K030920

MAR 1 0 2004

10.0 510 (k) SUMMARY

10.1 Submitter's Name

Francis X. Hursey,
President

10.2 Address

On Site Gas Systems. Inc.
35 Budney Road
Budney Industrial Park
Newington, CT 06111

10.3 Phone

888-748-3429 (Toll-free)
860-667-8888

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860-667-2222

10.5 Contact Person

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

10.6 Date of Preparation

March 17, 2003

10.7 Device Name

Portable Oxygen Generator with Medical Air

10.8 Trade Name

On Site Gas Systems Portable Oxygen Generation System with Medical Air

10.9 Common Name

Oxygen Concentrator with Medical Air

10.10 Proprietary Name

POGS 33

10.11 Classification Name

Portable Oxygen Generator with Medical Air

10.12 Legally Marketed Device Claiming Substantial Equivalency To:

K 020362 On Site Gas Systems Portable Oxygen Generation System
K 013223 Litton Systems Patient Ventilation Oxygen Concentrating System (PVOCS)

10.13 Description of the Device

The FDA-cleared On Site Gas Systems' Portable Oxygen Generation System 33, "POGS 33", (K020362) is being modified to include medical air, and compatibility with the Draegar Narkomed Anesthesia Machine. The system uses PSA technology, and supplies medical grade air and oxygen (USP oxygen 93%) at 50 PSIG nominal and lower output pressures in battlefield/ hospital settings in military facilities only.

The POGS 33 utilizes the same Draegar Narkomed Anesthesia Machine as the predicate, PVOCS. The POGS 33 utilizes the same oil-less scroll feed compressor in the production of medical air as does the predicate, PVOCS.

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

10.14 Intended Use of Device

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

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 the filtered compressed, dry 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.

Medical air is produced when the compressed air leaves the air storage tank and splits-off between the oxygen generator and medical air stream. This compressed air is produced from the same make and model oil-less scroll compressor as the predicate. The medical air passes through a pressure regulator and 0.01 micron filter. 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

For oxygen, the device meets the requirements of the FDA recognized standard covering Oxygen Concentrators, ASTM F 1464-93 and USP oxygen 93%, and is substantially equivalent to the predicate devices. For medical air, the device meets the requirements of the FDA recognized standard covering Medical Air, USP.

10.18 Conclusions

Based on the design, performance specifications, and intended use, the Oxygen Concentrators with medical air 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

MAR 1 0 2004

Mr. C. Barton Gullong
On Site Gas Systems Inc.
35 Budney Road
Budney Industrial Park
Newington, CT 06111

Re: K030920
Trade/Device Name: Portable Oxygen Generation System with Medical Air
Regulation Number: 868.5440
Regulation Name: Generator, Oxygen, Portable
Regulatory Class: II
Product Code: CAW
Dated: January 14, 2004
Received: January 15, 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. In addition, if you wish to change or expand your 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), 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

8.10 Statement of Indications for Use

8.10.1 510 (k) File Number

K030920

8.10.2 Device Name

On Site Gas Systems
Portable Oxygen Generation System – 33 (POGS 33)

8.10.3 Indications for Use

The POGS 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. POGS is compatible with commercial oxygen–consuming equipment and accessories, including D,E,H, K cylinder–filling accessories, ventilators, cannulas, and Draeger Narkomed Anesthesia Machine.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

510(k) Number: K030920

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