August 11, 2025

Bio-Med Device, Inc.
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K251245
Trade/Device Name: OxyMinder Pro (10310)
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL, CAP
Dated: June 30, 2025
Received: July 1, 2025

Dear Paul Dryden:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251245

Please provide the device trade name(s).

OxyMinder Pro (10310)

Please provide your Indications for Use below.

The OxyMinder Pro is an oxygen monitor with integrated pressure monitoring intended for continuous monitoring of the concentration of oxygen and pressure being delivered to patients ranging from newborns to adults. This device can be used in the hospital and subacute settings The monitor is not intended as a life supporting device or for diagnostics.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

Date Prepared: 1-Jul-25

Bio-Med Devices, Inc.
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Tel - 203-458-0202

Official Contact: Ken K Close - Regulatory Affairs Manager

Submission Correspondent: Paul Dryden
ProMedic, LLC
St. Petersburg, FL 33704

Proprietary or Trade Name: OxyMinder Pro

Common/Usual Name: Oxygen gas analyzer
Classification CFR: 21 CFR 868.1720
Classification Code: CCL
Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase

Classification CFR: 21 CFR 868.2600
Classification Code: CAP
Classification Name: Monitor, Airway Pressure

Predicate Device: Maxtec MaxO2ME+p (K221734)
Common/Usual Name: Oxygen gas analyzer
Classification CFR: 21 CFR 868.1720
Classification Code: CCL, CAP
Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase

Reference Device: Bio-med Devices, OxyMinder (K213948)
Common/Usual Name: Oxygen gas analyzer
Classification CFR: 21 CFR 868.1720
Classification Code: CCL
Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase

Device Description:
The OxyMinder Pro is an oxygen and pressure monitor capable of measuring the oxygen concentration from 18 to 100% (cleared under K213948) and pressure from 0 to 60 cmH2O (subject of this submission) that for convenience can be mechanically mounted on to the cleared blender.

The pressure is measured via a disposable pressure tubing that connects from the monitor to an adapter placed in the patient circuit. This sampling line is identical to that cleared in predicate Maxtec K221734. We have only updated the labeling to reflect the name of the sponsor.

As indicated the oxygen monitoring portion has been previously cleared, K213948. It utilizes a cleared oxygen sensor which outputs a voltage to determine the concentration of oxygen. The OxyMinder Pro calibrates at ambient air (21%) and 100% oxygen. The OxyMinder Pro is software controlled. Again, the oxygen monitoring feature and functions are unchanged and previously cleared under reference K213948.

The new pressure monitoring feature utilizes a pressure sensor which measures the pressure within a patient circuit. There is a disposable pressure tubing that connects between the patient circuit and the pressure sensor.

Indications for Use:
The OxyMinder Pro is an oxygen monitor with integrated pressure monitoring intended for continuous monitoring of the concentration of oxygen and pressure being delivered to patients ranging from newborns to adults. This device can be used in the hospital and subacute settings. The monitor is not intended as a life supporting device or for diagnostics.

Patient Population:
The population may be newborns to adults consistent with the predicate and reference

Environments of use:
Hospital and subacute settings.

We present the proposed device vs. the predicate in the **Table** below.

Attributes	Subject Bio-Med Devices OxyMinder Pro®	Predicate Maxtec MaxO₂ME+p K221734	Reference Bio-Med Devices OxyMinder K213948	Differences
Indications for Use	The OxyMinder Pro is an oxygen monitor with integrated pressure monitoring intended for continuous monitoring of the concentration of oxygen and pressure being delivered to patients ranging from newborns to adults. This device can be used in the hospital and subacute settings The monitor is not intended as a life supporting device or for diagnostics.	The MaxO2 ME+p is an oxygen monitor with integrated pressure monitoring intended for continuous monitoring of the concentration of oxygen and pressure being delivered to patients ranging from newborns to adults. It can be used in the hospital and subacute settings. The MaxO2 ME+p is not intended as a life-supporting device or life sustaining device.	The OxyMinder is intended for continuous monitoring of the concentration of oxygen being delivered to patients ranging from newborns to adults. This device can be used in the hospital and subacute settings. The monitor is not intended as a life supporting device or for diagnostics.	Similar to predicate for both oxygen and pressure. Similar to reference for oxygen monitoring.
Environments of Use	Hospital and subacute settings	Hospital and sub-acute settings	Hospital and subacute settings.	Similar Both devices are MRI Unsafe
Patient Population	newborns to adults	newborns to adults	newborns to adults	Similar (based on indications)
Oxygen sensing technology	Galvanic cell	Galvanic cell	Galvanic cell	Similar
Pressure Sensing technology	Pressure transducer with pressure tubing connected to the patient circuit	Pressure transducer with pressure tubing connected to the patient circuit	Pressure transducer with pressure tubing connected to the patient circuit	Similar
Pressure tubing	Disposable	Disposable	N/A	Identical tubing to predicate
Measurement Range	Oxygen: 18% – 100% O_2 Pressure:.0 to 60.0 cmH_2O	Oxygen: 0.0 to 100% O_2 Pressure: -15.0 to 60.0 cmH_2O	Oxygen: 18% – 100% O_2	The subject device is only intended for use with an air/oxygen blender which will not deliver oxygen below 18% and only positive pressures, thus this is the minimum range for the OxyMinder Pro®. The measurable ranges are the same as the reference K213948 for oxygen. Pressure is similar.
Resolution	Oxygen: O_2 % is displayed to nearest whole integer. Pressure: 0.1 cmH_2O	Oxygen: 0.1% O_2 Pressure: 0.5 cmH_20	Oxygen: O_2 % is displayed to nearest whole integer.	The OxyMinder Pro® verifies the proper oxygen concentration from the air/oxygen blender. The resolution of the air/oxygen blender knob is in 10% increments. The predicate can be used as a standalone oxygen monitor where the resolution of 0.1% is beyond the accuracy of the sampling cell.
Accuracy and Linearity	Oxygen ±1% of full scale at constant temperature and pressure. Pressure: ±0.5 cmH_2O	Oxygen: ±1% of full scale at constant temperature, RH and pressure when calibrated at full scale. Pressure: ±1.0 cmH_2O	Oxygen ±1% of full scale at constant temperature and pressure.	Similar

