GE Healthcare Finland Oy
Anna Pehrsson
Regulatory Affairs Leader
Kuortaneenkatu 2
Helsinki, FI-00510 Fi

Re: K183394
Trade/Device Name: CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO
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: March 29, 2019
Received: April 1, 2019

Dear Anna Pehrsson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Michael Ryan
Director
DHT1C: Division of ENT, 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)*

K183394

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

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories

GE Healthcare Finland Oy
Kuortaneenkatu 2, P.O. Box 900
FI-00031 GE
Finland
T: +358 10 39411

K183394 - 510(k) Summary

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

Date: December 05, 2018

Submitter: GE Healthcare Finland Oy,
Kuortaneenkatu 2, Helsinki,
FI-00510 FINLAND

Primary Contact Person: Anna Pehrsson
Regulatory Affairs Leader
GE Healthcare Finland Oy
phone (+358) 40 569 5018
email anna.pehrsson@ge.com

Secondary Contact Person: Joel Kent
Senior Regulatory Affairs Manager
GE Healthcare
phone +617 851 0943
email joel.kent@ge.com

Device names:

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

Common/Usual Name: Respiratory gas module and accessories

Classification Name:	21 CFR 868.1400 Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Product Code:	CCK
Additional Classification Names:	21 CFR 868.1720 Analyzer, Gas, Oxygen, Gaseous-Phase
	21 CFR 868.1850 Spirometer, Monitoring (W/WO Alarm)
	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)
Additional Product Codes:	CCL, BZK, CAP, CBR, BZL, CBQ, CBS, NHO, NHQ, NHP
Predicate Device(s):	K171028: CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories
Device Description:	The CARESCAPE Respiratory Modules E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX 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 (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 Special 510(k) introduces two new spirometry accessories: 2104297-001 D-lite++ Patient Spirometry Set, 2m/7ft and 2104297-002 D-lite++ Patient Spirometry Set, 3m/10ft. The design of the D-lite++ Patient Spirometry Sets is based on the design of previously cleared accessories 8004381 D-lite+ Spirometry Kit, adult, 2m/7ft and 8004382 D-lite+ Spirometry Kit, adult, 3m/10ft (510(k) K171028) used for spirometry, gas exchange and gas measurement and owned by GE Healthcare Finland Oy. The main modifications are in the design of the spirometry sensor part of the product; the gas sampling line connector shape and location have been modified and spirometry connector internal volumes have been expanded. The only new material introduced is cyanoacrylate glue CB 2011 used for attaching the spirometry connector to the sensor body. The only new manufacturing method introduced is ultrasonic welding used for attaching the gas sampling line connector to the sensor

body. The CARESCAPE Respiratory Module measurement specifications are unaffected except for a minor decrease in gas exchange VO2 and VCO2 accuracy specifications with respiration rates above 30 breaths/min when the measurement is performed using the D-lite++ Patient Spirometry Sets. The specification change does not raise different questions of safety or effectiveness of the CARESCAPE Respiratory Modules.

There are no changes to indications for use, hardware, software, mechanics or electrical safety of the CARESCAPE Respiratory Modules due to the D-lite++ Patient Spirometry Sets. The introduction of the D-lite++ Patient Spirometry Sets does not add or change the functionality or fundamental scientific technology of the CARESCAPE Respiratory Modules. The D-lite++ Patient Spirometry Sets employ the same fundamental scientific technology as the existing accessories 8004381 D-lite+ Spirometry Kit, adult, 2m/7ft and 8004382 D-lite+ Spirometry Kit, adult, 3m/10ft used for spirometry, gas exchange and gas measurement with the CARESCAPE Respiratory Modules.

Intended 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.

Technology:

The fundamental scientific technology of the CARESCAPE Respiratory Modules and accessories is the same as in the predicate devices (K171028). There are no changes to the measured parameters or calculations done by the host devices. The D-lite++ Patient Spirometry Sets employ the same fundamental technology for the spirometry, gas exchange and gas measurement as the existing accessories 8004381 D-lite+

Spirometry Kit, adult, 2m/7ft and 8004382 D-lite+ Spirometry Kit, adult, 3m/10ft used for these measurements.

The CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories is as safe and effective as the predicate device.

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

Summary of Non-Clinical Tests

The CARESCAPE Respiratory Modules and its applications comply with voluntary standards as detailed below. There are no changes or additions to the CARESCAPE Respiratory Modules' indications for use, fundamental scientific technology used, software, hardware, or mechanics related to the addition of the D-lite++ Patient Spirometry Sets.

Bench testing supports the substantial equivalence determination of the modified CARESCAPE Respiratory Modules when compared to the predicate device. Due to the device modification, verification testing was performed to confirm that the spirometry, gas exchange and gas accuracy measurements of the CARESCAPE Respiratory Modules perform as intended and within specification when the D-lite++ Patient Spirometry Sets are used in the measurement. Testing was also performed to ensure the tightness of the ultrasonic welding of the gas sampling line connector.

The CARESCAPE Respirator Module measurement specifications are unaffected except for a minor decrease in gas exchange VO2 and VCO2 accuracy specifications with respiration rates above 30 breaths/min when the measurement is performed using the new accessories. This change is considered clinically non-significant and it does not raise different questions of safety and effectiveness of the CARESCAPE Respiratory Modules.

A biological assessment was performed for the D-lite++ Patient Spirometry Sets to verify the D-lite++ Patient Spirometry Sets do not pose any biological safety risks for the patient when the products are used according to their intended use.

The completed testing supports the substantial equivalence determination of the modified CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories remains unchanged when compared to the predicate device.

Changes to the labeling, hardware and components of the CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories since the last clearance (K171028) reflect on-going product maintenance activities and do not affect product performance. It is concluded that the CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories are substantially equivalent to the predicate device.

The CARESCAPE Respiratory Modules have been designed and tested for compliance to the following standards:

1. IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests – Edition 3
3. IEC 62304:2015 Medical device software - Software life cycle processes
4. IEC 60601-1-6:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
5. IEC 62366:2014 Medical devices - Application of usability engineering to medical devices
6. ISO 80601-2-55:2011 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
7. ISO 14971:2007 Medical devices - Application of risk management to medical devices

Summary of Clinical Tests:

Clinical (807.92(b)(2)): The subject of this premarket submission, CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): The verification and analysis described above demonstrate that the modifications do not raise different questions regarding the safety, effectiveness or performance of the device. GE Healthcare therefore considers the CARESCAPE Respiratory Modules, E-

sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories to be as safe, as effective, and performance is substantially equivalent to the predicate device.