OCT 11 2012

pNeuton mini Ventilator

510(k) Summary – K121379
14 September 2012

Contact Information
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Device Trade Name
pNeuton mini Ventilator

Device Classification
Continuous Ventilator (21 CFR 868.5895, Product Code CBK)

Device Class
Class II

Predicate Devices
pNeuton Transport Ventilator model A
- manufactured by Airon Corporation
- 510(k) number K043085

BabyPAC 100 Ventilator
- manufactured by Smiths Medical International Ltd.
- 510(k) number K043495

Millennium Infant Ventilator
- manufactured by Sechrist Industries Inc.
- 510(k) number K993167

Babi Plus Nasal Cannula System
- manufactured by A Plus Medical
- 510(k) number K110471

Device Description

The pNeuton mini ventilator is a small, lightweight transport ventilator designed for use on patients from neonate to pediatric in size (400 gram to 25 kg). It is a time cycled, flow limited ventilator providing Continuous Mechanical Ventilation (CMV) or Intermittent Mandatory Ventilation (IMV). In these modes of ventilation, an adjustable inspiratory time, expiratory time and pressure is delivered to the patient. The patient is allowed to breath spontaneously between the mandatory breaths with little added work of breathing. A built-in PEEP / CPAP system can be set to provide expiratory positive pressure. The delivered oxygen is adjustable from 21 to 100 percent.

The pNeuton mini ventilator is a pure pneumatic ventilator. Electrical power is not used. The ventilator operates from oxygen and medical grade air input pressures from 40 to 70 psi. The various control systems that manage the time controls, PEEP / CPAP, and safety systems / pneumatic alarms is powered with pure oxygen to maintain stability and accuracy. There are no electronic controls or software in this device.

The device provides ventilation and CPAP support for the care of individuals who require respiratory assistance. The device is a restricted medical device for use by qualified medical personnel under the direction of a physician. The device may be used in pre-hospital environments, inter and intra-hospital patient transport, air and ground transport, and all areas of the hospital including the MRI (NOT for use in the presence of flammable anesthetics). The mini ventilator has been specifically designed for ruggedness and ease of use.

The pNeuton mini ventilator uses accessories during normal operation. The primary accessory is a patient tubing circuit to attach the device to the patient. The patient circuit is a single-use disposable device. The patient circuit uses the same major component (expiratory valve) included with the predicate pNeuton Ventilator K043085 with smaller diameter hoses.

Intended Use

The pNeuton mini is intended to provide ventilatory support for critically ill patients who require the following general types of ventilatory support:

- Positive pressure ventilation delivered invasively (via an ET Tube) or non-invasively (via a mask or nasal prongs)
- CMV and IMV mode of ventilation with or without PEEP / CPAP
- Provide oxygen or a mixture of medical air and oxygen

Patient population:

Neonates, infants, and children, from 400 g to 25 kg in weight

Environments of Use

- Inter and intra-hospital patient transport

- Air & ground transport – Pressurized and non-pressurized aircraft (to 15,000 ft)
- Intensive care units (short term use only - associated with patient transport)
- Emergency Departments
- Radiology suites including MRI (MR Conditional 3T)
- Operating rooms (short term use only - associated with patient transport)

Substantial Equivalence

The pNeuton mini ventilator shares substantial equivalency with the pNeuton model A Ventilator, the BabyPAC 100 Ventilator and the Millennium Infant Ventilator across the spectrum of patient population for which each was designed.

The pNeuton mini ventilator utilizes many similar components as found in the pNeuton model A Ventilator including an identical timing and pressure control system with patient / gas supply alarms. Due to the requirements of neonatal ventilation a precision air / oxygen blender is used instead of the air entrainment based oxygen mixing of the model A ventilator.

The pNeuton mini ventilator shares common modalities with the BabyPAC 100 Ventilator and the Millennium Infant Ventilator with significant overlap in the clinical range of function for their target population. The essential clinical function of each device is significantly similar and mimics each other in the typical frame of use by the health care providers. All are pneumatic based and applicable for the same areas of use.

