December 20, 2019

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

Re: K190008
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, MLD, DSI, BZQ, DXN, DQA, DPZ, DRT, DSJ, DSK, FLL, CCK
Dated: November 15, 2019
Received: November 18, 2019

Dear Joel Kent:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

for Jessica Paulsen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190008

Device Name
CARESCAPE ONE

Indications for Use *(Describe)*
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.

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:	December 20, 2019
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 analyzer, gas, carbon-dioxide, gaseous-phase 21 CFR 870.2340 electrocardiograph 21 CFR 870.2710 oximeter, ear 21 CFR 870.2700 oximeter 21 CFR 870.1425 computer, diagnostic, programmable 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 computer, blood-pressure 21 CFR 870.1130 system, measurement, blood-pressure, non-invasive 21 CFR 870.2910 thermometer, electronic, clinical 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 K071073, Patient Data Module (PDM) Additional predicates/reference devices: K132533 CARESCAPE Monitor B450 K022834 Pro1000 K080251 APEXPRO TELEMETRY SYSTEM K011000 TRAM module K051367 DASH 3000/4000/5000 monitoring systems K900598 TRAMSCOPE SYSTEM K171580 B105/B125 monitor K151063 Monitor B40 K110028 MASIMO RADICAL Y PULSE CO-OXIMETER K172482 The Nellcor pulse oximetry monitor interface cable. K053174 LOFLO C5 CO2 SENSOR K083750 CAPNOSTAT / CAPNOFLEX CO2 SYSTEM

Device Description (807.92(a)(4)):

CARESCAPE ONE is a new patient monitor device based on GE Healthcare predicate devices, the Patient Data Module (K071073) and the CARESCAPE B450 (K132533).

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 parameter, including 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. The ACM's are CARESCAPE TEMP, CARESCAPE PRES, CARESCAPE ECG, CARESCAPE SpO2 (TruSignal), CARESCAPE SpO2 – Nellcor, CARESCAPE SpO2 – Masimo and CARESCAPE CO2 – LoFlo. CARESCAPE SpO2 - Nellcor, CARESCAPE SpO2 - Masimo, and CARESCAPE CO2 - LoFlo have been developed by their respective companies/manufacturers (OEM) for use with the CARESCAPE ONE. The technology from each OEM has received 510(k) clearance and is adapted to function with the CARESCAPE ONE. The OEM technologies are not new and are not a part of this submission, only their integration into the Parameters/Active Cable Modules for use with the CARESCAPE ONE is covered in this 510(k).

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.

Intended Use: (807.92(a)(5)):	**Indications *(from labeling)***
	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
Technology (807.92(a)(6)):	The CARESCAPE ONE is a new multi-parameter monitor, introducing equivalent features and enhancements to existing features from two predicate devices. The primary predicate device is the PDM (K071073), and the main additional predicate used in this comparison is the CARESCAPE Monitor B450 with ESP V2 software (K132533).
	The CARESCAPE ONE can be used as a full-standalone multi-parameter monitor [equivalent to the CARESCAPE Monitor B450 (K132533) using the PDM (K071073)], providing the users the acquired display values, waveforms and alarms without the necessity of requiring a separate host monitor. The CARESCAPE ONE monitor's size is small and compact to support use in intra-hospital transport as well.

Some key features of the device are summarized below:

• The CARESCAPE ONE includes a touch screen display allowing the user to control the monitor's functions and display.
• CARESCAPE ONE can be used as a stand-alone monitor This is equivalent to the functionality to the predicate CARESCAPE Monitor B450 using the PDM module.
• The CARESCAPE ONE uses Active Cable Modules (also called Parameters) where the specific parameter electronics are encapsulated into the respective patient cables, allowing the monitor to be as compact as possible. In the PDM, the electronics related to a specific parameter, such as ECG, were contained within the PDM itself. In this case, the Active Cables Modules (ACMs) provide patient isolation, parameter data acquisition with signal conditioning, some signal processing, and USB communication back to the CARESCAPE ONE. The same technology to process and analyze the signals is maintained as compared to the predicate, and the equivalent functionality is maintained. However, the electronics are contained within the active cables themselves rather than inside the monitor.
• Incorporates an alarm system that complies with IEC 60601-1-8:2012. Also adds additional flexibility for clinicians to tailor the alarms to their particular patient needs such as the ability to select/adjust the alarm priority levels for certain alarms and adjust time delays/alarm trigger delays. Alarms are displayed and alerted with visual alerts and audio directly on the CARESCAPE ONE Monitor.
• Uses a Common Software Platform (CSP) that is used for the user interface, service interface, operating system, parameter data processing, alarms, trends, security, power management, and battery control. The operating system and display use a similar layout and look/feel as the CARESCAPE bedside monitors. This gives the user a similar experience across the various products.
• The CARESCAPE ONE incorporates the EK-Pro V14 arrhythmia detection algorithm into the monitor software. This is a slightly newer version of the EK-Pro algorithm that was utilized with the CARESCAPE Monitor B450 (EK-Pro v13), however it serves the same function and retains equivalent performance.
• The CARESCAPE ONE measures LoFlo Sidestream CO2. PDM did not measure CO2 on its own. The B450 does include the display of CO2 through associated parameter modules. The CARESCAPE ONE CO2 measurement technology has been