510(k) Summary
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Attributes	Subject Bio-Med Devices OxyMinder Pro®	Predicate Maxtec MaxO₂ME+p K221734	Reference Bio-Med Devices OxyMinder K213948	Differences
Total Accuracy	±2.5% Actual oxygen level over the full operating temperature range	±3% Actual oxygen level over full operating temperature range	±2.5% Actual oxygen level over the full operating temperature range	Similar
Response Time	90% of final value in approximately 6 seconds	90% of final value in approx.. 15 seconds at 23ºC	90% of final value in approximately 6 seconds	Similar response time for oxygen changes
Warm-up Time	None required	None required	None required	Similar
Operating Temperature	0° - 50° C [32° - 122° F]	15ºC – 40ºC (59ºF – 104ºF)	0° - 50° C [32° - 122° F]	Similar
Storage Temperature	0° - 40° C [32° - 104° F]	-15ºC – 50ºC (5ºF – 122ºF)	0° - 40° C [32° - 104° F]	Similar
Atmospheric Pressure	700 – 1010 mBars	800 – 1012 mBars	700 – 1010 mBars	Similar
Humidity	5 - 95%	0-95% (non-condensing)	5 - 95%	Similar
Power requirements	External DC and internal rechargeable lithium-ion battery	4 – AA Alkaline batteries	External DC and internal rechargeable lithium-ion battery	Subject device includes external power and rechargeable, appropriate for its intended use.
Battery Life	16 hours at 100% brightness.	Approx. 5000 hours, typical use	16 hours at 100% brightness.	Subject device is primarily used stationary (connected to air / oxygen blender) where external power is available.
Low Battery Indications	On-screen icon & audible alarm	"LOWBAT" icon on LCD display	On-screen icon & audible alarm	Similar
Oxygen Sensor Type	Analytical Industries PSR-11-917-J10 (510(k K952736)	Maxtec MAX-550E galvanic fuel cell	Analytical Industries PSR-11-917-J10 (510(k K952736)	Similar sensor to reference
Expected Oxygen Sensor Life	> 900,000 %O_2 Hours	> 1,500,000 %O_2 Hours, over 2 years typical application	> 900,000 %O_2 Hours	The sensor manufacturer provides the following specifications. 902,880 %O_2 Hours = 60 months in the following conditions: In air (20.9% O_2) at 25ºC and 1 atm. Changes in Oxygen levels, temperature and pressure produce a proportional change in output and an inversely proportional change in expected life.
Alarm Systems	Connect AC power (external power disconnected when battery is low) Low O_2 alarm Low Pressure alarm High O_2 alarm High Pressure alarm > 60 cmH_2O alarm	High/Low alarms, flashing yellow LEDs Nominal 975 Hz audio buzzer (IEC 60601-1-8)	Connect AC power (external power disconnected when battery is low) Low O_2 alarm Low Pressure alarm High O_2 alarm High Pressure alarm > 60 cmH_2O alarm	Similar More alarm functionality on subject device but is similar to the reference.

