October 21, 2021

GE Healthcare Finland Oy
Joel Kent
Senior Regulatory Affairs Manager
Kuortaneenkatu 2
Helsinki, Helsinki FI-00510
Finland

Re: K211171
Trade/Device Name: CARESCAPE Respiratory Modules E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, CCL, BZK, CAP, CBR, BZL, CBQ, CBS, NHO, NHQ, NHP
Dated: September 23, 2021
Received: September 27, 2021

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K211171

Device Name
CARESCAPE Respiratory Modules E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories

Indications for Use *(Describe)*
The CARESCAPE Respiratory Modules, (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE) are indicated for use with a host device for monitoring respiratory parameters (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and ventilatory parameters (airway pressure, flow and 13volume) of adult, pediatric and neonatal patients and gas exchange parameters (VCO2, VO2) of adult and pediatric patients.
When monitoring neonatal or other patients that have high respiration rate or low tidal volume these modules shall be used within the limits of respiration rates and tidal volumes to ensure specified measurement accuracy.
These modules are intended for use by qualified medical personnel only.

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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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: October 21, 2021

Owner/Submitter:
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00510 Helsinki
FINLAND

Primary Contact Person:
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Device names (807.92(a)(2)):

Trade Name: CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories

Common/Usual Name: Respiratory gas module and accessories

Classification Names: 21 CFR 868.1400 Analyzer, Gas, Carbon-Dioxide, Gaseous Phase

21 CFR 868.1720 Analyzer, Gas, Oxygen, Gaseous-Phase

21 CFR 868.1850 Spirometer, Monitoring (W/WO Alarm)

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21 CFR 868.2600 Monitor, Airway Pressure (Includes Gauge And/Or Alarm)

21 CFR 868.1700 Analyzer, Gas, Nitrous-Oxide, Gaseous-Phase (Anesthetic Conc.)

21 CFR 868.1730 Computer, Oxygen-Uptake

21 CFR 868.1500 Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)

21 CFR 868.1620 Analyzer, Gas, Halothane Gaseous-Phase (Anesthetic Conc.)

21 CFR 868.1500 Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)

21 CFR 868.1500 Analyzer, Gas, Isoflurane Gaseous-Phase (Anesthetic Concentration)

21 CFR 868.1500 Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)

Primary Product Code	CCK
Subsequent Product Code:	CCL, BZK, CAP, CBR, BZL, CBQ, CBS, NHO, NHQ, NHP
Predicate Device(s) (807.92(a)(3):	K183394 CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories

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

The CARESCAPE Respiratory Modules E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories measure respiratory parameters (concentrations of Carbon Dioxide, Oxygen, Nitrous Oxide and anesthetic agents in the patient's breath, as well as the patient's respiration rate), ventilatory parameters (airway pressure, flow and breathing volumes) and gas exchange parameters (oxygen consumption and carbon dioxide production) of hospital patients.

Parameters measured by the CARESCAPE Respiratory Modules are CO2, N2O, O2, Anesthetic agents, Agent ID, Spirometry, oxygen consumption (VO2) and carbon dioxide production

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(VCO2) depending on the model used. The CARESCAPE Respiratory Modules is a family of single-width plug-in parameter modules for modular monitoring systems. The CARESCAPE Respiratory Modules are of the diverting type, which means that a small continuous flow of gas is sampled from the patient's breath to the module for measuring the gas concentrations. The CARESCAPE Respiratory Modules acquire the signals detected by the module sensors, calculate the parameter values and communicate them to the host device. The CARESCAPE Respiratory Modules measure the patient's respiration rate and activate a status signal if no breaths are detected in 20 second time and the modules activate relevant status signals upon detecting failures or anomalies in the operation of the module hardware, software or gas sampling system.

The CARESCAPE Respiratory Modules do not trigger or issue any physiological or technical alarms by themselves. All management of alarms is entirely performed by the host devices based on parameter and status data received from the modules, as well as on the alarm condition data stored in the host device.

