPE ONE	Discussion of Differences
Number of traces (waveforms)	Up to 8 with 4 available on 2nd waveform page.	Up to 8 with 4 available on 2nd waveform page.	Identical
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.

There is no change in the electromagnetic compatibility, electrical safety, environmental (including Mechanical stress testing and

Package Testing) and usability compared to the predicate.

Software testing was completed for minor software updates for maintenance/bug fixes only. This included software design, development, verification, validation and traceability. There were no changes to function, operation, parameters monitored, or algorithms. 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.

CARESCAPE ONE has introduced and verified one new hardware component which is additional configuration of the CARESCAPE PRES parameter module, which contains a new connector type (cable connector) that was not included in the predicate CARESCAPE ONE (K190008).

Both the predicate and the new device comply with the same standards, except the new device complies with the more recent edition of the particulars for the following standards:

- IEC 80601-2-30:2018
- IEC 80601-2-49:2018
- ISO 80601-2-55:2018
- ISO 80601-2-56:2017+A1 2018
- ISO 80601-2-61:2017

The battery is identical to the predicate, but we now comply with the most recent battery standard IEC 62133-2:2017.

Verification evidence to show compliance with the updated standards are included in the submission. In order to meet the new standard requirements, we did not require any software or hardware changes compared to the predicate.

Clinical (807.92(b)(2)):	Summary of Clinical Tests:
	Clinical studies of the CARESCAPE ONE device performance were not required to establish substantial equivalence.
	A clinical study was conducted on the related GE TruSignal sensors, to provide an update to older data from previous predicated. There is no change to the GE TruSignal Parameter active cable module in hardware, software or pulse oximetry algorithm, or in the sensors used compared to the predicate CARESCAPE ONE (K190008).
	We have attached an updated Clinical Research Study Final Report: U-TruSignal SpO2, Testing in Neonates. This report continues to demonstrate compliance with the FDA guidance "Pulse Oximeters – Premarket Notification Submissions [510(k)s], Guidance for Industry and Food and Drug Administration Staff, March 4, 2013" where convenience samples were collected in neonatal patients to demonstrate clinical performance.
Conclusion (807.92(b)(3)):	GE Healthcare considers the CARESCAPE ONE to be substantially equivalent to the predicate device.