JUL 17 2003

K021841

Pneupac

Summary of Safety and Effectiveness

Submitter:	**Pneupac Ltd.**
Address:	**Bramingham Business Park, Enterprise Way, Luton, Bedfordshire, LU2 OAH United Kingdom.**
Telephone:	**(+44) (0) 1582 430000**
Contact:	**Regulatory Affairs & Quality Assurance Manager**
Prepared:	**14th November 2001**
Proprietary Name:	**compPAC Ventilator Model 200 & PS11 Power Supply/Charger**
Common/ Classification Name:	**Powered ventilator with power supply/ charger**
Predicate Device:	**Univent Eagle Battery Powered Emergency Ventilator (K905697)**

New Device Description:

The compPAC COM 200 ventilator is primarily gas powered and is housed in an easily carried, chemically hardened housing. The housing is designed to accept the long endurance battery that is used to drive a small compressor, which in turn provides the inflating gas, through an 'oscillator', to the casualty. All ambient air for the ventilation of the casualty passes into the system through a filter (NATO No: 4240-01-361-1319). About $^1/_3$ of the volume is compressed to drive the ventilator before expansion in an entrainment mixing device, which entrains the other $^2/_3$ by creating a sub-atmospheric pressure. It can be operated from a range of power sources: Battery/ Compressed gas/ Mains Electricity (via power supply/ charger unit) and Auxiliary vehicle electrical source (via power supply/ charger

Pneupac Limited,
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

New Device Description (ctd.):
unit) to provide maximum flexibility of operation in remote areas, in military campaigns and in disaster relief.
The compPAC COM 200 ventilator is a robust self-contained portable device comprising of the following standard kit parts:

- Control Module –
- Green case variant: Part No - 510A2433
  OR
- Yellow case variant: Part No - 510A2434
- Rubber Boot: Part No – 510A2271
- Filter: Part No – W7265
- Patient Valve and Hose assembly: Part No – 510A1082
- O_2 Auxiliary gas input lead, Schrader probe (BS5682): Part No – 510A2600
- Support ramp: Part No – 510A2372
- 28 volt open-ended Vehicle Supply lead to compPAC: Part No – 510A2564
- compPAC C200 User Manual: Part No – 504-2055/A

And the following fitted labels:

- Valance Panel Label: Part No – 504-228
- Instrument Panel Label: Part No – 504-227
- Supplementary O_2 Table Label: Part No – 504-224
- Battery fitting and removal instruction Label: Part No – 504-223
- Alarm Bezel Label (set of 2): Part No – 504-222

The module can be used individually as a robust self-contained portable device powered by a NiCad rechargeable battery specified for fitting inside the unit, which will provide approximately 2 hours continuous ventilation. The module weighs 18.7 lb with the battery installed. The ventilator has a socket to accept an external 24V d.c. supply from e.g. a vehicle electrical circuit. This enables the system to be used for extended periods wherever a 24-28V d.c. supply is available. The power requirement is less than 50 watts. If the Pneupac PS11 power supply (weight: 3.86 lb) is connected to this socket, simultaneous trickle charging of internal battery will

Pneupac Limited,
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

New Device Description (ctd.):

occur whilst the ventilator is running. When not required as a power supply it can be switched, to fast charge the battery whilst it is in situ inside the ventilator.
An input gas connector is provided to allow the compPAC ventilator to be connected to a 44 to 87 psig gas supply so that it can be operated independently of its internal battery electrical supply. In this way, if oxygen cylinders or liquid oxygen are available, 100% or 45% oxygen can be supplied to the casualty and the internal battery can be conserved. This facility also allows connection to air compressor systems.

Alternatively, there is a supplementary oxygen intake connector, in parallel with the filter, enabling 21-45% oxygen to be supplied to the casualty, from e.g. an oxygen cylinder, when the ventilator is operating on its compressor.

Calibrated controls for frequency and tidal volume are provided to set the required ventilation pattern. A fixed pressure relief valve is fitted to limit the peak inspiratory pressure to a maximum of 60 cm H_2O and provides a pneumatically operated audible high-pressure alarm (an adjustable pressure relief device will also be available in the future as a retro-fittable option). In addition an electronic high-pressure alarm sounds if the inflation pressure exceeds 60 cm H_2O.

Most of the controls and input and output connections are mounted on the front panel, which is deeply shrouded to give maximum protection from chemical "rain".

The module control panel has the following features:

- Minute Volume Control, This calibrated rotary control knob gives continuous adjustment of the minute volume delivered to the patient over the range 6 to 14 L/min.
- Frequency Control, This rotary control knob gives continuous adjustment of frequency over the range 10 to 30 breaths per minute.
  The I:E ratio is nominally constant at 1:1.6 throughout the range of frequency.
- Patient Inflation Pressure Manometer, range –10 to +100 cm H_2O.

Pneupac Limited,
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

New Device Description (ctd.):

- Oxygen Concentration Control – This two-position rotary control knob selects either the 100% or 45% inspired oxygen concentration when an oxygen supply is connected to the gas-input connector. When no external gas is connected this switch is disabled internally.
  In the 45% O_2 position the driving gas requirement is reduced by 66% and the balance of the gas supplied to the patient is entrained atmospheric air which is drawn through the filter canister.

- A mechanically operated visual alarm gives a warning that the supply gas has dropped to a pressure at which the ventilator will no longer be operating to specification (< 35 psi). With low pressure it shows red, with adequate pressure it shows white. Any visible red indicates that the supply should be changed. In most cases the display will begin to oscillate from white to partial red as the supply pressure falls to the lower threshold level.
  The visual indication will be accompanied by an electronically generated medium priority* audible warning..

