May 2, 2018

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

Re: K173807
Trade/Device Name: PM5950 Accu O2 Oxygen Analyzer
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL
Dated: March 12, 2018
Received: March 29, 2018

Dear James 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173807

Device Name
PM5950 Accu O2 Analyzer

Indications for Use *(Describe)*
The PM5950 Accu O2 Analyzer is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/oxygen mixture. The PM5950 Accu O2 Analyzer is not intended for use in continuous monitoring of oxygen delivery to patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Abbreviated 510K

Precision Medical, Inc. PM5950 Accu O2 Analyzer.

Revised 5/1/2018

1. Submitter Information

Submitter: Precision Medical, Inc.
300 Held Drive
Northampton, Pa.
18067

Facility Registration #: 2523148

Contact: James Parker
Quality Assurance Manager
Tel: (610)-262-6090 Extensions 2228
Fax: (610)-262-6080
Preparation Date: 11/17/2017 Revised Date: 5/1/2018

2. Device Name

Proprietary Name:	Accu O_2
Model number	PM5950
Common Name:	Oxygen Analyzer
Classification Name:	Analyzer, Gas, Oxygen, Gaseous-Phase
Classification Product Code:	CCL
Regulation number:	868.1720
Regulatory Status	Class II

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3. Predicate Device Equivalence

Precision Medical, Inc. is claiming substantial equivalence;

Primary Predicate Device; Substantial Equivalent:

Proprietary Name: $MAXO_2$®+AE
Model Number: R217P72
Manufactured by: Maxtec
2305 South 1070 West
Salt Lake City, Utah 84119

Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase
Premarket Notification #: K040484

Referenced Predicate Device;

Proprietary Name: Oxygen Monitor
Model Number: PM5900
Manufactured by: Precision Medical Inc.
300 Held Drive
Northampton, Pa 18067

Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase
Premarket Notification #: K063096

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4. Device Description (per 21 CFR 807.92)

General Description:

The PM5950 Accu O2 Analyzer measures and displays the amount of oxygen present, per-cent (%), in an air/oxygen breathing circuit.

Intended Use:

The PM5950 Accu O2 Analyzer is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/oxygen mixture. The PM5950 Accu O2 Analyzer is not intended for use in continuous monitoring of oxygen delivery to patient.

Indications for Use:

The PM5950 Accu O2 Analyzer is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/oxygen mixture. The PM5950 Accu O2 Analyzer is not intended for use in continuous monitoring of oxygen delivery to patient.

Contraindication:

The PM5950 Accu O2 Analyzer is not intended to actively monitor oxygen concentration or oxygen gas mixtures while being delivered to a patient. PM5950 Accu O2 Analyzer is not intended for use in a MRI environment.

Intended population \ Environment \ Conditions to be used for:

The PM5950 Accu O2 Analyzer is intended for use by trained professionals in Hospital, Home Care, Transport, and sub-acute institutions.

Prescription:

Caution! US. Federal Law restricts this device to sale by or on the order of a physician.

Principals of Operation:

Oxygen measurement is accomplished by placing an oxygen sensor into a breathing circuit. The sensor employs amperometric electrochemical measurement principles (e.g. galvanic fuel cell; lead oxygen battery). The sensor is a purchased and an existing legally marketed device.

The oxygen sensor is connected to the analyzer unit via an interface cable. The analyzer unit is battery powered. The analyzer is microprocessor based and interfaces with user push buttons and a LCD display. User push buttons allow the user to turn the unit on/off and to initiate calibration. The LCD provides indication of the per-cent oxygen measured, low battery indication and calibration required.

New Technologies/Features:

Neither new technologies nor features are incorporated

Configurations/Variations:

The PM5950 Accu O2 Analyzer will be provided in the configuration submitted; use of the Tee Adaptor is optional. No variations exist.