used by GE Healthcare in other existing bedside devices. The technology for this measurement has been cleared by its OEM developer, Respironics Novametrix LLC, with 510(k) K053174. This same technology was incorporated into GE Healthcare Solar and Dash bedside monitors with our Capnostat/Capnoflex CO2 System 510(k) K083750.
• The CARESCAPE ONE and the PDM can measure SpO2 with technology supplied by OEM manufacturers Masimo and Nellcor. The CARESCAPE ONE can also measure SpO2 with the GE Trusignal technology. This technology is used in multiple FDA cleared GE devices including the B105/B125 monitor (K171580) and the Monitor B40 (K151063).

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

Product Comparison versus Predicate Main features

Specification	**CARESCAPE B450 monitor with ESP V2 (K132533)**	**PDM (K071073)**	**CARESCAPE ONE**	**Discussion of Differences CARESCAPE ONE and Predicates**
Patient type	Adult, pediatric & neonatal	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)	Within a professional healthcare facility (Not intended for MRI)	Identical
Intrahospital transport within a professional healthcare facility.	Yes	Yes	Yes	Identical

Specification	CARESCAPE B450 monitor with ESP V2 (K132533)	PDM (K071073)	CARESCAPE ONE	Discussion of Differences CARESCAPE ONE and Predicates
Monitored Parameters	Parameters monitored by B450 with ESP V2 include: - hemodynamic (ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, cardiac output (thermodilution and pulse contour), temperature, mixed venous oxygen saturation, and central venous oxygen saturation), - respiratory (impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), spirometry, gas exchange) - neurophysiological status (electroencephalography, Entropy, Bispectral Index (BIS), and neuromuscular transmission).	Parameters monitored by PDM include: - hemodynamic (ECG, ST segment, arrhythmia detection, invasive pressures, NIBP, temperature, and pulse oximetry) - respiratory (impedance respiration)	Parameters monitored by CARESCAPE ONE include: - hemodynamic (ECG, ST segment, arrhythmia detection, invasive pressures, NIBP, temperature, and pulse oximetry) - respiratory (impedance respiration, CO2)	Equivalent. The CARESCAPE ONE monitors a subset of the parameters included for display on the B450. CARESCAPE ONE includes the same parameters for measurement acquisition as the PDM, with the addition of the LoFLo CO2 measurement. PDM does not include the CO2 parameter. The B450 does include the display of CO2 through associated parameter modules. The CARESCAPE ONE CO2 measurement technology has been used by GE Healthcare in other existing bedside devices. The technology for this measurement has been cleared by its OEM developer, Respironics Novametrix LLC, with 510(k) K053174. This same technology was incorporated into GE Healthcare Solar and Dash bedside monitors with our Capnostat/Capnoflex CO2 System 510(k) K083750. The additional parameters included in B450 which are not included in CARESCAPE ONE, such as anethetic agents, N2O, and BIS, are not necessary for the function and use of the CARESCAPE ONE monitor. These changes do not affect the determination of substantial equivalence.

