SEP 2 1 2012

5.0 510(k) Summary K121260

Submitter:
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Date Prepared: September 19, 2012

Trade Name: Trooper Oxygen Concentrator

Common Name: Portable Oxygen Concentrator

Classification: Class II, 21 CFR 868.5440

Product Code: CAW

Predicate Devices: The subject device is substantially equivalent to the following devices:

- Inogen One Oxygen Concentrator (K032818)
- EverGo Portable Oxygen Concentrator (K043615)

Device Description: The Trooper oxygen concentrator utilizes a molecular sieve and differential pressure swing adsorption to separate the gases in ambient air. The device takes the room air and concentrates the oxygen portion to produce a pulse of oxygen between 87-94 % in purity. When the patient inhales, the device senses the pressure change and is triggered to release the oxygen pulse. In between breaths, the device regenerates an oxygen pulse and waits for the next inhalation breath before dispensing it.

The front panel of the Trooper contains controls and indicators such as, device status indicator LEDs, an ON/OFF button, oxygen flow rate controls, and flow rate and battery status displays. The oxygen outlet is also located on the front panel of the device.

The VBOX Trooper oxygen concentrator system will be provided under a single model number, A-1000, which includes the following items:

- One (1) Trooper Oxygen Concentrator Unit
- Two (2) Li-Ion Batteries (only one connected to the device at a time)
- One (1) Auxiliary AC Power Supply
- One (1) Battery Charger
- One (1) Carrying case
- One (1) nasal cannula

- User manual

Trooper Device Specifications:

Dimensions (LxWxH)	6 x 2.5 x 6.25 inches
Weight	3.2 lbs (includes battery)
Materials	
Sieve Bed	Synthetic zeolite
Nasal Cannula	PVC (standard cannula supplied by Salter Labs)
Battery	Li-Ion
Performance Specifications	
Method of oxygen concentration	Molecular sieve (mechanical)
Process by which Oxygen is released	Differential pressure swing adsorption
Flow Rate	5 settings: 1 to 5 (flow rates equivalent to 1 LPM to 5 LPM)
Duration of flow	Pulsed
Trigger Sensitivity	≤ 0.13 cm water (≤ 12.7 Pa)
Oxygen concentration	87-94% at all settings
Software/ Hardware	Analog and digital electronics with microprocessor
Rechargeable Battery	Yes
Power Options	Battery, AC

Intended Use:

The VBOX Trooper oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The VBOX Trooper may be used in home, institution, vehicle and various mobile environments.

Summary Comparison to Predicate Devices:

	VBOX Trooper Oxygen Concentrator (Subject Device)	**Inogen One Oxygen Concentrator (Predicate Device)**	**EverGo Portable Oxygen Concentrator (Predicate Device)**
Manufacturer	VBOX, Inc.	Inogen	Philips Respironics
Classification	Class II	Class II	Class II
Product Code	CAW	CAW	CAW

Indications for Use	The VBOX Trooper oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The VBOX Trooper may be used in home, institution, vehicle and various mobile environments.	The Inogen One Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Inogen One may be used in home, institution, vehicle and various mobile environments.	The EverGo Portable Oxygen Concentrator is intended for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable and is capable of continuous use in home, institutional, and travel / mobile environments.
Prescription Required	Yes	Yes	Yes
Patient Interface	Standard nasal cannula	Standard nasal cannula	Standard nasal cannula
Dimensions (LxWxH)	6 x 2.5 x 6.25 inches	11.6 x 6.0 x 10.7 inches	12 x 6 x 8.5 inches
Weight	3.2 lbs (includes battery)	9.8 lbs (includes battery)	10 lbs (includes batteries)
Materials			
Sieve Bed	Synthetic zeolite	Synthetic zeolite	Synthetic zeolite
Nasal Cannula	PVC (standard cannula supplied by Salter Labs)	PVC (standard cannula supplied by Salter Labs)	Not supplied with the device
Battery	Li-Ion	Li-Ion	Li-Ion
Performance Specifications			
Method of oxygen concentration	Molecular sieve (mechanical)	Molecular sieve (mechanical)	Molecular sieve (mechanical)
Process by which Oxygen is released	Differential pressure swing adsorption	Differential pressure swing adsorption	Differential pressure swing adsorption
Flow Rate	5 settings: 1 to 5 (flow rates equivalent to 1 LPM to 5 LPM)	5 settings: 1 to 5 (flow rates equivalent to 1 LPM to 5 LPM) and one setting of "Satellite"	6 settings: 1 to 6 (flow rates equivalent to 1 LPM to 6 LPM)

Duration of flow	Pulsed	Pulsed	Pulsed
Trigger Sensitivity	≤ 0.13 cm water (≤ 12.7 Pa)	0.12 cm water (12 Pa)	0.16 cm water (16 Pa)
Oxygen concentration	87-94% at all settings	87-93% at all settings	86-92% at all settings
Software/ Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor
Rechargeable Battery	Yes	Yes	Yes
Power Options	Battery, AC	Battery, AC	Battery, AC

Functional and Safety Testing:

Applicable portions of the following standards were applied during development and testing of the Trooper Oxygen Concentrator:

- ASTM F1464-93:2005 Oxygen Concentrators for Domiciliary Use
- ISO 8359:1996 Oxygen Concentrators for medical use – Safety Requirements
- EN 60601-1-2:2007 – Medical Electrical Equipment-Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- EN 55011:2007 (including Amendment A2:2007) - Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Equipment
- Federal Communications Commission (FCC) Part 15 Subpart B
- IEC 60601-1:2003 Medical Electrical Equipment – Part 1: General Requirements for Safety
- ISO 10993-1:2009 Biological evaluation of medical devices

Bench testing was performed to provide assurance that the proposed device conforms to the requirements for its intended use. This included the following testing:

- Output gas composition (e.g. VOCs, particulate matter, ozone/carbon monoxide/carbon dioxide content)
- User display and LED functions
- Oxygen flow rate and concentration
- Electromagnetic compatibility and electrical safety
- Functional performance (e.g. trigger sensitivity and delay, pulse volume and duration)

- Output gas temperature

In addition, functional side-by-side comparison testing was performed to demonstrate substantial equivalence of the proposed device to each of the predicate devices. The following parameters were evaluated across all breath rates:

- Trigger Sensitivity
- Oxygen Pulse Timing
  - Pulse Time
  - Pulse Delay
  - Total Time to Deliver Pulse
- Pulse Volume
- Oxygen Purity
- Relative Fraction of Inspired Oxygen (FIO2)

The pulse delivery waveforms (liters per minute flow over time) were also assessed for the proposed device and each of the predicate devices.

Conclusion:

The similarities between the Trooper (proposed device) and the predicate devices referenced above with respect to the principles of operation, technology, materials, indications for use, and functional performance clearly support a conclusion of substantial equivalence.

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

Vbox, Incorporated
C/O Mr. Mark Job
Regulatory Technology Services, Limited Liability Company
1394 25TH Street, North West
Buffalo, Minnesota 53313

SEP 21 2012

Re: K121260
Trade/Device Name: Trooper Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: September 6, 2012
Received: September 7, 2012

Dear Mr. Job:

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 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,

for

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

4.0 Indications for Use Statement

Device Name: VBOX Trooper Oxygen Concentrator

Indications for Use:

The VBOX Trooper oxygen concentrator device is used on a prescriptive basis by patients requiring supplemental oxygen. It supplies a high concentration of oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The VBOX Trooper may be used in home, institution, vehicle and various mobile environments.

Prescription Use ___X____ (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 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: K121280