K040540

APR 2 9 2004

1. 510(K) SUMMARY

1.1 SUBMITTER

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

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

1.2 DEVICE / TRADE NAME

Trade Name: LTV 1000 Ventilator

Common Name: Ventilator

Classification Name: Ventilator, Continuous (Respirator) 868.5895

1.3 SUBMISSION DATE

Submission Date: April 1, 2004

1.4 DESCRIPTION

The LTV 1000 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, or CPAP modes of ventilation.
- Breath types including Volume, Pressure Control and Pressure Support.

The modifications intended to be cleared by this submission are:

- The addition of a High Breath Rate Alarm to alert operators to a patient's high breath rate condition.

- The addition of O_2 cylinder duration monitoring to provide a reference indicator of the approximate remaining usable time of an external O_2 cylinder based on operator entered input parameters.

- The addition of a 100% O_2 flush feature allowing the operator to elevate delivered FIO_2 for a preset time period.

- The addition of Automatic High O_2 Switchover to alert operators that a high O_2 pressure source is attached to the ventilator when a low O_2 pressure source has been selected. In this condition, the ventilator will switch to a high O_2 pressure source mode and set O_2 delivery to 21% or room air.

- A change in maximum allowable oxygen input pressure from 70 psig to 80 psig to allow broader compatibility with institutional oxygen sources.

1.5 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, or CPAP modes of ventilation.
- Breath types including Volume, Pressure Control and Pressure Support.

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

1.6 EQUIVALENCE TO PREDICATE DEVICE(S)

The LTV 1000 Ventilator listed modifications are substantially equivalent to the following listed devices:

Predicate Device	510(k) Clearance	Manufacturer
LTV 1000 Ventilator	K981371 – Initial clearance for Institutional and Transport settings. K984056 – Homecare settings. K002881 – Enhancements. K010608 - Lap Top Monitor. K032226 - 5 kg Patient Application.	Pulmonetic Systems, Inc. Colton, CA/Mpls., MN
T-Bird AVS	K981971	Bird Products, Palm Springs, CA

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

The table on the following pages compares the modifications/features of the LTV to the previously cleared LTV 1000 ventilator and the T-Bird AVS ventilator.

The LTV 1000 ventilator with the modifications listed is substantially equivalent to the predicate LTV 1000 (K032226) and the T-Bird AVS Ventilator (K981971) manufactured by Bird Products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Mr. Robert C. Samec
Vice President-Regulatory Affairs
Pulmonetic System, Incorporated
17400 Medina Road Suite 100
Minneapolis, Minnesota 55447

Re: K040540
Trade/Device Name: LTV 1000 Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: April 1, 2004
Received: April 2, 2004

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.

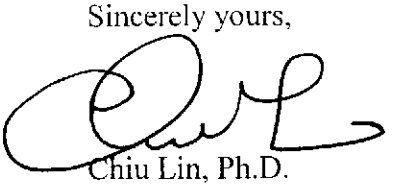
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.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): K040540

Device Name: Ventilator, Continuous (Respirator)

Indications For Use:

The LTV 1000 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 (11lbs.), who require the following types of ventilatory support:

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

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

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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

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