APR 2 2 2004

K040743

Date: March 16th, 2004

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

Proprietary: Datex-Ohmeda S/5 Avance Anesthesia System

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 Datex-Ohmeda S/5 Avance Anesthesia System is substantially equivalent to the following currently marketed device:

> Datex-Ohmeda S/5 Avance Anesthesia System - Class II - 21CFR868.5160, which has been the subject of a cleared 510(k) with FDA log number K032803
>
> Datex-Ohmeda 7900 Ventilator Enhancements Class II - 21CFR868.5160, which has been the subject of a cleared 510(k) with FDA log number K023366

The Datex-Ohmeda S/5 Avance Anesthesia System 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 and Aespire Anesthesia Systems. It is to be used only by trained and qualified medical professionals.

The Datex-Ohmeda S/5 Avance Anesthesia System 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 meters on the system display unit. The Avance 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 S/5 Avance is also available in wall-mount and pendant models. It is available with two or three gases, up to two vaporizer positions and up to three cylinder connections. All models have O2. The S/5 Avance comes with up to two optional gases (air, N2O). The S/5 Avance systems accept Tec 4, Tec 5, Tec 6, and Tec 7 vaporizers on a Selectatec manifold. Safety features and devices within the S/5 Avance are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The Avance 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 Avance, receives electronic power from the Avance and communicates measured values to the Avance for display on the system display unit.

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in the S/5 Avance 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 Ventilation (Optional) and Synchronized Mandatory Intermittent Ventilation(SIMV) (Optional) Mode. Ventilator parameters and measurements are displayed on the system display unit.

The Datex-Ohmeda S/5 Avance Anesthesia System 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: 1998 - 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 Datex-Ohmeda S/5 Avance Anesthesia System and the currently marketed device are substantially equivalent in design concepts, technologies and materials. The Datex-Ohmeda S/5 Avance Anesthesia System has been validated through rigorous testing that, in part, supports the compliance of S/5 Avance Anesthesia System to the standards listed above.

Contact: Dan Kosednar, RAC
Manager, Regulatory Planning and Submissions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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APR 2 2 2004

Mr. Dan Kosednar
Regulatory Planning and Submissions Manager
Datex-Ohmeda, Incorporated
P.O. Box 7550
Madison, Wisconsin 53707

Re: K040743
Trade/Device Name: Datex-Ohmeda S/5 Avance Anesthesia System
Regulation Number: 868.5160
Regulation Name: Gas Machine, Anesthesia
Regulatory Class: II
Product Code: BSZ
Dated: March 22, 2004
Received: March 24, 2004

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 (301) 594-4646. 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/dsma/dsmamain.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): K040743

Device Name: Datex-Ohmeda S/5 Avance Anesthesia System

Indications For Use:

The Datex-Ohmeda S/5 Avance 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 S/5 Avance 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 K040743