K103563

JUL - 1 2011

510(k) Summary
Precision Medical, Inc.
Portable Oxygen Concentrator

Submitter Information

Submitter	Precision Medical, Inc. 300 Held Drive Northampton, Pa. 18067
FDA registration number:	2523148
Contact	James Parker Quality Assurance Manager
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Preparation Date:	June 29, 2011
Device Name	Precision Medical EasyPulse portable oxygen concentrator (Model PM4150)
Proprietary Name:	Precision Medical EasyPulse portable oxygen concentrator (Model PM4150)
Common Name:	Portable Oxygen Generator
Regulation Number:	21CFR 868.5440
Product Code:	CAW Class II Device

Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence to the Invacare Flyer Model XPO100 (510K 071928)

Intended Use

The Precision Medical EasyPulse portable oxygen concentrator (model PM4150) is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device can be used in a home, institution, vehicle and for transportable use.

Description of device

The EasyPulse Portable Oxygen Concentrator (POC), model PM4150, was designed to provide mobility to patients requiring supplemental oxygen. The EasyPulse POC uses oxygen concentrator technology coupled with electronic conserving device technology to provide the patient with a lightweight, battery powered oxygen concentrator. The device can be used in the home, institution, vehicle and various mobile environments. A nasal cannula is used to direct the flow of oxygen from the device to the patient. The device is not intended to be life supporting or life sustaining.

The EasyPulse POC provides pulsed dose delivery to the user through a selection of 5 settings. Setting 1 delivers the lowest amount of oxygen and setting 5 provides the greatest amount of oxygen. Oxygen volumes for each setting and oxygen concentration are listed in the device specifications. Oxygen minute volume is controlled electronically by monitoring the user's breath rate. By monitoring the user's breath rate the bolus volume is adjusted to deliver the patient the same amount of oxygen per minute.

The EasyPulse POC offers the user multiple options to power the device. The device includes an internal lithium ion battery, not accessible by the patient, that will provide varying run times dependent upon the user setting chosen. Stated battery runtimes are listed in the device specifications. An external AC/DC power supply is included with the device. The AC/DC power supply allows the user to power the device from a standard 110 VAC outlet. An external DC/DC automobile adapter is also provided with the device. The external DC/DC automobile adapter allows the user to power the device from a standard 12V automobile accessory jack. When connected to either the AC/DC power supply or external DC/DC automobile adapter, the device will default to charging the internal battery when the device is in the OFF position. If the unit is turned on while attached to a power supply, the device will simultaneously run (provide oxygen) and charge the internal battery.

Specifications of Device

Dimensions	Height: 10.1" (25.4 cm)
	Width: 6.5" (16.5 cm)
	Depth: 4.5" (11.3 cm)
Weight	Device: 6.8 lbs (3.08 kg)
Altitude	Up to 9000 ft (2743 m)
Storage Temperature	41°F to 104°F (5°C to 40°C)
Operating Temperature	-2°F to 140°F (-20°C to 60°C)
Relative Humidity	Up to 95% Non-Condensing
Oxygen Concentration	87% to 95%
Oxygen Minute Volume	Setting 1: 240 +/-15% cc/min
	Setting 2: 380 +/-15% cc/min
	Setting 3: 520 +/-15% cc/min
	Setting 4: 660 +/-15% cc/min
	Setting 5: 780 +/-15% cc/min
Power	AC Power Adapter: 100-240 VAC (1.0 A @ 120 VAC)
	DC Power Adapter: 11-16 VDC (5.0 A @ 12 VDC)
Battery Duration (approximate)	Setting 1: 4.5 hrs
	Setting 2: 3.2 hrs
	Setting 3: 2.5 hrs
	Setting 4: 1.8 hrs
	Setting 5: 1.5 hrs
Sound (@ Setting 2)	44 dBA
Cannula	Maximum 7ft cannula

