JUN - 9 2004

Section 1 – 510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness
February 19, 2004

Maxtec, Inc
6526 S. Cottonwood Street
Salt Lake City, UT 84107 U.S.A.
Phone: (801) 266-5300
Fax: (801) 270-5590

Official Contact:	Gordon R. Roth - Quality System Manager
Proprietary or Trade Name:	$MAXO_2$+
Common/Usual Name:	Oxygen Analyzer
Classification Name:	Analyzer, Gas, Oxygen, Gaseous Phase
Predicate Device:	Caradyne - OxiCheck – K023565

Device Description:

The $MAXO_2$+ A(E) oxygen analyzer is a member of Maxtec's $MAXO_2$ analyzer line of oxygen analyzers and monitors. It utilizes the MAX-250 oxygen sensor and is engineered for long life, maximum reliability and stable performance.

Intended Use:

The $MAXO_2$+ is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/ oxygen mixture.

The $MAXO_2$+ is not intended for use in continuous monitoring of oxygen delivery to a patient.

Environment of Use:

The $MAXO_2$+ is intended for use in Hospitals, Home Care, Transport, and Sub-acute Institutions. The $MAXO_2$+ is not intended for use in a MRI environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2004

Mr. Gordon R. Roth
Quality System Manager
Maxtec, Incorporated
6526 South Cottonwood Street
Salt Lake City, Utah 84107

Re: K040484
Trade/Device Name: MAX0_2+ Model "A" and "AE"
Regulation Number: 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: May 25, 2004
Received: May 26, 2004

Dear Mr. Roth:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Statement of Indications for Use

510(k) Number (if known): K040484

Device Name: ---------- MAXO$_2$+ Oxygen Analyzer

Indications for Use: ---------- The MAXO$_2$+ is intended as a tool for use by qualified personnel to spot-check or measure oxygen concentration of a delivered air/ oxygen mixture

The MAXO$_2$+ is not intended for use in continuous monitoring of oxygen delivery to a patient.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/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)

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

510(k) Number: _____