K032803

MAR 1 0 2004

Date: January 7th, 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 Aestiva/5, with 7100 Ventilator, Anesthesia System - Class II - 21CFR868.5160, which has been the subject of a cleared 510(k) with FDA log number K000706

Datex-Ohmeda Excel 3000 (Aestiva), with 7900 Ventilator, Anesthesia System – Class II - 21CFR868.5160, which has been the subject of a cleared 510(k) with FDA log number K973896

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

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.

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
Rockville MD 20850

MAR 1 0 2004

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

Re: K032803
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: January 8, 2004
Received: January 9, 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.

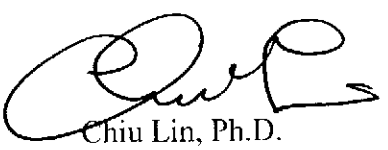
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K032803

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: K032803