K112402

maxtec
premier O2 solutions

DEC 14 2011

# 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Pre-Market Notification in compliance with 21 CFR Part 807, Subpart E, section 807.92, as a means of providing sufficient detail to provide understanding of the basis for a determination of substantial equivalence.

1) Submitter's name, address, telephone number, a contact person and the date the summary was prepared.

| | |
|---|---|
| Submitter's name/address: | Maxtec, LLC<br>6526 South Cottonwood Street<br>Salt Lake City, Utah 84107 |
| Phone: | (801) 266-5300 |
| Fax: | (801) 270-5590 |
| Contact Name: | Tammy Lavery, RAC |
| Contact Title: | Director of Regulatory and Quality |
| Contact Address: | Maxtec, LLC<br>Salt Lake City, UT 84107 |
| Phone: | (801) 327-9870 |
| Fax: | (801) 270-5590 |
| Date Summary prepared: | 08/19/2011 |

2) Subject device information:

| | |
|---|---|
| Device Name: | Ultrasonic Oxygen Gas Analyzer |
| Trade Name(s): | UltraMaxO2 Oxygen Analyzer |
| Common/Usual Name: | Oxygen Gas Analyzer |
| Classification Names: | Analyzer, Gas, Oxygen, Gaseous-phase |
| Classification: | II |
| Product Code: | CCL |
| CFR Reference: | 21 CFR 868.1720 |
| Classification Panel: | Anesthesiology |

3) The following predicate devices were used to establish substantial equivalence for the UltraMaxO2 Oxygen Analyzer:

- 510(k) # K072469: "DigiFLO Concentrator Analyzer"
- 510(k) # K984295: "Check O2 Plus Oxygen Analyzer"
- 510(k) # K983500: "Pro2 Check Oxygen Indicator"

4) Description of the subject device:

The UltraMaxO2 device is used for checking oxygen concentrator performance with the measure of oxygen purity, and flow at the outlet of an oxygen concentrator. Both the subject and predicate devices are capable of measuring oxygen concentration with an accuracy of at least +/- 3%. In addition, the subject and predicate devices are capable of measuring flow from 0 to 10 LPM with an accuracy of +/-



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0.2 LPM. The subject and predicate devices are battery powered and use ultrasonic based oxygen sensing. These devices are not intended to be used by patients who are prescribed oxygen, nor are they intended to continuously monitor or confirm oxygen delivery to a patient. As per predicates listed above, the indication noted has been cleared by the FDA.

The UltraMaxO2 Oxygen Analyzer functions by passing an ultrasonic pulse through the gas sample and measuring the amount of time required for the pulse to transit the sample chamber. The transit time is converted into a gas concentration via calibration data stored in the device. This can be done because the transit time varies according to the molecular mass of the gas in the chamber. Flow is determined using the difference between the ultrasonic pulse traveling against the flow and the ultrasonic pulse traveling with the flow. Pressure is measured using a separate pressure sensor that measures the pressure build-up in the device when the output port is blocked. The pressure is displayed in either kPa or PSI determined by a user operable switch in the battery compartment.

The materials of the UltraMaxO2 include ABS plastic for the enclosures and the ultrasonic oxygen sensor tube body, adhesive backed Polycarbonate labels, PVC tubing and nickel plated brass fittings for the flow path, electronic circuitry including transducers/receivers, pressure, temperature and humidity sensors and an LCD screen. Further detail concerning components is included as appropriate within the 510k submission.

5) Statement of indication for use:

The UltraMaxO2 Oxygen Analyzer is a tool used to measure oxygen purity, flow and pressure of an oxygen concentrator. The UltraMaxO2 Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes Hospitals, Nursing Homes, Extended Care Facilities, Patient Homes, and Respiratory Device Service and Repair Centers.

6) Technological characteristics:

The technological characteristics of the design, materials, chemical composition, and energy source, etc. of the UltraMaxO2 Oxygen Analyzer are, for the most part, the same as the predicate devices identified in 3) above. Maxtec has not introduced any new technological characteristics for the UltraMaxO2 device.

a. Non-clinical functional and performance tests for substantial equivalence testing and the results are noted in the attached table.

b. No clinical studies were performed No clinical studies were performed for the UltraMaxO2 as the device represents a well known technology for a recognized indication as evidenced in Section 5.0 by comparison to the predicate devices currently cleared for sale in the US market.

