



Food and Drug Administration  
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January 21, 2016

Datex-Ohmeda, Inc.  
James P. Raskob  
Regulatory Affairs Manager  
3030 Ohmeda Drive  
PO Box 7550  
Madison, WI 53707

Re: K151570

Trade/Device Name: Carestation 620/650/650c  
Regulation Number: 21 CFR 868.5160  
Regulation Name: Gas Machine for Anesthesia or Analgesia  
Regulatory Class: Class II  
Product Code: BSZ  
Dated: December 15, 2015  
Received: December 21, 2015

Dear Mr. Raskob,

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 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 Industry and Consumer Education 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.  
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)  
K151570

Device Name  
Carestation 620/650/650c

### Indications for Use (Describe)

The Carestation 620/650/650c anesthesia systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (pediatric, and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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GE Healthcare

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**Premarket Notification 510(k) Summary  
As required by section 807.92**

**Carestation 620/650/650c**

**GENERAL COMPANY INFORMATION as required by 807.92(a)(1)**

**COMPANY NAME/ADDRESS/PHONE/FAX:**

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**NAME OF CONTACT:**

Mr. James P. Raskob  
Ms. Monica Morrison (alternate)

**DATE:**

January 20, 2016

**DEVICE NAME as required by 807.92(a)(2)**

**TRADE NAME:**

Carestation 620/650/650c

**COMMON NAME:**

Gas Machine, Anesthesia

**CLASSIFICATION NAME:**

Anesthesiology, 73 BSZ, 21 CFR 868.5160, Gas machine for anesthesia or analgesia

**NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL  
EQUIVALENCE IS MADE as required by 807.92(a)(3)**

The Carestation 620/650/650c is substantially equivalent to the legally marketed  
(predicate) Avance CS<sup>2</sup> (K131945).

#### DEVICE DESCRIPTION as required by 807.92(a)(4)

The GE Carestation 620/650/650c anesthesia machines (Carestation 600 series) are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (pediatric and adult). The anesthesia systems are suitable for use in a patient environment such as hospitals, surgical centers, or clinics. They represent one of the systems in a long line of products based on the Datex-Ohmeda Aestiva (K000706), Aespire View (K122445) and Avance CS<sup>2</sup> (K131945) Anesthesia Systems. The Carestation 600 series anesthesia systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

The Carestation 600 series anesthesia systems supply set flows of medical gases to the breathing system using needle valve flow controlled gas mixing (O<sub>2</sub> with Air, O<sub>2</sub> with N<sub>2</sub>O, or O<sub>2</sub> with Air and N<sub>2</sub>O). Gas flows are adjusted by the user using needle valve control knobs on the main system frame, the flows are displayed on the system display unit as numerical digits and as electronic representations of flow meters. Some models (Carestation 650, 650c) also display the flow digits directly above the flow controls. Carestation 600 series systems are also equipped with an integrated pneumatic flow tube that indicates total mixed gas flow from the 2 or 3 needle valves in the gas mixer (prior to the vaporizer manifold). The Carestation 650/650c systems provide an option for auxiliary mixed Oxygen + Air flow delivery where O<sub>2</sub> with Air are blended and delivered to an auxiliary port used to support spontaneously breathing patients using a nasal cannula. An optional auxiliary O<sub>2</sub> supply includes a separate O<sub>2</sub> flow tube and needle valve flow control that delivers O<sub>2</sub> flow to an auxiliary port used to support spontaneously breathing patients using a nasal cannula. The gas flow from the optional auxiliary O<sub>2</sub> subsystem does not flow through the total flow tube. An optional auxiliary common gas outlet (ACGO) allows the clinician to direct the fresh gas flow of O<sub>2</sub>, Air, N<sub>2</sub>O, or anesthetic agent, through the ACGO port on the front of the system. The ACGO may be used to provide fresh gas to an auxiliary manual breathing circuit.

A large selection of frame options include central brake (Carestation 650) or individual caster brakes (Carestation 620), up to 3 breathing gases, optional storage drawers, and vaporizers are available to give the user control of the system configuration. The Carestation 600 series systems are also available in pendant and wall mount (Carestation 650c) models. All Carestation 600 series models have O<sub>2</sub> gas and come with one or two additional gases (Air, N<sub>2</sub>O, or both). Carestation 600 series systems include two vaporizer positions and are available with up to three back-up gas cylinder connections.

The system uses touchscreen technology, hard keys, and a ComWheel to access system functions, menus, and settings on a 15" color display. The display is mounted on an arm on the left side of the machine. It can be rotated via the arm toward, or away from, the system to adjust the horizontal position. An optional arm is available allowing it to be tilted up or down to adjust the vertical viewing angle, or be moved left or right to adjust the horizontal position of the display. The split screen field can be set to show gas trends, Spirometry loops, airway pressure (Paw) gauge, airway compliance, and optional ecoFLOW information. If none is selected, the waveforms expand to fill the split screen area.

The Carestation 600 series systems accept Tec 6 Plus and Tec 7 vaporizers on a 2-position Selectatec vaporizer manifold in the same way the Aestiva, Aespire View and Avance CS<sup>2</sup> machines use the Tec 6 Plus or Tec 7 vaporizers. Features and devices within the Carestation 600 series systems are designed to decrease the risk of hypoxic mixtures, multiple anesthetic agent mixtures, complete power failure, or sudden gas supply failures. The Carestation 600 series systems are available with optional integrated respiratory gas monitoring which can be physically integrated into the Carestation 600, receive electronic power from the Carestation 600, and communicate

measured values to the Carestation 600 for display on the system display unit. When supplied as an option, integrated respiratory gas monitoring is provided via the GE CARESCAPE series (E-sCAiO and E-sCAiOV) respiratory airway modules (K123195) which is identical to the module used on Avance CS<sup>2</sup>, or the N-CAiO respiratory airway module which was cleared as part of the GE B40 monitor (K133576).

