maxtec

premier O2 solutions

MAR - 1 2012

510(k) Summary of Safety and Effectiveness K113232

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 6526 South Cottonwood Street 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 Salt Lake City, UT 84107
Phone:	(801) 327-9870
Fax:	(801) 270-5590
Date Summary prepared:	10/19/2011

2) Subject device information:

Device Name:	Air/Oxygen Mixer
Trade Name(s):	MaxMixing Block
Classification Names:	Mixer, Breathing Gases, Anesthesia Inhalation
Common/Usual Name:	Breathing Gas Mixer
Classification:	II
Product Code:	BZR
CFR Reference:	21 CFR 868.5330
Classification Panel:	Anesthesiology

3) The following predicate devices were used to establish substantial equivalence for the MaxMixing Block/Analyzer System:

- 510(k) K884973 – FR6000 Flowmeter
- 510(k) K053232 – Precision Air Oxygen Blender
- 510(k) K081335 – Tenacore Oxygen Blender
- 510(k) K973646 – Bird Sentry Blender

4) Description of the subject device:

Both the subject and predicate devices are capable of measuring oxygen concentration with an accuracy of at least +/- 3%. As per predicates listed above, the indication noted has been cleared by the FDA.

5) Statement of indication for use:

The MaxMixing Block is designed to provide intermittent or continuous controlled flows of an air/oxygen gas mixture to infant, pediatric, and adult patients. The MaxMixing Block is intended to be used with a Maxtec Oxygen Analyzer device. The MaxMixing Block is a restricted medical device intended for use by qualified trained personnel under the direction of a physician in institutional environments where delivery and monitoring of air/oxygen mixtures is required.

6) Technological characteristics:

The MaxMixing Block uses the well known technology of two compensated thorpe tube flowmeter to control and measure medical grade air and oxygen at an accurate flow rate as per a calibrated reference pressure (50 psig +/- 5 psig). The two gases are then mixed in a mixing block for continuous air/oxygen delivery at oxygen concentrations of 21 – 100% as prescribed. There are no new technological characteristics introduced with respect to design, materials, chemical composition or energy source for the MaxMixing Block from those of flowmeters currently sold for medical use. There are differences with respect to mixers, in that the subject device has a wider pressure differential tolerance requirement since Oxygen concentration is much less affected by pressure differential as compared to the blender predicate devices. The blender predicate devices have a single gas failure alarm which is intended to indicate narrow pressure differential between air and Oxygen gas sources and failure of a single gas source, either air or Oxygen. The subject device also has a single gas failure alarm which indicates a broader pressure differential between air and Oxygen gas sources and failure of a single gas source, either air or Oxygen.

The intended use is the same as the combined predicate devices.

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.

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, RAC
Director of Regulatory and Quality
Maxtec, Inc
6526 South Cottonwood Street
Salt Lake City, Utah 84107

MAR - 1 2012

Re: K113232
Trade/Device Name: MaxMixing Block
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: February 20, 2012
Received: February 22, 2012

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,

for 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

1.2 Indications for Use Statement

510(k) Number (if known):_____

Device Name: MaxMixing Block

The MaxMixing Block, a breathing gas mixer designed to provide intermittent or continuous controlled flows of an air/oxygen gas mixture to infant, pediatric, and adult patients. The MaxMixing Block is intended to be used with a Maxtec Oxygen Analyzer. The MaxMixing Block is a restricted medical device intended for use by qualified trained personnel under the direction of a physician in institutional environments where delivery and monitoring of air/oxygen mixtures is required.

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

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

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: K113232