K123195

FEB 2 8 2013

## 510(k) Summary

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

Date: October 10, 2012

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

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

Common/Usual Name: Respiratory gas module

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)

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 868.1500 Analyzer, Gas, Enflurane, Gaseous-phase (Anesthetic conc.)

21 CFR 868.1500 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)

Product Code: CCK, CCL, BZK, CAP, CBR, CBQ, CBS, NHO, NHQ, NHP

Predicate Device(s): K051092: Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CaiOV, E-CaiO, E-COVX, E-COV, E-CO and accessories.

Device Description: The CARESCAPE™ Respiratory Modules, E-sCO, E-sCOV, E-sCAiO and E-sCAiOV 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) and ventilatory parameters (airway pressure, flow and breathing volumes) of hospital patients.

Parameters measured by the CARESCAPE™ Respiratory Modules and accessories are CO2, N2O, O2, Anesthetic agents, Agent ID and Spirometry 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 monitors 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-sCAiO, E-sCAiOV) 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. 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 CARESCAPE™ Respiratory Modules is a modified version of the predicate Datex-Ohmeda S/5™ Compact Airway Module (model family E-CAiOVX) E-CAiOVX, E-CaiOV, E-CaiO, E-COVX, E-COV, E-CO and accessories (K051092) with improved features and parameters.

The fundamental technology of the CARESCAPE™ Respiratory Modules is the same as the predicate devices.

The CARESCAPE™ Respiratory Modules is as safe and effective as the predicate devices.

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)

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

3. IEC 60601-1-4:2000 Consol. Ed. 1.1, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1. (General)

4. IEC60601-1-6:2006, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – collateral Standard: Usability

5. EN1041:2008, Information supplied by the manufacturer of medical devices

6. ISO 21647:2009, Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors

Except for the following clauses:

- Clause 49.101 The RGM shall provide at least a medium priority alarm signal when the power falls below the minimum value for normal operation.

This non-compliance is valid with following monitors: S/5 Anesthesia monitor (AM), S/5 Critical Care Monitor (CCM), S/5 Compact Anesthesia Monitor (CAM), S/5 Compact Critical Care Monitor (CCCM) and CARESCAPE B850.

- Clause 57.3 aa) Any detachable power supply cord of an RGM shall be protected against accidental disconnection at the appliance inlet.

This non-compliance is valid with following monitors: S/5

Anesthesia monitor (AM), S/5 Critical Care Monitor (CCM), S/5 Compact Anesthesia Monitor (CAM), S/5 Compact Critical Care Monitor (CCCM).

- Clause 102 Compliance with all the requirements of IEC 60601-1-8:2003

This non-compliance is valid with following monitors: S/5 Anesthesia monitor (AM), S/5 Critical Care Monitor (CCM), S/5 Compact Anesthesia Monitor (CAM), S/5 Compact Critical Care Monitor (CCCM).

- Clause 201.1.2 For each respiratory gas that an RGM is designed to monitor, the RGM shall provide a means to detect each gas reading alarm condition, with its minimum priority. If the RGM is capable of detecting the presence of more than one halogenated anaesthetic agent within a gas mixture, but not of quantifying gas levels and displaying the gas readings, it shall generate at least a medium priority alarm signal in the presence of such a mixture.

This non-compliance is valid with following monitors: S/5 Anesthesia monitor (AM), S/5 Critical Care Monitor (CCM), S/5 Compact Anesthesia Monitor (CAM), S/5 Compact Critical Care Monitor (CCCM), CARESCAPE B650 and CARESCAPE B850.

- Clause 201.1.2 If the RGM is capable of detecting, quantifying and displaying a mixture of halogenated agents, the RGM shall

a) generate at least a low priority alarm signal whenever it detects a mixture of halogenated agents of less

than three MAC; and

b) generate at least a medium priority alarm signal whenever it detects a mixture of halogenated agents of equal to or greater than three MAC.

This non-compliance is valid with following monitors: S/5 Anesthesia monitor (AM), S/5 Critical Care Monitor (CCM), S/5 Compact Anesthesia Monitor (CAM), S/5 Compact Critical Care Monitor (CCCM).

- Clause 201.8.3 The manufacturer-configured alarm preset for the audio-paused or alarm-paused interval shall be no greater than 2 min.

This non-compliance is valid with following monitors: S/5 Anesthesia monitor (AM), S/5 Critical Care Monitor (CCM), S/5 Compact Anesthesia Monitor (CAM), S/5 Compact Critical Care Monitor (CCCM).

7. IEC 62366:2007, Medical Devices – Application of usability engineering to medical devices (General)

Summary of Clinical Tests:

The subject of this premarket submission, CARESCAPE™ Respiratory Modules did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the CARESCAPE™ Respiratory Modules, E-sCO, E-sCOV, E-sCAiO and E-sCAiOV and accessories to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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

February 28, 2013

Mr. Rauno Ruoho
GE Healthcare Finland Oy
Kuortaneenkatu 2
Helsinki, Finland FIN-00510

Re: K123195
Trade/Device Name: CARESCAPE™ Respiratory Modules, E-sCO E-sCOV E-sCAiO and E-sCAiOV and Accessories
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: January 24, 2013
Received: January 28, 2013

Dear Mr. Ruoho:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123195

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

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

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**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K123195