DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 10, 2016

Maxtec, LLC
C/O Paul Dryden
Consultant
2305 South 1070 West
Salt Lake City, Utah 84119

Re: K153659
Trade/Device Name: MaxO_2ME
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL
Dated: May 12, 2016
Received: May 13, 2016

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)* K153659

Device Name

$MaxO_2ME$

Indications for Use *(Describe)*

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.

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

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration Office of Chief
Information Officer Paperwork Reduction Act
(PRA) *Staff PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
June 10, 2016

Official Contact: Bruce Brierley
President
Maxtec LLC
2305 South 1070 West
Salt Lake City, Utah 84119
Tel – 385-549-8070

Proprietary or Trade Name: $MaxO_2ME$

Common/Usual Name: Oxygen analyzer

Classification Name: 21CFR 868.1720
Class II
CCL

Predicate Device: Precision PM5900 - K063096

Reference Device: MiniOX – K961644

Device Description:
The $MaxO_2ME$ is a handheld oxygen analyzer/monitor capable of measuring the oxygen concentration from 0% to 100% in a sample gas. A MAX-550E oxygen sensor outputs a voltage which is used by the $MaxO_2ME$ to determine the concentration of oxygen based on a calibration at room air or 100% oxygen. The $MaxO_2ME$ contains alarms that can be controlled by the user to set a maximum or minimum allowable oxygen concentration.

Device Features:

- Oxygen sensor of approximately 1,500,000 O_2 percent hours and / or 2 years.
- External probe with 10 ft., extendable cable and diverter fitting for standard 15 mm "T" adapter.
- Operation using 4 AA alkaline batteries (4 x 1.5 volts) for approximately 5,000 hours of performance with typical use.
- Oxygen-specific, galvanic sensor that achieves 90% of final value in approximately 15 seconds at room temperature.
- Self-diagnostic check of analog and microprocessor circuitry.
- Low battery indication.
- Calibration reminder timer that alerts the operator, using a calibration icon on the LCD display, to perform a unit calibration.
- Adjustable high-level and low-level alarming capability with flashing LED and audible indication of alarm conditions.
- Smart high-low alarm setting to help adjust alarm settings quickly.
- Back-light display with auto ambient light level detection.
- Sleep Mode operation to extend battery life.

Indications for Use:
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.

Patient Population
The $MaxO_2ME$ may be used on equipment where one desires to measure and monitor the delivered oxygen concentration. This is independent of a patient population.

Contraindications
There are no contraindications.

Environments of Use
Pre-hospital, hospital and sub-acute settings

Substantial Equivalence
This discusses how one can find the $MaxO_2ME$ substantially equivalent to the predicate Precision Medical PM5900 (K063096).

Indications for Use
Table 1 outlines the indications for use for both devices and one can see that they are similar, namely oxygen monitor is intended for continuous monitoring of the concentration of oxygen being delivered to patients, not intended as a life supporting device.
Discussion: One can find the proposed device substantially equivalent to the predicate Precision Medical PM5900 (K063096). There are no differences which raise any new substantial equivalence concerns.

Environment of Use -Oxygen monitors have commonly been used in pre-hospital and healthcare settings. The reference to the types of equipment that the predicate discloses supports pre-hospital and healthcare setting.
Discussion: One can find the proposed device substantially equivalent to the predicate Precision Medical PM5900 (K063096). There are no differences which raise any new substantial equivalence concerns.

Population - The predicate submission does not disclose details on patient population but does include incubators which would suggest newborns.
Discussion: Based upon the available information one can find the proposed device substantially equivalent to the predicate Precision Medical PM5900 (K063096). There are no differences which raise any new substantial equivalence concerns.

Performance Specifications - The following is a list of the differences between the proposed device and the predicate.

- Response time is 15 seconds vs. 12 seconds for the predicate
    - The reference device MiniOX (K961644) has a response time of 20-30 seconds
- Warm-up time is 3 seconds less for the predicate (12 vs. 15 seconds)
- Operating temperature range is wide by 10 degrees for the predicate vs. the proposed.
- Battery life is about 50% less than the proposed device (2000 hours vs. 5000 hours)
- The Sensor Life is less for the predicate vs. the proposed
- High Oxygen Alarm range is smaller by 3 % points (19-99% vs. 16-100%)
    - The reference device MiniOX (K961644) has the identical high alarm range
- Size and weight are slightly different

Discussion:
While the subject device has some differences when compared to the predicate for the Response Time and High Alarm range, the reference device, MiniOX (K961644), which has similar intended use, population and environment has similar Response time and High alarm, which supports that the differences do not raise any new substantial equivalence concerns. The other differences, battery life, warm-up time, sensor

life and physical size are similar and the defenses are improvements vs. the predicate. As such they would not raise any new substantial equivalence concerns. One can find the proposed device substantially equivalent to the predicate Precision Medical PM5900 (K063096) and reference device MiniOX (K961644).

Non-clinical Testing

Performance Testing
We performed a number of tests to demonstrate that the proposed device performed as intended.

