April 1, 2023

Maxtec, LLC
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K221734
Trade/Device Name: Maxtec – MaxO2 ME+p
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL, CAP
Dated: February 28, 2023
Received: February 28, 2023

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,

James J. Lee -S

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia 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)*
K221734

Device Name

MaxO2 ME+p

Indications for Use *(Describe)*

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 sub-acute settings. The MaxO2 ME+p is not intended as a life-supporting device or life sustaining device.

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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Date Prepared: 31-Mar-23

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Official Contact: Sidra Hankins - VP of QARA

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: Maxtec – MaxO2 ME+p

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

Primary Predicate Device: Maxtec – MaxO2 ME - K153659
Secondary Predicate Device: Caradyne – Criterion 40 - K992101

Device Description:
The MaxO2 ME +p is a battery powered oxygen and pressure monitor in a single assembly. The oxygen monitor measures the oxygen concentration from a gas source, displays these measured concentrations, and provides user selectable high and low oxygen alarms. It also the user to monitor pressure simultaneously and provides user selectable high and low pressure alarms.

The MaxO2ME+p comply with the following standards:

- AAMI ANSI ES 60601-1: 2005 + A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- AIM Standard 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- IEC 60601-1-8 2006+A1 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 80601-2-55 2018 Particular requirements for the basic safety and essential performance of respiratory gas monitors

Indications for Use:
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 sub-acute settings.

The MaxO2 ME+p is not intended as a life-supporting device or life sustaining device.

Patient Population:
Newborns to Adult patients for MaxO2 ME+p.

Environments of use:
MaxO2 ME+p: Hospital and sub-acute settings.

We present the proposed device vs. the predicate and reference in the **Tables** below.

Table 1 - Comparison of the proposed device vs. the Primary Predicate MaxO2 ME

Attributes	Proposed $MaxO_2ME+p$	Primary Predicate Maxtec – MaxO2 ME K153659
Indications for Use	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 sub-acute settings.	The $MaxO_2ME$ 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 $MaxO_2ME$ is not intended as a life supporting device.
New indication	Adding pressure monitoring	N/A
Environments of Use	Hospital and sub-acute settings	Pre-hospital, hospital and sub-acute settings
Patient Population	Newborns to adults	Newborns to adults
Oxygen % Range	0.0 to 100%	0.0 to 100%
Oxygen Resolution	0.1%	0.1%
Accuracy and Linearity	±1% of full scale at constant temperature, RH and pressure when calibrated at fill scale	±1% of full scale at constant temperature, RH and pressure when calibrated at fill 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 approx. 15 seconds at 23ºC	90% of final value in approx. 15 seconds at 23ºC
Warm-up Time	None required	None required
Operating Temperature	15ºC – 40ºC (59ºF – 104ºF)	15ºC – 40ºC (59ºF – 104ºF)
Storage Temperature	-15ºC – 50ºC (5ºF – 122ºF)	-15ºC – 50ºC (5ºF – 122ºF)
Atmospheric Pressure	800 – 1013 mBars	800 – 1012 mBars
Humidity	0-95% (non-condensing)	0-95% (non-condensing)
Power requirements	4 – AA Alkaline batteries	4 – AA Alkaline batteries
Battery Life	Approx. 5000 hours, typical use	Approx. 5000 hours, typical use
Low Battery Indications	Battery indicator on LCD display	"LOWBAT" icon on LCD display
Sensor Type	Maxtec MAX-550E galvanic fuel cell	Maxtec MAX-550E galvanic fuel cell
Expected Sensor Life	> 1,500,000 $\%O_2$ Hours, over 2 years typical application	> 1,500,000 $\%O_2$ Hours, over 2 years typical application
Alarm Systems	High/Low alarms, flashing yellow LEDs Nominal 975 Hz audio buzzer (IEC 60601-1-8)	High/Low alarms, flashing yellow LEDs Nominal 975 Hz audio buzzer (IEC 60601-1-8)
Low Oxygen Alarm Range	15% - 99% (>1% lower than high alarm)	15% - 99% (>1% lower than high alarm)
High Oxygen Alarm Range	16% - 100% (>1% higher than low alarm)	16% - 99% (>1% higher than low alarm)

Attributes	Proposed MaxO₂ME+p	Primary Predicate Maxtec – MaxO2 ME K153659
Accuracy	Exact to display alarm value	Exact to display alarm value
Dimensions	3.6”(W) x 5.8”(H)x1.2”(D)	3.6”(W) x 5.8”(H)x1.2”(D)
Weight	Approx. 1.01 lbs.	Approx. 0.89 lbs.
Accessories	Diverter Tee adapter (15 mm x 22 mm fittings) Pressure monitoring line Mounting brackets DC power adapter	Diverter Tee adapter (15 mm x 22 mm fittings) Mounting brackets DC power adapter
Standards	ES 60601-1 IEC 60601-1-2 IEC 60601-1-8 ISO 80601-2-55	ES 60601-1 IEC 60601-1-2 IEC 60601-1-8 ISO 80601-2-55
Features related to pressure monitoring discussed in Table 2		

Table 2 - Comparison of the proposed device vs. the predicate.

