JUL 20 2011

Premarket Notification 510(k) Summary
As required by section 807.92
GE Datex-Ohmeda Aisys

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

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
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NAME OF CONTACT:

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

DATE:

June 6, 2011

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

TRADE NAME:

GE Datex-Ohmeda Aisys 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 GE Datex-Ohmeda Aisys is substantially equivalent in safety and effectiveness to the legally marketed (predicate) GE Datex-Ohmeda Aisys (K090233) and GE Datex-Ohmeda Engstrom ventilator (K093886).

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

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

The GE Datex-Ohmeda Aisys Carestation supplies set flows of medical gases to the breathing system using electronic gas mixing. Gas flows are selected by the user using the keypad and rotary controller on the main display unit and then displayed as electronic flow indicators on the system display unit. The Aisys is equipped with a pneumatic back-up O2 delivery system and traditional flow tube, as well. A large selection of frames, gases, and vaporizers are available to give the user control of the system configuration. The Aisys is also available in a pendant model. It is available with two or three gases, and up to three cylinder connections. All models have O2. The Aisys comes with up to two optional gases (air, N2O). Safety features and devices within the Aisys are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The Aisys system is available with optional integrated respiratory gas monitoring. When supplied as an option, the integrated respiratory gas monitoring is provided via the Datex-Ohmeda M-Gas Module (M-CAiO and M-CAiOV software revision 3.2 and above cleared via K001814) and E-Gas Module (E-CAiOVX software revision 4.5 and above cleared via K051092) which can be physically integrated into the Aisys, receive electronic power from the Aisys and communicate measured values to the Aisys for display on the system display unit.

The anesthetic agent delivery for the Aisys is controlled via an anesthesia computer through user input from the central display. The vaporization technology is based upon the electronic vaporizer cleared as part of the Datex-Ohmeda Anesthesia Delivery Unit (ADU) cleared via K973985. An Aladin cassette (also cleared as part of K973895) or Aladin 2 is inserted into the active cassette bay. The cassette holds the agent to be delivered - Halothane, Enflurane, Isoflurane, Desflurane or Sevoflurane. Agent is delivered as a percent volume/volume. The Aisys is designed to allow only one active cassette at a time. Per the user input into the main display, valves within the active cassette bay will open and allow agent to be delivered. The agent is mixed with gas from the FGC unit. After mixing, the combination of gases and agent is delivered to the breathing system and then on to the patient.

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in the Aisys Anesthesia System. 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 and secure 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) and Constant Positive Airway Pressure/Pressure Support Ventilation (CPAP/PSV). Ventilator parameters and measurements are displayed on the system display unit.

The system display unit is mounted to an arm on the top shelf of the Aisys. The arm is counter balanced and capable of moving vertically and/or horizontally, and also tilting the display, enabling the user to position the display to the most advantageous viewing position. The arm length is limited such that the display position is always within the footprint of the Aisys frame. The arm also supports the mounting of additional display units for a variety of patient monitors.

Several frame configurations are available, including one that allows for the physical integration of the GE Monitors (most recently cleared Carescape B850 via K092027 and Carescape B650 via K102239). This configuration also provides cable management solutions such that the necessary connections from the monitor display unit to the monitor are hidden within the Aisys frame. An additional option allows the monitor to be linked to the power supply of the Aisys such that when the Aisys is turned on, the monitor is also turned on. Additional configurations allow for the mounting of various patient monitors on the top shelf of the Aisys.

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

The GE Datex-Ohmeda Aisys 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. The Aisys is not suitable for use in a MRI environment.

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

The GE Datex-Ohmeda Aisys has been updated from the predicate version (K090233). There have been no changes to the intended use or fundamental scientific technology.

The software for the Aisys has been updated to introduce several new features. A summary of the changes to the software and display monitor include:

- Pediatric Improvements: O2 concentration resolution range improvement at low flows, reduction of spurious alarms when patient is adequately ventilated, improved control of the agent quick key, gas monitor ventilator Tidal Volume compensation, Breathing Tube Compliance On/Off option
- Highlight the border of the menu button for increased visibility
- Checkout improvement: Remove "Leak < 250" question
- Temporary gas flow suspension capability
- Improved "unconfirmed" setting notification
- Remind clinician to set the agent
- Ventilator defaults for each individual vent mode
- New ventilation mode: CPAP/PSV with backup breaths
- Lung mechanics procedure options of Vital Capacity and Cycling
- Procedures button added to the existing display monitor.Quick Keys

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

The GE Datex-Ohmeda Aisys 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 Aisys did not require clinical testing. The functionality of the modified software features were completely evaluated by performing nonclinical tests of design verification and validation testing.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the GE Datex-Ohmeda Aisys as compared to the predicate devices. The performance data demonstrates the device is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Care Business Area
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Madison, Wisconsin 53707-7550

JUL 20 2011

Re: K110213
Trade/Device Name: GE Datex –Ohmeda Aisys Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: July 13, 2011
Received: July 14, 2011

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
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Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: GE Datex-Ohmeda Aisys Anesthesia System

Indications For Use:

The GE Datex-Ohmeda Aisys 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. The Aisys is not suitable for use in a MRI environment.

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

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

510(k) Number: K110213