APR 1 2 2005 K050676

Date: March 14, 2005

Subject: 510(k) Summary of Safety and Effectiveness Information for the GE Datex-Ohmeda S/5 ADU

Proprietary: GE Datex-Ohmeda S/5 Anesthesia Delivery Unit

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 ADU is substantially equivalent to the following currently marketed device:

> GE Datex-Ohmeda ADU Carestation - Class II - 21CFR868.5160, which has been the subject of a cleared 510(k) with FDA log number K042154
>
> Datex-Ohmeda AS/3 Anesthesia Delivery Unit - Class II - 21CFR868.5160, which has been the subject of a cleared 510(k) with FDA log number K973985

The GE Datex-Ohmeda ADU is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. It is to be used only by trained and qualified medical professionals.

The GE Datex-Ohmeda ADU supplies set flows of medical gases to the breathing system using mechanical gas mixing. Gas flows are selected by the user using the rotary controller on the frame and then displayed as electronic flow indicators on the system display unit. The ADU is equipped with a traditional flow tube, as well. The ADU 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 ADU comes with up to two optional gases (air, N2O). Safety features and devices within the ADU are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

The anesthetic agent delivery for the ADU is controlled via an anesthesia computer through user input from that computer. An Aladin cassette 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 ADU is designed to allow only one active cassette at a time. Per the user input, valves within the active cassette bay will open and allow agent to be delivered. The agent is mixed with gas within the FGC unit. After mixing, the combination of gases and agent is delivered to the breathing system and then onto the patient.

The ADU Anesthesia Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. Sensors in the breathing circuit are used to control and monitor patient ventilation. 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. 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. Ventilator parameters and measurements are displayed on the system display unit.

The ADU must be used with additional monitoring that include at least inspired O2, expired volume, expired CO2 and Anesthetic Agent.

An RS-232 serial digital communications port connects to and communicates with external devices such a Datex-Ohmeda S/5 Anesthesia Monitor.

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). Additional configurations allow for the mounting of various patient monitors on the top shelf of the ADU.

The GE Datex-Ohmeda ADU 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: 2001 - 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2005

Datex Ohmeda, AB
c/o Mr. Dan Kosednar
Manager, Regulatory Submissions
Datex-Ohmeda, Incorporated
Life Support Solutions
P.O. Box 7550
Madison, Wisconsin 53707-7550

Re: K050676
Trade/Device Name: GE Datex-Ohmeda Anesthesia Delivery Unit (ADU)
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine, Anesthesia
Regulatory Class: II
Product Code: BSZ
Dated: March 15, 2005
Received: March 16, 2005

Dear 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.

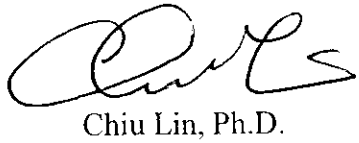
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0102. 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): K050676
Device Name: GE Datex-Ohmeda Anesthesia Delivery Unit (ADU)

Indications For Use:

The GE Datex-Ohmeda Anesthesia Delivery Unit 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, pressure support and synchronized intermittent mandatory (SIMV) ventilation modes. The ADU is not suitable for use in a MRI environment.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number K050676