510(k) Summary

Deployable Oxygen Concentration System (DOCS)

Type of FDA Submission: Abbreviated 510(k)

510(k) Number: K020330

Submitter Information

Submitter's Name: Pacific Consolidated Industries

Submitter's Address: 3430 West Carriage Drive
Santa Ana, California 92704-6412

Owner/Operator ID: 9049531

Contact Person: Lee W. Smith

Submitter's Phone: 714-979-9200 (Phone) 714-436-9150 (Fax)

Date of Preparation: January 29, 2002

Device Name

Common Trade Name: Deployable Oxygen Concentration System (DOCS)

Classification Name: Portable Oxygen Generator

Device Classification: 868.5440

Product Code: CAW

Predicate Legally Marketed Device Equivalence

Substantial equivalence is claimed to the following legally marketed predicate devices:

K014078 – Portable Oxygen Generator by On Site Gas Systems
K003472 – Model 6400-OM Oxygen Concentrator by SeQual Technologies Inc.
K003939 – Venture IOH 200 Home Fill II Complete Home Oxygen System by Invacare Corporation

All three devices operate on the principle of using a pressure differential to strip oxygen from the ambient air using a zeolite molecular sieve in an adsorption process, as does the DOCS device.

Compliance with Section 514 Performance Standards

The device meets the requirements of the FDA recognized standard covering Oxygen Concentrators, USP 24-NF 19 Oxygen 93%, and is substantially equivalent to the predicate devices.

Safe Medical Devices Act (SMDA) Statement

The oxygen supplied by the oxygen concentrator is supplemental and is not considered to be life supporting or life sustaining. The failure of the device would NOT have serious health consequences to the user.

Intended Use of Device

The Deployable Oxygen Concentration System (DOCS) is designed to reliably and continuously provide supplemental oxygen to patients who may have difficulty extracting oxygen from the air that they breathe. It is intended for supplemental use in Department of Defense medical facilities or institutions, in nursing locations, health care facilities, in sub-acute care, and/or in acute care environments, whether in peacetime conditions or in deployed military scenarios.

DOCS has the capability to supply pressurized oxygen to fill gas cylinders that can be transported to remote locations away from the DOCS system or to fill cylinders for a patient's ambulatory use.

The device has no contraindications.

The oxygen supplied by the oxygen concentrator is supplemental and is not considered to be life supporting or life sustaining.

The system is not sold or labeled as sterile.

Description of Device

The Deployable Oxygen Concentration System (DOCS) draws in normal air and produces an oxygen-rich output. The air we encounter in nature is a mixture of roughly 78% nitrogen, 21% oxygen, and 1% other trace gasses. The DOCS separates the nitrogen from the air, producing an output of concentrated oxygen at 93 percent from air by the molecular sieve process. It contains not less than 90.0 percent and not more than 96.0 percent, by volume, of O2, the remainder consisting mostly of argon and nitrogen.

DOCS employs an integral oxygen analyzer to provide control of oxygen purity.

The DOCS device is an electromechanical device consisting primarily of an oxygen concentrator that is molecular sieve type, a compressor module, and one or more oxygen collection cylinders. The oxygen concentrator operates by adsorbing water and nitrogen from filtered air. The resulting gas has increased oxygen at flow rates from 5 to 240 liters per minute at pressure of 100 psi nominal and high pressure cylinder filling capability.

Device Labeling

Where oxygen is piped directly from the collecting tank to the point of use, each outlet is labeled "Oxygen 93 Percent." All safety and operational labeling is clearly imprinted and easy to understand.

The system is not sold or labeled as sterile.

Comparison of Technological Characteristics

The primary function of the Deployable Oxygen Concentration System (DOCS) is to provide supplemental oxygen, and has molecular sieve technology as the means of oxygen concentration as do the predicate devices. The technological characteristics of the device and its intended use to supply supplemental oxygen are basically the same and raise no new questions of safety and effectiveness.

The technology is well established and has been used in other legally marketed products. There are no major technological differences.

The primary differences between the Deployable Oxygen Concentration System (DOCS) and predicate equipment are in:

- Overland mobility of the system using optional wheels
- Increased system size with volume output of up to 240 lpm
- Operation outside of the medical facility rather than inside with patients
- Application by the Department of Defense under deployed military scenarios.

Special Controls/Conformance to Recognized Standards

Deployable Oxygen Concentration System (DOCS) conforms to the recognized standard USP 24-NF 19 (through supplement Four, December 31,2001).

DOCS employs an integral oxygen analyzer to provide control of oxygen purity in accordance with the standard.

Summary of Performance Testing

Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the Deployable Oxygen Concentration System (DOCS), to demonstrate performance as intended and substantial equivalency to predicate devices. Testing involved the following areas:

- Purity
- Flow Rate
- Electrical Safety
- Mechanical
- Controls
- Device Performance

Acceptance criteria were based on US Army specifications (USAMMA), and those established in voluntary standards.

In all instances the device met all required performance criteria and functioned as intended, meeting the acceptance criteria.

Conclusions

In summary, Pacific Consolidated Industries has demonstrated that the Deployable Oxygen Concentration System (DOCS) is safe and effective. The combined testing and analysis of results provides assurance that the device meets its specifications, is safe and effective for its intended use, and is substantially equivalent to the currently marketed devices.

Truthfulness and Accuracy Statement

Partner of Pacific Consolidated Industries certifies that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Mr. Lee W. Smith
Pacific Consolidated Industries LLP
3430 West Carriage Drive
Santa Ana, CA 92704

Re: K020330
Deployable Oxygen Concentration System (DOCS)
Regulation Number: 868.5440
Regulation Name: Generator, Oxygen, Portable
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: March 7, 2002
Received: March 8, 2002

Dear Mr. Smith:

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 notifications, and receive FDA clearance prior to marketing the device.

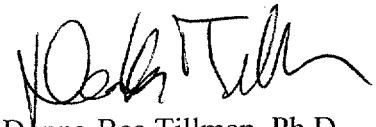
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: **K020330**

Name: **Deployable Oxygen Concentration System (DOCS)**

DOCS is intended to provide supplementary oxygen. The device is to be used by trained medical personnel for military use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The Counter Use ___ (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020330