K080692

Airon

JUN 20 2008

MACS CPAP System

510(k) Summary

Contact Information
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Application Date
March 7, 2008

Device Trade Name
MACS CPAP System

Common Name
CPAP device

Device Classification
Powered Emergency Ventilator and Positive End Expiratory Pressure Breathing Apparatus (21 CFR 868.5925 and 868.5965, Product Code BTL and BYE)

Device Class
Class II

Classification Panel
Anesthesiology

Predicate Devices
Pneuton Transport Ventilator
- manufactured by Airon Corporation
- 510(k) number K024344 and K043085

PortO_2Vent CPAPos
- manufactured by Emergent Respiratory Products
- 510(k) number K021520

Whisperflow Oxygen Flow Generator
- manufactured by Caradyne Limited (now Respironics)
- 510(k) number K982283

Device Description
The device provides CPAP support for the care of spontaneously breathing individuals who require oxygen assistance. The device is a restricted medical device for use by qualified medical personnel under the direction of a physician. The device may be used in pre-hospital environments, inter and intra-hospital patient transport, air and ground transport, and all areas of the hospital (NOT for use in the presence of flammable anesthetics or in the MRI). MACS has been specifically designed for ruggedness and ease of use.

The MACS CPAP device uses accessories during normal operation. The primary accessory is a patient tubing circuit and positive airway pressure face mask to attach the device to the patient. The patient circuit and face mask are single-use disposables. The patient circuit is the same circuit included with the previously cleared Pneuton Ventilator K024344 and K043085.

Intended Use
To provide CPAP to spontaneously breathing patients in the hospital, pre-hospital (EMS) and sub-acute / alternate site facility environments via Face Mask or endo-tracheal tube.

Substantial Equivalence
The MACS CPAP shares substantial equivalency with the Pneuton Ventilator, the PortO_2Vent CPAPos device and the Whisperflow Oxygen Flow Generator across the spectrum of patient population for which each was designed.

The MACS CPAP device utilizes identical components as found in the Pneuton Ventilator, being simply the CPAP subsystem inside of the Pneuton Ventilator put into it's own enclosure.

The MACS CPAP shares common modalities with the PortO_2Vent CPAPos and Whisperflow Oxygen Flow Generator with significant 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 providers. All are pneumatic controlled and applicable for the same areas of use.

Characteristic	MACS CPAP	Pneuton Ventilator	PortO_2Vent CPAPos	Whisperflow Oxygen Flow Generator
Intended Use – application	Provide CPAP for spontaneous breathing patients via mask or endo-tracheal tube	Provide continuous or intermittent mechanical ventilator support for the care of individuals who require mechanical ventilation. The CPAP subsystem provides CPAP for spontaneous breathing patients via mask or endo-tracheal tube	Provide CPAP for spontaneous breathing patients via mask	Provide CPAP for spontaneous breathing patients via mask or endo-tracheal tube

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Characteristic	MACS CPAP	Pneuton Ventilator	PortO$_2$Vent CPAPos	Whisperflow Oxygen Flow Generator
Environments of use	Hospital, pre-hospital (EMS) and sub-acute/alternate site facility environments	Hospital and pre-hospital (EMS) environments	Hospital and pre-hospital (EMS) environments	Hospital and pre-hospital (EMS) environments
Personnel Requirements	Training as physician, nurse, respiratory therapist, EMT	Training as physician, nurse, respiratory therapist, EMT	Training as physician, nurse, respiratory therapist, EMT	Training as physician, nurse, respiratory therapist, EMT
Operating principle	Pneumatic, demand flow system	Pneumatic, demand flow system	Pneumatic, demand flow system	Pneumatic continuous flow system
Input gas pressure	40 to 70 psi	40 to 70 psi	40 to 70 psi	60 psi
Patient circuit	Tubing with external expiratory valve and mask	Tubing with external expiratory valve and mask	Tubing with external expiratory valve and mask	Tubing with external CPAP valve and mask
Enclosure	Rugged, lightweight	Rugged, lightweight	Rugged, lightweight	None – venturi device
Displays	Manometer	Manometer	Manometer	None
Safety features	Internal high pressure release, anti-suffocation valve	Internal high pressure release, anti-suffocation valve	Internal high pressure release, anti-suffocation valve	None
Patient support modes	CPAP	CMV, IMV, CPAP	CPAP	CPAP
Peak Flow on demand (L/min)	140	140	100	140
CPAP levels (cm H_2O)	0 - 20	0 - 20	0 - 20	0 - 20
Internal oxygen control	2 position, 100% or 65%	2 position, 100% or 65%	100% only	28% to 100%
Materials in gas pathway	Identical to Pneuton ventilator	Cleared in K024344 and K043085	Unknown	Stainless steel, PVC
Accessories	Disposable patient circuit with mask, head strap, mobile stand, rail / pole mount bracket, travel bag, oxygen hose and oxygen tank.	Disposable patient circuit with mask, mobile stand, pole mount bracket, travel bag, oxygen hose and oxygen tank	Disposable patient circuit with mask, head strap, pole mount bracket, travel bag, oxygen hose and oxygen tank	Disposable patient circuit with CPAP valve, mask and head strap

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Summary of Non-Clinical Testing and Validation
The performance of the MACS CPAP System has been comprehensively tested. All functions as listed in the specifications have been validated. The device meets all test requirements as identified in the FDA Draft Emergency Resuscitator Guidance (April, 1993).

The MACS CPAP Device complies with the following voluntary standards:

- ISO 10651-5:2006 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators
- ISO 5356-1:2004 Anesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
- CGA V-5:2005 Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)

Clinical testing was not performed on this device. Safety and efficacy were established through non-clinical testing. The MACS CPAP System performs as intended according to its performance specification and is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

Mr. G. Eric Gjerde
President and Chief Executive Officer
Airon Corporation
129 West Hibiscus Boulevard, Suite S
Melbourne, Florida 32901

Re: K080692
Trade/Device Name: MACS CPAP System
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL, BYE
Dated: June 10, 2008
Received: June 18, 2008

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: K080692

Device Name: MACS CPAP System

Indications For Use: To provide CPAP to spontaneously breathing patients in the hospital, pre-hospital (EMS) and sub-acute / alternate site facility environments via Face Mask or endo-tracheal tube.

Prescription Use__X__ OR Over-The-Counter Use_____

(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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