K960041

OHMEDA

THE BOC GROUP

JUN 17 1997

Ohmeda Inc
Ohmeda Drive
PO Box 7550
Madison WI 53707-7550
608 221 1551

December 6, 1996

Subject:	510(k) Summary of Safety and Effectiveness Information for the Ohmeda APAC (Advanced Portable Anesthesia Care) System
Proprietary:	Ohmeda APAC (Advanced Portable Anesthesia Care) System
Common:	Gas Machine, Anesthesia
Classification:	Anesthesiology, 73BSZ, 21CFR868.5160

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

The Ohmeda APAC System is substantially equivalent to the following currently marketed device:

1. Ohmeda Excel Series Anesthesia Machines - Class II - 21CFR868.5160

The APAC is a self-contained, portable and lightweight anesthesia machine that includes the components and accessories necessary to deliver anesthesia. **Gases and vaporizers;** The APAC System delivers three breathing circuit gases: O_2 (cylinder or pipeline), N_2O (pipeline only), air (pipeline only). The APAC System includes a Tec 5 Vaporizer. **Ventilators;** The APAC System uses a 7800 Ventilator changed to use O_2 or air as the pneumatic power source. **Patient Safety;** Safety devices decrease the risk of: Hypoxic Mixtures; A flow control proportioning system keeps the O2 concentration higher than 23% at the fresh gas outlet for O2 and N2O mixtures. N2O flow decreases proportionally as the O2 supply decreases. N2O and air flow stops completely in case of total O2 supply failure. Complete power or sudden gas supply failures: Batteries continue 7800 Ventilator operation during a power failure. Ohmeda ventilators have power failure alarms. Ohmeda ventilators have alarms for low gas supply pressure. The APAC System has an alarm for O2 supply pressures less than 27 to 33 psig (186 to 228 kPa).

The Ohmeda APAC System was designed to comply with the applicable portions of the following voluntary standards;

1. ASTM F1161-88 for the Anesthesia Machine System
2. EN 60601-1-2, IEC 601-1-2 for the 7800 Ventilator
3. EN 60601-1, IEC 601-1 and IEC 601-2-13 for the 7800 Ventilator
4. DIN 13252 for the Tec 5 Sevotec 8%
5. DIN 13252 for the Tec 5 Fluotec 5%
6. DIN 13252 for the Tec 5 Enfluratec5%
7. DIN 13252 for the Tec 5 Isotec5%

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1997

Mr. Chuck Morreale
Ohmeda Inc.
Ohmeda Drive
P.O. Box 7550
Madison, Wisconsin 53707-7550

Re: K965041
Ohmeda Advanced Portable Anesthesia Care (APAC) System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: March 17, 1997
Received: March 19, 1997

Dear Mr. Morreale:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4646. 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): K965041

Device Name: Ohmeda APAC System

Indications For Use:

The APAC is a self-contained, portable and lightweight anesthesia machine that includes the components and accessories necessary to deliver anesthesia.

Gases and vaporizers
The APAC System delivers three breathing circuit gases:

- O_2 (cylinder or pipeline)
- N_2O (pipeline only)
- air (pipeline only)

The APAC System includes a Tec 5 Vaporizer

Ventilators
The APAC System uses a 7800 Ventilator changed to use O_2 or air as the pneumatic power source.

Patient Safety
Safety devices decrease the risk of:

Hypoxic Mixtures

- A flow control proportioning system keeps the O2 concentration higher than 23% at the fresh gas outlet for O2 and N2O mixtures.
- N2O flow decreases proportionally as the O2 supply decreases.
- N2O and air flow stops completely in case of total O2 supply failure.

Complete power or sudden gas supply failures

- Batteries continue 7800 Ventilator operation during a power failure.
- Ohmeda ventilators have power failure alarms.
- Ohmeda ventilators have alarms for low gas supply pressure.
- The APAC System has an alarm for O2 supply pressures less than 27 to 33 psig (186 to 228 kPa).

(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: K965041

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