DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 12, 2015

Datex-Ohmeda, Inc.
Trishia Mercier
Regulatory Affairs Leader
PO Box 7550
Madison, WI 53707

Re: K142679

Trade/Device Name: CARESCAPE R860
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, continuous, facility use
Class: II
Product Code: CBK
Dated: May 12, 2015
Received: May 13, 2015

Dear Ms. Mercier:

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 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142679

Device Name
CARESCAPE R860

Indications for Use *(Describe)*

The CARESCAPE R860 ventilator is designed to provide mechanical ventilation or support to neonatal, pediatric, and adult patients weighing 0.25 kg and above. The CARESCAPE R860 ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator that includes integrated monitoring of FiO2, airway pressure, flow, and volume.

Additional respiratory gas monitoring capabilities are supported through the use of optional GE patient monitoring modules.

Not all features are available for all patient types or product configurations.
The CARESCAPE R860 ventilator is not a pulmonary function calculation device.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

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

Date:	September 17, 2014
Submitter:	GE Healthcare Datex-Ohmeda, Inc. 3030 Ohmeda Drive P.O. Box 7550 Madison, WI 53707-7550 USA
Primary Contact Person:	Trishia Mercier Regulatory Affairs Leader Telephone: (608) 709-3260 Fax: (608) 646-6488 Email: Trishia.Mercier@ge.com
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Device Trade Name:	CARESCAPE R860
Common/Usual Name:	Ventilator, Continuous
Classification Names: Product Code: Regulation Number:	Ventilator, continuous, facility use CBK 21 CFR 868.5895
Predicate Device(s):	GE Datex-Ohmeda Engström Carestation, Engström Pro K111116 Maquet Servo-I Ventilator K123149
Intended Use:	The CARESCAPE R860 ventilator is designed to provide mechanical ventilation or support to neonatal, pediatric, and adult patients weighing 0.25 kg and above. The CARESCAPE R860 ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator that includes integrated monitoring of FiO2, airway pressure, flow, and volume. Additional respiratory gas monitoring capabilities are supported through the use of optional GE patient monitoring

	modules. Not all features are available for all patient types or product configurations. The CARESCAPE R860 ventilator is not a pulmonary function calculation device. The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

Device Description:

The CARESCAPE R860 is a flexible, adaptable, intuitive critical care ventilator. Touchscreen capability allows the user to quickly and easily access patient information and procedures. A wide selection of performance options gives the user full control of the system configuration. The CARESCAPE R860 features patient monitoring, patient ventilation, and the capability of interfacing with central information management systems.

The CARESCAPE R860 is designed to provide mechanical ventilation for adult, pediatric and neonatal patient types weighing 0.25 kg and above, and having degrees of pulmonary impairment varying from minor to severe.

The CARESCAPE R860 introduces a new user interface with touch screen capabilities. Icons represent configurable views of past (historical trends), present (patient status), and possible future patient needs through clinical decision support, including Spontaneous Breathing Trial to evaluate a patient's ability to breath spontaneously for a limited, specified duration of time.

This ventilator comes with standard ventilation modes as well as purchasable ventilation modes and clinical decision support features.

Standard ventilation modes:

- A/C VC (Assist Control Volume Control)
- A/C PC (Assist Control Pressure Control)
- A/C PRVC (Assist Control Pressure Regulated Volume Control)
- SIMV VC (Synchronized Intermittent Mandatory Ventilation Volume Control)
- SIMV PC (Synchronized Intermittent Mandatory Ventilation Pressure Control)
- CPAP/PS (Continuous Positive Airway Pressure/Pressure Support)
- SBT (Spontaneous Breathing Trial)

Purchasable ventilation modes:

- nCPAP (nasal Continuous Positive Airway Pressure)
- SIMV PRVC (Synchronized Intermittent Mandatory Ventilation Pressure Regulated Volume Control)

- BiLevel
- BiLevel VG (BiLevel airway pressure ventilation Volume Guaranteed)
- VS (Volume Support)
- NIV (Non-Invasive Ventilation)
- APRV (Airway Pressure Release Ventilation)

Additional features:

- FRC (Functional Residual Capacity)
- SpiroDynamics

The CARESCAPE R860 is based on the Engström Carestation feature set and contains similar performance characteristics to the Engström family of ventilators.

The CARESCAPE R860 is a microprocessor-based, pneumatically controlled, data driven ventilator which includes integrated FiO2, airway pressure, spirometry and volume monitoring and an Aerogen Aeroneb nebulizer control board. The ventilator consists of two main components: the display and the ventilator unit. The display allows the user to interface with the system through a resistive touch screen and Trim Knob with keys. The CARESCAPE R860 also includes an optional module bay which allows the integration of various Datex-Ohmeda patient monitoring modules with the ventilator.

