510(K) SUMMARY

K070594
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SUBMITTER

Pulmonetic Systems, Inc.
17400 Medina Road, Suite 100
Minneapolis, Minnesota 55447-1341

AUG - 1 2007

Contact Person: Robert C. Samec
(763) 398-8305 Telephone
(763) 398-8400 Facsimile

DEVICE / TRADE NAME

Trade Name: PALMTop PTV Models 8/10

Common Name: Ventilator

Classification Name: Ventilator, Continuous (Respirator) 868.5895

SUBMISSION DATE

Submission Date: August 1, 2007

DESCRIPTION

The **PALM**Top PTV Models 8/10 are designed for use on patients who require respiratory support or mechanical ventilation and weigh a minimum of 5 kg (11 lbs). They are suitable for service in homecare, hospital and transport environments as a source of continuous or intermittent positive pressure ventilatory support, delivered invasively or non-invasively.

The PTV platform provides for the following features:

- High performance ventilation in a small lightweight package
- A range of maneuvers including Inspiratory and Expiratory hold and synchronized Nebulization (touch screen models only)
- Internal flow generator, allowing the PTV to operate without an external compressed gas source
- Four distinct breath types offering a range of treatment options. CPAP with optional Pressure Support [1], SIMV[2], Control, Assist /

Control

- Configurable Apnea back-up ventilation
- NPPV[3] ventilation, providing an alarm package suitable for mask ventilation of patients whose needs do not extend to life support
- Volume Control, Pressure Control and PRVC[4] ventilation modes
- Adjustable alarm settings including High Peak Pressure, Low Peak Pressure, Low Minute Volume, and Apnea
- Oxygen blending from a high-pressure oxygen source (optional) or low-pressure oxygen bleed-in
- Lockable front panel controls
- A wide range of monitors including Breath Rate (f), I:E Ratio (Measured), MAP, Exhaled Minute Volume (VE), PEEP, PIP and Tidal Volume (Vte)
- Dynamic waveform and loop displays
- Graphic trending histogram display
- Real-time patient circuit pressure display
- Variable termination options for Pressure Support breaths, including maximum inspiratory time and percentage of peak flow
- Selectable Percentage of Peak Flow termination for Pressure Control breaths
- Leak Compensation to improve patient triggering when a circuit leak is present
- Operation from a variety of power sources including AC power, removable battery and external DC power sources
- Optional FIO_2 sensor package.
- Optional Oximetry module

INTENDED USE

PALMTop PTV Models 8/10 are designed for use on patients who require respiratory support or mechanical ventilation and weigh a minimum of 5 kg (11 lbs). They are suitable for service in homecare, hospital and transport environments as a source of continuous or intermittent positive pressure ventilatory support, delivered invasively or non-invasively.

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[1] Continuous Positive Pressure Ventilation
[2] Synchronized Intermittent Mandatory Ventilation
[3] Non-invasive Positive Pressure Ventilation
[4] Pressure Regulated, Volume Controlled

*PALM*Top Ventilators are restricted medical devices intended for operation by trained personnel under the direction of a physician and in accordance with all applicable state laws and regulations.

Federal law (USA) restricts the sale of this device except by or on the order of a physician.

Summary of Testing and Validation

Performance testing (Bench testing) verified that the Palmtop Models PTV 8/10 meet specified performance requirements and that the devices are substantially equivalent to the predicate devices listed below.

Predicate Device	510(k) Clearance	Manufacturer
LTV 1200 Ventilator	K060647	VIASYS Healthcare/Pulmonetic Systems, Inc. 17400 Medina Road, Suite 100 Minneapolis, MN 55447
LTV 1000 Ventilator	K981371 K984056	VIASYS Healthcare/Pulmonetic Systems, Inc. 17400 Medina Road, Suite 100 Minneapolis, MN 55447
iVent 201 Portable Ventilator with Pulse Oximeter	K021981	Versamed Corporation 2 Blue Hill Plaza Pearl River, NY 10965
TBird VELA Ventilator	K032451	VIASYS Healthcare/Bird Products Corporation 1100 Bird Center Drive Palm Springs, CA 92262

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2007

Pulmonetic Systems, Incorporated
C/O Mr. Robert C. Samec
Vice President- Quality Assurance/Regulatory Affairs
Division of VIASYS Healthcare
17400 Medina Road, Suite 100
Minneapolis, Minnesota 55447-1341

Re: K070594
Trade/Device Name: PALMTop PTV Models 8/10
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: July 26, 2007
Received: July 27, 2007

Dear Mr. Samec:

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) 276-0115. 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 (301) 443-6597 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

510(k) Number (if known): K070594

Device Name: **PALM**Top PTV Models 8/10

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PALMTop PTV Models 8/10 are designed for use on patients who require respiratory support or mechanical ventilation and weigh a minimum of 5 kg (11 lbs). It is suitable for service in homecare, hospital and transport environments as a source of continuous or intermittent positive pressure ventilatory support, delivered invasively or non-invasively.

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Federal law (USA) restricts the sale of this device except by or on the order of a physician.

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) (acting B.C.)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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