K030803

SEP 2 9 2003

Pneupac

Summary of Safety and Effectiveness

Submitter:	**Pneupac Ltd.**
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Contact:	**Regulatory Affairs & Quality Assurance Manager**
Prepared:	**24th October 2002**
Proprietary Name:	**paraPAC 'Transport' model 200D**
Common/ Classification Name:	**Gas powered Transport Ventilator with Electronic alarms**

New Device Description:

The paraPAC 'Transport' ventilator is a gas powered, time cycled, volume preset, pressure limited ventilator which uses the same technology as existing legally marketed devices. It depends solely on the pressure of the supply gas for its operation. Additionally, it incorporates an integrated electronic pressure alarm unit to alert the user to certain significant changes that may occur in the patient's ventilation. Loss of battery power for the alarm is signalled to the user but will have no effect on the ventilation performance of the paraPAC 'Transport' ventilator, nor affect the mechanically operated alarms and protection systems, which operate in an identical manner to the predicate devices.

The paraPAC 'Transport' ventilator consists of a control module and patient circuit comprising the following disposable items: Hose/ Patient Valve/ PEEP Valve/ Exhaust Collector and Mouthpiece.

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New Device Description (ctd.):

The module weighs 3.1 kilograms.
The module control panel has the following features:

- Adjustable Relief Pressure Control, range 20 to 80 cm H_2O.
- Air Mix (45% oxygen) / No Air Mix (100% oxygen) Selector.
- Inspiratory Time Range 3.0 to 0.5 seconds.
- Expiratory Time Range 6.0 to 0.5 seconds.
- Patient Inflation Pressure Manometer, range –10 to +100 cm H_2O.
- Flow Range 0.1 to 1.0 L/sec.
- Ventilation: Off (Spontaneous breathing)/ On (Spontaneous breathing/ Controlled Mandatory Ventilation).
- Supply Gas Failure Alarm – 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 (to EN 475) audible warning. In order to conserve the battery, if this audible alarm is ignored for more than 60 seconds the alarm system will ultimately switch itself off.
- 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.
  - Breathing detect indicator – Flashes Green LED each time a spontaneous breath is detected.
  - Low battery indicator - Flashes Yellow LED with audible alarm.

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Intended Use:

The paraPAC 200D 'Transport' ventilator is a portable, gas powered, time-cycled ventilator that is designed for ventilation during transportation and emergency ventilation of patients who have respiratory distress or insufficiency.

Performance Data:

The design of this ventilator uses currently available technology found in many legally marketed ventilators. Testing was performed to ensure that the paraPAC 'Transport' was safe and would perform within the environment(s) for which it is to be marketed.

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 passes all of these tests and met all requirements of the standards

Performance Data (ctd.):

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 paraPAC 'Transport' complied with the guidelines and standards and that they performed within their specifications and functional requirements.

Comparison testing of the paraPAC 'Transport' with its respective predicate counterparts: the babyPAC and paraPAC 'medic' was done to show that the performance of the delivered Tidal Volume, Frequency, Inspiration times and Expiration time 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 paraPAC

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'Transport' to the babyPAC and paraPAC 'medic' with integrated electronic alarms.

The testing described above indicates that there is no functional difference between the operation of the paraPAC 'Transport' with its predicate counterparts the babyPAC and paraPAC 'medic' with integrated electronic alarms for delivered Tidal Volume, Frequency, Inspiration times and Expiration time parameters. Based on these results, it is our determination that the device models are safe, effective and perform as well as the legally marketed predicate device(s).

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2003

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

Re: K030803
Trade/Device Name: paraPAC 'Transport' Model V 200D
Regulation Number: 21 CFR 868.5925
Regulation Name: Emergency Powered Ventilator (Resuscitator)
Regulatory Class: II
Product Code: BTL
Dated: July 8, 2003
Received: July 9, 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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Indications For Use

510(k) Number (if Known): K030803

Device Name: paraPAC 200D 'Transport' Emergency & Transport gas powered Ventilator

Indications For Use:

Intended Use:

The paraPAC 200D 'Transport' ventilator is a portable, gas powered, time-cycled ventilator that is designed for ventilation during transportation and emergency ventilation of patients who have respiratory distress or insufficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030803