K123957

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510(k) SUMMARY

Date Prepared: September 10, 2013

Submitters Information:

Submitter's Name: Smiths Medical International Ltd.

Address: Bramingham Business Park, Enterprise Way,
Luton, Bedfordshire, LU3 4BU, UK

Establishment Registration: 9611178

SEP 16 2013

Contact Person: Lori Berends
Sr. Regulatory Affairs Specialist
Phone: +1 (651) 628-7157
Fax: +1 (651) 628-7457

Product Name:

Proprietary Name: Pneupac® paraPAC plus™ Model 300/310 Ventilators

Common Name: Gas Powered Emergency and Transport Ventilators

Classification Name: Ventilator, Emergency, Powered & Attachment, Breathing Positive End Expiratory Pressure

Product Code: BTL (Ventilator)
BYE (CPAP)

Regulation Number: 21 CFR 868.5925 (Ventilator)
21 CFR 868.5965 (CPAP)

Predicate Device(s):

The predicate devices for the Pneupac® paraPAC plus™ Model 300/310 Ventilators and Pneupac® paraPAC plus™ Disposable CPAP Circuit and the reference 510(k) numbers are provided below:

Predicate Devices for Pneupac® paraPAC plus™ Model 300/310 Ventilators	**510(k)**
Smiths Medical Pneupac® Parapac® P200D Medic Ventilator	K020899
O Two Carevent System ATV+	K051469
Predicate Devices for Pneupac® paraPAC plus™ Disposable CPAP Circuit	**510(k)**
Vygon Boussignac CPAP Device	K013884
Pulmodyne CHF Flow Generation System	K080256

Device Description:

The Pneupac® paraPAC plus™ Model 300/310 Ventilators are gas powered portable medical devices intended for the ventilation of adults, children and infants (above approximately 10kg (or 22lb)) during transportation and emergency situations.

These models are the enhanced versions of the Pneupac® Parapac® P200D Medic (K020899) gas powered time cycled emergency and transport ventilator which is also one of the predicate devices. Similar to the Pneupac® Parapac® Parapac P200D, the Pneupac® paraPAC plus™ Model 300/310 Ventilators depend solely on the pressure of the supply gas for their operation. This enables them to be suitable for use in transport applications in vehicles including fixed and rotary winged aircraft.

As with the Pneupac® Parapac® P200D, these models also incorporate an integrated electronic pressure alarm unit to alert the user of certain significant changes (such as for high or low inflation pressure) that may occur in patient's ventilation. Loss of battery power for the alarm is signaled to the user, but will have no effect on the performance of the ventilator, nor affect the pneumatically operated alarms and the ventilators functioning.

Calibrated frequency and tidal volume controls are color coded to indicate the recommended settings for adults, children and infants.

A Positive End Expiratory Pressure (PEEP) control is provided to set PEEP between 0 and 20 cm H_2O. It also has a Continuous Positive Airway Pressure (CPAP) control to provide CPAP therapy for spontaneously breathing patients which is also one of the features of the predicate device, the O Two Carevent Systems (K051469). This is achieved by connecting a Pneupac® paraPAC plus™ Disposable CPAP Circuit to the Pneupac® paraPAC plus™ Model 310 Ventilator.

An air mix control in the Pneupac® paraPAC plus™ Model 300/310 Ventilators gives FiO_2 option of 0.50 or 1.0. This enables the device to provide a combination of air and oxygen.

The Pneupac® paraPAC plus™ Model 300/310 Ventilators use currently available technology found in many legally marketed ventilators. Testing was performed to demonstrate that they are safe and would perform within the environment(s) for which they are to be marketed.

Features on Pneupac® paraPAC plus™ Model 300/310 Ventilators:-

FEATURE	MODEL 300	MODEL 310
8 to 40 bpm Frequency Control	✔	✔
70 to 1500 ml Tidal Volume Control	✔	✔
Air Mix Control 100% or 50% Oxygen Concentration	✔	✔
Manual Breath Button	✔	✔
Demand Oxygen Therapy Function	✔	✔
Demand Inhibit of CMV	✔	✔
Electronic Alarm	✔	✔
PEEP Control on Ventilator		✔
Oxygen therapy Control		✔
CPAP Accessory to connect to oxygen therapy		✔

The Pneupac® paraPAC plus™ **Model 300** Ventilator consists of a control module with user manual, oxygen gas specific standard input hose and a standard disposable patient circuit.

The Pneupac® paraPAC plus™ **Model 310** Ventilator consists of a control module with user manual, oxygen gas specific standard input hose, standard disposable patient circuit, CPAP disposable patient circuit and hyperinflation bag (K970785).