This 510(k) introduces two new module models in the CARESCAPE Respiratory Modules family: E-sCAiOE and E-sCAiOVE. These new module models include added hardware compared to the modules cleared in K183394. The operation, measured parameters and performance specifications of the E-sCAiOE and E-sCAiOVE is identical to E-sCAiO and E-sCAiOV when used with the current module host devices cleared in the USA. The added modules E-sCAiOE and E-sCAiOVE have the same software as CARESCAPE Respiratory Modules cleared in K183394.

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The indications for use are edited to include the added modules. There are no other changes to the indications for use.

Intended Use: (807.92(a)(5)): The CARESCAPE Respiratory Modules (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE) are indicated for use with a host device for monitoring respiratory parameters (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate) and ventilatory parameters (airway pressure, flow and volume) of adult, pediatric and neonatal patients and gas exchange parameters (VCO2, VO2) of adult and pediatric patients.

When monitoring neonatal or other patients that have high respiration rate or low tidal volume these modules shall be used within the limits of respiration rates and tidal volumes to ensure specified measurement accuracy.

These modules are intended for use by qualified medical personnel only.

Technology (807.92(a)(6)): The fundamental scientific technology of the CARESCAPE Respiratory Modules and accessories is the same as in the predicate devices (K183394). There are no changes to the measured parameters or calculations done by the host devices.

A summary of the main changes compared to the predicate device is listed below.

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Product Comparison versus Predicate Main Features:

Module Characteristics	Predicate CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories (K183394)	Proposed CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories	Discussion of Differences
Indications for use	The CARESCAPE Respiratory Modules (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX) are indicated for use with a host device for monitoring respiratory parameters (CO2, O2, N2O, anesthetic agents, anesthetic agent identification, and respiratory rate) and ventilatory parameters (airway pressure, flow and volume) of adult, pediatric, and neonatal patients and gas exchange parameters (VCO2, VO2) of adult and pediatric patients. When monitoring neonatal or other patients that have high respiration rate or low tidal volume these modules shall be used within the limits of respiration rates and tidal volumes to ensure specified measurement accuracy. These modules are intended for use by qualified medical personnel only.	The CARESCAPE Respiratory Modules (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE and E-sCAiOVE) are indicated for use with a host device for monitoring respiratory parameters (CO2, O2, N2O, anesthetic agents, anesthetic agent identification, and respiratory rate) and ventilatory parameters (airway pressure, flow and volume) of adult, pediatric, and neonatal patients and gas exchange parameters (VCO2, VO2) of adult and pediatric patients. When monitoring neonatal or other patients that have high respiration rate or low tidal volume these modules shall be used within the limits of respiration rates and tidal volumes to ensure specified measurement accuracy. These modules are intended for use by qualified medical personnel only.	Equivalent Editorial change to add models E-sCAiOE and E-sCAiOVE to the indications for use statement. The change does not significantly affect safety and/or effectiveness.
Physical Properties			
Module size (H x W x D)	112 x 37 x 205 mm (4.4 x 1.5 x 8.7 in)	112 x 37 x 205 mm (4.4 x 1.5 x 8.7 in)	Identical
Module weight	0.7 kg (1.5 lb)	0.7 kg (1.5 lb)	Identical

