K063096

510(k) Summary

FEB 27 2007

Precision Medical, Inc. Oxygen Monitor

Submitter Information

Submitter	Precision Medical, Inc. 300 Held Drive Northampton, Pa. 18067
Contact	James Parker Quality Assurance Manager
Tel: Fax:	(610)-262-6090 Extensions 228 (610)-262-6080
Preparation Date:	October 2, 2006

Device Name

Proprietary Name:	Precision Oxygen Monitor
Common Name:	Oxygen Analyzer
Classification Name:	Analyzer, Gas Oxygen as per CFR 868.1720
Classification Product Code	CCL
Device Classification	Class II

Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence to the Cerion Hand Held Oxygen Analyzer. Now (Maxtec)
510K number K911344

Device Description

The Precision Medical, Inc. Oxygen monitor is a restricted medical device intended for use by qualified and trained personnel under the direction of a physician in institutional environments where monitoring of oxygen levels are required.
Additional information:
The Precision Medical, Inc. Oxygen monitor is made of two components, the monitor, and the sensor, attached by a coiled cable. The monitor houses the LCD screen, circuit board, key pad, and batteries. The sensor is a galvanic oxygen sensor that produces a millivolt signal that is proportional to partial pressure of oxygen being measured. The monitor converts the millivolt signal sent from the sensor to a percent oxygen concentration displayed on the LCD screen.

Precision Medical, Inc. will purchase the Sensor from
IT Dr. Gambert Gmbh
Hinter dem Chor 21
23966 Wismar
Germany
510K number K002384

Intended Use

The oxygen monitor provides continuous, direct monitoring of oxygen mixtures in a wide variety of medical applications such as anesthesiology [e.g. anesthesia machines], respiratory devices [e.g. respirators, ventilators, pediatric incubators], and oxygen therapy [e.g., oxygen tents]. The oxygen monitor is to be used by trained healthcare professionals under the supervision, or on the order, of a physician in a hospital [or other clinical setting. The Precision Medical, Inc. oxygen monitor is not intended for transport use. This device is not an oxygen supply source.

O2 Monitor Specifications	Predicate (Maxtec)	Precision Medical
Measurement Range	0.0 - 100%	0.0 - 100%
Resolution	0.10%	0.10%
Accuracy & Linearity	±1% of full scale at constant temperature, R.H. and pressure when calibrated at full scale.	±1% of full scale at constant temperature, R.H. and pressure when calibrated at full scale.
Total Accuracy	±3% Actual Oxygen Level over full operating temperature range	±3% Actual Oxygen Level over full operating temperature range
Response Time	90% of final value in approximately 15 seconds at 23°C	90% of final value in approximately 12 seconds at 25°C
Warm-up Time	none required	none required
Operating Temperature	15°C - 40°C [59°F - 104°F]	10°C - 45°C [50°F - 113°F
Storage Temperature	-15°C - 50°C [5°F - 122°F]	-15°C - 50°C [5°F - 122°F]
Humidity	0 - 95% [non-condensing]	0 - 95% [non-condensing]
Power Requirements	2, AA Alkaline Batteries [2 x 1.5 Volts]	4, AA Alkaline Batteries [4 x 1.5 Volts]
Battery Life	approximately 3000 hours in typical use	approximately 1500 hours in continuous use, Non alarm condition
Low Battery Indication	"LOW BAT" icon displayed on screen	"LOW BAT" icon displayed on screen
Sensor Type	Maxtec MAX-250E galvanic fuel cell	Precision Medical 504877 Galvanic fuel cell
Expected Sensor Life	>900,000% O2 Hours	>1,000,000% O2 Hours
Alarm System	high/low alarms, flashing red LEDs, audible alarm beeper	high/low alarms, flashing red LEDs, audible alarm beeper
Low Alarm Range	18% - 99%	18% - 99%
High Alarm Range	19% - 99%	19% - 99%
Alarm Accuracy	exact to displayed alarm value	exact to displayed alarm value
Dimensions	3.5"[W] x 5.5"[H] x 1.5"[D] [89mm x 140mm x 38mm]	3.6"[W] x 5.4"[H] x 1.5"[D] [89mm x 140mm x 38mm]
Weight	approximately 0.92 lbs. [417g]	approximately 1.11 lbs. [430g]
Cable Length	10 ft. [3m]	10 ft. [3m]
Diverter Fitting	fits industry standard, 15 mm "T" adapter	fits industry standard, 15 mm "T" adapter

Summary of Performance Testing

The Precision Medical, Inc. Oxygen Monitor has successfully pass tests in the following areas;
Mechanical / Climatic
Operating, Temperature, and Humidity range of the PM5900 Oxygen Monitor
Precision Medical Test # 699-4

Device Performance:
Performance testing, Accuracy: +/- 1% of full scale @ constant temperature and pressure when calibrated at full scale.
Precision Medical Test # 699-1

Electromagnetic Emissions & Immunity Tests per IEC 60601-1-2:2004
Performed by Retlif Testing Laboratories for Precision Medical, Inc,
Test Report No. R-2915P

Soft ware validation:
Following guidance document:
General Principles of Software Validation, Final Guidance for Industry and FDA Staff.

Conclusions

In Summary, Precision Medical, Inc. has demonstrated that the Precision Medical, Inc. oxygen Monitor 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.

Risk Analysis

Precision Medical, Inc. is using International Standard ISO 14971 Medical Devices Application of Risk management to medical devices
Risk analysis will be completed for this device, before the final release.
This document will be updated and released as part of design control.

Design control

Precision Medical, Inc. is in compliance with 21 CFR 820.30 for design control. The design inputs/outputs matrix has been developed using form PMF 202.
These documents will be completed before the release of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 27 2007

Re: K063096
Trade/Device Name: Precision Oxygen Monitor
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: January 29, 2007
Received: February 1, 2007

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.

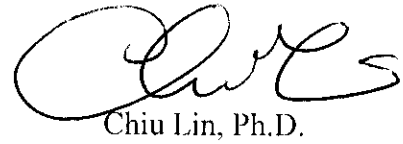
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 : K063096

Device Name: Precision Medical, Inc. Oxygen Monitor

Indications for Use:

The Precision Medical Oxygen Monitor is intended to measure the concentration of oxygen being delivered to the patient. The oxygen monitor is not intended as a life supporting device.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE

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