

K092135

Premarket Notification 510(k) Summary
As required by section 807.92

NOV 23 2009

The iVent101
Non-Confidential Summary of Safety and Effectiveness

~~Summary of Safety and Effectiveness~~

Submitter's Name:

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Contact Person:

Ms. Adrienne Lenz, RAC
Mr. Jim Raskob

Trade Name:

The iVent101

Classification:

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

A47

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, allowing 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 iVent₁₀₁ 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.

Intended 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. 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.



Food and Drug Administration
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VersaMed Medical Systems, Limited
C/O Adrienne Lenz, RAC
Director
Datex-Ohmeda, Incorporated
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NOV 23 2009

Re: K092135
Trade/Device Name: The iVent101
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU
Dated: October 28, 2009
Received: October 30, 2009

Dear Ms. Lenz:

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 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.

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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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

