March 28, 2023

Datex-Ohmeda, Inc.
Kimberly Mangum
Regulatory Affairs Director
3030 Ohmeda Drive, PO Box 7550
Madison, Wisconsin 53707-7550

Re: K213867
Trade/Device Name: Carestation 750/750c
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine For Anesthesia Or Analgesia
Regulatory Class: Class II
Product Code: BSZ
Dated: February 17, 2023
Received: February 22, 2023

Dear Kimberly Mangum:

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,

James J. Lee -S

James J. Lee, Ph.D.
Division 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)*

K213867

Device Name
Carestation 750/750c

Indications for Use *(Describe)*

The Carestation750/750c anesthesia systems are intended to provide monitored anesthesia care, general inhalation anesthesia and/ or ventilatory support to a wide range of patients (neonatal, 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Premarket Notification 510(k) Summary
As required by section 807.92
Carestation 750/750c
GENERAL COMPANY INFORMATION as required by 807.92(a)(1)
K213867

I. Submitter

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Date Prepared: March 24, 2023

II. DEVICE

Name of Device: Carestation 750/750c
Common or Usual Name: Gas Machine, Anesthesia (21 CFR 868.5160)
Regulatory Class: II
Product Code: BSZ

III. PREDICATE DEVICE

Primary Predicate: Carestation 620/650/650c, K151570
Reference Device: Avance CS2, K131945

IV. DEVICE DESCRIPTION

The GE Carestation 750/750c anesthesia machines (Carestation 750 series) are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonate, 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), Aisys CS^2 (K170872), Avance CS^2 (K131945), Carestation 620/650/650c (Carestation 600 series) (K151570) Anesthesia Systems. The Carestation 750 series anesthesia systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

The Carestation™ 750/750c anesthesia systems combine advanced anesthesia delivery, patient monitoring, and care information management. The contemporary, compact design allows for easy mobility and addresses many ergonomic considerations including an effective cable management solution, aesthetic covers, and an expandable work surface area. Optional integrated features include auxiliary common gas outlet, auxiliary O2 outlet, auxiliary O2+Air outlet, suction control, and respiratory gas monitoring. The system provides integration of ventilation and gas delivery on a 15-inch color graphical touchscreen interface. This system also features electronic gas mixing of oxygen and a balance gas of either N2O or Air. The Carestation 750 series represents one of the systems in a long line of products based on the Datex-Ohmeda Aestiva (K000706), AespireView (K122445), Aisys CS^2 (K170872), Avance CS2 (K131945), and Carestation 600 Series (K151570) Anesthesia Systems.

This anesthesia system is designed for mixing and delivering inhalation anesthetics (Isoflurane, Sevoflurane, or Desflurane), Air, O2, and N2O. This anesthesia system has Recruitment maneuvers, a feature to perform automated lung recruitment maneuver in a single step or in multi steps.

This anesthesia system uses electronic flow valve ventilation technology offering Volume Control Ventilation with tidal volume compensation and electronic PEEP. This technology also features Pressure Control Ventilation, optional Pressure Support Ventilation with an Apnea Backup (PSVPro™) that is used for spontaneously breathing patients, Synchronized Intermittent

Mandatory Ventilation (SIMV) modes, Pressure Control Ventilation-Volume Guarantee (PCVVG), Continuous Positive Airway Pressure + Pressure Support Ventilation (CPAP + PSV), and VCV Cardiac Bypass. In Volume Control Ventilation, a patient can be ventilated using a minimal tidal volume of 20 ml. In Pressure Control Ventilation, volumes as low as 5 ml can be measured. These advanced features allow for the ventilation of a broad patient range. The device includes the following basic components:

The Carestation 750 series anesthesia systems supply set flows of medical gases to the breathing system using an electronic gas mixer (O2 with Air or O2 with N2O). Gas flows are adjusted by the user on the touchscreen, the flows are displayed on the system graphical user interface assembly as numerical digits and as electronic representations of flow meters. The system provides an option for auxiliary mixed Oxygen + Air flow delivery where O2 with Air are blended and delivered to an auxiliary port used to support spontaneously breathing patients using a nasal cannula. An optional auxiliary O2 supply includes a separate O2 flow tube and needle valve flow control that delivers O2 flow to an auxiliary port used to support spontaneously breathing patients using a nasal cannula. The gas flow from the optional auxiliary O2 subsystem does not flow through the electronic gas mixer.