Attributes	Subject Bio-Med Devices OxyMinder Pro®	Predicate Maxtec MaxO₂ME+p K221734	Reference Bio-Med Devices OxyMinder K213948	Differences
	Recalibrate O_2 sensor Replace O_2 sensor Low battery		Recalibrate O_2 sensor Replace O_2 sensor Low battery	
Low Oxygen Alarm Range	18% - 100% (>1% lower than high alarm)	15% - 99% (>1% lower than high alarm)	18% - 100% (>1% lower than high alarm)	Similar but the same as the reference
Low Pressure Alarm Range	Off – 55 cmH_2O (> 1cmH_2O lower than high pressure alarm)	(--) Off, 1-30 cmH_2O	N/A	Similar
High Oxygen Alarm Range	19% - 105% (>1% lower than low alarm)	16% - 100% (>1% higher than low alarm)	N/A	Similar
High Pressure Alarm Range	5 – 60 cmH_2O (>1 cmH_2O higher than low pressure alarm)	1-60 cmH_2O, Off (--)	N/A	Similar
Alarm Accuracy	Exact to display alarm value	Exact to display alarm value	Exact to display alarm value	Similar
Pressure Alarm Resolution	1 cmH_2O	1 cmH_2O	N/A	Similar
Dimensions	7.86" W x 8.12" H x 4.39" D	3.6”(W) x 5.8”(H)x1.2”(D)	7.86" W x 8.12" H x 4.39" D	Similar
Weight	1.5 lbs.	Approx. 1.01 lbs.	1.5 lbs.	Similar
Accessories	Power Adaptor Mounting Bracket Galvanic cell pressure sampling line	Diverter Tee adapter (15 mmm x 22 mm fittings) Mounting brackets DC power adapter	Power Adaptor Mounting Bracket Galvanic cell	The OxyMinder Pro® oxygen sampling is a sidestream off the patient gas pathway through a separate port and manifold than that which is used to deliver the gas to the patient.
AutoPurge	The OxyMinder Pro® has a scheduled purge feature to allow an automated purge of the gas sources connected to the blender when the device is not in use. This allows purging of equal amounts of flow of oxygen and air from the gas sources, ensuring that any contamination to the air and oxygen sources caused by backflow through the blender will be purged	Not available	The OxyMinder Pro® has a scheduled purge feature to allow an automated purge of the gas sources connected to the blender when the device is not in use. This allows purging of equal amounts of flow of oxygen and air from the gas sources, ensuring that any contamination to the air and oxygen sources caused by backflow through the blender will be purged	This feature is not part of the patient performance or risk analysis. It is used when the blender is left connected to the gas sources and not in use. This feature is identical to K213948

Substantial Equivalence Discussion and Rationale

Table above compares the key features of the proposed device with the identified predicate – Maxtec MaxO2ME+p (K221734) and the reference Bio-Med Devices OxyMinder (K213948) for the oxygen measurement features. The comparison demonstrates that the proposed device with the pressure monitoring feature does not raise any new concerns of risk and can be found to be substantially equivalent.

Indications for Use –
The indications for use are similar for the proposed device when compared to the predicate and reference devices.
Discussion – Both devices are indicated for use for monitoring oxygen levels and pressure. Both devices have similar range and accuracy specification. Both devices have similar alarm functionality. Any difference does not raise new concerns of risk compared to the predicate.

Technology and construction –
The technology is similar to the predicate device using a galvanic fuel cell for oxygen measurement and a pressure transducer for pressure measurement technology.
Discussion – There are no differences that raise new concerns of safety or effectiveness.

Environment of Use –
The environments of use are similar to predicate which are clinical settings.
Discussion – The environments of use are similar.

Patient Population –The patient population of the predicate device is newborns to adults as is the subject device .
Discussion – The subject and predicate have identical patient populations

Non-Clinical Testing Summary –
Bench testing was performed that includes:
Shelf-life / Aging
Software Verification and Validation
Safety and ElectroMagnetic Compatibility
IEC 60601-1
IEC 60601-1-2
IEC 60601-1-8
Oxygen IEC 80601-2-55
Auto-purge
Oxygen Accuracy with Blender
Battery Charge Time
Battery Discharge Time
Battery Alarm Times

Discussion – The test results met the applicable standards and are similar to the reported performance of the predicate device.

Biocompatibility –
The only patient contacting materials is the pressure tubing line which has been sourced from the predicate which was evaluated and cleared under K221734. The subject device has the same indications for use, patient population and environment of use.
Discussion – As the subject device has the same patient contacting materials (indirect or gas pathway) and the sponsor is sourcing the identical disposable from the predicate, no additional biocompatibility testing is required.

Discussion of Differences –
There are no differences which raise new or different risk concerns when compared to the predicate or reference devices. Differences are discussed in Table 1. The subject device is intended to specifically be used with an air / oxygen blender. A secondary feature of the OxyMinder Pro® is the auto-purge feature, which was cleared under K213948. This feature mitigates gas line contamination in the hospital medical gas pipelines due to minimal backflow when air/oxygen blender is left connected and unused for extended periods of time. The predicate device is not limited to use with an air / oxygen blender.

The performance testing has demonstrated that the subject device met the applicable standard performance requirements. The above table plus the risk analysis did not identify any new or different risks compared to the predicate.

Substantial Equivalence Conclusion
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.