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K102750

510(k) Summary

10-Feb-11

Get-O_2, Inc.
27 Bayberry Lane
Westport, CT 06880

Tel – 603-570-2579

Official Contact: Richard P. Imbruce, Ph.D, President

Proprietary or Trade Name: O_2-in-a-box™ - Emergency Use – OTC
O_2-in-a-box™ - Rx use

Common/Usual Name: Portable oxygen generator

Classification Name: Portable Oxygen Generator
CAW – 868.5440

Predicate Devices: OxySure – Model 615 – K052396 – Emergency Use
Oxytec – Model 900 – K043615 – Rx use

Device Description

Indications for Use

Emergency Use – OTC
Intended to produce oxygen for emergency use.

There is a minimum 6 LPM flow rate for at least 15 minutes established a minimum total oxygen capacity of 90 liters.

Prescriptive Use –
A portable oxygen generator intended to produce oxygen to provide supplemental oxygen as prescribed by a physician.

Flow rate	Delivery Time	Total Oxygen Capacity
0.5 LPM	60 minutes	30 liters
3 LPM	30 minutes	90 liters

Environment of Use
Emergency – OTC – locations where emergency oxygen maybe needed
Rx use - Home, institutional, travel / mobile environments

Performance Testing
Performance testing was performed:

- VOC / $PM_{2.5}$ and Residual Hydrogen Peroxide
- Bacteria / Mold Testing
- Environmental testing – high and low temperature conditions

- Mechanical testing – vibration
- Flow rate and flow duration for Emergency OTC and Rx Use including external container temperature and temperature of gas at outlet
- % oxygen generated

The proposed devices met and passed all the performance testing as outlined above.

Comparative Table – OTC – Emergency Use

Features	Predicate OxySure K052396	Proposed Device O_2-in-a-box™ OTC - Emergency Use
Indications for use	To produce oxygen for emergency use	To produce oxygen for emergency use
Environment of Use	Home, emergency locations	emergency locations
Patient Population	Not discussed	No limitations
Contraindications	None	None
Method for oxygen generation	Chemical reaction	Chemical reaction
Patient interface	Standard oxygen mask or nasal cannula	Standard oxygen mask or nasal cannula
Specifications	% Oxygen – 99% Flow rate minimum – 6 LPM Duration at least15 minutes 90 liter oxygen capacity	% Oxygen – 99% Flow rate minimum – 6 LPM Duration at least15 minutes 90 liter oxygen capacity
Single use, disposable	Yes	Yes
OTC designation	Yes	Yes
Performance testing		
Flow rate	> 6 LPM	> 6 LPM
Duration of flow	At least 15 minutes	At least 15 minutes
% oxygen	>99%	> 99%
VOC / $PM_{2.5}$	Yes	Yes
Housing temperature	Yes	Yes
Temperature of gas at outlet	Yes	Yes
Accessories	Mask Oxygen cannula	Mask Oxygen cannula

OTC - Emergency Use Substantial Equivalence

The O_2-in-a-box™ for Emergency Use - OTC is viewed as substantially equivalent to the predicate device because:

Indications for Use –
Intended to produce oxygen for emergency use. There is a minimum 6 LPM flow rate for at least 15 minutes established a minimum total oxygen capacity of 90 liters.

Environment of use –
Locations where emergency oxygen may be needed.

Technology –
The O_2-in-a-box™ for Emergency Use - OTC utilizes chemicals to be mixed when the device is ready for use. There chemical reaction generates oxygen. The used a chemical reaction to generate oxygen is identical technology to predicate OxySure (K052396).

Materials –
The materials in the gas pathway have been tested via VOC and $PM_{2.5}$ as is expected for such devices. The test results demonstrate that the O_2-in-a-box™ for Emergency Use - OTC does not generate unwanted particulate matter or undesirable gases. This is similar to the predicate OxySure (K052396).

Environment of Use –
The O_2-in-a-box™ for Emergency Use - OTC has the identical environments of use, i.e. emergency settings, as does the predicate OxySure (K052396).

Patient Population –
The patient population is not specified by the predicate in the 510(k) Summary but the intended use is for individuals require oxygen in an emergency setting. This would be identical to the predicate OxySure (K052396).

Performance Specifications and Testing –
The O_2-in-a-box™ for Emergency Use - OTC has the minimum performance specifications required to meet emergency use, which are – at least a flow rate of 6 LPM for at least 15 minutes. This is identical to the predicate OxySure (K052396).