The Pneupac® paraPAC plus™ Disposable CPAP Circuit is an air entrainment device with an attached oxygen and pressure monitoring line for connection solely to the Pneupac® paraPAC plus™ 310 Model Ventilators. The Instructions for Use of the Pneupac® paraPAC plus™ Disposable CPAP Circuit state that it can only be used with the Pneupac® paraPAC plus™ Model 310 Ventilator. As the Pneupac® paraPAC plus™ Disposable CPAP circuit cannot be used without the Pneupac® paraPAC plus™ Model 310 Ventilator, the Pneupac® paraPAC plus™ Disposable CPAP circuit is considered as an integral part of the Pneupac® paraPAC plus™ Model 310 Ventilator for the purposes of this Premarket Notification.

The disposable patient circuits provided with the Pneupac® paraPAC plus™ Model 300/310 Ventilators are specifically designed for use with the Pneupac® paraPAC plus™ Model 300/310 Ventilators and the Instructions for Use state that these are the only circuits to be used with the Pneupac® paraPAC plus™ Model 300/310 Ventilators. As the Pneupac® paraPAC plus™ Model 300/310 Ventilators cannot be used without the patient circuit, the patient circuit is considered an integral part of Pneupac® paraPAC plus™ Model 300/310 Ventilators for the purposes of this Premarket Notification.

Indications for Use:

The paraPAC plus range are gas-powered emergency and transport portable ventilators that are primarily intended for use in transport applications in vehicles including fixed and rotary winged aircraft. They are suitable for emergency use at the accident scene, intra and inter-hospital transport and within medical facilities including medical imaging systems to 3 Teslas. They should only be used under the constant supervision of trained healthcare professionals. The devices are intended to provide ventilatory support to adults, children and infants (above approx. 10kg).

The devices also provide free flow oxygen therapy and CPAP therapy for spontaneously breathing patients.

Summary of Technological Characteristics:

The following characteristics of the Pneupac® paraPAC plus™ Model 300/310 Ventilators were compared with the Pneupac® paraPAC® P200D Medic and the O Two Carevent predicate devices:

1. Intended Use, Environments for use, Patient Population, Product Labeling
2. Physical attributes, Patient Connections and Breathing circuits
3. Display & Indicators
4. Waveform
5. Technical Specifications such as: Frequency & Flow Range, Tidal Volume Control, Manometer, I:E ratio, Relief pressure Range, Delivered Oxygen Concentration, PEEP, CPAP, Power source, Battery life, demand breathing parameters, operating and storage temperatures, Relative Humidity and MRI Conditions..
6. Alarms

The specifications for the Pneupac® paraPAC plus™ Disposable CPAP Circuit were also compared with the Boussignac CPAP and Pulmodyne CHF Flow System Predicate Devices for:

1. CPAP
2. Oxygen Delivery Range
3. Waveform
4. Mask Designs & Sizes
5. Manometer
6. Tubing and Head straps

The comparisons of these characteristics between the new and predicate devices show Substantial Equivalence. This conclusion was derived by comparing the product literature and specifications and by performing testing.

Summary of Non-Clinical Testing:

The Pneupac® paraPAC plus™ Model 300/310 Ventilators passed a series of tests that demonstrate that the Pneupac® paraPAC plus™ Model 300/310 Ventilators are capable of performing to their stated Intended Use in their intended environments and that they will not interfere electromagnetically with other equipment in the same environment.

- Mechanical durability (vibration, bump and drop) of the device was tested. Vibration and bump testing was performed against the requirements of clause 21 of BS EN 60601-1:1990, *Medical Electrical Equipment, Part 1: General Requirements for Safety* as modified by clause 21 of EN794-3:1999 *Lung ventilators- Part3: Particular Requirements for Emergency and Transport Ventilators* and clause 4.1 of *ISO 10651-3: 1997 Lung Ventilators for Medical Use- Part 3 Transport and Emergency Ventilators.* Drop Testing was performed to meet the requirements as stated in the standard *ISO 10651-3:1997 Lung Ventilators for Medical Use- Part 3 Transport and Emergency Ventilators* and *ISO 10651-5:2006 Lung ventilators for medical use- Part 5: gas powered emergency resuscitators.*
- Temperature and humidity testing was conducted against the requirements of clause 10 of EN 60601-1:1990 Medical *Electrical Equipment, Part 1: General Requirements for Safety modified by clause 10 of BS EN 794-3:1999- Lung Ventilators Part 3- Particular Requirements for emergency and Transport Ventilators.* Many of the design and test requirements are also contained in ISO 10651-5:2006 *Lung ventilators for medical use- Part 5: gas powered emergency resuscitators.*
- Electromagnetic compatibility issues were examined in accordance with EN60601-1-2:2002 *Medical electrical equipment Part 1: General requirements and tests*, as modified by clause *5.8 of ISO 10651-3 :1997 Lung Ventilators for Medical Use- Part 3 Transport and Emergency Ventilators.* The radiated immunity test field strength was 30V/m across a frequency range of 80MHz to 2.5GHz.
- Ventilator enclosures do not allow objects to enter which would cause a safety hazard. Ingress protection and Salt Fog testing were conducted in accordance with *BS EN 60529:1992 Specification for degrees of protection provided by enclosures* and

