JAN 8 2002

K014078

10.0 510 (k) SUMMARY

10.1 Submitter's Name

Francis X. Hursey,
President

10.2 Address

On Site Gas Systems. Inc.
100 Production Court
New Britain, CT 06051

10.3 Phone

888-748-3429 (Toll-free)
860-229-2799
860-225-9405

10.4 Fax

860-225-9531

10.5 Contact Person

C. Barton ("Bart") Gullong,
Vice President,
Marketing and Technical Services

10.6 Date of Preparation

November 30, 2001

10.7 Device Name

Portable Oxygen Generator

10.8 Trade Name

On Site Gas Systems Portable Oxygen Generator System

10.9 Common Name

Oxygen Concentrator

10.10 Proprietary Name

P.O.G.S.

10.11 Classification Name

Portable Oxygen Generator

10.12 Legally Marketed Device Claiming Substantial Equivalency To:

K 011844 Merits Health Products Oxygen Concentrators
K955549 Oxlife Oxygen Concentrators

10.13 Description of the Device

The On Site Gas Systems portable oxygen generator is a prescription device designed to provide an inexpensive supply of supplemental oxygen in a military environment without a continuous source of oxygen. The feed air compressor creates a vacuum to draw air into a holding talk. The air is then flushed through two tanks in series to provide continuous oxygen. The molecular sieve material adsorbs nitrogen, which comprises approximately 78% of the makeup of air. The resulting gas is approximately 93% oxygen.

The variations of the device are to allow for greater total flow, to accommodate more cannulas per device. The variations are designed and tested for same indication of use, safety and effectiveness; variations are substantially equivalent to predicate devices.

10.14 Intended Use of Device

The Oxygen Concentrators are intended to provide supplemental oxygen. Device is to be operated by trained medical personnel.

Our portable oxygen generator provides supplemental oxygen, where oxygen is currently present. Specifically for military battlefields, primary oxygen may be unavailable or not feasible. In this application, POGS can actually fill cylinders to provide primary oxygen besides.

10.15 Summary of Technological Characteristics of Device Compared to Predicates

The oxygen generator operates by using molecular sieve material to adsorb the nitrogen from filtered air. The resulting gas has an increased concentration of oxygen. This technology is well established, and has been used in the predicate device as well as other legally marketed products.

10.16 Discussion of Non-clinical Test to Support Determination of Substantial Equivalency

10.17 Performance Data

The device meets the requirements of the FDA recognized standard covering Oxygen Concentrators, ASTM F 1464-93, and is substantially equivalent to the predicate devices.

10.18 Conclusions

Based on the design, performance specifications, and intended use, the Oxygen Concentrators are substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

Mr. C. Barton Gullong
On Site Gas Systems, Inc.
100 Production Court
New Britain, CT 06051

Re: K014078
On Site Gas Systems Portable Oxygen Generator System
Regulation Number: 868.5440
Regulation Name: Generator, Oxygen, Portable
Regulatory Class: Class II (two)
Product Code: CAW
Dated: December 5, 2001
Received: December 11, 2001

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. In addition, if you wish to change or expand the current indications for use to include non-military environments, you will need to submit a new 510(k) premarket notification, and receive FDA clearance prior to marketing the device.

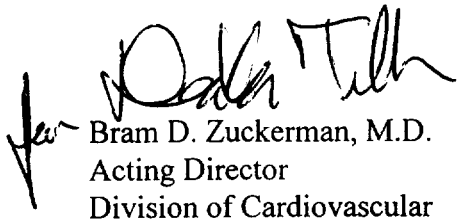
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8.10 Statement of Indications for Use

8.10.1 510 (k) File Number

K014078

8.10.2 Device Name

On Site Gas Systems
Portable Oxygen Generator System

8.10.3 Indications for Use

The POGS is intended to provide supplemental oxygen. Device is to be operated by trained medical personnel only for military use only.

Prescription use ✓

Division of Cardiovascular & Respiratory Devices
510(k) Number K014078