The Carestation 600 series Anesthesia Ventilator is used in the Carestation 600 series Anesthesia Systems. It is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. This version of the GE 7900 ventilator (cleared on K023366) is equipped with a built-in monitoring system for inspired oxygen (using an optional O<sub>2</sub> cell or optional integrated gas module), patient airway pressure and exhaled volume. Flow sensors in the breathing circuit are used to monitor and control patient ventilation. This allows for the compensation of gas and tubing compression losses, fresh gas contribution, and small gas leakage from the breathing absorber, bellows and pneumatic system connections. User setting and microprocessor calculations control breathing patterns. The user interface keeps ventilation settings in memory. The user may change settings with a simple ventilation parameter setting sequence. A bellows contains breathing gasses to be delivered to the patient and provides a barrier keeping patient gas separate from the ventilatory drive gas. Positive End Expiratory Pressure (PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward from the patient breathing circuit.

This ventilator comes with a standard ventilation mode as well as optional ventilation modes.

**Standard ventilation mode:**

VCV (Time Cycled, Volume Controlled ventilation)

**Optional ventilation modes:**

PCV (Time Cycled, Pressure Controlled ventilation)

VCV-SIMV (Synchronized Intermittent Mandatory Ventilation Volume Control)

PCV-SIMV (Synchronized Intermittent Mandatory Ventilation Pressure Control)

PSVPro (Pressure supported ventilation with apnea backup)

PCV-VG (Pressure Controlled ventilation – Volume Guaranteed)

PCV-VG-SIMV (Synchronized Intermittent Mandatory Ventilation, Pressure Controlled ventilation – Volume Guaranteed)

CPAP+PSV (Continuous Positive Airway Pressure/Pressure Support)

The system can include an internal, factory installed, suction regulator and control visible from the front of the machine. It can mount different monitors using an arm or shelf mounts. The mounting is achieved through a combination of GE Healthcare adapters and other third party mounts, including one that allows for the physical integration of the GE Monitor Series B650 (K102239).

**INTENDED USE as required by 807.92(a)(5)**

The Carestation 620/650/650c anesthesia systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (pediatric and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Carestation 600 series is primarily based on the Avance CS<sup>2</sup> feature set and contains similar ventilation performance characteristics. There is no change to the Intended Use of the anesthesia system. One difference is the Avance CS<sup>2</sup> utilizes an electronic gas mixing subsystem. The Carestation 600 series utilizes a mechanical needle valve gas mixing subsystem as is used in the Aespire View product.

**Primary device differences from Avance CS<sup>2</sup>**

**Software Features**

- Updated the Avance CS<sup>2</sup> “ecoFLOW” display option feature to accommodate up to 3 gasses and pneumatic flow controls
- User indicator when the Auxiliary Common Gas Outlet (ACGO) is active
- User indication when the new Optional auxiliary outlet for blended O<sub>2</sub> + Air is active
- Power down sequence when system is in therapy that requires user confirmation of shutdown within 10 seconds or normal operation is resumed

**Hardware Features**

- On/Standby switch is an electrical momentary contact type, not electro-pneumatic to manually shut off Air and Oxygen flow)
- Optional auxiliary outlet for blended O<sub>2</sub> + Air
- Mechanical needle valves used by clinicians to control up to 3 gasses at a time (verses electronic mixing of two gases in the Avance CS<sup>2</sup>)
- Flow sensor monitored flow control valve delivering drive gas to ventilate the patient
- Revised inspiratory/expiratory flow sensor design

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Carestation 620/650/650c has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with applicable voluntary standards has also been made to support safe use of the device in its intended environment. 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)
- Performance testing including the following test results:

Alarms
Breathing System
Display Unit Interaction
Display Unit Screens and Configuration
Electrical Power
Environmental – Altitude
Environmental – Shipping
Environmental – Temperature and Humidity
Gas Delivery
Physical Specifications and Frames
Pneumatics
Ventilation Accuracy
Ventilation Monitoring
Ventilation Delivery
Scavenging
Waveform Comparison

- Materials Testing including the following tests:
  - Volatile Organic Compounds
  - Particulate Testing
  - Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity

- Verification testing including electrical safety and electromagnetic compatibility testing with compliance to the following standards:
  1. AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (FDA Recognized)
  2. IEC 60601-1-2 Edition 3: 2007 (FDA Recognized)
  
- Simulated use testing (Validation)

Extensive non-clinical testing was performed to establish substantial equivalence of the Carestation 620/650/650c. Verification and validation testing was performed according to predetermined acceptance criteria, which concluded that the Carestation 620/650/650c is substantially equivalent to the predicate Avance CS<sup>2</sup>.

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

The Carestation 620/650/650c anesthesia machines incorporate modifications to the predicate Avance CS<sup>2</sup>. These modifications did not require clinical testing. The changes made were completely evaluated by non-clinical design verification and validation tests to verify and validate the safety and functionality of the anesthesia machines.

CONCLUSION:

GE Healthcare considers the Carestation 620/650/650c to be substantially equivalent to the predicate device.