K131945

Premarket Notification 510(k) Summary
As required by section 807.92
GE Datex-Ohmeda Avance CS^2

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

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda Inc.
3030 Ohmeda Drive
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-299-2132

NAME OF CONTACT:

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

DATE:

June 25, 2013

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

TRADE NAME:

GE Datex-Ohmeda Avance CS^2 Anesthesia System

COMMON NAME:

Gas Machine, Anesthesia

CLASSIFICATION NAME:

Anesthesiology, 73 BSZ, 21 CFR 868.5160 Gas Machine, Anesthesia

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

The modified GE Datex-Ohmeda Avance CS^2 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) GE Datex-Ohmeda Avance CS^2 (K123125).

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

The GE Datex-Ohmeda Avance and Avance CS^2 anesthesia machines are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). They represent one of the systems in a long line of products based on the Datex-Ohmeda Excel, Aestiva, and Aespire Anesthesia Systems. Avance systems are to be used only by trained and qualified medical professionals trained in the administration of general anesthesia.

The Avance and Avance CS^2 anesthesia systems supply set flows of medical gases to the breathing system using electronic gas mixing. Gas flows are selected by the user using the electronic controls on the main display unit and then displayed as electronic flow meters on the system display unit. The Avance systems are equipped with a pneumatic back-up O2 delivery system and traditional flow tube, as well. A large selection of frames options including central brake or individual caster brakes, gases, and vaporizers are available to give the user control of the system configuration. The Avance systems are also available in pendant models. Avance systems are available with two or three gases, up to three vaporizer positions and up to three cylinder connections. All models have O2. The Avance systems come with up to two optional gases (air, N2O).

The Avance systems accept Tec 6 Plus and Tec 7 vaporizers on a Selectatec manifold. Safety features and devices within the Avance systems are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The Avance systems are available with optional integrated respiratory gas monitoring. When supplied as an option, the integrated respiratory gas monitoring is provided via the GE Compact Gas Airway Modules Series: M-Gas Module (M-CAiO and M-CAiOV software revision 3.2 and above cleared via K001814) and E-Gas Compact Gas Airway Module (E-CAiOVX software revision 3.2 and above cleared via K051092) which can be physically integrated into the Avance, receive electronic power from the Avance and communicate measured values to the Avance for display on the system display unit. In addition to M-Gas and E-gas modules, the Avance CS^2 can utilize the GE CARESCAPE Respiratory Module (E-sCAiO, E-sCAiOV cleared via K123195).

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in the Avance Anesthesia Systems. It is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. The 7900 ventilator is equipped with a built-in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well as measure inspired oxygen concentration. This allows for the compensation of compression losses, fresh gas contribution and small leakage in the breathing absorber, bellows and system. User setting and microprocessor calculations control breathing patterns. The user interface keeps settings in memory. The user may change settings with a simple setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure (PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. An RS-232 serial digital communications port connects to and communicates with external devices. Ventilator modes for the device include Volume Control Ventilation (VCV), Pressure Control Ventilation (PCV) (optional), Synchronized Intermittent Mandatory Ventilation/Pressure Support (SIMV/PSV) (optional), Pressure Support Ventilation (PSVPro) (optional), Synchronized Intermittent Mandatory Ventilation-Pressure Control (SIMV-PC) (optional), Pressure Control Ventilation-Volume Guaranteed (PCV-VG) (optional), Constant Positive Airway Pressure/Pressure Support Ventilation (CPAP/PSV), Pressure Control Ventilation-Volume Guaranteed with Pressure Support Ventilation (SIMV PCV-VG) (optional), and Volume Control Ventilation Mode for Cardiac Bypass Mode (optional). Ventilator parameters and measurements are displayed on the system display unit.

Several frame configurations are available, including one that allows for the physical integration of the GE Monitor Series (cleared Carescape B850 via K092027 and B650 cleared on K102239). These configurations also provide cable management solutions such that the necessary connections from the monitor display unit to the monitor are hidden within the Avance frame. Additional configurations allow for the mounting of various patient monitors on the top shelf of the Avance.

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

The GE Datex-Ohmeda Avance CS^2 is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

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

The GE Datex-Ohmeda Avance CS^2 has been updated from the predicate version (K123125) to revise the product labeling to include specifications and use of the Avance CS^2 with the optional CARESCAPE respiratory module cleared on K123195. There has been no change to the indications for use or the fundamental scientific technology.

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

The GE Datex-Ohmeda Avance CS^2 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 (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

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

The modifications made to the GE Datex-Ohmeda Avance CS^2 did not require clinical testing. The functionality of the modified features was completely evaluated by performing nonclinical tests of design verification and validation testing.

CONCLUSION:

GE Healthcare considers the modified GE Datex-Ohmeda Avance CS^2 to be as safe, as effective, and have performance substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 8, 2013

Datex-Ohmeda, Incorporated
Mr. James P. Raskob
Regulatory Affairs Leader
3030 Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550

Re: K131945
Trade/Device Name: GE Datex-Ohmeda Avance CS^2 Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: July 8, 2013
Received: July 9, 2013

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.

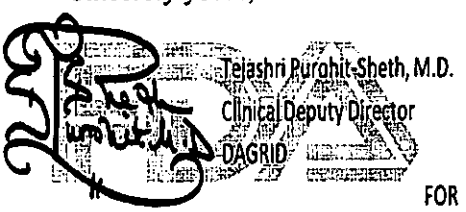
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



FOR

Kwame Ulmer, M.S.
Acting Division 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): K131945

Device Name: GE Datex-Ohmeda Avance CS^2 Anesthesia System

Indications For Use:

The GE Datex-Ohmeda Avance CS^2 Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Prescription Use _XXX_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
2013.08.07 17:15:18 -04'00'

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

510(k) Number: K131945