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001 4 2007

K071527

FDA 510k SUBMISSION FILE
Pneupac VR1 Air Mix

SECTION 2

510(k) Summary



Deltac[®]

Rivona[®]

GRACEBY[®]

A Wallace[®]

Pneupac[®]



Summary of Safety and Effectiveness

Submitter: Smiths Medical International Ltd.

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Contact: Senior UK Regulatory Manager

Prepared: 5th April 2007

Proprietary Name:
Pneupac VR1 Airmix

Common/ Classification Name: Gas powered Emergency and Transport
Ventilator

Regulatory Class: II (two)

Product Code: BTL

Classification Number: 21 CFR 868.5925

Predicate Device: Pneupac VR1 Standard (K051322)
Oxylog 1000 (K0107093)

New Device Description:

Pneupac VR1 Airmix is intended for emergency resuscitation by medical personnel, paramedics and ambulance technicians inside and outside hospital and for ventilation by medical personnel inside and outside hospital in emergency situations and for intra- and inter- hospital transport.

The Pneupac VR1 Airmix allows two modes of ventilation, automatic and manual. In automatic mode the device cycles in accordance with the setting of the single tidal volume/frequency control that changes the tidal volume and frequency dependently whilst maintaining a constant I:E ratio of 1:2. In manual mode, preset breaths, singly or in a controlled breathing pattern may be selected by use of an omni-directional lever or push button. The tidal volume and rate possible are limited by the position of the single tidal volume/frequency control.

The Pneupac VR1 Airmix includes a control for providing oxygen concentrations of either 100% or 50% nominal.

The Pneupac VR1 Airmix uses the same technology as existing legally marketed devices and depends solely on the pressure of the supply gas for its operation.

The Pneupac VR1 Airmix incorporates a pneumatic high-pressure audible alarm which dumps excess patient pressure according to the in-built relief pressure (40 cmH₂O standard, 60cmH₂O optional) which operates in an identical manner to the predicate devices.

The Pneupac VR1 Airmix consists of a hand-held control module connected to the patient at its outlet via a mask, endotracheal tube or laryngeal mask airway and is used with various patient circuits and accessories comprising the following items;

- User replaceable patient valve
- Oxygen input gas hose assemblies
- Breathing filter
- Biological breathing filter kit (optional for contaminated atmospheres)
- Masks, airways and airway adjuncts
- Manual suction
- Oxygen therapy kits
- Oxygen cylinders and regulators
- Carrying bag
- Breathing circuits
- PEEP accessories



New Device Description (ctd.):

The specifications for the recommended, optional biological breathing filter are as follows;

- Filter efficiency at least 99.99% efficient against a 0.3micron mass median aerodynamic diameter aerosol challenge at 32 l/min.
- Airflow resistance at 32 l/min. is 10-17 mm H₂O
- Connector size 40mm DIN NATO compatible threads

The mass of Pneupac VR1 Airmix is 1.001lb, 0.455kg

The Pneupac VR1 Airmix control module has the following features;

- Interdependent and continuous control of tidal volume and frequency from 150ml/25bpm to 1050ml/10bpm using a single tidal volume/frequency control
- Demand breathing system
- Spontaneous breathing under power failure
- Audible pressure relief alarm
- Integrated, user replaceable patient valve
- Automatic or Manual mode selector
- Manual mode push button and omni-directional lever
- Airmix control for providing oxygen concentrations of either 100% or 50% nominal

Intended Use:

The Pneupac VR1 Airmix is a hand-held, portable, time cycled, gas powered, flow generator ventilatory resuscitator that is suitable for emergency and transport use and will operate safely in an MRI environment up to 3 Tesla.

It is designed for use by qualified medical caregivers, paramedics and other trained personnel for the following conditions:

- Pneupac VR1 Airmix - Ventilatory resuscitator intended for use on adults and children above a bodyweight of 22 lb (10 kg) with either respiratory distress/ insufficiency or no respiratory function and including a control for providing oxygen concentrations of either 100% or 50% nominal.

Performance data:

Testing was performed to ensure that the Pneupac VR1 Airmix was safe and would perform within the environment(s) for which it is to be marketed.

Safety testing was conducted in accordance with;

ASTM F 920-93 'Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans',

The resuscitator passed all of these tests and met all requirements of the standards.

Environmental and performance testing was performed in accordance with;

- Operating environment compliance, ETR848 to ASTM F920-93 section 8.2 and Smiths input requirements
- Storage temperature/humidity, ETR848 to ASTM F920-93 section 8.1 and Smiths input requirements
- Vibration, ETR835 to MIL-STD 810F section 514.4 and RTCA DO160D section 8 profile C
- Altitude, ETR853 to MIL-STD 810F section 500.4, RTCA DO160D section 4.6.2 10,000ft to 20,000ft and Smiths input requirements
- MRI, ETR 917 to 3 Tesla
- IP rating, ETR849 to IEC 529 rating IP5x, IPx5 and Ipx6
- Driving sand & dust, ETR849 to RTCA DO160D section 12
- Oxygen consumption

Performance data (ctd.):

- Mechanical shock (drop), ETR863 to ASTM F920-93 section A1.5.4 and EN794-3:1998 section 21.102
- Rigidity, ETR 921 to EN60601-1:1990
- Impact, ETR 919 to EN60601-1:1990
- Cleaning & sterilisation, ETR 743 AND ETR 926

The results demonstrated that the Pneupac VR1 Airmix complied with the guidelines and standards and that it performed within its specifications and functional requirements.

A comparison table was constructed to show the similarity in performance between Pneupac VR1 Airmix and the predicate devices Pneupac VR1 (standard) and Oxylog 1000.

Based on these results, it is our determination that the device model(s) are safe, effective and perform as well as the legally marketed predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Colin Walters
Senior UK Regulatory Manager



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smiths Medical International Limited
C/O Mr. Donald Alexander
Vice President Regulatory Affairs
Smiths Medical MDPM, Incorporated
North 7 W22025 Johnson Drive
Waukesha, Wisconsin 53186

OCT 4 2007

Re: K071527
Trade/Device Name: Pneupac VR1 Airmix
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: September 20, 2007
Received: September 26, 2007

Dear Mr. Alexander:

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): K071527

Device Name: Pneupac VR1 Airmix

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over The Counter Use _____
(Part 21 CFR 801 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: K071527