K973896

APR 21 1998

Memorandum

OHMEDA

THE BOC GROUP

January 23rd, 1998

Subject:	510(k) Summary of Safety and Effectiveness Information for the Ohmeda Excel 3000 Anesthesia Gas System
Proprietary:	Ohmeda Excel 3000 Anesthesia Gas System
Common:	Gas Machine, Anesthesia
Classification:	Anesthesiology, 73BSZ, 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 Ohmeda Excel 3000 Anesthesia Gas System is substantially equivalent to the following currently marketed device:

1. Ohmeda Excel Series Anesthesia Machines - Class II - 21CFR868.5160
2. Ohmeda APAC (Advanced Portable Anesthesia Care) System - Class II - 21 CFR868.5160
3. Ohmeda 7900 Anesthesia Ventilator - Class II - 21CFR868.5895

The Excel 3000 Anesthesia Gas System is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, vaporizers and ventilators, give full control of the system configuration. The Excel 3000 is available in wide or narrow trolley and pendant models. The narrow trolley and pendant come with two or three gases, two vaporizer positions and up to four cylinder connections. The wide trolley comes with two, three or four gases, three vaporizer positions and up to five cylinder connections. All models have O2 and N2O. The Excel 3000 comes with up to two optional gases (air, CO2, heliox). All Excel systems accept Tec 4, Tec 5 and Tec 6 vaporizers. Excel 3000 systems use either the 7900 Ventilator, 7800 Ventilator, or the 7000 Ventilator, along with being able to accept integral monitors for vital signs and respiratory gases. Safety features and devices within the Excel 3000 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

The Ohmeda Excel 3000 Anesthesia Gas System was designed to comply with the applicable portions of the following voluntary standards;

1. ASTM F1208-94 - Anesthesia Breathing Circuit Standard
2. EN 60601-1, IEC 601-1: 1988 - Medical Electrical Equipment
3. Draft ISO DIS 7767 - Oxygen monitors for monitoring patient breathing mixtures
4. CEN 475 - Electrically generated alarm signals
5. IEC 601-1-4:1996 - Collateral Standard for Programmable Medical Electrical Equipment

The Ohmeda Excel 3000 Anesthesia Gas System and the currently marketed devices are substantially equivalent in design concepts, technologies and materials. The Ohmeda Excel 3000 Anesthesia Gas System has been validated through rigorous testing that, in part, support the compliance of the Ohmeda Excel 3000 Anesthesia Gas System to the above mentioned standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

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

Re: K973896
Ohmeda Excel 3000 Anesthesia System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: January 23, 1998
Received: January 26, 1998

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 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973896

Device Name: Ohmeda Excel 3000 Anesthesia Gas System

Indications For Use:

The Excel 3000 Anesthesia Gas System is a gas machine that supplies set flows of medical gases to the breathing system. A large selection of frames, gases, vaporizers and ventilators, give full control of the system configuration. The Excel 3000 is available in wide or narrow trolley and pendant models. The narrow trolley and pendant come with two or three gases, two vaporizer positions and up to four cylinder connections. The wide trolley comes with two, three or four gases, three vaporizer positions and up to five cylinder connections. All models have O2 and N2O. The Excel 3000 comes with up to two optional gases (air, CO2, heliox). All Excel systems accept Tec 4, Tec 5 and Tec 6 vaporizers. Excel 3000 systems use either the 7900 Ventilator, 7800 Ventilator, or the 7000 Ventilator, along with being able to accept integral monitors for vital signs and respiratory gases. Safety features and devices within the Excel 3000 decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Ruggiero

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

510(k) Number: K973896

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