March 17, 2022

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

Re: K213948
Trade/Device Name: OxyMinder
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL
Dated: February 25, 2022
Received: February 28, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213948

Device Name
OxyMinder

Indications for Use *(Describe)*
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.

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

Date Prepared: 17-Mar-22

Bio-Med Devices, Inc.
61 Soundview Rd
Guilford, CT 06437 USA
Tel - 203-458-0202

Official Contact: Ken K Close - Regulatory Affairs Manager

Submission Correspondent: Paul Dryden
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, FL 33704

Proprietary or Trade Name: OxyMinder

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

Predicate Device: Maxtec MaxO2ME (K153659)
Common/Usual Name: Oxygen gas analyzer
Classification CFR: 21 CFR 868.1720
Classification Code: CCL
Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase
Class: Class II

Device Description:
The OxyMinder is an air / oxygen blender mounted oxygen monitor capable of measuring the oxygen concentration from 18 to 100%. A Bio-Med specified oxygen sensor mounted to the blender outputs a voltage which is used by the OxyMinder to determine the concentration of oxygen. The OxyMinder calibrates at ambient air (21%) and 100% oxygen. The OxyMinder is software controlled.
To measure the gas mixture of the blender the OxyMinder takes a sample of the gases to the sensor through a separate port and manifold which is separate from the gas pathway to the patient. This sample is then exhausted to the room. The OxyMinder sampling stream is not part of the gas pathway to the patient.

The OxyMinder is used for continuous monitoring of the concentration of oxygen delivered to patients via air oxygen blenders. The monitor provides the following features:

- Continuously displays the concentrated Oxygen level delivered to a patient.
- Accepts user inputs via touch screen or button (power button).
- Provides visual alarm messages, and audible alarms.
- Displays the current alarm setting levels (High and Low O_2 alarms).
- Provides on-screen configuration tools such as O_2 sensor calibration, touchscreen calibration, audio test, etc.
- Monitors and displays the battery level and power source.
- Ensures clean hospital airlines by automatically purging system periodically.

The OxyMinder is designed to be mounted to a Bio-Med Devices air / oxygen blender via a manifold that houses the oxygen sensor and a solenoid.

In addition to the primary function of monitoring oxygen concentration, the OxyMinder provides an automatic gas supply line purge function.

Indications for Use:
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.

Patient Population:
The monitor is not population dependent. As it fits on a cleared Bio-Med blender, the blender has established the population.

Environments of use:
Hospital and subacute settings.

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

Attributes	Predicate Maxtec MaxO$_2$ME (K153659)	Subject Bio-Med Devices OxyMinder	Differences
Indications for Use	The MaxO$_2$ME oxygen monitor is intended for continuous monitoring of the concentration of oxygen being delivered to patients ranging from newborns to adults. It can be used in the pre-hospital, hospital and sub-acute settings. The MaxO$_2$ME is not intended as a life supporting 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
Environments of Use	Pre-hospital, hospital and sub-acute settings	Hospital and subacute settings	Similar Subject device does not include pre-hospital which is not in its intended use Both devices are MRI Unsafe
Patient Population	newborns to adults	newborns to adults	Similar (based on indications)
Measurement Range	0.0 to 100%	18% – 100% O_2	The subject device is only intended for use with an air/oxygen blender which will not deliver oxygen below 18%, thus this is the minimum range for the OxyMinder.
Resolution	0.1%	Displayed to nearest whole integer	The OxyMinder 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	$\pm$1% of full scale at constant temperature, RH and pressure when calibrated at full scale	±1.0% of full scale at constant temperature and pressure	Similar
Total Accuracy	$\pm$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 approx.. 15 seconds at 23ºC	90% of final value in approximately 6 seconds	Similar
Warm-up Time	None required	None required	Similar
Operating Temperature	15ºC – 40ºC (59ºF – 104ºF)	0° - 50° C [32° - 122° F]	Similar

