

K 060549

MAY 4 2006

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 Facsimile

1.2 DEVICE / TRADE NAME

Trade Name: Automobile Lighter Power Cord

Common Name: Ventilator Accessory

Classification Name: Ventilator, Continuous (Respirator) 868.5895

1.3 SUBMISSION DATE

Submission Date: March 1, 2006

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 addition intended to be cleared by this submission is:

- The addition of the Automobile Lighter Power Cord to be externally attached to the LTV Series to power the LTV Ventilator while operating in an automobile. The power cord is designed to connect to +12V automobile cigarette lighter or auxiliary power outlets capable of supplying as least 20 amperes of current.

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 Automobile Lighter Power Cord is substantially equivalent to the following listed devices:

Predicate Device	510(k) Clearance	Manufacturer
LP-6 Ventilator with Cigarette Lighter Cable Y-CG1230	K905244	Puritan Bennett Pleasanton, CA 94588

SUBSTANTIAL EQUIVALENCE SUMMARY TABLE

Predicate Device	Modified Device	Discussion of Differences and Similarities
LP-6 Ventilator with Cigarette Lighter Cable P/N Y-CG1230 (K905244)	LTV 1000 Ventilator with Automobile Lighter Power Cord P/N 11544	Same intended use.



MAY 4 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K060549
Trade/Device Name: Ventilator, Continuous (Respirator)
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: March 1, 2006
Received: March 2, 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 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.

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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