Attributes	Proposed MaxO₂ME+p	Secondary Predicate Caradyne Criterion 40 K992101
New indication	Pressure monitoring	Pressure monitoring
Indications for Use	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 sub-acute settings.	Intended to measure airway pressure when used with positive pressure devices. The device alarms when the airway pressure falls outside the user selected high and low alarm limits and displays peak pressure and real-time airway pressures. It may be used with positive pressure devices which do not include pressure measurement capabilities, e.g., resuscitation bags or basic ventilators, or as an independent backup pressure monitor for devices with pressure measurement capabilities. The device has been designed for stationary and intra-institution transport only.
Environments of Use	Hospital and sub-acute settings	Hospital, sub-acute institutions, home care
Patient Population	Newborns to adults	Not specified
Technology	Microprocessor controlled device	Microprocessor controlled device
Pressure sensor type	Solid-state pressure transducer	Solid-state pressure transducer

Displayed information	Low pressure alarm setting High pressure alarm setting Alarm silence indicator Power supply indicator Average (mean) pressure Audible and visual alarm	Low pressure alarm setting High pressure alarm setting Status of alarm silence and time remaining Peak pressure Real-time pressure Power source and status Audible and visual alarm
Attributes	**Proposed** **MaxO$_2$ME+p**	**Secondary Predicate** **Caradyne Criterion 40** **K992101**
Pressure Measurement Range	-15 to +60 cmH$_2$O	Up to +99 cmH$_2$O
Pressure Resolution	1 cmH$_2$O	1 cmH$_2$O
Display resolution	0.5 cmH$_2$O	0.5 cmH$_2$O
Total Accuracy	$\pm$ 1 cmH$_2$O	$\pm$ 1 cmH$_2$O
Low alarm range	1 – 30 cmH$_2$O	1 – 20 cmH$_2$O
High alarm range	1 – 60 cmH$_2$O	5 - 99 cmH$_2$O
Alarm delay	3 seconds (pressure only)	1-20 sec
Zero calibration	Yes	Yes
System interface	Disposable tubing with filter and with or without Nafion connects to in-line tee or face mask	Disposable tubing with filter connects to in-line tee or face mask
Operating Temperature	15ºC – 40ºC, 0-95% RH	15ºC – 45ºC, 15-95% RH
Storage Temperature	-15ºC – 50ºC @ 95% RH	-40ºC – 60ºC@ 95% RH
Atmospheric Pressure	800 – 1013 mBars	No specified
Power requirements	4x – AA alkaline batteries	AC / DC
Battery Life	5000 hours	Up to 24 hours
Biocompatibility	Externally communicating, tissue, permanent	Externally communicating, tissue, permanent
Standards	ES 60601-1 IEC 60601-1-2 AIM Standard 7351731:2017 IEC 60601-1-8 ISO 80601-2-55	IEC 601-1 IEC 601-1-2
Features related to oxygen monitoring discussed in Table 1		

Substantial Equivalence Discussion and Conclusion

As discussed the only new feature is the addition of the pressure monitoring feature. As all other features and performance are identical to the reference, we will only discuss the new pressure monitoring feature.

Indications for Use
The subject device, MaxO2 ME+p, have added the feature of measuring and monitoring pressure. The indications are similar to the primary predicate K152659 Maxtec – MaxO2 ME for measuring oxygen concentration and the secondary predicate K992101, Caradyne - Criterion 40 for measuring and monitoring pressure.

Environment of Use
The subject device, MaxO2 ME+p, has similar environments of use when compared to the primary predicate K152659 Maxtec – MaxO2 ME and the secondary predicate K992101, Caradyne - Criterion 40. However, the subject device is not intended for the home care setting like the secondary predicate. This difference does not raise different concerns of safety or effectiveness.

Population
The subject device, MaxO2 ME+p, has similar patient population as the primary predicate K152659 Maxtec – MaxO2 ME and the secondary predicate K992101, Caradyne - Criterion 40. The K992101, Caradyne - Criterion 40 did not specify a patient population, but measurement of pressure would have included the same population as the subject device.

While it is not specified in the predicates, the population does not raise different concerns of safety or effectiveness.

Performance Specifications
The subject device, MaxO2 ME+p, has similar performance specifications when compared to the secondary predicate K992101, Caradyne - Criterion 40.

There are differences in the pressure measurement range between the devices with the subject device limited to a maximum of 60 cmH_2O and the predicate measures up to 99 cmH_2O. The alarm setting ranges are also adjusted for this lower maximum pressure.

The alarm delay for the subject device is 3 seconds as compared to the predicate which can be up to 20 seconds. This difference does not raise different concerns of safety or effectiveness.

Non-clinical Testing
We performed a number of tests to demonstrate that the proposed device performed as intended. Testing includes:

- AAMI ANSI ES 60601-1: 2005 +A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- AIM Standard 7351731: 2017 Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- IEC 60601-1-8: 2012 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 80601-2-55: 2018 Particular requirements for the basic safety and essential performance of respiratory gas monitors

Biocompatibility
Patient contacting materials were evaluated per:

- ISO 10993-5:2009 - Cytotoxicity
- ISO 10993-10:2010 – Sensitization and Irritation
- ISO 10993-11:2017 – Material Mediated Pyrogenicity
- ISO 10993-18:2020 – Chemical Characterization with a Toxicological Risk Assessment
- ISO 18562-2:2017 – Particulate Material
- ISO 18562-3:2017 – VOC with Toxicological Risk Assessment

Animal
No animal testing was performed.

Clinical
No human clinical testing was performed.

Conclusion
We have performed a comparison of specifications in the above table and found the proposed model to be substantially equivalent.