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K100957

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510(k) Summary

Deployable Oxygen Concentration System (DOCS)

JAN 2 1 2011

Type of FDA Submission	Traditional 510(k)

Submitter Information

Submitter's Name:	Pacific Consolidated Industries
Submitter's Address:	12201 Magnolia Avenue Riverside, California 92503-4820
Owner/Operator ID:	9049531
Contact Person:	Gary W. Clark
Submitter's Phone:	(951) 479-0872 (Phone) (951) 479-0861 (Fax)
Date of Preparation:	April 5, 2010

Device Classification

Classification Name:	Portable Oxygen Generator
Device Classification:	868.5440
Product Code:	CAW
Panel:	Anesthesiology and Respiratory Therapy Devices

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Deployable Oxygen Concentration System (DOCS) Family

Predicate Legally Marketed Device Equivalence

Substantial equivalence is claimed to the legally marketed predicate devices previously submitted under K020330 – Deployable Oxygen Concentration System (DOCS) and K061414 – Expeditionary Deployable Oxygen Concentration System (EDOCS) & Mobile Oxygen Storage Tank (MOST).

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) family of devices generates and delivers USP grade 93% ± 3% oxygen. The oxygen supplied by these units is for supplemental use and is not considered to be life supporting or life sustaining.

DOCS family devices may be used to fill high pressure oxygen cylinders for use in locations remote to the DOCS unit or for ambulatory patient use.

These devices are to be used only by trained personnel in disaster relief, crisis response or humanitarian relief situations where bottled or bulk oxygen is not readily available, as hospital backup systems, in local emergencies where disaster has rendered the primary oxygen supply unusable, or by trained military personnel in peacetime or wartime support of Armed Forces.

Description of Device

The Deployable Oxygen Concentration System (DOCS) is a family of electromechanical devices that use a molecular sieve to adsorb nitrogen, water and carbon dioxide from filtered air, producing an output of high purity oxygen (93 ± 3 %) via the Vacuum Swing Adsorption process. The remainder of the gas product consists mostly of argon and nitrogen.
Depending on the unit size, the resulting high purity oxygen can be delivered at flow rates ranging from 66 to 500 liters per minute at a pressure of 50 - 100 psig under standard conditions.
Selected models may be configured with one or two integral high pressure compressors or an accessory high pressure compressor may be added to some models. These high pressure units are capable of filling oxygen cylinders to 2,250 or 3,000 psig.

Device Labeling

Each member of the DOCS family is clearly labeled with the following:

- 93% ±3% Oxygen
- Not for use in oil-rich or flammable atmosphere
- Rx Only

Comparison of Technological Characteristics

The technological characteristics of these devices and their intended use to supply supplemental oxygen are the same as the predicate devices and raise no new questions of safety and effectiveness.

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Special Controls/Conformance to Recognized Standards

The Deployable Oxygen Concentration System (DOCS) family conforms to the recognized standard USP 30-NF 25 and employs an integral oxygen analyzer to monitor and control oxygen purity in accordance with the standard.

The DOCS has been tested under IEC 60601-1-1 and has passed the required "Safety requirements for medical electrical systems" tests.

The DOCS has been tested under IEC 60601-1-2 and has passed the required Electromagnetic Compatibility tests.

Summary of Performance Testing

Testing was conducted to establish the performance and reliability characteristics of the DOCS family, to demonstrate performance as intended and substantial equivalency to predicate devices. Testing involved the following areas:

- Purity
- Flow Rate
- Electrical Safety
- Mechanical Operation
- Hardware and Software Controls
- Environmental Conditions

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

Conclusions

In summary, Pacific Consolidated Industries has demonstrated that the DOCS family members meet their specifications, are safe and effective for their intended use, and are substantially equivalent to the currently marketed devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Gary Clark
Pacific Consolidated Industries, LLC
12201 Magnolia Avenue
Riverside, California 92503

JAN 21 2011

Re: K100957
Trade/Device Name: Deployable Oxygen System (DOCS) Family
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: January 7, 2011
Received: January 11, 2011

Dear Mr. Clark:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

Indications for Use

510(k) Number (if known): K100957

Device Name: Deployable Oxygen System (DOCS) Family

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 Schultz

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

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