DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 17, 2017

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

Re: K171028
Trade/Device Name: CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX 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: July 5, 2017
Received: July 17, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S
2017.08.17 06:34:11 -04'00'

for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K171028

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

Indications for Use *(Describe)*
The CARESCAPE Respiratory Modules (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, EsCAiOV, 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.

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GE Healthcare Finland Oy
Kuortaneenkatu 2, P.O. Box 900
FI-00031 GE
Finland
T: +358 10 39411
F: +358 9 1463310

K171028

510(k) Summary

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

Date: July 5, 2017

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: Rauno Ruoho
Regulatory Affairs Director
GE Healthcare Finland Oy
phone (+358) 10-394-3624
email rauno.ruoho@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 conc.) 21 CFR 868.1620 Analyzer, Gas, Halothane Gaseous-phase (Anesthetic conc.) 21 CFR 868.1500 Analyzer, Gas, Desflurane, Gaseous-phase (Anesthetic conc.) 21 CFR 868.1500 Analyzer, Gas, Isoflurane Gaseous-phase (Anesthetic conc.) 21 CFR 868.1500 Analyzer, Gas, Sevoflurane, Gaseous-phase (Anesthetic conc)
Additional Product Codes:	CCL, BZK, CAP, CBR, BZL, CBQ, CBS, NHO, NHQ, NHP
Predicate Device(s):	K150245: CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX
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 detected signals from the sensors of the modules, 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.

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 modified CARESCAPE Respiratory Modules E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessories do not add any new technology or software to existing predicate device CARESCAPE Respiratory Modules.

The sample gas return feature is added to CARESCAPE Respiratory Modules. The feature may only be used with host device anesthesia machines which have 510(k) clearance for the gas return feature.

The technology of the CARESCAPE Respiratory Modules and accessories is the same as in the predicate device.

The CARESCAPE Respiratory Modules and accessories is as safe and effective as the predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests

The CARESCAPE Respiratory Modules and its applications comply with voluntary standards as detailed below. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

There are no changes or additions to module software, hardware, mechanics or accessories related to the addition of sample gas return feature. Based on this, testing of the modules is only done to cover any possible effects introduced by the gas return circuit in the host device. An evaluation was performed to account for gas return connection and gas return filter impact on the gas measurement accuracy, sample flow measurement accuracy as well as pump and filter lifetime. System level

Volatile Organic Component (VOC) and particulate matter testing was performed to evaluate new components and materials in the dry gas path.

Changes to the labeling, hardware and components of the CARESCAPE Respiratory Modules since the last clearance of the CARESCAPE Respiratory Modules (K150245) reflect on-going product maintenance activities and do not affect product safety and performance. It is concluded that the CARESCAPE Respiratory Modules and accessories are substantially equivalent to the predicate device.

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

1. IEC 60601-1:1988, A1:1991, A2:1995, Corr1:1995, Medical electrical equipment Part 1: General Requirements for Safety - Second Edition
2. IEC 60601-1-2:2001, A1:2004, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests - Edition 2.0
3. 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
4. IEC 60601-1-4:1996 + A1:1999, Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
5. IEC 62304:2006, Medical device software - Software life-cycle processes
6. IEC 60601-1-6:2006, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability – Edition 2.0
7. IEC 60601-1-6:2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
8. IEC 62366:2007, Medical Devices – Application of usability engineering to medical devices

9. ISO 21647:2004 + C1:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors
10. EN 1041:2008, Information supplied by the manufacturer of medical devices
11. ISO 14971: 2007 Medical devices - Application of risk management to medical devices

Summary of Clinical Tests: 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: GE Healthcare 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.