Datex-Ohmeda, Inc.
Monica Morrison
Regulatory Affairs
3030 Ohmeda Drive, PO Box 7550
Madison, Wisconsin 53707-7550

Re: K210384
Trade/Device Name: Carescape R860
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: October 5, 2021
Received: October 6, 2021

Dear Monica Morrison:

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,

Brandon Blakely, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210384

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.

O2 Therapy is intended to be used for all adult patients and pediatric patients greater than 10 kg in weight.

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)

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 R860

510(k) Summary

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

Date:		November 3, 2021
Submitter:		Datex-Ohmeda, Inc. (GE Healthcare) 3030 Ohmeda Drive PO Box 7550 Madison, WI 53707-7550 USA
Primary Contact Person:		Monica Morrison Datex-Ohmeda, Inc. 3030 Ohmeda Drive PO Box 7550 Madison, WI 53707-7550 Telephone: +1 (608) 515-3077 Fax: +1 (608) 646-7464 Email: monica.morrison@ge.com
Secondary Contact Person:		Kimberly Mangum Datex-Ohmeda, Inc. 3030 Ohmeda Drive Madison, WI 53707-7550 Telephone: +1 (267) 400-5180 Email: kimberly.mangum@ge.com
Device Trade Name:		CARESCAPE R860
Common/Usual Name:		Ventilator, Continuous
Classification Names:		Ventilator, continuous, facility use
Product Code:		CBK
Predicate Device	510(k) Number	K142679
	Trade Name	CARESCAPE R860
	Product Code	CBK
Reference Device	510(k) Number	K193228
	Trade Name	Hamilton G5
	Product Code	CBK, DQA
Intended Use/ Indications for 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. O2 Therapy is intended to be used for all adult patients and pediatric patients greater than 10 kg in weight. 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 offering invasive and non-invasive ventilation support. 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. Icons represent configurable views of past (historical trends), present (patient status), and future patient needs (clinical decision support). The CARESCAPE R860 features patient monitoring, patient ventilation, and the capability of interfacing with central information management systems.

The CARESCAPE R860 ventilator is intended for healthcare facility use, including within-facility transport.

The ventilator offers multiple 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)
- 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)

In addition, a breathing support mode, O2 Therapy, is being added as a new feature in this 510(k). The O2 Therapy mode is available for adult and pediatric patients weighing greater than 10kg.

Optional functionality includes integrated respiratory gas monitoring, capabilities to measure SpiroDynamics, and calculation of functional residual capacity of mechanically ventilated patients. The integrated respiratory gas monitoring is provided via the Datex-Ohmeda Gas Modules, which are physically integrated into the CARESCAPE R860, can 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 a microprocessor-based, pneumatically controlled, data driven ventilator which includes integrated FiO2, airway pressure, spirometry and volume monitoring. 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 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.

Summary of changes in this 510(k):

This 510(k) proposes changes to the hardware and software of the CARESCAPE R860. However, there are no changes to the intended use or fundamental scientific technology of the ventilator. The fundamental function and operation of the CARESCAPE R860 is unchanged compared to the predicate CARESCAPE R860 with v10 software. This 510(k) introduces v11 software, which includes O2 Therapy, a non-invasive high flow oxygen therapy support mode, an upgrade to the display operating system, and additional user-configurable options. Hardware changes include the addition of alternative components and accessories.

Determination of Substantial Equivalence:

The CARESCAPE R860 ventilator is substantially equivalent to the predicate CARESCAPE R860 (K142679) and the reference device, Hamilton G5 (K193228), as described in the following table:

Substantial Equivalence to the predicate CARESCAPE R860			
Specification	**Predicate Device** **CARESCAPE R860 with v10 software** **K142679**	**Proposed** **CARESCAPE R860 with v11 software** **(this 510(k))**	**Discussion of Differences**
Device Name	CARESCAPE R860	CARESCAPE R860	Identical to CARESCAPE R860 with v10 software
Product Code	CBK	CBK	Identical to CARESCAPE R860 with v10 software
Manufacturer	Datex-Ohmeda, Inc.	Datex-Ohmeda, Inc.	Identical to CARESCAPE R860 with v10 software
Indications for 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 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.	Substantially Equivalent – The indications for use are essentially unchanged from the predicate device CARESCAPE R860 with v10 software. The only addition to the intended use language is to specifically identify that for the newly added O2 Therapy feature, it is intended only for adults and pediatric patients greater than 10 kg in weight.

