OCT - 7 2003

K023366

Date: June 17, 2003

Subject: 510(k) Summary of Safety and Effectiveness Information for the 7900 Ventilator Enhancements to the Datex-Ohmeda Aestiva/5 Anesthesia System

Proprietary: Datex-Ohmeda 7900 Anesthesia Ventilator

Common: Ventilator, Continuous

Classification: Anesthesiology, 73 CBK, 21 CFR 868.5895

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

The 7900 Ventilator Enhancements to the Datex-Ohmeda Aestiva/5 Anesthesia System are substantially equivalent to the following currently marketed devices:

1. Ohmeda 7900 Anesthesia Ventilator – Class II – 21CFR868.5895, which has been the subject of a cleared 510(k) with FDA log number K960964
2. Ohmeda Excel 3000 Anesthesia Gas System – Class II – 21CFR868.5895, which has been the subject of a cleared 510(k) with FDA log number K973896
3. Datex-Engstrom 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
4. Puritan Bennett 7200 ICU Ventilator – Class II – 21CFR868.5895, which has been the subject of a cleared 510(k) with FDA log number K930017

This version of the Datex-Ohmeda 7900 Ventilator is used in Datex-Ohmeda Aestiva/5 Anesthesia Systems. 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 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. 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 tot he 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. Ventilatory modes for the device, include Volume Mode, Pressure Control Mode, Synchronous Intermittent Mandatory Ventilation (optional), Pressure Support with Apnea Backup Ventilation (optional). This device is to be used only by trained and qualified medical professionals.

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Facsimile 608-222-9147

The 7900 Ventilator Enhancements to the Datex-Ohmeda Aestiva/5 Anesthesia System are 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. ASTM F1101-90 – Standard Specification for Ventilators Intended for Use During Anesthesia
6. ISO 5358 - Anesthetic Gas Machines
7. ASTM F1209-94 – Anesthesia Breathing Circuit Standard
8. EN 475 – Electrically Generated Alarm Signals
9. ASTM F1463-93 – Standard Specification for Alarm Signals

The 7900 Ventilator Enhancements to the Datex-Ohmeda Aestiva/5 Anesthesia System and the currently marketed devices are substantially equivalent in design concepts, technologies and materials. The 7900 Ventilator Enhancements to the Datex-Ohmeda Aestiva/5 Anesthesia System have been validated through rigorous testing that, in part, supports the compliance to the standards listed above.

Contact: William E. Exner
Vice President, Regulatory and Quality Affairs

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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OCT - 7 2003

Mr. William E. Exner
Vice President, Quality Regulatory Affairs
Datex-Ohmeda, Incorporated
P.O. Box 7550
Madison, Wisconsin 53707

Re: K023366
Trade/Device Name: 7900 Ventilator Enhancements for Datex-Ohmeda Aestiva/5 Anesthesia
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 7, 2003
Received: July 10, 2003

Dear Mr. Exner:

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

510(k) Number (if known): K023366

Device Name: 7900 Ventilator Enhancements for Datex-Ohmeda Aestiva/5 Anesthesia System

Indications For Use:

This version of the Datex-Ohmeda 7900 Ventilator is used in Datex-Ohmeda Aestiva/5 Anesthesia Systems. 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 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. 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 tot he 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. Ventilatory modes for the device, include Volume Mode, Pressure Control Mode, Synchronous Intermittent Mandatory Ventilation (optional), Pressure Support with Apnea Backup Ventilation (optional).

This device is to be used only by trained and qualified medical professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

C Watson

(Division Sign-Off)
Division of Dental, Infection Control, and
General Hospital Devices

510(k) Number: K023366

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109) (Optional Format 1-2-96)