JUN 27 2006 K061609

Date: June 8th, 2006

Subject: 510(k) Summary of Safety and Effectiveness Information for the GE Datex-Ohmeda Aisys Carestation

Proprietary: GE Datex-Ohmeda Aisys Carestation

Common: Gas Machine, Anesthesia

Classification: Anesthesiology, 73 BSZ, 21 CFR 868.5160

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The GE Datex-Ohmeda Aisys Carestation is substantially equivalent to the following currently marketed device:

> Datex-Ohmeda Aisys - Class II - 21CFR868.5160, which has been the subject of a cleared 510(k) with FDA log number K042154

The GE Datex-Ohmeda Aisys Carestation is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. It represents the next system 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) which is physically integrated into the Aisys, receives electronic power from the Aisys and communicates 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.

The GE Datex-Ohmeda Aisys Carestation was designed to comply with the applicable portions of the following voluntary standards;

1. UL 2601 – General requirements for Medical Electrical Equipment
2. EN 740 – Anesthetic Work Stations
3. EN/IEC 60601-1: General requirements for Medical Electrical Equipment
4. EN/IEC 60601-1-2: Medical Electrical Equipment - Electromagnetic Compatibility
5. EN 475 – Electrically Generated Alarm Signals
6. ASTM F1463-93 – Standard Specification for Alarm Signals
7. ASTM F1208-94 – Anesthesia Breathing Circuit Standard
8. ASTM F1101-90 – Standard Specification for Ventilators Intended for Use During Anesthesia
9. ISO 5358 - Anesthetic Gas Machines

The GE Datex-Ohmeda Aisys Carestation and the currently marketed device are substantially equivalent in design concepts, technologies and materials. The GE Datex-Ohmeda Aisys Carestation has been validated through rigorous testing that, in part, supports the compliance of GE Datex-Ohmeda Aisys Carestation to the standards listed above.

Contact: Dan Kosednar, RAC
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUN 27 2006

Datex-Ohmeda, Incorporated
Dan Kosednar
Manager, Regulatory Affairs Planning and Submission
Life Support Solutions
P.O. Box 7550
Madison, Wisconsin 53707-7550

Re: K061609
Trade/Device Name: GE Datex-Ohmeda Aisys
Regulation Number: 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: June 8, 2006
Received: June 9, 2006

Dear Mr. Mr. Kosednar:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

Indications For Use:

The GE Datex-Ohmeda Aisys 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)

Sign-Off)
of Anesthesiology, General Hospital,
Control, Dental Devices
Number K061609