JUL 2 9 2004

K041664

510(k) Summary for Portable Oxygen Generator System: POGS 33C

Date: July 16, 2004

Applicant: On Site Gas Systems, Inc
35 Budney Road
Newington, CT 06111
Fax: 860.667.8888
Phone: 860.667.2222

Contact: C. Bart Gullong, Vice-President, Marketing and Technical Services
Email: bgullong@onsitegas.com

Trade Name: Portable Oxygen Generator System: POGS 33C

Common Name: Oxygen Concentrator

Establishment
Registration Number: 3003637574

Manufactured at: (Same as Applicant)

Classification Name: Oxygen Concentrator

Reason for 510(k): Design changes (1) adding additional compatible equipment (Impact 754/M
Univent/Eagle) and (2) reducing weight.

Product code: CAW, CFR 21 § 868.5440 Class II

Legally Marketed Device to which
Substantial Equivalence is claimed:

Portable Oxygen Generator System: POGS 33 K030920

Description:
The Portable Oxygen Generation System 33 (POGS 33C) has been designed to accommodate Military Personnel with a source of supplemental oxygen in a setting where liquid oxygen may be unavailable, and of medical air to drive respiratory equipment. Aeromedical evacuation and ground based medical missions require medical support systems capable of providing therapeutic oxygen. The gaseous oxygen generator will also be required to provide oxygen at the prescribed flow rates and pressures required to operate the oxygen-driven equipment included in the AFMS deployable medical assemblages. Requirements are based on the mobile, deployable oxygen system, operational requirements document that has been issued by the United States Air Force.

This system is based on the Pressure Swing Adsorption principle and uses a molecular sieve to separate gases 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 93% minimum, with an oxygen purity level average of 95%. Included with the generator is a secured accessory kit including medical-grade oxygen hose and flow regulators for the outlets.

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

Indications For Use:
The POGS 33C is intended to provide medical grade air and oxygen (USP oxygen 93%) at 50 PSIG nominal and lower output pressures in hospitals, surgical suites, and other clinical settings in military facilities only. 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.

Conclusion:
Non-clinical bench testing conducted by On Site Gas Systems, Inc, as provided, is sufficient in establishing substantial equivalence of the POGS 33C to the predicate device on which SE is claimed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2004

Mr. C. Bart Gullong
Vice President
On-Site Gas Systems, Incorporated
35 Budney Road
Budney Industrial Park
Newington, Connecticut 06111

Re: K041664
Trade/Device Name: Portable Oxygen Generation Systems (POGS) 33C
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: June 17, 2004
Received: June 25, 2004

Dear Mr. Gullong:

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 (301) 594-4646. 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/dsma/dsmamain.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

Indications for Use

510(k) Number: K041664

Device Name: Portable Oxygen Generation System (POGS) 33C

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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)

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

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