DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

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

Re: K041524
Trade/Device Name: GE Datex-Ohmeda Aptaér Heliox Delivery System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 27, 2004
Received: August 30, 2004

Dear Mr. Kosednar:

This letter corrects our substantially equivalent letter of June 17, 2004 regarding the trade name.

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 (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 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 continue 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/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

K041524

SEP 20 2004

Date: June 4, 2004

Subject: 510(k) Summary of Safety and Effectiveness Information for the GE Datex-Ohmeda Aptaér Heliox Delivery System

Proprietary: GE Datex-Ohmeda Aptaér Heliox Delivery System

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 GE Datex-Ohmeda Aptaér Heliox Delivery System is substantially equivalent to the following currently marketed device:

> Viasys Avea Ventilator - Class II - 21CFR868.5895, which has been the subject of a cleared 510(k) with FDA log number K022674.
>
> Puritan Bennett 7200 Series Ventilator –Class II - 21CFR868.5895, which has been the subject of several cleared 510(k)s, most recently with FDA log number K922705

The GE Datex-Ohmeda Aptaér Heliox delivery system is designed to deliver heliox from a source gas cylinder to spontaneously breathing patients via a facemask using pressure support. A built-in nebulizer, the Aerogen Aeroneb Pro (K021175) is provided for adding nebulized medication to the delivered heliox. The system is designed for facility use and should only be used under the orders of a clinician.

The Aptaér Heliox Delivery System is not intended as a life support device and is not intended for intubated patients.

The GE Datex- Aptaér Heliox Delivery System was designed to comply with the applicable portions of the following voluntary standards;

1. UL 2601 – General requirements for Medical Electrical Equipment
2. ASTM F100 – Particular Requirements for Critical Care Ventilators
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. CGA V-1 ad ISO 5145 Medical Gas Cylinders – Threaded Cylinders
7. EN 980 Graphical Symbols

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

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

Indications for Use

510(k) Number (if known): K041524

Device Name: GE Datex-Ohmeda Aptaér Heliox Delivery System

Indications For Use:

The GE Datex-Ohmeda Aptaér Heliox delivery system is designed to deliver heliox from a source gas cylinder to spontaneously breathing patients via a sealed facemask using pressure support. A built-in nebulizer, the Aerogen Aeroneb Pro (K021175) is provided for adding nebulized medication to the delivered heliox. The system is designed for facility use and should only be used under the orders of a clinician.

The Aptaér Heliox Delivery System is not intended as a life support device and is not intended for intubated patients.

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)

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

510(k) Number: K041524