The Carestation 750 series models include up to 3 breathing gases with O2 and Air as standard, and N2O as an optional breathing gas. The systems include two vaporizer positions compatible with, Isoflurane, Sevoflurane, and Desflurane vaporizers. The Carestation 750 is available with up to three back-up gas cylinder connections. The Carestation 750 series systems are also available in pendant (Carestation 750c) models.

The system uses touchscreen technology, hard keys, and a Comwheel to access system functions, menus, and settings on a 15'' color graphical user interface assembly (aka display). The graphical user interface

assembly 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. The arm is available allowing the display to be tilted up or down to adjust the vertical viewing angle or be tilted left or right to adjust the horizontal position of the display. An optional arm can be raised/lowered and rotated 360 degrees. A split screen field can be set to show gas trends, Spirometry loops, a Paw gauge, airway compliance, and optional ecoFlow information. If none is selected, the waveforms expand to fill the split screen area.

The Carestation 750 series systems accept Tec 6 Plus, Tec 7, and Tec 820/850 series vaporizers on a 2-position Selectatec manifold. Safety features and devices within the systems are designed to decrease the risk of hypoxic mixtures, multiple anesthetic agent mixtures, complete power failure, or sudden gas supply failures. The Carestation 750 series systems are available with optional integrated respiratory gas monitoring which can be physically integrated into the system, receive electronic power from the Carestation 750/750c, and communicate measured values to the Carestation 750/750c for display on the system graphical user interface assembly. When supplied as an option, integrated respiratory gas monitoring is provided via the GE CARESCAPE series (EsCAiO or E-sCAiOV) respiratory airway modules (GE Healthcare Finland Oy, CE 0537) which is identical to the module used on Avance CS2.

The Anesthesia Ventilator used in the Carestation 750 series Anesthesia Systems is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. This version of the GE 7900 ventilator is equipped with a built-in system for monitoring inspired oxygen (using an optional O2 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 settings 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 patent breathing circuit.

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

Standard ventilation modes:

- VCV (Time Cycled, Volume Controlled Ventilation)
- PCV (Time Cycled, Pressure Control Ventilation)

Optional ventilation modes:

- 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). The Carestation 750 system also includes an optional cable management solution, which can help user to manage the various cables attached to the system.

V. INDICATIONS FOR USE

The Carestation750/750c anesthesia systems are intended to provide monitored anesthesia care, general inhalation anesthesia and/ or ventilatory support to a wide range of patients (neonatal, 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Carestation 750 series is primarily based on the predicate device Carestation 600 series feature set (K151570) and contains identical or comparable hardware and software components. A comparison of the CS750 and predicate device technological characteristics is provided as **Table 1** below.

Table 1: Carestation 750/750c Technological Characteristics Comparison

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
Pneumatic System	Supplies set flows of medical gases to the breathing system using electronic controlled gas mixing of 2 gasses (O2 with Air or O2 with N2O).	Supplies set flows of medical gases to the breathing system using mechanical controlled gas mixing of 2 gasses (O2 with Air or O2 with N2O) or 3 gases (O2, Air, and N2O).	Supplies set flows of medical gases to the breathing system using electronic controlled gas mixing of 2 gasses (O2 with Air or O2 with N2O).
Gas Supply	The gas mixing subsystem is a two gas mixer providing a mixture of O2 and Air or O2 and N2O (100% O2 or 100% Air (21% O2) can also be selected).	The gas mixing subsystem is a three gas mixer providing a mixture of O2 and Air or O2 and N2O or O2, Air and N2O (100% O2 or 100% Air (21% O2) can also be selected).	The gas mixing subsystem is a two gas mixer providing a mixture of O2 and Air or O2 and N2O (100% O2 or 100% Air (21% O2) can also be selected).
O2 Flow	A pressurized gas source (pipeline, or regulated cylinder), supplies O2 directly to the gas mixing subsystem.	A secondary pressure regulator in the gas mixing subsystem regulates constant O2 gas pressure and supplies it to the O2 flow control valve.	A pressurized gas source (pipeline, or regulated cylinder), supplies O2 directly to the gas mixing subsystem.
Air and N2O flow	Air gas flows from a pressurized gas source (pipeline or regulated cylinder) to the Air/N2O selector valve on the gas mixing subassembly.	Air gas flows from a pressurized gas source (pipeline or regulated cylinder) to the Air selector valve or a secondary pressure regulator (optional) on the gas mixing subassembly.	Air gas flows from a pressurized gas source (pipeline or regulated cylinder) to the Air/N2O selector valve on the gas mixing subassembly.
Gas Mixer	Digital display and control of flows using an electronic mass air flow sensor to provide electronic mixing and proportioning of gases (O2 and Air or N2O).	Digital display of flows with traditional needle valve flow control and flow head mixing and proportioning of gases (Air, O2, N2O).	Digital display and control of flows using an electronic mass air flow sensor to provide electronic mixing and proportioning of gases (O2 and Air or N2O).

