JUN - 3 2004

K040790

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/Breathing circuits

Common Name: Ventilator

Classification Name: Ventilator, Continuous (Respirator) 868.5895

1.3 SUBMISSION DATE

Submission Date: March 26, 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 modification intended to be cleared by this submission is:

The addition of commercially available heated wire breathing circuit inspiratory/expiratory limbs manufactured and distributed by Allegiance Healthcare Corporation (K000697), as an option to the ventilator breathing circuits specified for use

commercially available humidifier with heated wire controller* to provide heated and humidified air under a physicians order/supervision.

*Fisher & Paykel Models:
MR 730 (K913368)
MR 850 (K020332)

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 with breathing circuits.	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
Allegiance Airlife Heated Ventilator Breathing Circuits	K000697	Allegiance Healthcare Corporation

The LTV 1000 Ventilator with breathing circuits, 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 page compares the modification of the LTV 1000 breathing circuits to the previously cleared LTV 1000 ventilator/breathing circuits and the Allegiance Airlife Heated Wire Breathing Circuits. Allegiance Healthcare Corporation, the manufacturer of the Airlife Heated Wire

Breathing Circuits is the selected supplier for the Heated Wire Breathing Circuit inspiratory/expiratory limbs to be utilized with the LTV 1000 ventilator.

The LTV 1000 ventilator/breathing circuits with the modification listed are substantially equivalent to the predicate LTV 1000 ventilator/breathing circuits (K981371) and the Allegiance Airlife Heated Wire Breathing Circuits (K000697), intended for use with commercially available ventilators.

SUBSTANTIAL EQUIVALENCE SUMMARY TABLE

LTV 1000 with Modification	LTV 1000 (Predicate Device) (K981371)	Allegiance Airlife Heated Wire Breathing Circuit Limb(s) (K000697) Predicate Device	Discussion of Differences and Similarities
Model 15090-001 **Heated** Circuit Assy., 6', SPU, Adult w/PEEP	Model 10820 Circuit Assy., 6', SPU, Adult w/PEEP	RT600-850 Adult Inspiratory Limb, Heated, 6'.	Airlife Adult Heated Wire Inspiratory Limb replaces PSI Adult Inspiratory Limb.
Model 15090-002 **Heated** Circuit Assy., 6', SPU, Adult PEEPless	Model 10822 Circuit Assy., 6', SPU, Adult PEEPless	RT600-850 Adult Inspiratory Limb, Heated, 6'.	Airlife Adult Heated Wire Inspiratory Limb replaces PSI Adult Inspiratory Limb.
Model 15090-003 **Heated** Circuit Assy., 6', SPU, Pediatric w/PEEP	Model 10821 Circuit Assy., 6', SPU, Pediatric w/PEEP	RT609-856 Pediatric Inspiratory Limb, Heated, 6'.	Airlife Pediatric Heated Wire Inspiratory Limb replaces PSI Pediatric Inspiratory Limb.
Model 15090-004 **Heated** Circuit Assy., 6' SPU, Pediatric PEEPless	Model 10823 Circuit Assy., 6', SPU, Pediatric PEEPless	RT609-856 Pediatric Inspiratory Limb, Heated, 6'.	Airlife Pediatric Heated Wire Inspiratory Limb replaces PSI Pediatric Inspiratory Limb.
Model 15091-001 **Heated** Circuit Assy., 5', SPU, Adult w/ PEEP	Model 10820 Circuit Assy., 6', SPU, Adult w/PEEP	RT500-853 Adult Inspiratoty/Expiratory Limbs, Heated, 5'.	Airlife Adult Heated Wire Inspiratory/Expiratory Limb replaces PSI Adult Inspiratory/Expiratory Limb. Length reduced from 6' to 5'.
Model 15091-002 **Heated** Circuit Assy., 5', SPU, Adult PEEPless	Model 10822 Circuit Assy., 6', SPU, Adult PEEPless	RT500-853 Adult Inspiratoty/Expiratory Limbs, Heated, 5'.	Airlife Adult Heated Wire Inspiratory/Expiratory Limb replaces PSI Adult Inspiratory/Expiratory Limb. Length reduced from 6' to 5'.
Model 15091-003 **Heated** Circuit Assy., 5', SPU, Pediatric w/PEEP	Model 10821 Circuit Assy., 6', SPU, Pediatric w/PEEP	RT509-852 Pediatric Inspiratoty/Expiratory Limbs, Heated, 5'.	Airlife Pediatric Heated Wire Inspiratory/Expiratory Limb replaces PSI Pediatric Inspiratory/Expiratory Limb. Length reduced from 6' to 5'.
Model 15091-004 **Heated** Circuit Assy., 5', SPU, Pediatric PEEPless	Model 10823 Circuit Assy., 6', SPU, Pediatric PEEPless	RT509-852 Pediatric Inspiratoty/Expiratory Limbs, Heated, 5'.	Airlife Pediatric Heated Wire Inspiratory/Expiratory Limb replaces PSI Pediatric Inspiratory/Expiratory Limb. Length reduced from 6' to 5'.
Model 15092-001 Assy. **Heated** Inspiratory Limb Assy., 6', SPU, Pediatric	Model 10823 Circuit Assy., 6', SPU, Pediatric PEEPless	RT609-856 Pediatric Inspiratory Limb, Heated, 6'.	Airlife Pediatric Heated Wire Inspiratory Limb replaces PSI Pediatric Inspiratory Limb.
Model 15092- 002 Assy. **Heated** Inspiratory Limb Assy., 6', SPU, Adult	Model 10820 Circuit Assy., 6', SPU, Adult w/PEEP	RT600-850 Adult Inspiratory Limb, Heated, 6'.	Airlife Adult Heated Wire Inspiratory Limb replaces PSI Adult Inspiratory Limb.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2004

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

Re: K040790
Trade/Device Name: Modification to LTV 1000 Ventilator/Breathing Circuits
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 24, 2004
Received: May 25, 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):

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

510(k) Number: K040790