4/12/99

K984056

510 k Summary

SUBMITTER

Pulmonetic Systems, Inc
930 S. Mt. Vernon Ave. Suite 100
Colton, CA 92324-3928
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Contact Person: Douglas DeVries
Date Prepared: November 11, 1998

DEVICE NAME

Trade Name: LTV 1000
Common Name Ventilator
Classification Name: Ventilator, Continuous (Respirator)

PREDICATE DEVICE

The primary predicate device is the TBird Homecare Ventilator (K981971), manufactured by Bird Products Corp. of Palm Springs, CA.

DESCRIPTION

The LTV1000 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 10 kg (22 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 LTV 1000 is a self-contained mechanical ventilator suitable for continuous life support in institutional, home, and transport settings. The ventilator is slightly larger than a "laptop computer" and is self-contained in that it can be operated without the need for externally supplied compressed air. The unit may be operated from external AC power through the use of an external AC/DC converter, or may be operated for approximately one hour using an internal rechargeable battery pack.

The following major features are included:

- Modes: Assist/Control, SIMV, CPAP, Apnea Backup
- Breath Types: Volume Control, Pressure Control, Pressure Support, Spontaneous
- Flow Triggering
- Oxygen Blending
- PEEP
- Monitors: Calculated Peak Flow, Exhaled Tidal Volume, I:E Ratio, Mean Airway Pressure, Real Time Airway Pressure, Peak inspiratory Pressure, PEEP, Total Breath Rate, Total Minute Volume
- Alarms: Apnea, High Pressure Limit, Low Peak Pressure, Low Minute Volume, Disconnect, Low & Lost External Power, Low & Empty Internal Battery, Oxygen Inlet Pressure

The ventilator uses an internal flow generator to provide the pressurized gas source. All breath types are delivered by an electromechanical inspiratory flow valve. An oxygen blender meters oxygen as required to meet the current setting of the O_2% control. Mechanical valves are provided internally for overpressure relief and sub-ambient relief functions.

The patient circuit is comprised of a single leg inspiratory tube connected to an exhalation system located proximal to the patient connection. The exhalation valve system will consist of a piloted exhalation valve, a PEEP valve, and a flow transducer combined in a compact package. Additional small bore tubing is included to transmit the flow, pressure and exhalation drive signals.

INTENDED USE

The LTV1000 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 10 kg (22 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, and transport settings.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO THE PREDICATE DEVICE

The following table sets forth a comparison of the major technological characteristics of the LTV 1000 to the predicate device, the TBird Ventilator (K981971), manufactured by Bird Products Corp. of Palm Springs, CA.

Characteristic	LTV 1000 Vent	Predicate Device Bird TBird Ventilator (K981971)	Discussion of Differences and Similarities
Compressed Air Source	Internal, Flow Generator driven by a brushless DC motor.	Internal, Flow Generator driven by a brushless DC motor.	The flow generator is similar in that both devices use a rotating element driven by a brushless DC motor. The LTV differs in that the flow generator operates at a constant speed and is not used to control the beginning and end of inspiration as does the predicate device. This constant speed operation is equivalent to the operation of other ventilators, such as the Quantum (K962517) mfg by Healthdyne Technologies.
Inspiratory Flow Control	Variable poppet valve positioned by a rotary actuator.	No separate valve, breath control is effected through variable speed control of the flow generator.	The rotary actuator driven flow control valve used on the LTV 1000 is similar to flow valves used on other currently marketed ventilators the Servo Ventilator 900C (K811102) mfg by Siemens. Even though the 900C is not a home care ventilator, this flow control method is approved for use in comparable clinical settings.
Exhalation Valve	External Piloted balloon type.	Internal, diaphragm driven by a linear actuator.	The external piloted exhalation valve used on the LTV 1000 is similar to types used on other currently marketed ventilators, for example the Nellcor Puritan Bennet LP 10 ventilator, (K905244).

Characteristic	LTV 1000 Vent	Predicate Device Bird TBird Ventilator (K981971)	Discussion of Differences and Similarities
PEEP Valve	External, spring loaded diaphragm type.	Internal, controlled by closed loop control of the linear actuator.	The external spring loaded PEEP valve used on the LTV 1000 is similar to types used on other currently marketed ventilators, for example the Nellcor Puritan Bennet LP 10 ventilator, (K905244).
Exhalation Flow Xducer	Differential Pressure Type, fixed orifice.	Differential Pressure Type, variable orifice.	Transducer is similar.
Control System	Microprocessor based analog and digital electronics.	Microprocessor based analog and digital electronics.	Control system is similar.
Package	Sheetmetal and thermoplastic elastomer.	Sheetmetal, thermoplastic, and thermoplastic elastomer.	The LTV 1000 employs a sheetmetal chassis, protected by elastomeric side panels to provide enhanced durability.
Displays	7-segment, alpha-numeric, and single lamp LEDs.	7-segment, alpha-numeric, and single lamp LEDs.	Displays are similar

NON-CLINICAL PERFORMANCE TESTING

Pursuant to establishing functional and technical equivalence to the predicate device, a non clinical test program was completed to insure that the device met its stated specifications. Validation activities included running test procedures written to validate the requirements as specified in the following documents:

- System Specification
- Software Requirements Specification
- System Hazards Analysis
- ASTM F 1100-90 Standard Specification for Ventilators for Use in Critical Care
- ASTM F 1246-91 Standard Specification for Electrically Powered Home Care Ventilators

The test procedures were divided into 3 primary categories:

ASTM tests	Tests that verify the ventilator meets ASTM standards
Performance Tests	Tests that verify the ventilator meets performance specifications including tolerance and accuracy issues.
Functional Tests	Tests that verify the ventilator meets behavioral specifications (Primarily Software)

Test procedures were written for individual tests specifying: the requirement being tested, the number of units to be tested, the equipment to be used, test set-up instructions, the data to be recorded. In general, test procedures were written to test each parameter over the entire range of operation while varying other relevant parameters such as patient lung condition and environment. For example, the Set Tidal Volume function was tested over its entire range (50 - 2000 ml) and over worst case combinations of the following parameters:

- Patient Compliance
- Patient Resistance
- Temperature/Humidity of Patient breathing gas.
- Ventilator Operating Temperature.

A validation report was written that summarizes the results of these tests. The ventilator was found to perform to specifications with exceptions as noted in the validation report. If a parameter was found to be non-compliant, a procedure was described in the report to ensure the anomaly does not present a hazard to the patient or user.

CONCLUSION

The comparison analysis and validation test results demonstrate the device is substantially equivalent to the predicate device and appropriate for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 1999

Mr. Douglas DeVries
Chief Executive Officer
Pulmonetic Systems
930 S. Mt. Vernon Avenue, Suite 100
Colton, CA 92324

Re: K984056
Trade Name: LTV 1000
Regulatory Class: II (two)
Product Code: CBK
Dated: February 18, 1999
Received: February 23, 1999

Dear Mr. DeVries:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please not the regulation entitled, " Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities

under the Act, may be obtained from the Division of Small Manufacturers 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,

for Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

The LTV1000 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 10 kg (22 lbs), who require the following types of ventilatory support:

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

Arthur A. Ciarkowski

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984056

Prescription Use X
(Per 21 CFR 801.109)