FEB - 4 2005

K050055

December 28th, 2004

Subject: 510(k) Summary of Safety and Effectiveness Information for the GE Datex-Ohmeda Aestiva/5 MRI Anesthesia System
Proprietary: Datex-Ohmeda Aestiva/5 MRI Anesthesia System
Common: Gas Machine, Anesthesia
Classification: Anesthesiology, 73CBK, 21CFR868.5160

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

The Aestiva SmartVent MRI Anesthesia System is substantially equivalent to the following currently marketed device:

1. Datex-Ohmeda Aestiva SmartVent MRI Anesthesia System - Class II - 21CFR868.5160

The Aestiva/5 MRI provides the functional feature set offered by the conventional Aestiva 3000 (K973896) to the clinician with the added ability to be used in the MR environment (as cleared in K993410). Among those standard Aestiva 3000 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent (Including those cleared in K023366) along with the Aestiva breathing circuit. The Aestiva/5 MRI is constructed of primarily non-ferrous materials to help prevent attraction to the cryogenic magnets in the MRI systems. The Aestiva/5 MRI performed to specifications when tested directly next to an MRI device of the field strength listed in the product labeling. Safety features and devices within the Aestiva/5 MRI decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

The Aestiva SmartVent MRI was designed to comply with the applicable portions of the following voluntary standards:

1. EN 740 - Anesthetic Work Stations
2. EN 60601-1, IEC 601-1: 1988 - Medical Electrical Equipment
3. EN 60601-1-2, IEC 601-1-2: 1998 - Medical Electrical Equipment - Electromagnetic Compatibility
4. ISO 5358 - Anesthetic Gas Machines
5. ASTM F1208-94 – Anesthesia Breathing Circuit Standard

In addition, the FDA Document, A Primer on Medical Device Interactions wi Resonance Imaging Systems, was used to help determine testing and labeling requirements.

The Datex-Ohmeda Aestiva/5 MRI and the currently marketed devices are substantially equivalent in design concepts, technologies and materials. The Datex-Ohmeda Aestiva/5 MRI has been validated through rigorous testing that, in part, support the compliance of Aestiva/5 MRI to the above mentioned standards.

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Datex-Ohmeda, Inc.
P.O. Box 7550
Madison, WI 53707-7550
www.datex-ohmeda.com
Toll Free 800-345-2700
Facsimile 608-222-9147

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K050055
Trade/Device Name: GE Datex-Ohmeda Aestiva/5 MRI Anesthesia System
Regulation Number: 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: January 10, 2005
Received: January 11, 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) 276-0120. 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/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): K050055

Device Name: GE Datex-Ohmeda Aestiva/5 MRI Anesthesia System

Indications For Use:

The Aestiva/5 MRI Anesthesia System provides the functional feature set offered by the conventional Aestiva/5 to the clinician with the added ability to be used in the MR environment. Among those standard Aestiva/5 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent along with the Aestiva breathing circuit. The Aestiva/5 MRI Anesthesia System performed to specifications when tested directly next to 1.5 and 3.0 Tesla shielded MRI devices in a field strength that did not exceed 300 gauss.

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: K050055