Specification	CARESCAPE B450 monitor with ESP V2 (K132533)	PDM (K071073)	CARESCAPE ONE	Discussion of Differences CARESCAPE ONE and Predicates
Parameters Acquisition Method	B450 connects to multiple parameter acquisition modules, including PDM (Masimo and Nellcor), E-sCO, E-sCOV, E-sCAiO, E-sCAiOV, E-miniC, E-PSM, E-EEG, E-BIS, E-COP, E-ENTROPY, E-MASIMO, E-NMT, E-NSATX, E-P, E-PP, and E-PT for acquisition of measured parameters that are displayed on the B450.	The PDM is a parameter acquisition module, which includes the parameter acquisition electronics within the frame of the PDM.	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	Equivalent The same parameter acquisition technology is utilized in the CARESCAPE ONE as in the predicate PDM, however, some of the specific parameter electronics are encapsulated into the respective patient cables, allowing the monitor to be as compact as possible. In the PDM, the electronics related to a specific parameter, such as ECG, were contained within the PDM itself. In this case, the Active Cables Modules (ACMs) provide patient isolation, parameter data acquisition with signal conditioning, some signal processing, and USB communication back to the CARESCAPE ONE. The same technology to process and analyze the signals is maintained as compared to the predicate, and the equivalent functionality is maintained. However, the electronics are contained within the active cables themselves rather than inside the monitor. The additional measured parameter compared to PDM is CO2 as summarized in the line item above. The measurement technology and functionality remain equivalent to the predicate.
EK-Pro arrhythmia detection algorithm	EK-Pro V13	EK-Pro v11	EK-Pro V14	The CARESCAPE ONE incorporates the EK-Pro V14 arrhythmia detection algorithm into the monitor software. This is a slightly newer version of the EK-Pro algorithm that was utilized with the CARESCAPE Monitor B450 (EK-Pro v13), however it serves the same function and retains equivalent performance.

Specification	CARESCAPE B450 monitor with ESP V2 (K132533)	PDM (K071073)	CARESCAPE ONE	Discussion of Differences CARESCAPE ONE and Predicates
Size (H x W x D)	290 mm x 310 mm x 160 mm (11.4 in x 12.1 in x 6.2 in)	Height 6.4 cm (2.5 in.) maximum Width 14.0 cm (5.5 in.) maximum Depth 21.6 cm (8.5 in.) maximum	155 mm x 270 mm x 65 mm (6.1 in x 10.6 in x 2.6 in) Note: Excludes dock	Equivalent. The CARESCAPE ONE is a patient monitor and performs the function of both CARESCAPE PDM and CARESCAPE B450 combined. As a patient monitor, the CARESCAPE ONE has reduced size making it easier to transport and mount. This improvement does not impact the determination of substantial equivalence since it is only a change in the physical size of the device.
Weight	4.7 kg (10.4 lbs) with two batteries but without modules	1.0 kg (2.2 lbs.) without optional battery 1.2 kg (2.6 lbs.) with optional battery	1.85 kg (4.1 lbs) with battery	Equivalent. The CARESCAPE ONE is a patient monitor and performs the function of both CARESCAPE PDM and CARESCAPE B450 combined. As a patient monitor, the CARESCAPE ONE has reduced weight making it easier to transport and mount. This improvement does not affect the determination of substantial equivalence since it is only a change in the weight of the of the device making it lighter than the predicate combination that performed similar functions.
Battery Type	Lithium-Ion	Lithium-ion	Lithium-ion	Identical
Display size	12.1 in	Not Applicable	7 inch	Equivalent. The smaller form factor of the CARESCAPE ONE required a smaller screen compared to the B450. The PDM does not have a display screen as it was used as a parameter acquisition module to communicate data to a patient monitor, like B450. The smaller screen is intended to make the device more transportable. The parameter data, waveforms, and alarms adequately fit on the display. This smaller screen does not affect the determination of substantial equivalence since it is only a change in the screen size of the device with specific design to display numerics and waveforms as the predicate.

Specification	CARESCAPE B450 monitor with ESP V2 (K132533)	PDM (K071073)	CARESCAPE ONE	Discussion of Differences CARESCAPE ONE and Predicates
Display type	Active matrix color TFT LCD	Not Applicable	Active matrix color TFT LCD	Identical to B450.
Number of traces (waveforms)	Up to 6, or up to 12 if optional dual display is used.	Not Applicable	Up to 8 with 4 available on 2nd waveform page.	Equivalent. The lower number of waveforms shown at one time, 4 verses 6, and 8 verses 12, is due to having a smaller screen and smaller set of available parameters. These technical differences are intentional to make the CARESCAPE ONE more transportable. The CARESCAPE B450 patient monitor also supports some specialized parameters which includes more waveforms, and these specialized parameters are not available with the CARESCAPE ONE. The CARESCAPE ONE can show 8 waveforms with swiping to a second page/screen while the CARESCAPE B450 requires a second physical display. Waveforms for all parameters supported by the CARESCAPE ONE can be displayed at the same time using the second waveform page. The lower number of waveforms shown does not affect the determination of substantial equivalence since the device displays waveforms for the parameters it specifies.
Operating System	Linux 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)	Not Applicable	5 software packages: Emergency Care (ED), Critical Care (ICU), Operating Room (OR), Post-Anesthesia Care (PACU), Neonatal Care (NICU)	Identical.

