K043615

3.1 Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness
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December 28, 2004

OxyTec Medical Corp.
5150 E. La Palma Ave.
Suite 203
Anaheim Hills, CA 92807

Tel: (714) 701-9933
Fax: (714) 701-9931

Official Contact: Charles Atlas, President

Proprietary or Trade Name: OxyTec 900

Common/Usual Name: Portable oxygen generator (concentrator)

Classification Name: Portable oxygen generator

Device: OxyTec 900

Predicate Devices: AirSep – LifeStyle – K020324

Device Description:

The OxyTec 900 is a small, portable oxygen concentrator which operates by pressure swing adsorption, molecular sieve. It has various flow rate settings, utilizes a conserver trigger method, and delivers 89% $\pm$ 3% pure oxygen. It is capable of continuous use in the home, institutional settings and mobile environments. It may be powered by 100-250 VAC, 12-14 VDC or batteries.

Indications:

Indications for Use --	The OxyTec 900 is intended for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable and is capable of continuous use in the home, institutional, and travel / mobile environments.
Patient Population --	Patients requiring supplemental oxygen.
Environment of Use --	Home, Hospital, Sub-acute Institutions, Mobile environments

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Comparison to Predicate Devices:

	OxyTec 900	Predicate
Attributes		
Indications for use	The OxyTec 900 is intended for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable and may be used in the home, institutional, and travel / mobile environments.	AirSep Lifestyle – K020324 Same
Environments of use	Home, Hospital, Sub-acute Institutions, Mobile environments	Same
Patient Population	Patients requiring supplemental oxygen	Same
Contraindications	None	Same
Technology		
Oxygen separation	PSA – pressure swing adsorption	Yes
Portable, battery operated	Yes	Yes
Oxygen purity	89% ± 3%	AirSep – 90% ± 3%
Alarms	Various user alarms	Yes
Variable flow settings with pulsed doses	Yes	Yes
Conserver integrated in the system	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices

There are no significant differences between the proposed device, OxyTec 900 and the identified predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

OxyTec Medical Corporation
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K043615
Trade/Device Name: OxyTec 900
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: December 29, 2004
Received: January 4, 2005

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.

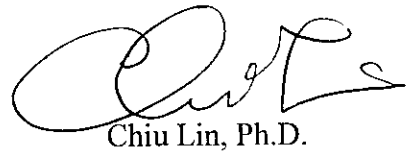
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

3.3 Indications for Use

510(k) Number: K043615 (To be assigned)

Device Name: OxyTec 900

Indications for Use: The OxyTec 900 is intended for prescription use by patients requiring high concentrations of oxygen on a supplemental basis.

It is small, portable and is capable of continuous use in the home, institutional, and travel / mobile environments.

Prescription Use XX **or** **Over-the-counter use __**
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K043615