APR 2 5 2000

K993410

October 8th, 1999

Subject:	510(k) Summary of Safety and Effectiveness Information for the Datex-Ohmeda Aestiva SmartVent MRI Anesthesia System
Proprietary:	Datex-Ohmeda Aestiva SmartVent 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 3000 Anesthesia System - Class II - 21CFR868.5160
2. Ohmeda Excel MRI Anesthesia System - Class II - CFR868.5160

The Aestiva SmarVent MRI provides the functional feature set offered by the conventional Aestiva 3000 to the clinician with the added ability to be used in the MR environment. Among those standard Aestiva 3000 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent along with the Aestiva breathing circuit. The Aestiva SmartVent MRI is constructed of primarily non-ferrous materials to help prevent attraction to the cryogenic magnets in the MRI systems. The Aestiva SmartVent 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 SmartVent 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
4. EN 60601-1-2, IEC 601-1-2: 1998 - Medical Electrical Equipment - Electromagnetic Compatability
5. ISO 5358 - Anesthetic Gas Machines
6. ASTM F1208-94 – Anesthesia Breathing Circuit Standard

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2000

Mr. Daniel Kosednar
Datex-Ohmeda, Inc.
Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550

Re: K993410
Aestiva SmartVent MRI Anesthesia System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: February 14, 2000
Received: February 15, 2000

Dear Mr. Kosednar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993410

Device Name: Datex-Ohmeda Aestiva SmartVent MRI Anesthesia Gas System

Indications For Use:

The Aestiva SmarVent MRI provides the functional feature set offered by the conventional Aestiva 3000 to the clinician with the added ability to be used in the MR environment. Among those standard Aestiva 3000 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent along with the Aestiva breathing circuit. The Aestiva SmartVent MRI performed to specifications when tested directly next to a 1.5 Tesla shielded MRI device in a field strength that did not exceed 300 gauss.

(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 Cardiovascular, Respiratory, and
Neurological Devices

510(k) Number: K993410

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

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number