The user interface for control of nebulization is provided via the ventilator display unit. The standard nebulizer board is provided with the CARESCAPE R860. Users have the option to configure the system to use an external pneumatic nebulizer in place of the standard nebulizer.

Optional accessories common to the CARESCAPE R860 and the predicate Engström family of ventilators include a trolley/cart, integrated air compressor, support arm, humidifier and water trap mounting brackets. Additional optional accessories include airway modules, intratracheal pressure sensor, auxiliary electrical outlets, adjustable mounting rail, nebulizer and components, and module bay.

The optional medical air compressor is intended for use as an accessory to provide a dry, filtered, breathable compressed air supply. The compressor is installed in the base of the ventilator cart. The compressor is powered from AC mains only. A source of compressed oxygen is required to be connected to ventilator equipped with the optional compressor. The use of an integrated air compressor was first cleared on the predicate Engström Carestation and Engström Pro in K050597.

Optional functionality includes integrated respiratory gas monitoring, capabilities to measure SpiroDynamics via a GE supplied intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method. The integrated respiratory gas monitoring is provided via the Datex-Ohmeda Gas Modules, E-CO, E-COV, E-COVX, E-CAiO, E-CAiOV, E-CAiOVX (K051092), E-MiniC module (K052582), or E-sCO, E-sCOV, E-sCAiO, E-sCAiOV (K123195) which are physically

integrated into the CARESCAPE R860, receive electronic power from the CARESCAPE R860 and communicate measured values to the CARESCAPE R860 for display on the system display unit.

Summary of the Technological Characteristics of the Device:

The CARESCAPE R860 is based on the Engström Carestation feature set and contains similar performance characteristics to the Engström family of ventilators. Changes include the addition of an upgraded display, new graphical user interface, added accessories and upgraded software. The CARESCAPE R860 is designed to be compliant with ANSI/AAMI ES60601-1:2005 (R 2012), Medical electrical equipment, Part 1: General requirements for basic safety and essential performance and the relevant collateral standards. There are no changes to the intended use or fundamental scientific technology of the ventilator.

Summary of Non-Clinical Testing for the Device:

The CARESCAPE R860 ventilator has been thoroughly tested through verification of specifications and validation, including software validation, to ensure the product is substantially equivalent to the predicate Engstrom Carestation. Verification of compliance with applicable standards has also been completed. The following quality assurance measures were applied during the development of the CARESCAPE R860 system:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Testing on unit level
- Integration testing
- Performance Testing (Verification)
- Safety Testing (Verification)
- Simulated Use/User Requirements Testing (Validation)
- Standards Compliance – the list of standards to which the CARESCAPE R860 complies is listed below:
    - ANSI/AAMI ES60601-1:2005 (R 2012
    - IEC 60601-1-2:2007 + 2010 Interpretation
        - Includes additional testing applicable to RFID frequency ranges of 125 kHz/134 kHz, 13.56 MHz, 902-915 MHz and 2.4 GHz
    - IEC 60601-1-6: 2010
    - IEC 60601-1-8: 2006
    - ISO 80601-2-12:2011 + Technical Corrigendum 1

- IEC 62366:2008
- ISO 5356-1
- IEC 62304

Extensive non-clinical testing was performed to establish substantial equivalence of the CARESCAPE R860. Verification and validation testing was performed according to pre-determined acceptance criteria, which concluded that the CARESCAPE R860 is substantially equivalent to the predicate Engström Carestation.

Summary of Clinical Testing for the Device:

The CARESCAPE R860 ventilator incorporates modifications to the predicate Engstrom Carestation. These modifications did not require clinical testing. The changes made were completely evaluated by non-clinical tests to verify and validate the substantial equivalence of the ventilator.

Summary of Changes:

The following is an overview of the differences between the proposed CARESCAPE R860 and the predicate Engström Carestation:

- Upgraded 15 inch LCD and Tough Screen
- Simplified graphic User Interface for the features that exist in 7.x, but with a simplified hierarchy, designed for ease of use
- Updated the names of the ventilation modes
- Added Volume Support for Adult and Pediatric patients
- Updated accessories list, including addition of a new optional compressor, the EVair compressor, Inspiratory Safety Guard, Accessory Rail and updated gas monitoring modules from GE
- Visual differentiation of the neonatal patient type from the adult and pediatric patient type. Labeling will more clearly designate the neonatal patient type from the adult and pediatric
- Updated User Requirements Manual and Technical Reference Manual which reflect the new user interface
- Compliant with ANSI/AAMI ES60601-1:2005 (R 2012), Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

Determination of Substantial Equivalence:

Datex-Ohmeda, Inc., doing business as GE Healthcare, considers the CARESCAPE R860 to be as safe and as effective, and performance is substantially equivalent to as the predicate device, the Engström Carestation. The summary above demonstrates that there are no new questions of safety or effectiveness for the CARESCAPE R860.