510(K) SUMMARY

K060647

SUBMITTER

MAY 25 2006

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

Contact Person: Robert C. Samec
(763) 398-8305 Telephone
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DEVICE / TRADE NAME

Trade Name: LTV 1200 Ventilator

Common Name: Ventilator

Classification Name: Ventilator, Continuous (Respirator) 868.5895

SUBMISSION DATE

Submission Date: March 9, 2006

DESCRIPTION

The LTV 1200 ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is suitable for use in institutional, home and transport settings, and is applicable for adult and pediatric patients weighing at least 5 kg (11 lbs.), who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control, SIMV, CPAP, or NPPV modes of ventilation.
- Breath types including Volume, Pressure Control and Pressure Support.

The modifications intended to be cleared by this submission are:

- Incorporation of optional internal PEEP control, replacing the optional external mechanical PEEP valve used with the previously cleared LTV 1000 Ventilator.
- The addition of a Low PEEP alarm.

- The addition of optional Patient Setting Control Presets to assist clinicians in initially setting patient ventilation set parameters.

- The addition of NPPV mode setting enhancements to assist the clinician in setting up NPPV mode ventilation.

- The addition of externally accessibility to the device internal battery for trained service personnel battery replacement.

- The designation of the modified LTV 1000 Ventilator as the VIASYS LTV 1200 Ventilator.
  (Note: The previously cleared Pulmonetic Systems LTV 1000 will continue to be marketed without the modifications listed in this submission).

The LTV 1000 Ventilator, previously cleared for homecare, institutional and transport use is now being submitted for clearance with the listed modifications.

INTENDED USE

The LTV ventilator 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 adult and pediatric patients weighing at least 5 kg (11 lbs.), who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control, SIMV,CPAP, or NPPV modes of ventilation.
- Breath types including Volume, Pressure Control and Pressure Support.

The ventilator is suitable for use in institutional, home and transport settings.

EQUIVALENCE TO PREDICATE DEVICE(S)

The modified LTV 1000 with the modifications listed is substantially equivalent to the predicate device(s) listed.

Predicate Device	510(k) Clearance	Manufacturer
iVent 201 Portable Ventilator	**K011957**	**Versamed Corporation 2 Blue Hill Plaza Pearl River, NY 10965**
AVEA Ventilator	**K022674**	**Bird Products Corporation 1100 Bird Center Drive Palm Springs, CA 92262**
LTV 1000 Ventilator	**K051767**	**Pulmonetic Systems, Inc. 17400 Medina Road, Suite 100 Minneapolis, MN 55447**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2006

Mr. Robert C. Samec
Vice President-Product Assurance
Pulmonetic Systems, Incorporated
17400 Medina Road, Suite 100
Minneapolis, Minnesota 55447-1341

Re: K060647
Trade/Device Name: Ventilator, Continuous (Respirator), Model LTV 1200
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 9, 2006
Received: May 10, 2006

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.

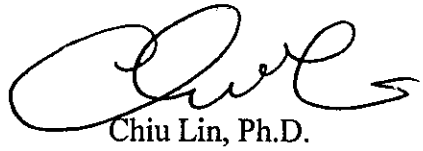
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 (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):

Device Name: Ventilator, Continuous (Respirator)

Indications for Use:

The LTV 1200 ventilator 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 adult and pediatric patients weighing at least 5 kg (11 lbs), who require the following types of ventilatory support:

- Positive Pressure Ventilation, delivered invasively (via ET tube) or non-invasively (via mask).
- Assist/Control, SIMV, CPAP, or NPPV modes of ventilation.

The ventilator is suitable for use in institutional, home, or transport 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 of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K060647