- Electronic alarm bezel indicating:
  - High Pressure Indicator – Flashes Red LED with audible alarm at set relief pressure and with continuous positive pressure.
  - Normal Cycle Indicator – Flashes Green LED every time inflation pressure rises through 10 cm H_2O.
  - Low Pressure/ Disconnect Indicator – Flashes Yellow LED with audible alarm if pressure does not rise through 10 cm H_2O within ten seconds.
  - Silence button – silences audible alarm for 60 seconds. Flashes Orange LED to indicate to the operator that the audible alarm is silenced.
  - Electrical power indicator - Flashes Yellow LED with audible alarm.

  The PS11 power supply/ charger for use in association with the compPAC ventilator has the following controls and features:
  - Line Output – In conjunction with the negative common, a +28V dc output for general purpose use or for powering the compPAC ventilator when the appropriate lead is fitted. The output is fully protected against short circuits and overload.

Pneupac Limited,
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

New Device Description (ctd.):

- Trickle charge output – In conjunction with the negative common, a +28V dc output exclusively for use with the compPAC 200 ventilator. This line provides a trickle charge facility for the compPAC's internal Clansman battery.
- Battery Charge Output – In conjunction with the negative common, this is the output used to charge a Clansman +28V dc NiCad battery.
- On/Off Switch – The switch on the front panel of the PS11 selects two different operating modes:-
- 28V dc & Trickle Chg. ON: This activates the 28V dc Line and Trickle Charge outputs and open circuits the compPAC internal battery.
- Output OFF & Charge Battery: This activates the Battery Charge output and removes power from the 28V dc Line and Trickle Charge outputs.

When the compPAC is operating its internal compressor, the incoming air is filtered. The specifications of the recommended filter are as follows:-

- Filter efficiency is at least 99.99% efficient against a 0.3µm Mass Median Aerodynamic Diameter aerosol challenge at 32 L/min.
- Airflow resistance at 32 Liters per Minute is 10 to 17 mm H_2O
- Connector size is 40mm DIN NATO compatible threads.

Intended Use:

The Pneupac compPAC 200 ventilator is a self contained portable gas powered automatic ventilator intended to provide emergency ventilation, in a battlefield environment only, to adult and pediatric patients greater than 20 kg. The compPAC 200 is suitable for emergency and transport use in situations where conventional portable ventilators are not suitable.

Performance Data:

The design of this ventilator uses currently available technology found in many legally marketed ventilators. Testing was performed to ensure that the compPAC 200 and PS11 Power supply/ charger were safe and would perform within the environment(s) for which they are to be marketed.

Pneupac Limited,
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

Pneupac

Summary of Safety and Effectiveness

Performance Data (ctd):

Safety testing was conducted in accordance with the Draft Reviewer's Guidance for Ventilators, July 1995, EN794-3 'Lung Ventilators – Part 3 Particular requirements for emergency and transport ventilators'' 1999 and EN60601-1 'Medical Electrical Equipment – Part 1 General requirements for safety': 1990. The ventilator and power supply/ charger passes all of these tests and met all requirements of the standards
Environmental testing was performed in accordance with EN 60601-1-2: 1993 and EN794-3: 1999.

Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/ humidity testing has been completed. The results demonstrated that the compPAC 200 and Power supply/ charger complied with the guidelines and standards and that they performed within their specifications and functional requirements.

Comparison testing of the compPAC model 200 with its predicate counterpart the Univent Eagle was done to show that the performance of the delivered Minute Volume and Frequency parameters are the same for each. The tests were performed across the ventilator's entire range. All measurements were within the specified tolerances of the ventilators. These data support substantial equivalence of the compPAC model 200 to the Univent Eagle.

The testing described above indicates that there is no functional difference between the operation of the compPAC model 200 with its predicate counterpart the Univent Eagle for delivered Minute Volume and Frequency parameters. Based on these results, it is our determination that the device model is safe, effective and performs 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
Regulatory Affairs and Quality Assurance Manager

Pneupac Limited,
Bramingham Business Park,
Enterprise Way, Luton, Beds. LU3 4BU
Tel: +44 (0) 1582 430000
Fax: +44 (0) 1582 430001
e-mail: pneupac@smiths-industries.com
www.pneupac.co.uk

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Pneupac Limited
C/O Mr. Donald J. Alexander
Vice President of Regulatory Affairs
BCI, Incorporated
N7 W22025 Johnson Road
Waukesha, Wisconsin 53186-1856

Re: K021841
Trade/Device Name: compPAC 200 Ventilator Models 200 & PS11 Power Supply
Regulation Number: 868.5925
Regulation Name: Powered Emergency Ventilator (Resuscitator)
Regulatory Class: II
Product Code: 73 BTL
Dated: April 16, 2003
Received: April 18, 2003

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 (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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) SUBMISSION: K021841 ATTACHMENT # 6a

Indications For Use

510(k) Number (if Known): K021841

Device Name: compPAC 200 powered Ventilator

Indications For Use:

Intended Use:

The Pneupac compPAC 200 ventilator is a self contained portable gas powered automatic ventilator intended to provide emergency ventilation, in a battlefield environment only, to adult and pediatric patients greater than 20 kg. The compPAC 200 is suitable for emergency and transport use in situations where conventional portable ventilators are not suitable.

(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: K021841

Prescription Use ✓ OR Over The Counter Use _____
(Per 21 CFR 801.109)