VersaMed Medical Systems Inc.
2 Blue Hill Plaza Bldg. 2
Pearl River, NY 10965
USA

MAR 1 6 2009

Non-Confidential Summary of Safety and Effectiveness

Summary of Safety and Effectiveness

Submitter's Name:

VersaMed Medical System Inc.

Contact Person:

Mr. Jerry Korten
Tel: 845 770 8240
Fax: 845 770 8250

Owner / Operator:

General Electric Co.
3135 Easton Turnpike
Fairfield, CT 06828

Owner / Operator Number:

9912004

Trade Name:

The iVent101

Classification:

Name:	Continuous ventilator
Product code:	73 CBK, 73 NOU
Classification panel:	868-5895
Class:	2
Panel:	Anesthesiology

Device Description:

The iVent101 is a compact, portable, microprocessor-controlled ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation .A turbine-powered air source and a rechargeable internal battery provide freedom from wall air and power outlets . Internal flow and pressure are read through flow/pressure sensors. Clinical data [Tidal Volume, Rate, PIP, FiO2, Peak Flow, Inspiratory Time, I:E Minute Volume] are presented on machine screen.

All the operator actions are performed on the LCD touch-screen on the front panel, allows, rapid control and continuous real-time monitoring of patient ventilation. Alarm settings are fully adjustable. Optional Waveform and Diagnostic Software package displays pressure and flow waveform data, loops, trends, and logged totals in a full array of time slices and presentation modes.

The iVent101 can use external AC or DC power supply and contains an integrated battery.

The $iVent_{101}$ is equipped with two configurations, which differs in the patient circuit type that connects to the machine. One configuration is to be used with a standard one limb patient circuit, and the second configuration is to be used with a standard dual limb patient circuit. The two configurations are incorporating the same infrastructure and can be easily replaced by the user.

The iVent101 is capable of providing the following types of ventilatory support:

- Assist/Control and SIMV with either Volume, Pressure, or Pressure Regulated Volume Control (PRVC)
- CPAP with Pressure Support
- Adaptive Bi-Level for either NIV or invasive ventilation.

Intended use:

The intended use of the iVent101 ventilator is to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The intended patient population includes infants from 5 kg through adult patients.

The iVent101ventilator is suitable for use in institution, home and portable settings

Predicate Devices:

The iVent101 is substantially equivalent to:

- LTV1200 cleared under K060647
- iVent201 cleared under K061627
- PLV Continuum II cleared under K034032
- Legendair XL2 cleared under K070899

Substantial Equivalence and Technological Characteristics:

The iVent101 is viewed as substantially equivalent to the following predicate devices;

- LTV1200 cleared under K060647
- iVent201 cleared under K061627
- PLV Continuum II cleared under K034032
- Legendair XL2 cleared under K070899

The iVent101 is viewed as substantially equivalent to the predicate device since them:

1. Have the same intended use:

2. Have the same environment for use:

3. Have the same patient popultion :

4. Employ a same technology [utilized an internal compressor to generate compressed air and breathe delivery is controlled by software algorithms as the predicates]

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the iVent101 complies with the following voluntary standards:

ASTM F 1100-90, "Standard specification for ventilators intended for use in critical care ventilators".

ASTM F 1246-91," Standard specification for ventilators intended for use in home care ventilators".

Draft Reviewer guidance for ventilators , July 1995

ISO 10651-2," Lung Ventilators for medical use – Particular requirements for Home Care Ventilators", Second Edition (2004)

ISO 10651-6," Medical Electrical Equipment" part 1-6: General requirements for safety-collateral standard: Usability, First Edition (2004)

IEC 60601-1," Medical Electrical Equipment – General requirements for safety", Second edition (1990) , #2 (1995) , 13(1996)

IEC 60601-2-12," Medical electrical equipment. Part 2: Particular requirements for the safety of lung ventilators for medical use", Second Edition(2001).

IEC 60601-1-2, "Electromagnetic Compatibility (EMC)", 2005

IEC 60601-1-8, "General requirements for safety – collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems", First Edition (2003).

UL 60601-1," Medical Electrical Equipment, Part1: General Requirements for safety " , first edition (2003) .

Summary of clinical performance:

The safety and efficacy of mechanical ventilation is well established in scientific research and literature. Due to comprehensive scientific literatures, performance tests per ASTM 1246-91, ASTM 1100-90, IEC and ISO standards, VersaMed believes that clinical studies are not required to determine the safety and efficacy of the device.

Conclusions from Non-clinical Tests:

The iVent101 performs as intended according to its performance specification. The iVent101 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2009

Mr. Jerry Korten
CEO
VersaMed Medical Systems, Incorporated
2 Blue Hill Plaza
Building 2, 3rd Floor
Pearl River, New York 10965

Re: K081845
Trade/Device Name: The iVent101
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK , NOU
Dated: March 9, 2009
Received: March 12, 2009

Dear Mr. Korten:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting 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): K081843

Device Name: **The iVent101**

Indications for Use:

The iVent101 ventilator [with single or dual limb configuration] is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for infants from 5 kg through adult patients who require invasive or non-invasive support via the following ventilatory modalities:

- Assist/Control and SIMV with either Volume, Pressure, or Pressure Regulated Volume Control (PRVC)
- CPAP with Pressure Support
- Adaptive Bi-Level for either NIV or invasive ventilation.

The iVent101 ventilator is suitable for use in institution, home and portable settings.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081843