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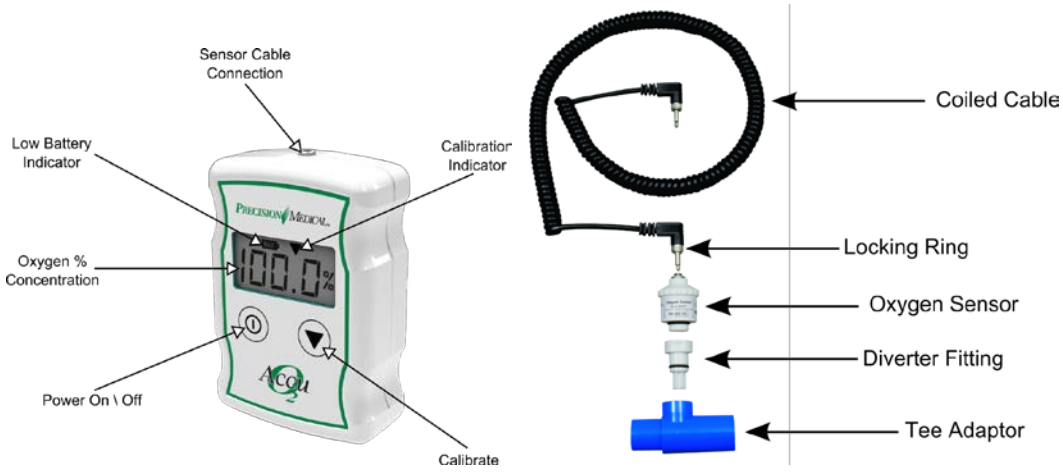
Key Functional Elements:



The device consists of four basic elements:

Base Device: The Base Device is a portable / mountable enclosure that houses the device electronic circuitry, a 3 ½" backlight display, membrane keypad, sensor interface jack and 2 AA Alkaline Batteries.

Extendible Cable: The extendible cable allows connection of the sensor the Base Device. The cable can be extended up to 10 feet from the side of the device.

Oxygen Sensor W/ Diverter Fitting: The Oxygen sensor is a galvanic fuel cell that generates a voltage output relative to the measured percent oxygen. The Oxygen Sensor (with diverter) is designed to fit industry standard, 15 mm I.D. "T" adaptors.

Tee Adaptor: The Tee adaptor is used to connect the Oxygen Sensor and Diverter Fitting to an oxygen pathway circuit.

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The device User interface

ITEM NAME	DESCRIPTION
Power Key 	The Power Key turns the Oxygen Analyzer ON and OFF.
Calibration Key 	Pressing the Calibration Key calibrates the Oxygen Analyzer with air or oxygen.
	Calibration Symbol - The calibration symbol is located on the display and is timed to activate when a calibration is necessary, or when a calibration is being conducted.
	Low Battery Symbol - The low battery indicator is located on the top of the display and is only activated when the voltage on the batteries is below a normal operating level.
- - -	Invalid Reading Symbol – failed sensor, failed cable , invalid calibration
100.0 %	Oxygen Concentration Reading. (0.0 to 100.0 %)

Technical Specifications

Base Device Specifications

Dimensions: (Analyzer without cable and sensor attached):

Depth: 1.30” (3.32 cm)
Width: 2.90” (7.30 cm)
Height: 4.00” (10.23 cm)
Cable Length: 10 ft. (3.05m) (fully extended)

Weight:

Device Weight: 0.35 lbs (5.60 oz / 0.15 kg)

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(Includes: analyzer, sensor, batteries and cable)

Operating Conditions:

Temperature:	50ºF - 113ºF (10ºC - 45ºC)
Altitude:	Sea Level to 8000 feet
Humidity:	0-95% non-condensing

Storage Conditions:

Temperature:	5°F - 122°F (0°C - 50°C)
Humidity:	0 - 95% non-condensing

Mode of Operation: Continuous

Electrical Classification: Internally powered Medical Electrical equipment

Diverter Fitting: Fits industry standard, 15 mm “T” adapter

Measurement Range: 0.0 - 100% Oxygen

Resolution: 0.1 %

Total Accuracy: ± 3.0% Actual Oxygen Level over full operating temperature range

Drift of Measurement: < +/-1% of full scale at constant temperature, pressure and humidity

Response Time: 90% of final value in less than 12 seconds at 77°F (25ºC)

Warm-up Time: Not required

Low Battery Indication: Low battery icon displayed

Patient Contact: None

Classifications:

Protection against electric shock:	Internally powered equipment
Protection against water:	IPX1 (Drip Proof)
Mode of Operation:	Continuous
Sterilization:	Non-Sterile Device
Flammable anesthetic mixture:	Not suitable for use in presence of a flammable anesthetic mixture

Sensor Specifications:

Sensor Type:	Galvanic oxygen sensor; Precision Medical PN 504877
Expected Sensor Life:	> 1,000,000 O2 % Hours