Predicate Comparison

Feature/Specification		Precision Medical	Invacare
Intended Use		The Precision Medical EasyPulse POC (model PM4150) is intended to provide supplemental oxygen to persons requiring oxygen therapy. The Precision Medical POC can be used in a home, institution, vehicle and various mobile environments.	The Invacare XP02 is intended to be used by patients with respiratory disorders who require supplemental oxygen. It supplies a high concentration of supplemental oxygen and is used with a nasal cannula to channel oxygen from the concentrator to the patient. The Invacare XP02 can be used in a home, institution, vehicle and various mobile environments. The Invacare XP02 does not, nor is it intended to sustain or support life.
Method by which oxygen is released		Molecular Sieve (mechanical)	Molecular Sieve (mechanical)
Process by which oxygen is released		Pressure/Vacuum Swing Absorption	Pressure Swing Absorption
Sieve Bed Material		Synthetic Zeolite	Synthetic Zeolite
Software/Hardware		Analog & digital electronics w/ microprocessor	Analog & digital electronics w/ microprocessor
Flow control		Microprocessor controlled valves	Microprocessor controlled valves
Weight		6.8 lbs w/ internal battery	< 7.0 lbs w/ internal battery
Outside Dimensions	Height	10.0"	10.0"
	Width	6.5"	7.0"
	Depth	4.5"	4.3"
Oxygen %		87% to 95% all flow rates	87% to 95.6% all flow rates
Flow Rates		Pulse Flow (Minute Volume) Tolerance +/-15% Setting 1: 260 cc/min Setting 2: 380 cc/min Setting 3: 520 cc/min Setting 4: 660 cc/min Setting 5: 760 cc/min	Pulse Flow (Minute Volume) Tolerance Not Available Setting 1: 240 cc/min Setting 2: 360 cc/min Setting 3: 480 cc/min Setting 4: 600 cc/min Setting 5: 700 cc/min
Operating Temperature		41 to 104°F (5 to 40°C) All power sources	41 to 95°F (5 to 35°C) All power sources 95 to 104°F (35 to 40°C) continuous use w/ AC or DC adapter 95 to 104°F (35 to 40°C) limited use w/ internal battery
Storage Temperature		-2 to 140°F (-20 to 60°C)	-2 to 140°F (-20 to 60°C)
Operating Humidity		Up to 95% RH non-condensing	15% to 60% RH non-condensing
Storage Humidity		Up to 95% RH non-condensing	Up to 95% RH non-condensing
Operating Altitude		Up to 9000 ft	Up to 10000 ft
Sound Level (@ Setting 2)		44 dBA	45 dBA
Power options		AC/DC Power supply Input: 100-240 VAC , 50/60 Hz Output: 18 VDC, 60W DC/DC Power supply Input: 11-16 VDC , 50/60 Hz Output: 18 VDC, 60W	AC/DC Power supply Input: 100-240 VAC , 50/60 Hz Output: 18 VDC, 60W DC/DC Power supply Input: 11-16 VDC , 50/60 Hz Output: 18 VDC, 60W
Battery		Non-removable Lithium-Ion - 14.4 VDC, 5.0 Ah	Non-removable Lithium-Ion - 14.8 VDC, 5.2 Ah
System Alarms		Low Battery Warning Low Battery Alarm No Breath Detect Alarm Excessive Breath Rate Alarm Compressor Alarm (Abnormal Motor Current) Battery Temperature Alarm Motor Temperature Alarm Pressure Alarm Fan Failure Alarm Motor Connection Alarm Battery Connection Alarm Performance Alarm (Monitor system pressures)	Low Battery Warning Low Battery Alarm Battery Discharged Alarm No Breath Detect Alarm Breath Rate Over Capacity Alarm System Too Hot/Cold for Start Alarm System Too Hot/Cold Running Alarm Battery Too Hot/Cold Stuck Button Alarm Operating Alarm (Abnormal Operating Conditions) Compressor Alarm (Abnormal Compressor Conditions) System Alarm (Abnormal System Conditions)

Comparison Technology

The only significant difference relative to the predicate is the predicate device uses a PSA (Pressure Swing Adsorption) cycle while the Precision Medical POC opted for use of a VPSA (Vacuum Pressure Swing Adsorption) cycle. Both cycle types are proven technology and used in various other devices on the market. Precision Medical felt a VSPA cycle provided advantages in reducing complexity of the pneumatic circuit and reducing power consumption.