the *RTCA DO160F:2007 Environmental Conditions and Test Procedures for Airborne Equipment.*

- Suitability for use in air ambulance aircraft was tested according to *BS EN 13718-1:2008 Medical vehicles and their equipment. Air ambulances. Requirements for medical devices used in air ambulances* and *RTCA DO 160F:2007 Environmental Conditions and Test Procedures for Airborne Equipment*

Performance tests and results for the Pneupac® paraPAC plus™ Model 300/310 Ventilators and accessories are documented by in-house engineering test reports (ETRs) and independent test-house reports (AQL EMC Ltd. *Based in Dorset, UK for* EMC Testing and TRaC *based in Warwick, UK for* Environmental Testing). Test results cover both the models 300 and 310. Tests were performed to assess the durability, effectiveness, and resistance to environmental conditions in use and in storage. Additional performance testing of the Pneupac® paraPAC plus™ Model 300/310 Ventilators consisted of in- house engineering tests for oxygen consumption, accessories output, rigidity, cleaning and sterilization, storage, and life testing of the electronic alarm battery.

A Human Factors Engineering (HFE) Study was carried out to validate the usability of the Pneupac® paraPAC plus™ Model 300/310 Ventilators in accordance with the FDA guidance document on *'Applying Human Factors and Usability Engineering to Optimize Medical Device Design' June 2011*, *'IEC/ISO 62366:2007 Application of usability engineering to medical devices standard'* and the *'ANSI/AAMI HE75: 2009 – 'Human factors engineering – design of medical devices'*. The results of the study show overall success of the usability of these ventilator models in the intended environment.

The results demonstrated that the Pneupac® paraPAC plus™ Model 300/310 Ventilators complied with the guidelines and standards and that they performed within their specifications and functional requirements.

Biocompatibility

Biocompatibility Assessment of the device was performed on the materials used to construct them. The Pneupac® paraPAC plus™ Model 300/310 Ventilators incorporating the Pneupac® paraPAC plus™ Disposable CPAP Circuit, Gas input hose and Patient circuits are found to be biocompatible in accordance with ISO 10993-1:2009 *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing.*

Conclusion

Based on the Indications for Use, technological characteristics, materials of construction, performance testing, and packaging configuration, the Pneupac® paraPAC plus™ Model 300/310 Ventilators are Substantially Equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 16, 2013

Smiths Medical International, Limited
Ms. Lori Berends, Sr. Regulatory Affairs Specialist
Bramingham Business Park
Enterprise Way
Luton Bedfordshire
United Kingdom LU3 4BU

Re: K123957
Trade/Device Name: Pneupac® ParaPAC Plus™ Model 300/310 Ventilators
Regulation Number: 21 CFR 868.5925
Regulation Name: Powered Emergency Ventilator
Regulatory Class: II
Product Code: BTL, BYE
Dated: August 12, 2013
Received: August 13, 2013

Dear Ms. Berends:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K123957

Device Name: Pneupac® paraPAC plus™ Model 300/310 Ventilators

Indications for Use:

The Pneupac® paraPAC plus™ Model 300/310 Ventilators are gas-powered emergency and transport portable ventilators that are primarily intended for use in transport applications in vehicles including fixed and rotary winged aircraft. They are suitable for emergency use at the accident scene, intra and inter-hospital transport and within medical facilities including medical imaging systems to 3 Teslas. They should only be used under the constant supervision of trained healthcare professionals. The devices are intended to provide ventilatory support to adults, children and infants (above approx. 10kg).
The devices also provide free flow oxygen therapy and CPAP therapy for spontaneously breathing patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Albert E. Moyal -S

c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13005 9331, cn=Albert E. Moyal -S 2013.09.13 15:11:41 -04'00'

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123957