- ISO 80601-2-55 Performance of respiratory gas monitors
- ISTA2A Shipping Validation Test Report
- Sensor performance Test Report
- Gas leakage Test Report
- Interfering gas effects Test Report
- Temperature compensation Test Report
- Drift of measurement accuracy Test Report
- MaxO_2ME Operating and Storage Environment Report
- Device Cleaning Report and Disinfection Test
- Measurement accuracy Test Report
- IEC 60601-1 - Electrical safety
- IEC 60601-1-2 – EMC
- IEC 60601-1-8 – Alarms
- Shelf-life / Real-time

Discussion: In all cases the proposed device passed or meets the acceptance criteria. One can find the proposed device substantially equivalent to the predicate Precision Medical PM5900 (K063096).

Biocompatibility - The materials that are in the gas pathway for the oxygen sensor, "Tee" adapter and diverter, are identical to other Maxtec supplied or cleared products which has similar intended use, population, environment of use and type of patient contact. As such no biocompatibility testing was performed.

Per G95-1 and ISO 10993-1:2009, these materials would be considered as:

- Externally communicating, Tissue contact, and Duration of Use – prolonged (> 24 hours, < 30 days)

Animal - No animal testing was performed.

Clinical - No human clinical testing was performed.

Substantial Equivalence Conclusion-
It is sponsor's opinion that the MaxO_2ME oxygen analyzer based upon the comparative testing is substantially equivalent to the predicate device.

Attributes	Proposed $MaxO_2ME$	Predicate Precision Medical – PM5900 (K063096)
Indications for Use	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.	Intended to measure the concentration of oxygen being delivered to the patient. The oxygen monitor is not intended as a life supporting device
Environments of Use	Pre-hospital, hospital and sub-acute settings	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). Can be considered Pre-hospital, hospital and sub-acute settings
Patient Population	The $MaxO_2ME$ may be used on equipment where one desires to measure and monitor the delivered oxygen concentration. This is independent of a patient population.	Not specific but includes reference to pediatrics and incubators which would imply newborns and older
Measurement Range	0.0 to 100%	0.0 to 100%
Resolution	0.1%	0.1%
Accuracy and Linearity	$\pm$1% of full scale at constant temperature, RH and pressure when calibrated at fill scale	$\pm$1% of full scale at constant temperature, RH and pressure when calibrated at fill scale
Total Accuracy	$\pm$3% Actual oxygen level over full operating temperature range	$\pm$3% Actual oxygen level over full operating temperature range
Response Time	90% of final value in approx. 15 seconds at 23^{o}C	90% of final value in 12 seconds at 25^{o}C Reference device – MiniOX – K961644 90% in 20 to 30 seconds
Warm-up Time	None required	None required
Operating Temperature	15^{o}C – 40^{o}C (59^{o}F – 104^{o}F)	10^{o}C – 45^{o}C (50^{o}F – 113^{o}F)
Storage Temperature	-15^{o}C – 50^{o}C (5^{o}F – 122^{o}F)	-15^{o}C – 50^{o}C (5^{o}F – 122^{o}F)
Atmospheric Pressure	800 – 1012 mBars	Up to 8,000 ft.
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. 1,500 – 2,000 hours, typical use
Low Battery Indications	"LOWBAT" icon on LCD display	Icon on LCD display
Sensor Type	Maxtec MAX-550E galvanic fuel cell	Galvanic fuel cell

Attributes	Proposed **MaxO_2ME**	Predicate **Precision Medical – PM5900 (K063096)**
Expected Sensor Life	> 1,500,000 %O_2 Hours, over 2 years typical application	> 1,000,000 %O_2 Hours
Alarm Systems	High/Low alarms, flashing yellow LEDs Nominal 975 Hz audio buzzer (IEC 60601-1-8)	High/Low alarms, flashing yellow LEDs
Low Oxygen Alarm Range	15% - 99% (>1% lower than high alarm)	15% - 99% (>1% lower than high alarm) Reference device – MiniOX – K961644 15 – 99%
High Oxygen Alarm Range	16% - 100% (>1% higher than low alarm)	18% - 99% (>1% higher than low alarm) inconsistent Summary shows 19-99%, literature shows 18-100% Reference device – MiniOX – K961644 16 – 100%
Accuracy	Exact to display alarm value	Exact to display alarm value
Materials	The materials in the gas pathway are considered as Externally communicating, Tissue contact, and Duration of Use – prolonged (> 24 hours, < 30 days) The components of the sensor and diffuser are identical to the Maxtec components cleared under K131252 and Tee adapter is identical to Envitec K122290. These components have similar intended use, population, environment of use and type of patient contact	
Dimensions	3.6”(W) x 5.8”(H)x1.2”(D)	3.6”(W) x 5.4”(H)x1.7”(D)
Weight	Approx. 0.89 lbs.	Approx. 1.11 lbs.
Cable length	9 ft.	10 ft.
Accessories	Diverter Tee adapter (15 mmm x 22 mm fittings) Mounting brackets DC power adapter	Diverter Tee adapter (15 mmm x 22 mm fittings) Mounting brackets DC power adapter