Attributes	Predicate Maxtec MaxO$_2$ME (K153659)	Subject Bio-Med Devices OxyMinder	Differences
Storage Temperature	-15ºC – 50ºC (5ºF – 122ºF)	0° - 40° C [32° - 104° F]	Similar
Atmospheric Pressure	800 – 1012 mBars	345 – 2068 mBars	Similar
Humidity	0-95% (non-condensing)	5 - 95%	Similar
Power requirements	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	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	"LOWBAT" icon on LCD display	On-screen icon & audible alarm	Similar
Sensor Type	Maxtec MAX-550E galvanic fuel cell	Analytical Industries PSR-11-917-J10 (510(k K952736)	Similar
Expected Sensor Life	> 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% O2) 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	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 O2 alarm High O2 alarm Recalibrate O2 sensor Replace O2 sensor Low battery	Similar More alarm functionality for the subject device

Attributes	Predicate Maxtec MaxO$_2$ME (K153659)	Subject Bio-Med Devices OxyMinder	Differences
Low Oxygen Alarm Range	15% - 99% (>1% lower than high alarm)	18% - 100% (>1% lower than high alarm)	Similar
High Oxygen Alarm Range	16% - 99% (>1% higher than low alarm)	19% - 105% (>1% lower than low alarm)	Similar
Alarm Accuracy	Exact to display alarm value	Exact to display alarm value	Similar
Dimensions	3.6”(W) x 5.8”(H)x1.2”(D)	7.86" W x 8.12" H x 4.39" D	Similar
Weight	Approx. 0.89 lbs.	1.5 lbs.	Similar
Materials in Gas Pathway	The oxygen sensor	No materials in the patient gas pathway	The OxyMinder sampling stream is sidestream off the patient gas pathway through a separate port and manifold than that which is used to deliver the gas to the patient.
Accessories	Diverter Tee adapter (15 mmm x 22 mm fittings) Galvanic cell Mounting brackets DC power adapter	Galvanic cell Power Adaptor Mounting Bracket	Similar except the oxygen sampling gas stream is not in the patient gas pathway.
AutoPurge	Not available but has a manual purge when the blender is on.	The OxyMinder 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.

Substantial Equivalence Discussion and Rationale

The table above compares the key features of the proposed device with the identified predicate – Maxtec MaxO2ME (K153659). The comparison demonstrates that the proposed devices 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 device.
Discussion – Both devices are indicated for use for monitoring oxygen levels. Both devices have equivalent range and accuracy specification. Both devices have similar alarm functionality. Minor difference does not raise different concerns of risk than the predicate.

Technology and construction –
The technology is identical to the predicate device using a galvanic fuel cell for measurement technology.
Discussion – The differences in how the gas is measured and additional features do not raise different concerns of safety or effectiveness compared to the predicate.

Environment of Use –
The environments of use are similar to predicate which are clinical settings.
Discussion – The subject device does not include pre-hospital which is in keeping with its use with the compatible Bio-Med Devices air / oxygen blender.

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 –

A series of non-clinical performance / bench testing was performed that includes:

- Shelf-life / Aging
- Software Verification and Validation
- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-8
- IEC 80601-2-55
- Auto-purge functionality
- Oxygen Accuracy with Blender
- Battery Performance Testing

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

Biocompatibility –
The predicate device has materials in the gas pathway, the subject device does not.
Discussion – As the subject device has not patient contacting materials (indirect or gas pathway) biocompatibility testing is not applicable

Discussion of Differences –

There are no significant differences in critical function between the proposed device and the predicate device. The subject device is intended to specifically be used with only a Bio-Med Devices cleared air / oxygen blender. A secondary feature of the OxyMinder is the auto-purge feature, which 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 only an air / oxygen blender, has a manual purge feature when it is in use, and can be used in the pre-hospital environment.

The performance testing has demonstrated that the subject device met the applicable standard performance requirements. The above table plus the risk analysis do 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 be substantially equivalent.