K051767

JUL 29 2005

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: June 28, 2005

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 modification intended to be cleared by this submission is:

- The addition of Spontaneous Breathing Trial (SBT) function allowing the clinician to more easily determine a patient's ability to be weaned from ventilation.

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
Engstrom Carestation	K041775- Initial clearance	GE Datex-Ohmeda

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

The table on the following pages compares the modification/feature of the LTV to the previously cleared LTV 1000 ventilator

The LTV 1000 ventilator with the modification listed is substantially equivalent to the predicate LTV 1000 (K032226) and the Engstrom Carestation (K041775).

SUBSTANTIAL EQUIVALENCE SUMMARY TABLE

Characteristic (LTV Modification)	LTV 1000 (Predicate Device)	Engstrom Carestation (Predicate Device)	Discussion of Differences and Similarities
Spontaneous Breathing (SBT)	Clinicians manually set the CPAP mode/parameters and alarm parameters to start breathing trials. An informational alarm will appear with two minutes left in the study and when the trial has ended. At trial end, the ventilator will return to the previous mode and settings.	Clinicians manually set the CPAP mode/parameters and alarm parameters to start breathing trials. An informational alarm will appear with two minutes left in the study. At trial end, the ventilator will return to the previous mode and settings.	The software application to allow input presets for CPAP mode/parameters and alarm parameters is an addition to the existing LTV 1000 preset menu options and does not introduce any additional or new patient risk or involve the application of new technology.
	SBT time duration available by menu selection (15-120 minutes)	SBT time duration available by menu selection (5-60 minutes)	Longer time duration is provided at the request of clinicians.

The LTV 1000 ventilator with the modification listed is substantially equivalent to the predicate LTV 1000 (K032226) and the Engstrom Carestation (K041775).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2005

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

Re: K051767
Trade/Device Name: LTV 1000 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator
Regulatory Class: II
Product Code: CBK
Dated: June 28, 2005
Received: June 30, 2005

Dear Mr. Samec:

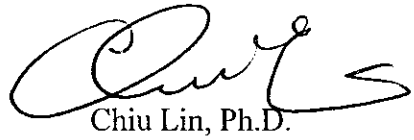
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 (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, 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 Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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