Specification	CARESCAPE B450 monitor with ESP V2 (K132533)	PDM (K071073)	CARESCAPE ONE	Discussion of Differences CARESCAPE ONE and Predicates
Patient Network functionality	WLAN, LAN	Not Applicable	Not Applicable	CARESCAPE ONE is not a networked monitor. Patient monitors do not require connection to a clinical network for safe and effective use. Therefore, this change does not affect the determination of substantial equivalence since it has been designed not to be directly connected to the network.
Patient Network Ethernet port connector (RJ45-8-pin)	Yes Three Ethernet ports: Network MC, Network IX, Unity Network ID.	Yes Powered Ethernet TCP/IP and USB	No One Ethernet port for service tools.	Equivalent. The Ethernet port on the CARESCAPE ONE is intended for access to service functions when connected to the F0 Dock. This port is not intended for nor will it communicate on a clinical network. CARESCAPE ONE is not a networked monitor. Patient monitors do not require connection to a clinical network for safe and effective use. Therefore, this change does not affect the determination of substantial equivalence since it is only a change in the use of the network connection for service use since this device does not connect to the patient network.
Defaults available	User selectable arrhythmia alarm levels, Parameter settings and alarm levels, default alarm limits, display layout, parameter priority, catheters, drugs and common events defaults. Up to 8 different pre-configured or custom defaults available. Not all parameters have configurable alarm priorities.	Not Applicable	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.	Equivalent. The CARESCAPE ONE does not support catheters, drugs and common events. Other defaults available are equivalent. Support for these are features and not essential to the use of the device, and therefore this change does not affect the determination of substantial equivalence since it is only a change due to the fact that the device supports different parameters compared to the predicate.
Alarm Classification (IEC)	Four levels — High, Medium, Low and Informational	Not Applicable	Four levels — High, Medium, Low and Informational	Identical to B450. The predicate PDM is a parameter acquisition module that provides data to the host devices. PDM does not have a display and does not provide alarms; alarms are provided from the host device. The CARESCAPE ONE is a combination of the parameter acquisition technology and function from the PDM, and the display functionality of the B450.

Specification	CARESCAPE B450 monitor with ESP V2 (K132533)	PDM (K071073)	CARESCAPE ONE	Discussion of Differences CARESCAPE ONE and Predicates
Alarm Notification	Audible and visual	Not Applicable	Audible and visual	Identical
Technical alarms	System generated alarms to notify the user of special conditions.	Not Applicable	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.

The hardware bench testing included electromagnetic compatibility, electrical safety, environmental (including Mechanical stress testing and Package Testing) and usability.

The CARESCAPE ONE has been found to be safe and effective for the intended users, uses and use environments. Extensive usability work has been completed for CARESCAPE ONE and the predicate devices including critical task identification through use-based hazard analysis, multiple rounds of formative usability testing and summative testing, among other activities.

Software testing included software design, development, verification, validation and traceability. 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 was considered as a "Major" level of concern.

The CARESCAPE ONE monitor does not have direct contact with the patient. There are patient cables that can have unintended/intermittent intact skin contact with the patient and appropriate biocompatibility testing has been completed for those components.

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 map to 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.

Testing was completed for all parameter performance characteristics, including applicable consensus standards for ECG/Respiration, Invasive Blood Pressure, Temperature, SpO2, and CO2. The algorithms with changes compared to the predicates, EK-Pro V14 arrhythmia and TruSignal V3 SPO2 were validated as described below.

For EK-Pro V14 performance values for the applicable characteristics as defined in the ANSI/AAMI EC57:1998 (R)2012 standard has been provided to support a comparison of the EC57 results for the EK-Pro V14 algorithm (the subject device) to the predicate version EK-Pro V13 (K132533). The comparison demonstrates that the EC57 results and performance values are substantially equivalent between the subject V14 and predicate V13 versions of EK-Pro.

The accuracy of the SpO2 parameter as measured with the U-TruSignal ACM medical device (with TruSignal V3) during motion and non-motion conditions as compared to CO-oximetry in a controlled desaturation study was completed using the method as set forth by ISO 80601-2-61:2011 and the FDA guidance Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff, March 2013.

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 as safe, as effective, and the performance to be substantially equivalent to the predicate device.