The predicate comparison table shows the EasyPulse POC is similar to the Invacare XPO2. Both devices have similar intended use, use similar methods for extracting oxygen from the atmosphere, have similar environmental specifications, similar oxygen purity and provide similar power options.

Summary of Performance Testing

Electromagnetic Compatibility Testing Performed per:	
EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility
Mechanical and Electrical Safety Testing Performed per:	
UL 60601-1, 1st Edition 2006-04-26	Medical electrical Equipment, Part 1: General Requirements for Safety
CAN/CSA-C22.2 No.601.1-M90, 2005	Medical electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-1:1998, A1:1991, A2:1995	Medical electrical Equipment, Part 1: General Requirements for Safety
IEC 60068-2-6	Sinusoidal Vibration
IEC 60068-2-27	Shock/Bump
IEC 60068-2-64	Random Vibration
VOC and Particulate Testing Performed per:	
EPA $PM_{2.5}$	Particulate Matter
ASTM D5466	Standard Test Method for Determination of Volatile Organic Chemicals in Atmospheres (Canister Sampling Methodology)
21 CFR 801.415	Ozone Levels
EPA NAAQS - Carbon Monoxide	Carbon Monoxide Levels
OSHA Permissible Exposure Limits	Carbon Dioxide Levels
Performance Testing:	
738-2 Weight and Dimensions	Measure overall weight and size of device
738-3 Operating Temperature	Verify performance at extremes of operating temperature range
738-4 Storage Temperature	Subject packaged device to extremes of storage temperature range
738-5 Barometric Pressure Range	Verify performance at maximum altitude
738-6 Functionality	Verify basic functions of test units
738-8 Outlet Temperature	Measure gas outlet temperature under max operating temperature
738-9 Oxygen Concentration	Measure O2 concentration after operating for 1 hour
738-10 Mean Oxygen Concentration	Measure O2 concentration over 9 hour period
738-11 Bolus Volume	Measure O2 minute volume for each setting, at every breath rate from 15-35 breaths/min Measure bolus volume @ setting 5 over 9 hour period
738-12 Basic Performance	Measure O2 concentration and bolus volume for each setting
738-13 Internal Battery Charging	Measure battery runtimes for each setting and battery charge time
738-14 Sound Level	Measure sound of device while operating
738-15 Trigger Delay/Sensitivity	Measure trigger delay and trigger sensitivity
738-16 ISTA Drop Test	Packaging drop test

Conclusions

In Summary, Precision Medical, Inc. has demonstrated that the Precision Medical, Inc. Portable Oxygen Concentrator is safe and effective. The combined testing and analysis of results provides assurance that the device meets the specifications and is safe and effective for the intended use.

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

Precision Medical Inc.
C/O Mr. James Parker
Quality Assurance Manager
300 Held Drive
Northhamption, Pennsylvania 18067

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Re: K103563
Trade/Device Name: Precision Medical Easy Pulse Portable Oxygen Concentrator (Model PM4150)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Concentrator
Regulatory Class: II
Product Code: CAW
Dated: June 27, 2011
Received: June 28, 2011

Dear Mr. Parker:

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,

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

510 (k) number (if known) _K103563_____

Device Name: Precision Medical EasyPulse portable oxygen concentrator (Model PM4150)

Indications for use:

The Precision Medical EasyPulse portable oxygen concentrator (model PM4150) is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device can be used in a home, institution, vehicle, and for transportable use.

(Please do not write below this line- continue on another page if needed)

Concurrence of CDRH, office of device Evaluation (ODE)

Prescription Use: X Or Over the counter use_____

(Per 21 CFR 801.109) (Optional Format 1-2-9)

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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