	The CARESCAPE R860 ventilator is not a pulmonary function calculation device. The system is designed for facility use, including withinfacility transport, and should only be used under the orders of a clinician.	O2 Therapy is intended to be used for all adult patients and pediatric patients greater than 10 kg in weight. 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.	
Contraindications	None	None	Identical to CARESCAPE R860 with v10 software
Patient Population	Adult, pediatric, infant and neonatal patients weighing 0.25 kg and above	Adult, pediatric infant and neonatal patients weighing 0.25 kg and above. O2 Therapy is intended to be used for all adult patients and pediatric patients greater than 10 kg in weight.	Substantially Equivalent – the CARESCAPE R860 with v11 software patient population is substantially equivalent to the CARESCAPE R860 with v10 software patient population The specific patient population for O2 therapy was added for additional clarity.
Environment of Use	The system is designed for facility use, including within-facility transport.	The system is designed for facility use, including within-facility transport.	Identical to CARESCAPE R860 with v10 software
Key standards met	• IEC 60601-1:2005 + A1 (2012) Medical Electrical Equipment – Part 1: General Requirements for Safety • IEC 60601-1-2:2007 + 2010 Interpretation, Medical electrical equipment - Part 1-2: Collateral standard: Electromagnetic compatibility - Requirements and tests • IEC 60601-1-6: 2010, Medical electrical equipment - Part 1-6: Collateral Standard: Usability • IEC 60601-1-8: 2006, Medical Electrical Equipment – Part 1-8 - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	• IEC 60601-1:2005 + A1 (2012) Medical Electrical Equipment – Part 1: General Requirements for Safety • IEC 60601-1-2:2014 Interpretation, Medical electrical equipment - Part 1-2: Collateral standard: Electromagnetic compatibility - Requirements and tests • IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability • IEC 60601-1-8 Edition 2.1 2012-11, Medical electrical equipment - Part 1-8: General requirements for basic safety and	Substantially Equivalent – the CARESCAPE R860 with v11 software complies with the latest versions of applicable FDA-recognized standards. Therefore, this product is substantially equivalent to the predicate CARESCAPE R860 with v10 software.

	• ISO 80601-2-12:2011 + Technical Corrigendum 1, Medical electrical equipment, Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators • IEC 62366:2008, Medical devices - Application of usability engineering to medical devices • ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets	essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems • ISO 80601-2-12 First edition 2011-04-15, Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators [Including: Technical Corrigendum 1 (2011)] • IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)] • IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes • ISO 18562-1 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process • ISO 18562-2 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter • ISO 18562-3 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds • ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment -	

