K092636

5. 510(k) Summary

JAN - 7 2010

POGS 65/130 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.
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Contact Person:

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Date Prepared: September 1, 2009

Trade Name: POGS 65/130, Portable Oxygen Generation System
Common Name: POGS 65

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 33C, 510(k) K063454, On-Site Gas Systems, Inc.

Description of Device:

The Portable Oxygen Generation System 65/130 (POGS 65) has been designed to accommodate medical personnel that require a portable, reliable source of supplemental oxygen in a setting where liquid oxygen may be unavailable.

Requirements are based on the deployment oxygen system- medium (DOGS-M), operational requirements documents that have been issued by the United States Air Force and the United States Army. These two services are preparing a joint requirement document. 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 the oxygen boost and distribution system.

The POGS 65/130 is a system that generates USP 93% oxygen at a flow rate of up to 65 LPM at a pressure of 50-60 PSI. Included with the generator are medical-grade oxygen hose for both low and high pressure, spare parts and tools that are required, but may be not be easily accessible to the user. The POGS 65/130 is compatible with commercial oxygen consuming equipment and accessories, including D, E, H, K, and M cylinder filling accessories, ventilators, nasal cannulas, Draeger Narkomed Anesthesia machines and Impact Univent/Eagle 754/754M Ventilators. It also connects with the high pressure Hospital Oxygen Backup System and the low-pressure Patient Oxygen Distribution System.

A complete POGS 65/130 system consists of two (2) feed air compressors, two (2) oxygen generators, one (1) boost and distribution center, and one (1) oxygen back-up system. Each feed air compressor and oxygen generator pair is designed to provide up to 65 LPM independently or can operate in parallel to achieve up to130 LPM to provide the user flexibility in the deployment of their resources. The approach is modular and enables the user to add or subtract systems to meet the requirements of the situation. Each POGS 65 pair responds to the oxygen demand that is being used and when operated in parallel, will load share between the pair.

The boost and distribution system receives the oxygen from up to two oxygen generators. The boost and distribution system can feed the oxygen to 1) the hospital distribution system, 2) fill the back-up system, 3) fill cylinders or 4) fill the hospital back-up system depending upon the requirements of the situation. To ensure patient care, the hospital distribution system has priority over all other options. One or more type of cylinder or back-up system may be filled in conjunction with supplying the hospital distribution system. The System includes the capability to evacuate high pressure oxygen cylinders to 25 inches Hg vacuum prior to filling.

Indications for Use:
The POGS 65/130 is intended to generate and deliver USP 93% supplemental oxygen. This device is intended to be used only by trained personnel in disaster relief and emergency preparedness situations, military settings or where bottled oxygen is not readily available.

Difference with Predicate Device:
The POGS 65/130 has included several improvements identified through the operation of the POGS 33C by the military around the world. To roughly double the oxygen output of the system in the same footprint, a new molecular sieve material, MDX made by UOP was used in place of the Oxysieve 5 made by UOP used in the POGS 33C. An input and exhaust valve block has replaced individual valves. The

valve block is designed by the same company, MAC, that produces the individual valves, thus we are confident of the lifetime, materials and quality of the components. The system control has been upgraded from a mechanical timer to a PLC. We utilize PLC's throughout the rest of our product line and the manufacturer, Allen-Bradley, is a well known manufacturer of PLC's. The functionality improvement is mainly in the areas of maintenance and troubleshooting and the ease of operation is improved as even those with limited experience with the system can quickly place it into operation and ensure continuous oxygen generation. The POGS 65/130 is *not* required to produce medical air, therefore there are no provisions for dew point or CO monitoring of the air.

Improvements from Previously Cleared Device:
Several improvements have been made to the predicate device. Improvements to the feed air compression packaging, increased oxygen production, enhanced user interface, and improved operator manuals 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.

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Silver Spring, MD 20993-0002

Mr. Guy Hatch
Chief Executive Officer
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JAN - 7 2010

Re: K092636
Trade/Device Name: POGS 65/130 Portable Oxygen Generation System
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: December 31, 2009
Received: January 4, 2010

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

4. Indications for Use

510(k) Number: K092636

Device Name: POGS 65/130 Portable Oxygen Generation System

Indications for Use:

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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)

L Schultheis

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

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