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
Aux O2 option	An auxiliary O2 gas supply to provide O2 gas to the patient through internal connections and control with an auxiliary O2 flowmeter.	An auxiliary O2 gas supply to provide O2 gas to the patient through internal connections and control with an auxiliary O2 flowmeter.	Not a comparison point
Aux O2+Air gas delivery option	The Aux O2+Air gas delivery option provides an auxiliary O2+Air gas mixture to the patient through internal connections and control with the O2 and Air fresh gas controls.	The Aux O2+Air gas delivery option provides an auxiliary O2+Air gas mixture to the patient through internal connections and control with the O2 and Air fresh gas controls.	Not a comparison point
ACGO	Use the optional Auxiliary Common Gas Outlet (ACGO) switch to direct the fresh gas flow through the ACGO port on the front of the system.	Use the optional Auxiliary Common Gas Outlet (ACGO) switch to direct the fresh gas flow through the ACGO port on the front of the system.	Not a comparison point
O2 Flush	The O2 flush button supplies a high flow of O2 to the breathing system.	The O2 flush button supplies a high flow of O2 to the breathing system.	Not a comparison point
ALT O2	The Alternate O2 control is not an auxiliary source of O2. The Alternate O2 is intended to be used when in certain failures, such as the electronic gas mixer is not available or the display screen has failed.	None	ALT O2 as the auxiliary source of O2 for electronic gas mixer
Vaporizers Compatibility	Carestation 750 series provide a two position vaporizer manifold to support up to 2 active positions for Tec series GE vaporizers.	Carestation 620/650/650c provides a two position vaporizer manifold to support up to 2 active positions for Tec series GE vaporizers.	Not a comparison point

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
Respiratory Gas Monitors Compatibility	Airway Gas Option is: - CARESCAPE series: E-sCAiO and E-sCAiOV. The CAiOV feature set of the CARESCAPE series E-sCAiOVX and EsCAiOVE Airway Modules	Airway Gas Option is : - CARESCAPE series: E-sCAiO and E-sCAiOV. - The CAiOV feature set of the CARESCAPE series E-sCAiOVX and E-sCAiOVE Airway Modules N-CAiO (without Spirometry connector)	Airway Gas Option is: - CARESCAPE series: EsCAiO and E-sCAiOV. The CAiOV feature set of the CARESCAPE series EsCAiOVX and E-sCAiOVE Airway Modules
Optional Integrated Suction Regulation	The vacuum suction regulator uses an external vacuum supply. The venturi suction regulator uses the system air supply source.	The vacuum suction regulator uses an external vacuum supply. The venturi suction regulator uses the system air supply source.	Not a comparison point
Optional Gas Scavenging	Yes	Yes	Not a comparison point
Breathing System	The integrated circle breathing system can be used for both manual (bag) and mechanical (automatic) patient ventilation. The breathing system includes bellows assembly, APL valve, bag-to-vent switch, CO2 bypass assembly.	The integrated circle breathing system can be used for both manual (bag) and mechanical (automatic) patient ventilation. The breathing system includes bellows assembly, APL valve, bag-to-vent switch, CO2 bypass assembly.	Not a comparison point
Flow Sensors	Variable orifice flow sensor (autoclavable) with pneumatic and electrical connections located in the inspiratory outlet and expiratory inlet inside the breathing system. The outer chamber of the sensor is heated.	Variable orifice flow sensor (autoclavable) with pneumatic and electrical connections located in the inspiratory outlet and expiratory inlet inside the breathing system. The outer chamber of the sensor is heated.	Not a comparison point
CO2 Absorber Canister	CO2 absorber canister absorbs CO2 in the gas path from bellows.	CO2 absorber canister absorbs CO2 in the gas path from bellows.	Not a comparison point

