DEC 9 2005

K052396

VIII. 510(k) Summary

Submitted By:

OxySure Systems, Inc.
2611 Internet Blvd. Suite 109
Frisco, Texas 75034

Contact:

Mr. Julian Ross
Chief Executive Officer
OxySure Systems, Inc.
2611 Internet Blvd, Suite 109
Frisco, Texas 75034
Telephone: (214) 618-7918
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Device:

Device Classification Name:	Portable Oxygen Generator
Device Generic Name:	Portable Oxygen Generator
Device Trade Name:	OxySure™ Portable Oxygen Generator, Model 615

Predicate Device:

Canogen Portable Oxygen Generator
Model 615
Canogen International, Ltd.
Syosset, New York
510(k) Number: K982243

Device Description:

The OxySure™ System creates medically pure [USP] oxygen at an average flow rate of 6.5 liters per minute for 15 minutes from a catalytic reaction of dry compounds.

Intended Use:

The OxySure™ System is intended to produce oxygen for emergency use.

Technological Characteristics:

The OxySure™ System is comprised of an outer housing, self-contained disposable cartridges that house the dry compounds and water, and a single-use mask and tubing system to deliver the oxygen to the user.

Testing:

Predetermined amounts of base powder, water and catalyst were combined in the system to commence the chemical reaction and the chemical reaction commenced instantaneously. There was no stirring, swirling, or agitation of any kind administered or required to commence the reaction. Measurements of flow rate, oxygen purity, humidity and temperature were recorded at 15-second intervals, commencing upon the addition of the catalyst.

Conclusion:

The OxySure™ System is substantially equivalent to the legally marketed Portable Oxygen Generator device in intended use and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Mr. Julian T. Ross
President & CEO
OxySure Systems, Incorporated
2611 Internet Boulevard, Suite 109
Frisco, Texas 75034

Re: K052396
Trade/Device Name: OxySure Portable Oxygen Generator, Model 615
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: November 30, 2005
Received: December 1, 2005

Dear Mr. Ross:

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

8/29/2005

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: OxySure™ Portable Oxygen Generator, Model 615

Indications for Use:

The OxySure™ System is intended to produce oxygen for emergency use.

Prescription Use ☐
(21 CFR 801 Subpart D)

And/Or

Over-The-Counter Use ☒
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

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

510(k) Number K052396