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5. Difference in technology from MAXO$_2$®+AE R217P72 (Predicate) to PM5950 Accu O$_2$ Analyzer

Technical difference	**MAXO$_2$®+AE** **(Primary Predicate)** K040484	**PM5900 Oxygen Monitor** **(Reference Predicate)** K063096	**PM5950 Accu O$_2$ Analyzer** K173807
Intended Use	The MAXO2+ is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/oxygen mixture. The MAXO 2+ is not intended for use in continuous monitoring of oxygen delivery to a patient.	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.	The PM5950 Accu O2 Analyzer is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/oxygen mixture. The PM5950 Accu O2 Analyzer is not intended for use in continuous monitoring of oxygen delivery to patient.
Calibration	After the device is turned on it will automatically calibrate to room air. The display should be stable and reading 20.9%.	The device requires manual calibration	The device requires manual calibration.

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6. Certifications

The PM5950 Accu O2 Analyzer was tested in compliance with FDA recognized consensus standard *ISO 80601-2-55:2011: Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors* and meets the requirements of the standard.

- IEC 60601-1:2005-12 Third Edition: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6:2013-3.1 Medical Electrical Equipment - Part 1 -6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
- IEC 61000-3-2 Edition 3.2:2009: Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current < 16A per phase)
- IEC 61000-3-3 Edition 2.0: 2008: Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in low-voltage supply systems, for equipment with rated current < 16A per phase and not subject to conditional connection
- IEC 61000-4-2 Edition 2.0 2008-12: Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test
- IEC 61000-4-3 Edition 3.2: 2010-04: Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-4 Edition 2.1: 2011-03: Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test
- IEC 61000-4-5 Edition 2.0: 2005-11: Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test
- IEC 61000-4-6 Edition 4.0: 2013-10: Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio frequency fields.
- IEC 61000-4-8 Edition 2.0: 2009-09: Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
- IEC 61000-4-11Edition 2.0: 2004-03: Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques –Voltage dips, short interruptions and voltage variations immunity test

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7. Table of Comparisons to Predicate Device

Specifications	R217P72 MAXO$_2$®+AE (Primary Predicate) K040484	PM5900 Oxygen Monitor (Referenced Predicate) K063096	PM5950 Accu O_2 Analyzer
Weight (device only)	0.4 lbs. (170g)	1.11 lbs (0.50 kg)	0.33 Lbs. (150g)
Dimensions (inches):			
Length	1.5”	1.72”	1.3”
Height	4.0”	5.44”	4.0”
Width	3.0”	3.56”	2.9”
Electrical Requirements	2, AA Alkaline batteries (2 x 1.5 Volts)	4, AA Alkaline batteries (4 x 1.5 Volts)	2, AA Alkaline batteries (2 x 1.5 Volts)
Operating temp range	15˚C - 40˚C (59˚F - 104˚F)	10ºC - 45ºC (50ºF- 113ºF)	10ºC - 45ºC (50ºF- 113ºF)
Storage temp range	-15˚C - 50˚C (5˚F - 122˚F)	-15°C- 50°C (5°F - 122°F)	-0°C- 50°C (32°F - 122°F)
Humidity	0 - 95% non-condensing	0 - 95% non-condensing	0 - 95% non-condensing
Mode of Operation:	Continuous	Continuous	Continuous
Electrical Classification:	Internally powered Medical Electrical equipment	Internally powered Medical Electrical equipment	Internally powered Medical Electrical equipment
Protection against water:	IPX1	IPX1	IPX1
Measurement Range:	0.0 – 100.0%	0.0 – 100.0%	0.0 – 100.0%
Resolution:	0.1 Increments	0.1 Increments	0.1 Increments
Total Accuracy:	± 3% Actual Oxygen Level over full operating temperature range	± 3% Actual Oxygen Level over full operating temperature range	± 3% Actual Oxygen Level over full operating temperature range

