510K072348

OCT 2 7 2008

# 510(k) Summary
# Precision Medical, Inc. Oxygen concentrator

## Submitter Information

| | |
|---|---|
| Submitter | Precision Medical, Inc.<br>300 Held Drive<br>Northampton, Pa.<br>18067 |
| Contact | James Parker<br>Quality Assurance Manager |
| Tel: | (610)-262-6090 Extensions 228 |
| Fax: | (610)-262-6080 |
| Preparation Date: | August 17, 2007 |

## Device Name

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|---|---|
| Proprietary Name: | Precision Oxygen Concentrator |
| Common Name: | Oxygen concentrator |
| Classification Name: | Concentrator, oxygen |
| Classification Product Code: | CAW |
| Regulation number: | 868.5440 |

## Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence to the Respironics Oxygen concentrator ,L4
Manufactured by:
Respironics Inc.
1001 Murry Ridge Lane.
Murrysville, Pa 15668
510 K number: K061261

## Device Description

Precision Medical, Inc. Concentrator is a medical device that produces concentrated oxygen from room air. The concentrator uses a molecular sieve and a pressure differential absorption process to concentrate oxygen from air.

## Intended Use

The Precision Medical Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. The concentrator is intended for use in the home or hospital institutional environment.

**Table of Comparisons to Predicate Device**

| Specifications | Respironics | Precision Medical | Precision medical test number | ISO 8359 :1996 Clause | Meets The requirement |
|---|---|---|---|---|---|
| Oxygen % | 93% ±3% | 93% ±3% | 731-1,22,23 | 8.1,50.4,50.5 | Meets requirements |
| Liter flow | 0.5 to 5.0 liters per minute | 0.5 to 5.0 liters per minute | 731-24 | 8.1,50.6,50.5 | Meets requirements |
| Flow accuracy | | 10%or ±200ml | 731-14 | 8.1,50.3 | Meets requirements |
| Operating temperature | 55 to 90 °F | 55 to 90 °F | 731-4A | 7-42.3 | Meets requirements |
| Storage temperature | -30 to 160°F | -30 to 140°F | 731-5 | 60601-1 Section 10.1 | Meets requirements |
| Humidity | Up to 95% noncondensing | Up to 95% noncondensing | 731-5 | 60601-1 Section 10.1 | Meets requirements |
| Power requirements | 120 vac ±10% 360w 60 HZ | 120 vac ±10% 450w 60 HZ | 731-15 | | Meets requirements |
| Power alarm | LED and audible | LED and audible | 731-10 | | Meets requirements |
| O2 concentration Alarm | LED and audible | LED and audible | 731-10 | | Meets requirements |
| Warm up time | ≤ 10 minutes | ≤ 10 minutes | 731-1 | 8.1,50.4 | Meets requirements |
| Dimensions | 29inches x 15 inches x 10 inches | 29inches x 15 inches x 10 inches | 731-2 | | na |
| Weight | ≤ 31lbs. | ≤ 36lbs. | 731-2 | | na |
| Sound level | 45 dBA | 53.3dBA | 731-9 | 4.6,26.1 | Meets requirements |
| Out let pressure | 5.5psi | 5.0psi | 731-19 | 8.1,50.8 | Meets requirements |
| Back pressure | Unknown | 1.0psi | 731-20 | 8.1, 50.7 | Meets requirements |
| Out let gas temp | unknown | Max above abient 0.5°F or 0.3°C | 731-18 | 7,42.3 | Meets requirements |

### *Summary of Performance Testing*

The Precision Medical, Inc. Oxygen Concentrator will successfully pass tests in the following areas;

Mechanical / Climatic
Device Performance
Life test
Alarm testing

### *Conclusions*

In Summary, Precision Medical, Inc. has demonstrated that the Precision Medical, Inc. 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
9200 Corporate Boulevard
Rockville MD 20850

Mr. James Parker
Quality Manager
Precision Medical, Incorporated
300 Held Drive
Northampton, Pennsylvania 18067

OCT 2 7 2008

Re: K072348
Trade/Device Name: Precision Medical Inc. Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: October 17, 2008
Received: October 20, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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: K072348

Device Name: Precision Medical Inc. Concentrator

Indications For Use:

The Precision Medical Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. The concentrator is intended for use in the home or hospital institutional environment.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J. Shi, M.D.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



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