		Conical connectors: Part 1: Cones and sockets • AIM 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard	
Energy delivered	Air and Oxygen	Air and Oxygen	Identical to the predicate CARESCAPE R860 with v10 software
Ventilation Modes	1.Volume Control (A/C VC) 2.Pressure Control (A/C PC) 3.Pressure Regulated, Volume Control (A/C PRVC) 4.Synchronized Intermittent Mandatory Ventilation, Volume Control (SIMV VC) 5.Synchronized Intermittent Mandatory Ventilation, Pressure Control (SIMV PC) 6.Synchronized Intermittent Mandatory Ventilation, Pressure Regulated Volume Control (SIMV-PRVC) 7.BiLevel Airway Pressure Ventilation (BiLevel) 8. BiLevel Airway Pressure Ventilation Volume Guarantee (BiLevel VG) 9.Constant Positive Airway Pressure/Pressure Support (CPAP/PS) 10.Apnea backup (available in SIMV VC, SIMV PC, SIMV PRVC, BiLevel VG, BiLevel, APRV, CPAP/PS, and VS) 11.Noninvasive ventilation (NIV) (not available in neonatal mode) 12.Infant Nasal CPAP (nCPAP)	1.Volume Control (A/C VC) 2.Pressure Control (A/C PC) 3.Pressure Regulated, Volume Control (A/C PRVC) 4.Synchronized Intermittent Mandatory Ventilation, Volume Control (SIMV VC) 5.Synchronized Intermittent Mandatory Ventilation, Pressure Control (SIMV PC) 6.Synchronized Intermittent Mandatory Ventilation, Pressure Regulated Volume Control (SIMV-PRVC) 7.BiLevel Airway Pressure Ventilation (BiLevel) 8. BiLevel Airway Pressure Ventilation Volume Guarantee (BiLevel VG) 9.Constant Positive Airway Pressure/Pressure Support (CPAP/PS) 10.Apnea backup (available in SIMV VC, SIMV PC, SIMV PRVC, BiLevel VG, BiLevel, APRV, CPAP/PS, and VS) 11.Noninvasive ventilation (NIV) (not available in neonatal mode) 12.Infant Nasal CPAP (nCPAP)	Identical to CARESCAPE R860 with v10 software. No new modes of ventilation are introduced to the CARESCAPE R860 with the v11 software. Note that a new breathing support mode, O2 Therapy is introduced. As this is not a ventilation mode, it is discussed separately (see below).

	13.Volume Support (VS) 14.Airway Pressure Release Ventilation (APRV) 15.Spontaneous Breathing Trial (SBT)	13.Volume Support (VS) 14.Airway Pressure Release Ventilation (APRV) 15.Spontaneous Breathing Trial (SBT)	
Breathing Support Mode	n/a	O2 Therapy The O2 Therapy mode is available for adult and pediatric patients weighing greater than 10kg.	Substantially equivalent, refer to the table below for substantial equivalence comparison to the reference device, Hamilton G5.
Software	Currently released software	Updated software which includes modifications to: - Add O2 Therapy (high flow oxygen therapy) - Minor user-configurable changes to ventilator options - Upgraded operating system of the display software including cybersecurity enhancements - Improved Checkout routine	Substantially equivalent – the CARESCAPE R860 with v11 software incoprorates the new High Flow O2 Therapy feature, along with several minor changes to the device software and hardware. Verification and validation was performed to demonstrate that the changes to the software continue to comply with applicable standards and guidances, and the product continues to meet the performance specifications. The modifications do not affect the intended use, nor do they significantly affect the technological characteristics of the device. The features of the CARESCAPE R860 are substantially equivalent to the predicate.
Hardware Component Updates	As cleared under K142679	Alternative versions of previously cleared components have been introduced and reviewed under this 510(k). The alternative versions continue to provide mechanical ventilation and ventilatory support to patients, and are substantially equilvanet to those on the existing CARESCAPE R860 as cleared under K142679.	Substantially equivalent – Alternate versions of certain components have been introduced. There is no impact on the safety or effectiveness of the component or the CARESCAPE R860 ventilator as a result of the alternative designs. There is no change to the clinical use of the device.

