DEC 2 0 2004 K043085

Airon

Pneuton Ventilator

Special 510(k) Summary

Contact Information
G. Eric Gjerde
President
Airon Corporation
17 East Melbourne Ave
Melbourne, FL 32901
Tel: 321-821-9433
Fax: 321-821-9443
email: egjerde@pneuton.com

Application Date
November 5, 2004

Device Trade Name
Pneuton Ventilator

Common Name
Transport ventilator

Device Classification
Continuous Ventilator (21 CFR 868.5895, Product Code CBK)

Device Class
Class II

Classification Panel
Anesthesiology

Predicate Devices
Pneuton Transport Ventilator
- manufactured by Airon Corporation
- 510(k) number K024344

Pneupac Transport Ventilator
- manufactured by Pneupac Ltd
- 510(k) number K030803
- currently marketed in the USA through Smiths Medical

Device Description

Pneuton (pronounced "new-ton") is a small, lightweight transport ventilator designed for use on patients from pediatric to adult in size (23 kg and higher). It is a time cycled, flow limited ventilator providing Continuous Mechanical Ventilation (CMV) or Intermittent Mandatory Ventilation (IMV). In these modes of ventilation, an adjustable respiratory rate and tidal volume are delivered to the patient. The patient is allowed to breath spontaneously between the mandatory breaths with little added work of breathing. A built-in PEEP / CPAP system can be set to provide expiratory positive pressure. The delivered oxygen is adjustable at 65 or 100 percent.

Pneuton is a pneumatic ventilator. Electrical power is not required for patient ventilation. The pneumatic system operates at input pressures from 41 to over 66 psi. Various control systems manage the tidal volume and rate control, PEEP / CPAP, and safety systems / pneumatic alarms.

This premarket submission makes the following changes to the Pneuton Ventilator:

- adds a patient disconnect alarm system to the ventilator. The alarm includes audible and visual indication of patient disconnect
- changes the minimum respiratory rate from 2 to 3 breaths per minute
- changes to the minimum peak inspiratory pressure from 10 to 15 cm H_2O
- increases the MRI compatibility to 3 tesla

The ventilator will be marketed as a finished component, both with and without the changes identified above. The Pneuton Ventilator model A includes the changes; model S is the original device without the changes.

The Pneuton Ventilator uses accessories for normal operation which are included with this submission. The primary accessory is a patient tubing circuit to attach the ventilator to the patient. The patient circuit is the same circuit included with the previously cleared Pneuton Ventilator K024344. Additional external accessories will be sold with the device including a remote alarm adapter, travel case, pole stand, mounting brackets, oxygen hose and oxygen tanks.

Intended Use

The device is intended for continuous or intermittent mechanical ventilator support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified medical personnel under the direction of a physician.

Specifically, the ventilator is applicable for adult and pediatric patients, 23 kg (50 lbs.) and greater who require the following general types of ventilatory support:

- positive pressure ventilation delivered invasively (via an ET Tube) or non-invasively (via a mask)
- CMV and IMV modes of ventilation
- with or without PEEP / CPAP
- with oxygen or a mixture of air and oxygen

The ventilator is suitable for use in:

- Pre-hospital transport applications including accident scene, emergency rescue vehicles
- Hospital ICU and transport applications including emergency, radiology, surgery, recovery and MRI departments
- Air transport via helicopter or fixed wing

Substantial Equivalence

The changes to the Pneuton Ventilator share substantial equivalency with the original Pneuton Ventilator and the Pneupac Ltd. Pneupac Transport Ventilator across the spectrum of patient population for which each was designed. The devices share common modalities (CMV, IMV, PEEP / CPAP) and significantly overlap in the clinical range of function for their target population. The essential clinical function of each device is significantly similar and mimics each other in the typical frame of use by the health care provider. Each are pneumatic controlled and applicable for the same areas of use. The alarm system added to the Pneuton Ventilator is substantially equivalent to the alarm system in the Pneupac Transport Ventilator.

Characteristic	Changed Pneuton (model A)	Original Pneuton (model S)	Pneupac Transport	Discussion
Intended Use – patient population	Adult - Pediatric	Adult - Pediatric	Adult - Pediatric	Equivalent
Intended Use – application	Inter and intra-facility transport, MRI	Inter and intra-facility transport, MRI	Inter and intra-facility transport, MRI	Equivalent
Operating principle	Pneumatic	Pneumatic	Pneumatic	Equivalent
Input gas pressure	40 to 70 psi	40 to 70 psi	37 to 87 psi	Substantially equivalent
Patient circuit	Tubing with external expiratory valve	Tubing with external expiratory valve	Tubing with external expiratory valve	Equivalent
Enclosure	Rugged, lightweight	Rugged, lightweight	Rugged, lightweight	Equivalent
Displays	Manometer	Manometer	Manometer	Equivalent
Safety features	Adjustable high pressure release, internal high pressure release, anti-suffocation valve	Adjustable high pressure release, internal high pressure release, anti-suffocation valve	Adjustable high pressure release	Substantially equivalent
Alarms	Low gas source, patient disconnect	Low gas source	Low gas source, high pressure, patient disconnect	Substantially equivalent

Characteristic	Changed Pneuton (model A)	Original Pneuton (model S)	Pneupac Transport	Discussion
Modes of ventilation	CMV, IMV, CPAP	CMV, IMV, CPAP	CMV, PEEP	Substantially equivalent
Tidal volume	360 - 1500	360 - 1500	50 - 1500	Substantially equivalent
Respiratory rate	3 - 50	2 - 50	7 - 60	Substantially equivalent
Flow (L/min)	36	36	6 - 60	Pneuton uses a fixed inspiratory flow
PEEP / CPAP	0 - 20	0 - 20	external	Pneuton has an internal PEEP/CPAP system
Peak pressure	15 - 75	10 - 75	20 - 80	Substantially equivalent
I : E ratio	Continuously adjustable by controlling I time and E time using volume and rate controls	Continuously adjustable by controlling I time and E time using volume and rate controls	Continuously adjustable by controlling I time and E time	Substantially equivalent
Internal oxygen control	2 position, 100% or 65%	2 position, 100% or 65%	2 position, 100% or 50%	Substantially equivalent

Summary of Non-Clinical Testing and Validation

The performance of the Pneuton Ventilator has been comprehensively tested. All functions as listed in the specifications have been validated. The ventilator meets all test requirements as identified in the FDA Reviewer Guidance for Ventilators.

The Pneuton complies with the following standards:

- ASTM F 1100-90 Ventilators Intended for Use in Critical Care
- MIL STD 810 E Test Method Standard for Environmental Engineering Considerations and Laboratory Tests
- ISO 10651-3 Lung Ventilators for Medical Use. Particular requirements for emergency and transport ventilators

Clinical testing was not performed on this device. Safety and efficacy were established through non-clinical testing. The Pneuton Ventilator model A performs as intended according to it's performance specification and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2004

Mr. G Eric Gjerde
President
Airon Corporation
17 East Melbourne Avenue
Melbourne, Florida 32901

Re: K043085
Trade/Device Name: Pneuton Ventilator, Model A
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 9, 2004
Received: December 10, 2004

Dear Mr. Gjerde:

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/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 Statement

510(k) Number K043085

Device Name: Pneuton Ventilator, Model A

Indications For Use:

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Prescription Use__XX__ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(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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