K043495

smiths

APR 22 2005

Smiths Medical International Limited
Bramingham Business Park
Enterprise Way Luton LU3 4BU UK
Tel: +44 (0)1582 430000 Fax: +44 (0)1582 430001
www.smiths-medical.com

Summary of Safety and Effectiveness

Submitter:	**Smiths Medical International Ltd.**
Address:	**Bramingham Business Park, Enterprise Way, Luton, Bedfordshire, LU2 OAH United Kingdom.**
Telephone:	**(+44) (0) 1582 430000**
Contact:	**Senior UK Regulatory Manager**
Prepared:	**15th March 2005**
Proprietary Name:	**babyPAC 100**
Common/ Classification Name:	**Gas powered Emergency and Transport pressure generator type Ventilator with Electronic alarms**
Regulatory Class:	**II (two)**
Product Code:	**BTL**
Classification Number:	**21 CFR 868.5925**
Predicate Devices:	**babyPAC Gas Powered Emergency and Transport pressure generator type Ventilator (K970158) paraPAC 'medic' Gas Powered Emergency Ventilator with integrated electronic alarms (K020899)**

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New Device Description:

The babyPAC ventilator consists of a control module with a disposable conventional Y patient circuit. It is a gas powered, time cycled, pressure generator which depends solely on the pressure of the supply gas for its operation. The babyPAC 100 additionally incorporates an integrated electronic pressure alarm unit which becomes operational during Controlled Mandatory Ventilation (CMV) modes. It alerts the user to certain significant changes which may occur in the patient's ventilation. Loss of
battery power for the alarm is signaled to the user but will have no effect on the ventilation performance of the babyPAC ventilator, nor affect the mechanically operated alarms and protection systems that exist on the predicate babyPAC (K970158) already on the market.

The babyPAC 100 portable ventilator is designed for use as an emergency and transport ventilator in ambulances and hospitals, and can be used in an MRI environment up to 3 Teslas. It is particularly suitable for ventilation during transportation and for resuscitation of infants (above approx 11lb [5 kg]) and neonates up to 44 lb (20 kg).

The control module of the babyPAC ventilator is rugged by virtue of its thick section structural foam plastic case and the use of anti-shock mountings for the gauge and internal pneumatics and electronics. The controls are recessed to minimise the possibilities of damage and inadvertent operation.

The babyPAC 100 portable ventilator consists of a control module and the following items: 22mm disposable Polyethylene respirator hose/ 22mm OD female connector and Paediatric 'Y' piece connector.
The module weighs 8.25 lb (3.75 kilograms).
The module control panel has the following features:

- Adjustable Relief Pressure Control, range 12 to 80 cm H_2O.
- Inspiratory Time Control, range 0.25 to 2.0 seconds.
- Expiratory Time Control, range 0.25 to 4.0 seconds.
- Inspiratory Pressure Control, range 12 to 70 cm H_2O, with click action warning at and above 40 cm H_2O.
- PEEP/ CPAP Control, range 0 to 20 cm H_2O with click action warning at and above 10 cm H_2O.
- IMV Control, range Expiratory time 2.5 to 40 seconds with CPAP Pressure level and oxygen concentration as selected.
- Patient Inflation Pressure Manometer, range –10 to +100 cm H_2O.

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New Device Description (ctd.):

- Variable Oxygen Concentration, range 45 (approx) to 100% with oxygen only as supply. 21 to 70 % with oxygen and air supplies
- Supply Gas Failure Alarm indicators– One for air, the other for oxygen, these mechanically operated visual alarms give 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 they show red, with adequate pressure they show white. Any visible red indicates that the supply should be changed. Each indicator is dedicated to the particular supply gas indicated on the indicator transparent cover: 'air' and 'O_2' 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: 1995) audible warning.

- Electronic alarm bezel indicating:
  - High Pressure/ Constant Positive Inflation 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 eight seconds.
  - Silence button – silences audible alarm for 60 seconds. Flashes Orange LED to indicate to the operator that the audible alarm is silenced.
  - Single Gas Operations indicator – Flashes a Green LED as a burst of 3 flashes every 30 seconds, whenever the ventilator is being used with only a single gas input (ie: oxygen or air only). In the event that the single gas fails (ie: where the audible gas failure alarm has been silenced because only one gas is being used) the Low Pressure/ Disconnect Indicator will activate together with the audible alarm.
  - Low battery indicator - Flashes Yellow LED with audible alarm.

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Intended Use:

The babyPAC 100 is a portable gas powered transport ventilator, suitable for use in an MRI environment up to 3 Tesla, which features a battery powered integrated electronic pressure alarm unit. It is designed for use by qualified medical caregivers, paramedics and other trained personnel, for ambulance, hospital, emergency and transport ventilation of patients during respiratory distress or insufficiency. It can be used on neonates and infants up to a bodyweight of 44lb (20 kg).

Performance Data:

The design of this ventilator uses currently available technology found in many legally marketed ventilators. Testing was performed to ensure that the babyPAC 100 was safe and would perform within the environment(s) for which it is to be marketed.

Safety testing was conducted in accordance with 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

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 babyPAC 100 complied with the guidelines and standards and that they performed within their specifications and functional requirements.

Comparison testing of the babyPAC 100 with its predicate counterpart the babyPAC (K970158) 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 predicate babyPAC (K970158) to the babyPAC 100. Additionally, comparison testing of the babyPAC 100 with its other predicate counterpart, the paraPAC 'medic' P200 (K020899) was done to show that the ventilator was safe for use in an MRI environment up to 3 Teslas and that the performance of the electronic integrated alarms system is the same for each.

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The testing described above indicates that there is no functional difference between the operation of the babyPAC 100 with its predicate counterpart the babyPAC for delivered Tidal Volume, Frequency, Inspiration times and Expiration time parameters, and no functional difference between the operation of the babyPAC 100 with its other predicate counterpart, the paraPAC 'medic' (K020899) for safe use in an MRI environment up to 3 Teslas and operation of the integrated electronic alarms. Based on these results, it is our determination that the device model is safe, effective and performs as well as the legally marketed predicate devices.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2005

Smiths Medical International, Limited
C/O Mr. Donald Alexander
Vice President Regulatory Affairs
Smiths Medical P.M., Incorporated
N7 W22025 Johnson Drive
Waukesha, Wisconsin 53186

Re: K043495
Trade/Device Name: babyPAC 100
Regulation Number: 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: February 20, 2005
Received: April 6, 2005

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) 276-0115. 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,

Janette Y. Michaud M.D.

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): K043495

Device Name: babyPAC 100

Indications For Use: The babyPAC 100 is a portable gas powered transport ventilator, suitable for use in an MRI environment up to 3 Tesla, which features a battery powered integrated electronic pressure alarm unit. It is designed for use by qualified medical caregivers, paramedics and other trained personnel, for ambulance, hospital, emergency and transport ventilation of patients during respiratory distress or insufficiency. It can be used on neonates and infants up to a bodyweight of 44lb (20 kg).

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: K043495