DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2004

Jerome Korten
President and CEO
Versamed Corporation
2 Blue Hill Plaza
Pearl River, NY 10965

Re: K981668
Trade/Device Name: SmartVent™ 201 Portable Ventilator
Regulatory Class: II (Two)
Product Code: 73 CBK
Dated: January 10, 1999
Received: January 14, 1999

Dear Jerome Korten:

This letter corrects our substantially equivalent letter of April 7, 1999. 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.

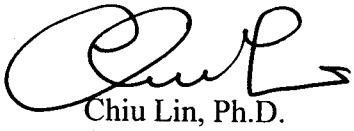
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 and additionally Part 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (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

INDICATIONS FOR USE

510(k) Number (if known): K981668

Device Name: ***SmartVent™ 201 Portable Ventilator***

Indications for Use:

The ***SmartVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

- Assist/Control (Pressure Controlled or Volume Controlled)
- SIMV (Pressure Controlled or Volume Controlled)
- CPAP/PSV

The ***SmartVent™ 201*** ventilator is suitable for intra-hospital use, home and alternate-site use, transport and energy use.

The ***SmartVent™ 201*** ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the technical specification limits.

(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 K981668

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over the Counter Use _____

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

510(k) Number: K981668

4/7/99

510(k) Summary

Ultramind International Ltd.

SmartVent™ 201 Portable Ventilator

510(k) Number K 981668

Submitter's Name:

A.M.E. Ltd.
14 Raul Wallenberg St.
Ramat Hachayal,
Tel-Aviv 69719, Israel

Contact Person:

Shoshana Friedman
117 Ahuzah St.
Ra'ananna 43373, Israel
Tel: 972-9-771-8130
Fax: 972-9-771-8131

Trade Name:

SmartVent™ 201 Portable Ventilator (Temporary name)

Classification Name:

Continuous Ventilator

Classification:

The FDA has classified these devices as a class II device (product code 73 CBK) and are reviewed by the Anesthesiology, Respiratory, and Defibrillator Devices Group.

Predicate Devices:

The ***SmartVent™ 201 Portable Ventilator*** is substantially equivalent to:

- TBIRD VS & AVS Ventilators (Bird Product Co.), cleared under K950484
- Oxylog 2000 (Dräger, Inc.), cleared under K943531.

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the ***SmartVent™ 201 Portable Ventilator*** complies with the following voluntary standards: ASTM F1100-90, ASTM F1246-91, MIL-STD-810E, ISO 10651-1, ISO 10651-2, ISO 10651-3, EN 60601-1-1, EN 60601-1-2.

Indication for Use:

The ***SmartVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

- Assist/Control (Pressure Controlled or Volume Controlled)
- SIMV (Pressure Controlled or Volume Controlled)
- CPAP/PSV

The ***SmartVent™ 201*** ventilator is suitable for inter-hospital use, home and alternate-site use, transport and emergency use.

The ***SmartVent™ 201*** ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the technical specification limits.

Device Description:

The ***SmartVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is designed to treat a variety of clinical conditions. It can deliver oxygen-enriched air and may be used to administer nebulized medications by inhalation. The

SmartVent™ 201 can use external AC or DC power supply and contains an internal battery. Its operation is controlled by the ***SmartVent™ 201 Software.***

Substantial Equivalence:

Based on a series of safety and performance testing including a comparative study and analysis of similarities and differences we believe that the ***SmartVent™ 201*** is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.