K073694
page 1 of 3

510(k) Summary
Non-Confidential Summary of Safety and Effectiveness
Page 1 of 3
29-May-08

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

Tel – 845-770-2840 x 101
Fax – 845-770-2850

MAY 30 2008

S. Deler – VP Quality Assurance and Regulatory Affairs

Proprietary or Trade Name: VersaMed *iVent*™ 201 MR Conditional

Common/Usual Name: Ventilator, continuous, facility use

Classification Name: Ventilator, continuous, facility use

Device: *iVent*™ 201 MR Conditional

Predicate Devices: VersaMed *iVent*™ 201 – K061627
Maquet SERVO-I – K063404

Device Description:

The iVent™ 201 MR Conditional is a compact, portable, fully featured, microprocessor-controlled ventilator offering the versatility and capability of larger and costlier ventilators. A turbine-powered air source and a rechargeable internal battery provide freedom from wall air and power outlets. An intuitive turn and click control knob, quick choice push buttons, and a bright, well-organized, easy-to-read screen allow 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.

Optional equipment:

- Non-invasive pulse oximeter (not to be used in MR environments)
- Remote Alarm Adapter

Testing has been performed according to ASTM F2052-06-e1 in 1.5 and 3.0 Tesla environments.

Indications for Use:

The *iVent*™ 201 MR Conditional is a portable, computer controlled, electrically powered intensive care ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for use with adult through pediatric patients, who require invasive or non-invasive assistance via 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 *iVent*™ 201 MR Conditional ventilator is suitable for use in the ICU and all other hospital areas, including Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field, in all hospital-type facilities, alternate care sites, transport, emergency and in the home environment. The *iVent*™ 201 MR Conditional ventilator is MR Conditional.

The optional non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate and is suitable for use in all above mentioned areas, excluding MR environments.

The *iVent*™ 201 MR Conditional ventilator is a restricted medical device intended for use by qualified, trained personnel under the direct supervision of a physician.

Patient Population:	Adult and pediatric
Environment of Use:	ICU and all other hospital areas, including Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field, in all hospital-type facilities, alternate care sites, transport, emergency and in the home environment.

Differences Between Other Legally Marketed Predicate Devices

The VersaMed *iVent*™ 201 MR Conditional ventilator system is viewed as substantially equivalent to the following predicate devices – VersaMed *iVent*™ 201 - K061627 and Maquet SERVO-i – K063404.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

Features	Predicates	**Proposed Device** VersaMed *iVent*™ 201 MR Conditional
Indications for use Already cleared	The *iVent*™ 201 is a portable, computer controlled, electrically powered intensive care ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for use with adult through pediatric patients, who require invasive or non-invasive assistance via 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 *iVent*™ 201 ventilator (with or without the non-invasive Pulse Oximeter option) is suitable for use in the ICU and all other hospital areas, in all hospital-type facilities, alternate care sites, transport, emergency and in the home environment. The non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate and is suitable for use in all above mentioned areas, excluding MR environments. The *iVent*™ 201 ventilator is a restricted medical device intended for use by qualified, trained personnel under the direct supervision of a physician. VersaMed – K061627	Same plus MR environment (MR Conditional)
Expanded Indications for Use	Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field. Maquet – K063404	Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field. MR Conditional
Environment of Use	MR environments - Not to exceed 3.0 Tesla K063404 – Maquet SERVO-i	Same Not to exceed 3.0 Tesla
Patient Population	Adult and pediatrics – K061627	Same
Contraindications	None	Same
MR Testing	ASTM F2502 not known (K063404)	ASTM F2502-06-e1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

VersaMed Medical Systems, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, FL 34134-2958

Re: K073694
Trade/Device Name: iVent™ 201 MR Conditional
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 15, 2008
Received: May 19, 2008

Dear Mr. Dryden:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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 Statement

510(k) Number: K073694 (To be assigned)

Device Name: *iVent*™ 201 MR Conditional

Indications for Use:

The *iVent*™ 201 MR Conditional is a portable, computer controlled, electrically powered intensive care ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for use with adult through pediatric patients, who require invasive or non-invasive assistance via 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 *iVent*™ 201 MR Conditional ventilator is suitable for use in the ICU and all other hospital areas, including Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field, in all hospital-type facilities, alternate care sites, transport, emergency and in the home environment. The *iVent*™ 201 MR Conditional ventilator is MR Conditional.

The optional non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate and is suitable for use in all above mentioned areas, excluding MR environments.

The *iVent*™ 201 MR Conditional ventilator is a restricted medical device intended for use by qualified, trained personnel under the direct supervision of a physician.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073694