The O_2-in-a-box™ for Emergency Use – OTC is equivalent to the predicate, OxySure (K052396), for performance specifications and testing.

The rationale for choosing the predicate is summarized as follows:

RX Use Substantial Equivalence

The O_2-in-a-box™ for Rx Use is viewed as substantially equivalent to the predicate devices because:

Comparative Table – Rx Use

Features	Predicate Oxytec Model 900 K043615	Proposed Device O_2-in-a-box™ OTC - Emergency Use
Indications for use	For prescription use by patients requiring high concentration of oxygen on a supplemental basis	For prescription use by patients requiring oxygen on a supplemental basis
Environment of Use	Home, institutional, travel / mobile environments	Home, institutional, travel / mobile environments
Patient Population	Require supplemental oxygen	Require supplemental oxygen
Contraindications	None	None
Method for oxygen generation	Molecular sieve	Chemical reaction
Patient interface	Standard oxygen mask or nasal cannula	Standard oxygen mask or nasal cannula
Single use, disposable	No	Yes
Rx designation	Yes	Yes
Who designates use and sets flow rate	Clinician prescribes and designate flow rate	Clinician prescribes and designate flow rate
Who administers oxygen	Caregivers, self directed	Caregivers, self directed
Performance testing		
Flow rate range	> 1-5 lpm	0.5 LPM and 3.0 LPM
Duration of flow / O_2 capacity	Limited by battery life	0.5 LPM – 60 min – 30 l O_2 3.0 LPM – 30 LPM – 90 l O_2
% oxygen	89% +/- 3%	> 99%
VOC / $PM_{2.5}$	Yes	Yes
Housing temperature	< 45°C	< 45°C
Temperature of gas at outlet	Ambient at patient interface	< 45°C at outlet Ambient at patient interface
Accessories / Patient interface	Mask Oxygen cannula	Mask Oxygen cannula

Indications –
The O_2-in-a-box™ for Rx Use is intended to provide supplemental oxygen to individuals as prescribed by a clinician. These indications are identical to predicate – Oxytec (K043615).

Technology –
The O_2-in-a-box™ for Rx Use utilizes chemical reaction technology which is equivalent to the predicate OxySure (K052396) for flow rates < 6 LPM.

Environment of Use –
The O_2-in-a-box™ for Rx Use is intended to be used in environments which are equivalent to the predicate Oxytec (K043615). These can include home, institutional, travel / mobile environments.

Patient Population –
The O_2-in-a-box™ for Rx Use has the identical patient population, those requiring supplemental oxygen, as the predicate Oxytec (K043615). In addition, as defined in the FDA guidelines for devices delivery < 6 LPM or 90 liters oxygen capacity they are to be considered prescriptive.

Performance Specifications –
The O_2-in-a-box™ for Rx Use has similar performance specifications, variable flow rates, as the predicate Oxytec (K043615).

Since this is a prescriptive device, the prescriber is to instruct the patient as to the prescribed flow rates of oxygen needed and the proposed device will be matched to those prescribed requirements. This is similar to the predicate Oxytec (K043615) device.

Performance Testing –
To demonstrate safety we have performed the following bench tests:

- VOC / $PM_{2.5}$ and Residual Hydrogen Peroxide
- Bacteria / Mold Testing
- Environmental testing – high and low temperature conditions
- Mechanical testing – vibration
- Flow rate and flow duration for Emergency OTC and Rx Use including external container temperature and temperature of gas at outlet
- % oxygen generated

Materials and Biocompatibility –
To demonstrate biocompatibility, all the materials in the gas pathway have been tested via VOC and $PM_{2.5}$ and found to be within the acceptable limits as outlined in Volatile Organic Compounds (VOC) test method - EPA TO-15 VOC and Particulate Material (PM) test method – NIOSH 0500 $PM_{2.5}$.

Conclusion –
The O_2-in-a-box™ for Rx Use is equivalent to the predicates for indications for use, environments of use, patient population, technology, and performance specifications.

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

FEB 11 2011

Geto2, Incorporated
C/O Mr. Paul Dryden
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

Re: K102750
Trade/Device Name: O^2-in-a-box™ portable oxygen generator –Emergency – OTC
O^2-in-a box™ - Rx use
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: February 3, 2011
Received: February 4, 2011

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. 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

Indications for Use Statement

510(k) Number: K102750

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Indications for Use:

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Environment of use – locations where emergency oxygen maybe needed

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K102750

Indications for Use Statement

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Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

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

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