Characteristic	pNeuton mini Ventilator	pNeuton A Ventilator	BabyPAC Ventilator	Millennium Ventilator
510(k) number		K043085	K043495	K993167
Intended Use – application	Provide continuous or intermittent mechanical ventilation and / or CPAP for neonate to child patients (400 g to 25 kg) via mask, nasal prongs or endo-tracheal tube	Provide continuous or intermittent mechanical ventilation and / or CPAP for pediatric to adult patients via mask or endo-tracheal tube	Provide continuous or intermittent mechanical ventilation and / or CPAP for neonate to child patients up to 20 kg	Provide continuous or intermittent mechanical ventilation and / or CPAP for neonate to pediatric patients up to 50 kg
Environments of use	Hospital, pre-hospital and transport environments	Hospital, pre-hospital, transport and sub-acute/alternate site facility environments	Ambulance, hospital, emergency and transport environments	Hospital environment
Operation environmental requirements	-15 to 49 °C (5 to 120 °F), 15 to 95 percent humidity	-5 to 40 °C (23 to 104 °F), 15 to 95 percent humidity	-10 to 40°C (14 to 104 °F)	

Personnel Requirements	Training as physician, nurse, respiratory therapist	Training as physician, nurse, respiratory therapist, EMT	Training as qualified medical caregiver, paramedics and other trained personnel	Training as physician, nurse, respiratory therapist
Operating principle	Pneumatic driven and controlled with pneumatic alarms	Pneumatic driven and controlled with pneumatic alarms	Pneumatic driven and controlled with electronic alarms	Pneumatic driven and electronically controlled
Gas Input(s)	40 to 70 psi	40 to 70 psi	40 to 87 psi	40 to 60 psi
Patient circuit	Tubing with external expiratory valve and proximal pressure line	Tubing with external expiratory valve	Tubing with external attached expiratory valve	Tubing with external attached expiratory valve
Enclosure	Rugged, lightweight	Rugged, lightweight	Rugged, lightweight	Single enclosure on stand for hospital use
Displays	Manometer	Manometer	Manometer	Electronic screen
Safety features	Internal high pressure release, spontaneous breathing safety valve	Internal high pressure release, spontaneous breathing safety valve	None	Internal high pressure release
MRI compatibility	MRI Conditional 3T	MRI Conditional 3T	MRI Conditional 3T	None

Patient support modes	CMV, IMV, CPAP	CMV, IMV, CPAP	CMV, IMV, CPAP	Assist / Control, SIMV / IMV, CPAP
Maximum working pressure limitation	80 cm H_2O	80 cm H_2O	80 cm H_2O	70 cm H_2O
Maximum inspiratory flow	20 L/min	Mandatory – 36 L/min Spontaneous – 140 L/min	10 L/min	40 L/min
Inspiratory time Control setting: Accuracy:	0.25 to 2.0 sec ± 10%	label as tidal volume 0.6 to 2.0 sec ± 10%	0.25 to 2.0 sec ± 0.8 sec	0.1 to 3.0 sec
Expiratory time Control setting: Accuracy:	0.25 to 20.0 sec ± 10%	label as resp rate 0.6 to 20.0 sec ± 10%	0.25 to 40 sec ± 0.8 sec	0.3 to 30.0 sec
Peak patient pressure Control setting: Accuracy:	15 – 60 cm H_2O ± 2 cm H_2O	15 – 75 cm H_2O ± 10%	10 – 70 cm H_2O ± 15%	5 – 70 cm H_2O

