510(k) Summary

Non-Confidential Summary of Safety and Effectiveness

12-Feb-07

FEB 22 2007

Maxtec, Inc.
6526 South Cottonwood 300 West
Salt Lake City, UT 84107

Tel – 801-266-5300
Fax – 801-270-5590

Official Contact: Tod Cook- QA

Proprietary or Trade Name: $MaxO_2$ CU

Common/Usual Name: Oxygen analyzer with flowmeter and gas source

Classification Name: Analyzer, Oxygen, Gaseous-phase

Device: $MaxO_2$ CU

Predicate Devices: Maxtec – MAXO2 + - K040484
Ceramatec – Handi – K973282
Sensidyne – K010328

Device Description:

The $MaxO_2$ CU is a combination of a continuous use oxygen monitor and a venturi oxygen dilution system in one device. An analogous device could be assembled by attaching a wall-mount oxygen flow meter to a commercially available venturi and attaching the venturi to a standard in-line oxygen analyzer. The $MaxO_2$ CU offers this set-up to the clinician in one package. There are two models, one with adjustable flow and adjustable FiO_2. The other has fixed flow and adjustable FiO_2. The flow adjustment is accomplished by adjusting the flow of oxygen through the venturi orifice. The adjustable oxygen % is accomplished by adjusting the flow of oxygen into the region surrounding the venturi orifice. This oxygen is drawn into the venturi stream in place of room air, increasing oxygen content in the mixture. The oxygen analyzer electronics, sensor, and programming are identical to the $MaxO_2$+ predicate K040484.

Indications for Use:

Indicated Use -- The $MaxO_2$ CU is a continuous use monitor of oxygen concentration in a patient breathing environment. It may be provided with an oxygen concentration dilution method which could be of a flowmeter, manifold or venturi design, which can deliver a set or adjustable FiO_2 oxygen concentrations and flow rates to the patient. It is not intended for use with life supporting systems.

Environment of Use -- Hospital, Sub-acute institutions, Homecare, intra-hospital transport

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Device Attributes:

Attribute	$MaxO_2$ CU
Features	
Display range	0-100% oxygen
Display Resolution	0.1% oxygen
Response Time	90% of final value in ~ 15 seconds @ 23C
Accuracy	± 3% full scale
Linearity error	< 3% of reading
Drift	< 1% oxygen over 8 hours
Humidity influence	±3% full scale
Humidity conditions	0-95% RH non-condensing
Pressure influence	Proportional to changes in atmospheric pressure
Operating temperature	15 – 40°C
Storage temperature	-15 to 55°C
Recommended storage temperature	-20 to 55°C
Battery power indicator	Indicator on LCD
Analyzer life	Battery life – 5000 hours (user replaceable) Sensor life >900,000 % oxygen hours
Sensor type	Galvanic fuel cell
Power requirement	2 replaceable AA battery
Weight	N/A
Display	3 digit LCD
On / Auto-off button	Standard ON/OFF (No auto OFF)
Connection or use with other components allowing for adjustment of flow and FiO2	Yes Built in oxygen diluter (venturi or flowmeter manifold).
Calibrations	Calibrate to room air or 100% oxygen
Alarms	None Except Low battery
Materials	Same as K040484
Performance	None under 514

Differences between Other Legally Marketed Predicate Devices

The $MaxO_2$ CU is viewed as substantially equivalent to the following predicate device – Maxtec Max O_2 + - K040484, Ceramatec – Handi – K973282, and Sensidyne – K010328.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2007

Maxtec, Incorporated
C/O Mr. Paul Dryden
ProMedic, Incorporated
3460 Pointe Creek Court, #102
Bonita Springs, Florida 34134

Re: K063488
Trade/Device Name: Max0_2 CU
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: January 23, 2007
Received: January 24, 2007

Dear Mr. 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.

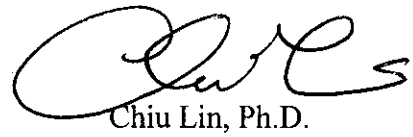
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

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510(k) Number: K063488 (To be assigned)

Device Name: $MaxO_2$ CU

Indications for Use:

The $MaxO_2$ CU is a continuous use monitor of oxygen concentration in a patient breathing environment. It may be provided with an oxygen concentration dilution method which could be of a flowmeter, manifold or venturi design, which can deliver set or adjustable FiO_2 oxygen concentrations and flow rates to the patient. It is not intended for use with life supporting systems.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

W. Maly for M. Husband

K063488