K063454

5. 510(k) Summary

MAY - 9 2007

POGS 33 Portable Oxygen Generation System

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:
On-Site Gas Systems, Inc.
35 Budney Road
Newington, CT 06111

Contact Person:
Guy T. Hatch, Chief Operating Officer
Phone: 860-667-8888, extension 267
Fax: 860-667-2222
e-mail: ghatch@onsitegas.com

Date Prepared: October 3, 2006

Trade Name: POGS 33C, Portable Oxygen Generation System
Common Name: POGS

Classification Names: Oxygen Concentrator

Device Classification:

Regulatory Class:	Class II
Product Code:	CAW
Classification Panel:	Anesthesiology
Regulation Number:	21 CFR 868.5440

Predicate Devices:
POGS 33, 510(k) K041664, On-Site Gas Systems, Inc.

Description of Device:
The Portable Oxygen Generation System 33 (POGS 33C) has been designed to accommodate medical personnel with a source of supplemental oxygen in a setting where liquid oxygen may be unavailable, and of medical air to drive respiratory equipment. Aero-medical evacuation and ground based medical missions require medical support systems capable of providing therapeutic oxygen. Requirements are based on the mobile, deployment oxygen system, operational requirements document that has been issued by the United States Air Force. This system is based on the Pressure Swing Absorption principle and uses

a molecular sieve to separate gasses from the filtered ambient air. The oxygen is stored and delivered to the patient(s) through one of four ports with a total maximum flow of 33 liters-per-minute at 50 PSIG. The oxygen concentration purity level is at 90% +/- 3%. Included with the generator is a secured accessory kit including medical-grade oxygen hose and flow regulators for the outlets. The POGS 33C is compatible with commercial oxygen consuming equipment and accessories, including D, E, H, and K cylinder filling accessories, ventilators, cannulas, Draeger Narkomed Anesthesia machines and Impact Univent/Eagle 754/754M Ventilators.

Medical air output of up to a total of 30 liters-per-minute at 50 PSIG is also provided.

Indications for Use:
The POGS is intended to generate and deliver USP 93%supplemental oxygen and medical grade air. This device is intended to be used only by trained personnel in disaster relief and emergency preparedness situations, or military settings where bottled oxygen is not readily available.

Difference with Predicate Device:
The POGS 33 C device, cleared through K041664, is fundamentally the same device as the POGS 33C in this submission, with several minor improvements. The technological characteristics are identical to the predicate device. The indications for use now include populations other than military facilities. The expanded indications do not change the function of the device or the intended therapeutic value of the device. The large number of devices utilized in hostile environments and in mobile operations make this device uniquely suited for disaster and emergency preparedness situations and where bottled oxygen may be unavailable, not changing the safety or effectiveness of the device. Labeling will continue to require that trained personnel operate this equipment.

Improvements from Previously Cleared Device:
Several minor improvements have been made to the predicate device. Fittings have been converted to stainless steel to eliminate corrosion, the sieve beds were converted to aluminum for weight considerations, and reliability improvements to the Microboost were made. Improvements to the feed air compression packaging, improved connectors to minimize breakage, improved operator manuals and labeling are provided with the new device.

Non-Clinical Performance:
Performance Standard ASTM F-1464-93 was used.
Non-clinical bench testing conducted by On-Site Gas Systems, Inc. is sufficient in establishing substantial equivalence on the POGS 33C to the predicate device on which substantial equivalence is claimed, including oxygen purity evaluations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Guy Hatch
Chief Executive Officer
On-Site Gas Systems, Incorporated
35 Budney Road
Newington, Connecticut 06111

MAY - 9 2007

Re: K063454
Trade/Device Name: POGS 33C Portable Oxygen Generation System
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: April 26, 2007
Received: April 27, 2007

Dear Mr. Hatch:

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.

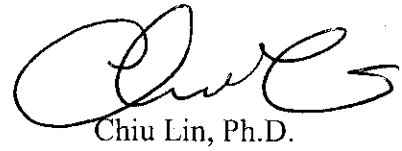
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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-. 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 (240) 276-3150 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

4. Indications for Use

510(k) Number K063454:

Device Name: POGS 33C Portable Oxygen Generation System

Indications for Use:

The POGS 33C is intended to generate and deliver USP 93% supplemental oxygen and medical grade air. This device is intended to be used only by trained personnel in disaster relief and emergency preparedness situations, or military settings where bottled oxygen is not readily available

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(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)

(Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...(k) Number: K063454