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Specifications	R217P72 MAXO$_2$®+AE (Primary Predicate) K040484	PM5900 Oxygen Monitor (Referenced Predicate) K063096	PM5950 Accu O_2 Analyzer
Response Time:	90% of final value in approximately 15 seconds at 23°C	90% of final value in less than 12 seconds at 77°F (25ºC)	90% of final value in less than 12 seconds at 77°F (25ºC)
Warm-up Time:	none required	none required	none required
Low Battery Indication:	Low battery icon displayed on graphics screen	Low battery icon displayed on graphics screen	Low battery icon displayed on graphics screen
Interface	Two button On\Off, Cal	Two button On\Off, Cal	Two button On\Off, Cal
Sensor Type	Maxtec MAX 13/CAG-13 Galvanic fuel sensor (0-100%)	Maxtec MAX 13/CAG-13 Galvanic fuel sensor (0-100%)	Maxtec MAX 13/CAG-13 Galvanic fuel sensor (0-100%)
Sensor Life	2-years in typical applications	2-years in typical applications	2-years in typical applications
Drift of Measurement:	< +/-1% of full scale at constant temperature, pressure and humidity	< +/-1% of full scale at constant temperature, pressure and humidity	< +/-1% of full scale at constant temperature, pressure and humidity
Alarms	None	high/low alarms, respective flashing red LEDs and graphics, 68db audible alarm @ 1 meter	None

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8. Declarations of Conformity and Summary Reports

The following list is high level summary of the tests that were used to demonstrate substantial equivalence.

IEC 60601-1 3rd + A1 (60601_1k) Report CB_PM5950

IEC 60601-1-2 EMC Test Report_PM5950

IEC 60601-1-6 _ IEC 62366 COMPLIANCE Report_PM5950

ISO 80601-2-55_2011 Compliance Report_PM5950

IEC 60068-2-27& 64 Shock & Vibration Test_PM5950

ISO 14971 Risk Management File PM5950_101617

The following list is a summary of the tests performed by Precision Medical Inc. that were used to demonstrate substantial equivalence.

811-1	Ingress of water ISO 80601-2-55 (201.11.6.5)
811-2	Oxygen Analyzer Measurement Accuracy ISO 80601-2-55:2011 (201.12.1.101,102,104)
811-3	Shock & Vibration Testing for PM5950 Oxygen Analyzer ISO 80601-2-55:2011 (201.15.3.5.101)
811-4	EMC Testing for PM5950 Oxygen Analyzer ISO 80601-2-55:2011 (202.6.2)
811-6	Oxygen Analyzer - Leakage to Atmosphere ISO 80601-2-55:2011 (201.102)
811-7	Operating and Storage Temp
811-7A	Operating and Storage Temperature of the PM5950 O2 Analyzer Review
811-8	Software Validation of PM5950
811-10	Effects of Elevation-Barometric Pressure Change
811-11	Drop Test of PM5950 in Shipping Box
811-12	Performance Test
811-13	Process Validation of the PM5950
811-15	Life Expectancy of the Keypad
811-16	Label Durability
811-17	Cleaning and disinfection of ME Equipment of ME Systems

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811-18 Compatibility with substances used with ME Equipment

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for PM5950 Oxygen Analyzer was considered to be "Moderate" because a failure of the Device Software could result in Minor Injury to a patient, and a malfunction of a latent design flaw in the Device Software may lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

9. Conclusions

Precision Medical's PM5950 Accu O2 Analyzer operates in the same manner as the Primary Predicate Device: MAXO2+AE. The Referenced Predicate Device, Precision Medical PM5900, is only presented to indicate no new technologies or features have been developed or incorporated. Compliance testing indicates the technical specifications presented have been achieved. The PM5950 Accu O2 Analyzer has the same Intended/Indicated use as the Primary Predicate Device. Precision Medical's PM5950 Accu O2 Analyzer has the same therapeutic use. Precision Medical's PM5950 Accu O2 Analyzer is substantially equivalent to the Primary Predicate Device.

The Precision Medical PM5900 Oxygen Monitor was used a reference predicate device as the same applied consensus standard was used for compliance testing (ISO 80601-2-55:2011). The significant difference between the Precision Medical, Inc PM5900 Oxygen Monitor and PM5950 Accu O2 Analyzer is that the Oxygen Monitor may be used to continuously monitor and contains alarms.

The PM5950 Accu O2 Analyzer is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/oxygen mixture. The PM5950 Accu O2 Analyzer is not intended for use in continuous monitoring of oxygen delivery to patient.

In summary, Precision Medical, Inc had demonstrated that the Precision Medical, Inc PM5950 Accu O2 Analyzer is as safe and as effective as the predicate device. The combined non-clinical testing and analysis of results provides assurance that the device meets the specifications and is as safe, as effective, and performs as well as or better than the legally marketed predicate MAXO2+AE device..