7) The conclusion drawn from the non-clinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices identified in 3) above.

## Subject Device and Predicate Comparative Table

| | UltraMax O2 Oxygen Analyzer - Subject Device | DigiFlow Concentrator Analyzer- K072469 | Check O2 Plus Oxygen Analyzer - K984295 | Pro2 Check Oxygen Indicator- K983500 |
|---|---|---|---|---|
| **Indications for Use** | The UltraMax$O_2$ Oxygen Analyzer is a tool used to measure oxygen purity, flow and pressure of an oxygen concentrator. The UltraMax$O_2$ Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes hospitals, nursing homes, extended care facilities, patient homes, and respiratory device service and repair centers. | Same | Same | Same |
| **Sensor** | Ultrasonic | Same | Same | Same |
| **Low Battery Alarm or Indictor** | Low Battery Indicator | Same | Same | Same |
| **Measurement Capability - $O_2$ Measurement Range** | 20.9 – 96% | 20.8 – 95.7% | 73 – 95.6% | 20.9 – 100% |
| **Accuracy of Oxygen Concentration** | +/- 1.5% Full Scale (at constant temp. & optimal flow) | +/- 1.8% | +/- 2% Full Scale | +/- 2% Full Scale (at constant temp and pressure) |
| **Measurement Capability - Flow Range** | 0 – 10 LPM | $O_2$ 0 – 20 LPM Air 0 – 10 LPM | 0 – 6 LPM | 0 – 10 LPM |
| **Accuracy of Flow Measurement** | +/- 0.2 LPM | +/- 0.2 LPM Both $O_2$ and Air | +/- 0.3 LPM (5% of full scale) | +/- 0.3 LPM (3% of full scale |
| **Measurement Capability - Pressure Range** | 0.5 – 50 PSI 3.4 – 344 kPa | 0 – 35 PSI (as noted in 510(k) and 0-30 noted in attached labeling) 0 – 207 kPa | 0 – 10 PSI 0 – 68.95 kPa | 0 – 10 PSI |
| **Accuracy of Pressure** | +/- 0.5% | +/- 0.5% | +/- 2% Full Scale | +/- 1% Full Scale |
| **Power Source & Requirements** | 2 Batteries: AA (Alkaline) – 2 x 1.5 V | 1 Battery: Alkaline 9 V | 1 Battery: Alkaline 9 V | 1 Battery: Alkaline 9 V |
| **Display and Low Battery Indicator** | LCD | Same | Same | Same |
| **Dimensions** | 3.16" x 5.10" x 1.04" (80.3mm x 129.5mm x 26.4mm) | 9" x 1.5" x 1" | 3.3" x 7.5" x 1.25" | 3.60" x 5.75" x 1.29" |
| **Response Time** | Less than or equal to 17 sec. | 0.1 sec | 1 min and 45 sec +/- 5 sec | 10 sec. |
| **Weight** | 0.4 lbs (181 g) | 179 g | 10 oz. (295 g) | 9 oz. (255.15 g) |
| **Operating Temperature** | 15 – 40 C° (59 – 104 F°) | 10 – 40 C° (From Original Submission and 10 – 45 C° in attached labeling.) | 15 – 35 C° (59 – 95 F°) | 0 – 41 C° (32 – 105 F°) |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Tammy Lavery
Director of Regulatory and Quality
Maxtec, LLC
6526 South Cottonwood Street
Salt Lake City, Utah 84107

DEC 14 2011

Re: K112402
Trade/Device Name: UltraMaxO2 Oxygen Analyzer
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: December 9, 2011
Received: December 12, 2011

Dear Ms. Lavery:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

*1.3 Indications for Use Statement*

510(k) Number (if known): K112402

Device Name: UltraMaxO2 Oxygen Analyzer

Indications for Use:

The Indications for use for the Maxtec Handheld Oxygen Analyzer and Accessories are as follows:

The UltraMaxO2 Oxygen Analyzer is a tool used to measure oxygen purity, flow and pressure at the outlet of an oxygen concentrator. The UltraMaxO2 Oxygen Analyzer is intended to be used in an environment where oxygen concentrators are being serviced or repaired. This includes Hospitals, Nursing Homes, Extended Care Facilities, Patient Homes, and Respiratory Device Service and Repair Centers.

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112402