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
Ventilator Engine	The ventilator engine is located in the middle pan of the system, under the user work surface. A precision flow servo system control gas flow to the patient.	The ventilator engine is located in the middle pan of the system, under the user work surface. A precision flow servo system control gas flow to the patient.	Not a comparison point
System Mountings	Carestation 750 is a trolley mounted configuration while the Carestation 750c can be configured and installed with a pendant mounted version.	Carestation 650 and Carestation 620 are a trolley mounted configuration while the Carestation 650c can be configured and installed with either a pendant or wall mounted version.	Not a comparison point
Cable Management	Clip and cubby are to fix cables, rear cover could shield hoses and cables.	Clips are to fix cables.	Not a comparison point
Electrical Subsystem	The electrical system consists of two main computing units: the Graphical user interface assembly (previously known as the display unit) and the Anesthesia Computer Board (ACB). The other key electrical boards are Power Management Board, Sensor Interface Board, and Mixer Interface Board.	The electrical system consists of two main computing units: the Graphical user interface assembly (previously known as the display unit) and the Anesthesia Computer Board (ACB). The other key electrical boards are Power Management Board, Sensor Interface Board, and Frame Interface Board.	Mixer Interface Board to support electronic mixer
Touch Screen	Projective Capacitive (P-Cap) touch screen detects touch by measuring the capacitance at each addressable electrode. P-Cap touch screen software driver.	Surface acoustic wave (SAW) detects touch by measuring SAW on the route SAW P-Cap touch screen software driver.	Not a comparison point

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
Software Subsystem	The software provides user interface, power management, and controls the delivery of therapy to patients. As the segregation strategy, the Carestation 750 series software is comprised of below top-level Software Items/Units. • Display Computer/Display Unit • Power Supply Controller/Power Subsystem • Front Panel Controller • Anesthesia Control • Board/Anesthesia Computer • Mixer Interface Board Subsystem • Sensor Interface Board Subsystem • Mixer	The software provides user interface, power management, and controls the delivery of therapy to patients. As the segregation strategy, the Carestation 600 series software is comprised of below top-level Software Items/Units. • Display Computer/Display Unit • Power Supply Controller/Power Subsystem • Front Panel Controller • Anesthesia Control Board/Anesthesia Computer • Frame Interface Board Subsystem • Sensor Interface Board Subsystem	Not a comparison point
ecoFLOW	ecoFLOW option within the split screen that shows a visual indicator reference for the total gas flows, agent usage, cost and approximate minimum O2 flow needed to maintain the clinician's desired inspired O2 concentration. Carestation 750 series flows are limited to only O2, Air or N2O.	ecoFLOW option within the split screen that shows a visual indicator reference for the total gas flows, agent usage, cost and approximate minimum O2 flow needed to maintain the clinician's desired inspired O2 concentration. Carestation 620/650/650c allows all 3 gases to be present due to traditional needle valve flow control.	ecoFLOW option within the split screen that shows a visual indicator reference for the total gas flows, agent usage, cost and approximate minimum O2 flow needed to maintain the clinician's desired inspired O2 concentration. Avance CS^2 flows are limited to only O2, Air or N2O.
User Interface	Color display with Com Wheel or touch activation. Quick keys provide quick activation access via the touch screen user interface. Seven quick keys available for ventilation and three quick keys available for gas.	Color display with Com Wheel or touch activation. Quick keys provide quick activation access via the touch screen user interface. Seven quick keys available for ventilation.	Not a comparison point

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
Operating System	The graphical user interface operating system on Carestation 750 series is WEC 2013 (Windows).	The graphical user interface operating system on Carestation 600 series is CE6 (Windows).	Not a comparison point
Display Arm	User Interface is mounted on an arm on the left side of the machine. It can be rotated left or right via the arm toward or away from the system to adjust the horizontal position. Both standard arm and premium arm can be tilted up or down to adjust the vertical angle or be tilted left or right to adjust the horizontal angle of the User Interface. Premium arm can also be raised/lowered and rotated 360 degrees.	User Interface is mounted on an arm on the left side of the machine. It can be rotated left or right via the arm toward or away from the system to adjust the horizontal position. For the Carestation 650 and 650c it can also be tilted up or down to adjust the vertical angle or be tilted left or right to adjust the horizontal angle of the User Interface. The Carestation 620 uses a basic arm that allows the User Interface to move left and right but does not tilt.	Not a comparison point
HDX GUI Style	Added Modern Interface Style (HDX), user can enable in Super User System Config menu.	Classic GUI Interface Style exists on Carestation 600.	Not a comparison point
Super user and service mode passwords	User could change super user password and service password. New Password Entry item will be restricted to a 6-22 digit password. User could set new password to protect the device with only authorized personnel entering the Super User mode and Service mode.	The different 5 digit passwords of Super user and Service mode are fixed, user could not change the passwords.	Not a comparison point