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Parameter specifications			
Gas sampling flow rate	120 ±20 ml/min	120 ±20 ml/min	Identical
Respiration Rate: Measurement range	4 to 100 breaths/min	4 to 100 breaths/min	Identical
Respiration Rate: Breath detection	1 vol% peak to peak change in CO2 level	1 vol% peak to peak change in CO2 level	Identical
Measurements of CO2, N2O and anesthetic agent concentrations and identification of anesthetic agents			
Measurement principle	Non-dispersive Infrared sensor	Non-dispersive Infrared sensor	Identical
CO2 Measurement range	0 to 15 vol% (0 to 15 kPa) (0 to 113 mmHg)	0 to 15 vol% (0 to 15 kPa) (0 to 113 mmHg)	Identical
CO2 Accuracy	± (0.2vol%+2% of reading)	± (0.2vol%+2% of reading)	Identical
N2O Measurement range	0…100vol%	0…100vol%	Identical
N2O Accuracy	±(2 vol% + 2% of reading) ±(2 vol% + 8% of reading for concentrations 85…100 vol%	±(2 vol% + 2% of reading) ±(2 vol% + 8% of reading for concentrations 85…100 vol%	Identical
Anesthetic agents measured	Halothane, Enflurane, Isoflurane, Sevoflurane, Desfurane	Halothane, Enflurane, Isoflurane, Sevoflurane, Desfurane	Identical
Anesthetic agent Measurement ranges	Hal, Enf, Iso: 0 to 6 vol% Sev: 0 to 8 vol% Des: 0 to 20 vol%	Hal, Enf, Iso: 0 to 6 vol% Sev: 0 to 8 vol% Des: 0 to 20 vol%	Identical
Anesthetic agents Accuracy	±(0.15vol%+5% of reading)	±(0.15vol%+5% of reading)	Identical
Measurement of oxygen concentration			
Measurement principle	Differential paramagnetic measurement	Differential paramagnetic measurement	Identical
Measurement range	0 to 100 vol%	0 to 100 vol%	Identical
Accuracy	± (1 vol%+2% of reading)	± (1 vol%+2% of reading)	Identical

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Spirometry measurements			
Measurement principle	Pressure signals conducted to the module from D-Lite or Pedi-Lite airway adapters by a double lumen tube	Pressure signals conducted to the module from D-Lite or Pedi-Lite airway adapters by a double lumen tube	Identical
Airway pressure Measurement range	-20 … +100 cmH_2O	-20 … +100 cmH_2O	Identical
Airway Pressure Accuracy	±1 cmH_2O	±1 cmH_2O	Identical
Airway Flow Measurement range	-100…+100 l/min. (adults) -25…+25 l/min (pediatric)	-100…+100 l/min. (adults) -25…+25 l/min (pediatric)	Identical
Tidal volume Measurement range	150…2000 ml (adults) 5…300 ml (pediatric)	150…2000 ml (adults) 5…300 ml (pediatric)	Identical
Tidal Volume Accuracy	±6 % or 30 ml adult ±6 % or 4 ml pediatric	±6 % or 30 ml adult ±6 % or 4 ml pediatric	Identical
Minute volume Measurement range	2…20 l/min. (adults) 0.1…5 l/min. (pediatric)	2…20 l/min. (adults) 0.1…5 l/min. (pediatric)	Identical
Gas Exchange measurements			
VO2 measurement range	20 to 1000 ml/min	20 to 1000 ml/min	Identical
VO2 measurement accuracy	With D-lite, D-lite+ and Pedi-lite: ±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65%) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85%) With D-lite++ ±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65% and respiration rate≤ 30 breaths/min) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85% or respiration rate> 30 breaths/min) Not valid with O2+N2O mixtures.	With D-lite, D-lite+ and Pedi-lite: ±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65%) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85%) With D-lite++ ±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65% and respiration rate≤ 30 breaths/min) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85% or respiration rate> 30 breaths/min) Not valid with O2+N2O mixtures.	Identical Identical Identical
VCO2 measurement range	20 to 1000 ml/min	20 to 1000 ml/min	Identical
VCO2	With D-lite, D-lite+ and Pedi-lite:	With D-lite, D-lite+ and Pedi-lite:	Identical