Substantial Equivalence to the reference device, Hamilton G5			
Specification	**Reference Device** **Hamilton G5** **K193228**	**Proposed** **CARESCAPE R860 with v11 software** **(this 510(k))**	**Discussion of Differences**
O2 Therapy	HFO therapy (High Flow Oxygen therapy) delivers heated and humidified gas at a set FiO2 and flow rate through an unsealed heated patient interface.	O2 Therapy (High Flow Oxygen therapy) delivers heated and humidified gas at a set FiO2 and flow rate through an unsealed heated patient interface. - Circuits: intended to be delivered through a single-limb or dual-limb heated circuit	Substantially equivalent - High Flow Oxygen (O2) Therapy is being added to the CARESCAPE R860. The High Flow Oxygen therapy feature is substantially equivalent to the predicate Hamilton G5 ventilator. The technology for the delivery of High Flow Oxygen therapy, which is delivery of a set oxygen concentration (FiO2) at a fixed flow rate, is not novel or new to the ventilator. The intended patient for High Flow Oxygen therapy on both products is a spontaneously breathing patient. A heater/humidifier is required for the delivery of High Flow Oxygen from both ventilators to improve patient comfort, due to the drying nature of oxygen. The O2 Therapy mode is available for adult and pediatric patients weighing greater than 10kg. It is not indicated for neonates. Verification evidence demonstrates that the performance and specifications of the O2 Therapy function on the CARESCAPE R860 are equivalent to those on the Hamilton G5. The O2 Therapy feature on the CARESCAPE R860 does not differ in its technological characteristics, function, or performance and therefore, it is substantially equivalent.

Substantial Equivalence to the reference device, Hamilton G5			
Specification	**Reference Device** **Hamilton G5** **K193228**	**Proposed** **CARESCAPE R860 with v11 software** **(this 510(k))**	**Discussion of Differences**
High Flow Oxygen Therapy Flow Rate	Adult/Ped: 1 to 60 liters/minute	Adult/Ped: 2 to 60 liters/minute	Equivalent to the Hamilton G5. The flow range was narrowed slightly (lower end of the flow rate is 2LPM instead of 1 LPM in the Hamilton G5). This does not affect the safety or performance of this feature. Testing has been completed as documented in the 510(k) to demonstrate the device meets these specifications.
High Flow Oxygen Therapy FiO2 (%)	Adult/Ped: 21% to 100%	Adult/Ped: 21% to 100%	Identical to the Hamilton G5

The CARESCAPE R860 ventilator has been thoroughly tested through verification of specifications and validation, including software validation, to ensure safe use of the device in its intended use environment. 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
- Safety and Performance Testing (Verification)
- Standards compliance (verification)
- User Requirements Testing (Validation)

Summary of Non-Clinical Tests:

Non-clinical testing was performed to establish substantial equivalence of the CARESCAPE R860. Verification and validation testing has been performed according to predetermined acceptance criteria, which concluded that the CARESCAPE R860 is substantially equivalent to the predicate devices. Testing included:

- Software verification and validation
- Waveform comparison analysis
- System verification
- Accuracy testing
- Stress testing

Where the changes to the ventilator affected compliance with applicable consensus standards, testing was performed to confirm continued compliance, or to demonstrate compliance with the recognized version of the standard. The ventilator complies with the following applicable standards:

- IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012
- IEC 60601-1-2: 2014
- IEC 60601-1-6: 2010 + AMD:2013
- IEC 60601-1-8: 2006 +A1:2012
- ISO 80601-2-12: 2011
- ISO 80601-2-55: 2018
- IEC 62366: 2015
- IEC 62304: 2006
- ISO 18562-1: 2018
- ISO 18562-2: 2018

- ISO 18562-3: 2018
- ISO 5356-1

The modified CARESCAPE R860 has been shown to comply with the applicable standards referenced above, and the device meets the specifications and user requirements.

Summary of Clinical Tests:

The subject of this premarket submission, CARESCPE R860, incorporates modifications to the predicate device, the legally marketed CARESCAPE R860 ventilator. These modifications did not require clinical studies to support substantial equivalence.

Conclusion:

Datex-Ohmeda, Inc., doing business as GE Healthcare, considers the CARESCAPE R860 with the changes proposed in this 510(k) submission to be substantially equivalent to the predicate device, the CARESCAPE R860. The summary above demonstrates that there are no new questions of safety or effectiveness for the CARESCAPE R860.