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
Recruitment Maneuver	Use the Single Step recruitment maneuver to deliver a pressure breath for a set time. Use the Multi Step recruitment maneuver to deliver pressure breaths through a series of ventilation steps.	Use the Vital Capacity procedure to deliver a pressure breath for a set time. Use the Cycling procedure to deliver pressure breaths through a series of ventilation steps.	Not a comparison point
Direct access to important functions	A button bar is at the right side of the user graphical interface to allow direct user access to 10 important functions: Audio Pause, Alarm Setup, Auto Limits, System Setup, Next page, Trends, Recruitment Maneuver, Pause Gas Flow, Timer function , End case.	A button bar is at the right side of the user graphical interface to allow direct user access to 10 important functions: Audio Pause, Alarm Setup, Auto Limits, System Setup, Next page, Trends, Spirometry, Procedures, Timer function, End case.	Not a comparison point
Recourse & Recovery	When Display Computer (DC) software error occurs a processor reset will initiate the DC reboot. However, the Anesthesia Computer (AC) will keep working by using the current parameters, when the system reboot successfully it will go to Therapy mode directly by using setting values recovered by Anesthesia Computer software. DISPLAY COMPUTER RESTARTED alarm will be displayed on screen.	None	Not a comparison point
Checkout failure troubleshooting message panel	If checkout tests failed, it will display a troubleshooting message panel with problem statement and step by step messages to instruct user to remove the failure.	The preoperative checkout and calibration are digitally shown and guided according to the menu.	Not a comparison point
DatexOhmeda COM changes	DatexOhmeda COM exists on Carestation 700 (updates made)	DatexOhmeda COM exists on Carestation 600.	Not a comparison point

Specification	Proposed Device Carestation 750/750c	GE Datex-Ohmeda Predicate Device Carestation 620/650/650c	Reference Device Avance CS^2 (K131945)
New Mixer and Alternate O2 checkout test	Electronic Mixer and Alternate O2 checkout	None	Electronic Mixer and Alternate O2 checkout
Gas Setup and Preset menu, Alt O2, Air Only and related Alarms	Electronic mixer, alternate O2, and Air only mode	None	Electronic mixer, alternate O2, and Air only mode
Remove latch alarm	The latched alarms could be removed because alarm log history could be used instead.	Latched alarms exist as a feature in Carestation 600 series.	Not a comparison point
Principles of Operation: Control and Phase Variables	Anesthesia machine settings are separated into five categories: • Gas Flow (Electronic gas mixer) and Breathing Circuit Controls • Main Ventilation Parameters • Breath Timing • Patient Ventilation Synchrony • Safety	Anesthesia machine settings are separated into five categories: • Gas Flow (Mechanical gas mixer) and Breathing Circuit Controls • Main Ventilation Parameters • Breath Timing • Patient Ventilation Synchrony • Safety	Gas Flow (Electronic gas mixer)
Ventilation Modes	VCV, PCV, VCV-SIMV, PCV-SIMV, PSVPro, PCV-VG, PCV-VG-SIMV, CPAP-PSV	VCV, PCV, VCV-SIMV, PCV-SIMV, PSVPro, PCV-VG, PCV-VG-SIMV, CPAP-PSV	Not a comparison point
Safety Standards	Compliance with applicable FDA recognized consensus standards	Compliance with applicable FDA recognized consensus standards	Not a comparison point

GE HealthCare

VII. PERFORMANCE DATA

The Carestation 750/750c has been thoroughly tested through verification of specifications and validation, including software validation for a major level of concern software. 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 (Verification) including but not limited to accuracy testing, environmental testing, tip testing and threshold testing
- Biocompatibility Testing including particulate matter (PM), Volatile Organic Compounds (VOC) and leachables in condensate (Classified as Limit exposure based on ISO18562-1:2017)
- Safety testing (Verification) including electrical safety and electromagnetic compatibility testing
- Simulated use testing (Validation)

The product was designed and tested for compliance to FDA recognized consensus standards including the following:

Standard	FDA Recognition Number
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, , Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4
IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	19-8
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IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes	13-79
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	1-134
ISO 18562-2 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter	1-135
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	1-136
ISO 18562-4 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate	1-137
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	19-30
ISO 17664:2017 Second edition 2017-10 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices	14-515

Bench testing was performed to establish substantial equivalence of the Carestation 750/750c. Verification and validation testing was performed according to predetermined acceptance criteria, which concluded that the Carestation 750/750c is substantially equivalent to the predicate Carestation 620/650/650c.

Clinical Testing

The Carestation 750/750c anesthesia machines incorporate modifications to the predicate Carestation 620/650/650c. 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

The subject device and the predicate device have the same intended use, and the technological differences do not raise different questions of safety and effectiveness.