Flow Rate Control setting: Accuracy:	6, 8, 10, 15, 20 L/min ± 10%	Non adjustable @ 36	Non adjustable @ 10	2 to 32 L/min
CPAP Control setting: Accuracy:	0 - 20 cm H_2O ± 2 cm H_2O	0 - 20 cm H_2O ± 5%	0 – 20 cm H_2O ± 15%	0 - 20 cm H_2O
Oxygen Control setting: Accuracy:	21 to 100% ± 3%	2 choices, 65 or 100 ± 10%	21 to 100% ± 8%	21 to 100%
Measurements Pressure sensor type: Position:	Mechanical gauge Use proximal airway signal	Mechanical gauge Use internal signal	Mechanical gauge Use internal signal	Transducer Proximal airway
Measurements Volume sensor type: Position:	None	None	None	None
Monitored parameters Parameter / range: Accuracy: Parameter / range: Accuracy: Parameter / range: Accuracy:	Pressure –10 to 80 ± 2 cm H_2O	Pressure –10 to 80 ± 2 cm H_2O	Pressure –10 to 100 ± 2 cm H_2O	Pressure –10 to 70 I:E ratio 4:1 to 1:10 Resp rate 0 to 150
Alarms Parameter / range: Default setting: Parameter / range: Default setting: Non-adjustable:	High pressure 10 - 70 cm H_2O 30 cm H_2O Patient disconnect, low gas supply	No adjustable alarms N/A Patient disconnect, low gas supply	High pressure 12 - 80 cm H_2O Patient disconnect, low gas supply, low battery	High pressure 5 - 70 cm H_2O High rate 2 to 150 Patient disconnect, low PEEP, apnea, low gas supply, low electrical power, vent inop
Battery Type: Operating time:	None N/A	None N/A	3/3.6 volt lithium 1 year	
Materials in gas pathway	Identical to Pneuton ventilator	Cleared in K043085		

The pNeuton mini Ventilator can provide non-invasive and invasive ventilation to the intended patient population. To provide invasive ventilation the Airon patient breathing circuit includes a wye piece with a standard 15 mm ID fitting for connection to an endo-tracheal tube. To provide non-invasive ventilation (NIV), accessory kits are used to

replace the wye piece with appropriate tubing and patient interfaces (nasal prongs or mask).

Two NIV kits are available for use with the Airon patient breathing circuit. One NIV kit is called the NIC CK CPAP Kit. This is the same device as the Babi Plus Infant Nasal Cannula System cleared under K110471 by A Plus Medical.

The other NIV kit is called the NIC FM CPAP Kit. The NIC FM CPAP Kit is substantially equivalent in the indications for use, environment of use, patient population, material and function to the A Plus Medical Nasal Cannula Kit (K110471). The NIC FM CPAP Kit includes both nasal prongs and nasal masks while the A Plus Medical Nasal Cannula Kit only has nasal prongs. The addition of the nasal mask, which is Class 1 exempt under 21 CFR 868.5580 and Product Classification BYG – Oxygen mask, allows for the patient interface pressure points to be switched from inside of the nares (prongs) to outside (mask). . The essential clinical function of each device is significantly similar and mimics each other in the typical frame of use by the health care providers

Characteristic	NIC FM CPAP Kit	Babi Plus Nasal Cannula System
510(k) number		K110471
Intended Use – application	Single patient use device intended for use with neonates, infants and children under 10 Kg requiring a non-invasive nasal interface during intermittent or continuous gas flow therapy	Single patient use device intended for use with neonates, infants and children under 10 Kg requiring a nasal prong interface during intermittent or continuous gas flow therapy
Environments of use	Hospital critical care unit	Hospital critical care unit
Connection to Airon patient circuit	10 mm male connectors in kit fit 10 mm female connectors in patient circuit. Length of tubing to patient interface is 10 mm.	10 mm male connectors in kit fit 10 mm female connectors in patient circuit. Length of tubing to patient interface is 10 mm.
Patient interfaces	6 sizes of nasal prongs and 4 sizes of nasal mask	8 sizes of nasal prongs
Inspiratory flow resistance	1.0 to 1.7 cm H_2O	1.1 to 1.3 cm H_2O
Expiratory flow resistance	1.2 to 1.4 cm H_2O	1.2 to 1.4 cm H_2O
Materials in gas pathway	Silicone, K-resin, Polypropylene	Silicone, K-resin, Ethyl Vinyl Acetate (EVA) tubing, Polyvinyl chloride (DEHP, DAP free)

Summary of Non-Clinical Testing and Validation

The performance of the pNeuton mini ventilator has been comprehensively tested. All functions as listed in the specifications have been validated. The device meets all test requirements as identified in the FDA Draft Reviewer Guidance for Ventilators (April, 1995).