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measurement accuracy	±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65%) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85%) With D-lite++ ±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65% and respiration rate≤ 30 breaths/min) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85% or respiration rate> 30 breaths/min) Not valid with O2+N2O mixtures	±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65%) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85%) With D-lite++ ±10 % or ±10 ml, whichever is greater (FiO2 ≤ 65% and respiration rate≤ 30 breaths/min) ±15 % or ±15 ml, whichever is greater (FiO2: 65%...85% or respiration rate> 30 breaths/min) Not valid with O2+N2O mixtures	Identical Identical
Front panel connectors			
Gas sampling line connector	The D-fend Pro water trap located on the module front panel includes a gas sampling line connector.	The D-fend Pro water trap located on the module front panel includes a gas sampling line connector.	Identical
Gas exhaust line connector	The module front panel includes a gas exhaust connector for connecting the gas exhaust line.	The module front panel includes a gas exhaust connector for connecting the gas exhaust line.	Identical
Spirometry connectors	E-sCAiOV and E-sCAiOVX: Two spirometry connectors for connecting the spirometry tubes.	E-sCAiOV, E-sCAiOVX and E-sCAiOVE: Two spirometry connectors for connecting the spirometry tubes.	Identical
Mechanical interface for connecting the fresh gas sampling line	Not available	The E-sCAiOE and E-sCAiOVE module front panel includes a fresh gas sample connector utilized in some anesthesia applications.	Equivalent The fresh gas connector is only utilized in some anesthesia machine applications. When the fresh gas sample connector is not in use, the operation of E-sCAiOE and E-sCAiOVE is identical to E-sCAiO and E-sCAiOV, respectively.

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Labeling			
Module Front Panel Labeling	The labeling on the module front panel includes the following items: Module type (eg. E-sCO) Gas input (symbol ISO 7000-0794) Gas exhaust (symbol ISO 7000-0795) Spirometry inputs (E-sCOV, E-sCOVX, E-sCAiOV, E-sCAiOVX only, text "Spirometry") Spirometry key labeling (Save Loop Change Loop) BF type applied part (symbol IEC 60417-5333)	The labeling on the module front panel includes the following items: Module type (eg. E-sCO) Gas input (symbol ISO 7000-0794) Gas exhaust (symbol ISO 7000-0795) Spirometry inputs (E-sCOV, E-sCOVX, E-sCAiOV, E-sCAiOVX, E-sCAiOVE only, text "Spirometry") Spirometry key labeling (Save Loop Change Loop) (E-sCOV, E-sCOVX, E-sCAiOV, E-sCAiOVX, E-sCAiOVE only) BF type applied part (symbol IEC 60417-5333) The E-sCAiOE and E-sCAiOVE modules include symbol "input" ISO 7000-0794 next to the fresh gas connector.	Equivalent The E-sCAiOE and E-sCAiOVE modules have symbol ISO 7000-0794 next to the fresh gas connector as required by ISO 80601-2-55:2018 clause 201.7.2.101 e). The addition does not affect safety and/or effectiveness of the device.
Module user's manual	The modules have a user's manual that describes the usage, technical specifications and safety of the CARESCAPE Respiratory Modules.	The modules have a user's manual that describes the usage, technical specifications and safety of the CARESCAPE Respiratory Modules. The user's manual has been revised to refer to the E-sCAiOE and E-sCAiOVE modules in various instances. Also an explanation for the fresh gas connector and a note indicating only qualified service personnel is authorized to remove the protecting screw have been added. In addition to the modifications required due to the addition of the E-sCAiOE and E-sCAiOVE modules, other minor editorial clarifications have been made.	Equivalent The user's manual has been updated to describe the fresh gas connector and to advise that only qualified service personnel is authorized to interact with the connector. Other updates to the user's manual are considered minor editorial updates. This does not affect safety and/or effectiveness of the device.

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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 Respiratory Modules, demonstrating the design meets the specifications.

Biocompatibility testing related to System level Volatile Organic Compounds (VOC) and particulate matter testing has been executed to cover biocompatibility for the new materials in the dry gas path.

Hardware testing of the modules included gas accuracy verification, gas module pneumatics verification and leakage verification. In addition, functionality with a host device during the Fresh Gas Sample Check has been verified.

Testing compliance of the device with the applicable standards was completed as follows:

- IEC 60601-1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014: Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-49: 2011: Medical electrical equipment Part 2-49: Particular requirements for the safety essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55: 2011: Medical electrical equipment Part 2-55: Particular requirements for the basic safety and

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essential performance of respiratory gas monitors

Environmental testing was successfully completed per the safety and particular standard above as well as ISTA 2A:2011.

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 is considered "Major" level of concern, the same as the

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

The subject of this premarket submission, the CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE Healthcare considers the CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE and accessories to be as safe, as effective, and performance is substantially equivalent to the predicate device.