K090233

MAR 5 2009

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.
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2476

NAME OF CONTACT:

Mr. James P. Raskob
Ms. Adrienne Lenz, RAC (alternate)

DATE:

March 4, 2009

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 Avance (K081844) and the GE Datex-Ohmeda Aisys (K073707).

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. 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 K# 001814) and E-Gas Module (E-CAiOVX 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 onto 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 Mode, Pressure Control Mode, Pressure Support with Apnea Backup Mode (Optional) and Synchronized Intermittent Mandatory Ventilation (SIMV) Mode (Optional). 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 Datex-Ohmeda S/5 Anesthesia Monitor (most recently cleared via K030812). 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 S/5 AM to be linked to the power supply of the Aisys such that when the Aisys is turned on, the S/5 AM 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. 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 (K073707). 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 include:

- Alarm Improvements. Improvements are made to the alarms to reduce nuisance alarms. These changes are the same as have been implemented in Avance 6.0 (K081844). The Vaporizer failure hardware alarm was improved to match the functionality of the existing Aisys Mixer hardware alarm. An audio alarm was added to the current Alternate O2 Button Pressed video message.
- User Configurations. Addition of more default configurations.
- Usability Improvements Waves/Pages. The system will have more screen configurability for waveforms and the numerics.
- Checkout Improvements. Low pressure leak check, breathing circuit leak check, system check flow sensor and agent delivery checkout tests were enhanced.
- MAC Age. The mathematical calculation for MAC will now be able to be made accounting for the patient age. This is the same as is displayed on the S/5 Anesthesia Monitor (K030812, K051400).
- Vaporizer Settings. To aid the filling process the system defaults to automatically depressurize the vaporizer cassette when the agent is turned off.
- Preset ventilator settings based on patient weight for PCV-VG mode. The preset ventilator settings at the start of a case can now be based on patient weight for PCV-VG mode, similar to the way preset vent settings can be been based on patient weight for VCV mode in the previous Aisys.
- Auto exit PSVPro backup mode. The system will now automatically exit SIMV-PC vent mode upon recognition of spontaneous breathing and resume PSVPro™ when patient resumes spontaneous breathing (change was previously made manually).
- Calibrate flow sensors reminder. An informational alarm message will appear when the system is not in therapy between cases to remind the user to calibrate the flow sensors if flows sensors have not been calibrated for 24 hours. Currently the manuals give this instruction.

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 the following standards has also been made to support safe use of the device in its intended environment.

Standard	Title
EN 740 :1998	Anesthesia Workstations and their components
EN 60601-1:1990	Medical Electrical Equipment Part 1: General Requirements for Safety Incorporates Corrigendum July 1994; Includes Amendments A1:1993, A11:1993, A12:1993, A2:1995, A13:1996, IEC 601-1:1998 + A2:1995 + Corrigendum 1995, Modified
EN 60601-1-1:2000	Medical Electrical Equipment - Medical Electrical Systems
EN 60601-1-2:2001	Medical Electrical Equipment - Electromagnetic Compatibility
IEC 60601-1-4:2000	Safety of Programmable Electronic Medical Systems
EN 475:1995	Electrically Generated Alarm Signals
EN 850:1997	Small Medical Gas Cylinders - Pin Indexed
EN 980:1997	Graphical Symbols
EN 1041:1998	Information to be supplied with medical devices
EN 1089-3:1997	Color coding for medical gases
ISO5356-1:1996	Conical Connectors
EN 1820:1997	Reservoir Bags
IEC 60601-2-13: 1998	Particular requirements for the safety of anaesthetic workstations

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.

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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2009

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

Re: K090233
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: January 29, 2009
Received: February 3, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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. 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: K090283