The pNeuton mini ventilator complies with the following voluntary standards:

- ASTM: F1100 90 - Ventilators Intended for Use in Critical Care
- ISO: 10651-3: 1997 - Lung Ventilators for Medical Use- Particular requirements for emergency and transport ventilators
- RTCA DO-160G - Environmental Conditions and Test Procedures for Airborne Equipment, as applicable
- MIL-STD-810F – Environmental Engineering Considerations and Laboratory Tests, as applicable
- CGA V-5:2008 Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)
- ASTM F2052 - 06e1 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119 – 07 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Specific non-clinical tests included:

- Specification verification and waveform tests. Following the requirements of ASTM F1100 90, all operational functions were tested to meet required specifications. This included operation at the extremes of input gas pressures as specified. Waveform tests using Pressure / Time, Flow / Time and Volume / Time graphics showed that the accuracy and precision of breath delivery meets or exceeds specifications during four different clinical simulated conditions.
- Reliability and endurance tests. Tests were performed to demonstrate reliability of performance during the entire device lifetime, under conditions comparable to the clinical environment as specified. Following the requirements of ASTM F1100 90, the device operated continuously for 2,200 hours at two different clinical simulated conditions. In addition, reliability tests were performed for an additional 240 hours at the extremes of environmental conditions which may be encountered during clinical use of this transport ventilator. Following these tests operation was verified using specification verification and waveform tests as described above.
- Environmental and mechanical safety. The device was tested and passed the environmental / mechanical safety tests identified in the following standards:
  - RTCA DO-160G, section 4, Altitude and Overpressure tests using Category A2

  - RTCA DO-160G, section 4 & 5, Temperature Variation tests of Procedure 5.3.1 using Category A4
  - RTCA DO-160G, section 6, Humidity tests using Category A
  - RTCA DO-160G, section 8, Robust Vibrations Tests for Category R
  - RTCA DO-160G, section 10, Spray Proof Test using Procedure 10.3.3
  - ISO 10651-3: 1997, section 21.6c), Bump test in accordance with IEC 68-2-29, test Eb
  - MIL-STD-810F, section 500.4, Procedure III, Rapid decompression
  - MIL-STD-810F, section 514.5, Procedure I, Jet Aircraft Random Vibration Test
- Testing for MRI environments. All tests were performed according to ASTM F2052 - 06e1 and ASTM F2119 – 07 using a 3 Tesla scanner. There was no induced displacement force, performance variance or artifact generated in the scans. The pNeuton mini ventilator is not intended for implant so the assessment of magnetic field interactions for this product specifically involved evaluations of translational attraction and function in relation to exposure to a 3 Tesla MR system only.

Clinical testing was not performed on this device. Safety and efficacy were established through non-clinical testing and risk analysis. The pNeuton mini ventilator performs as intended according to its performance specification and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 11 2012

Airon Corporation
G. Eric Gjerde
President & CEO
751 North Drive, Unit 6
Melborne, Fl 32934

Re: K121379
Trade/Device Name: pNeuton mini Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 17, 2012
Received: September 18, 2012

Dear Mr. Gjerde :

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
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: K121379

Device Name: pNeuton mini Ventilator

Indications For Use: The pNeuton mini is intended to provide ventilatory support for critically ill patients who require the following general types of ventilatory support:

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Environments of Use

- Inter and intra-hospital patient transport
- Air & ground transport – Pressurized and non-pressurized aircraft (to 15,000 ft)
- Intensive care units (short term use only - associated with patient transport)
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- Operating rooms (short term use only - associated with patient transport)

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: K121379