K040738

APR 3 0 2004

510(k) Summary

Mobile Oxygen Storage Tank (MOST)

Type of FDA Submission: Traditional 510(k)

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:	Tarik Naheiri
Submitter's Phone:	714-979-9200 (Phone) 714-436-9150 (Fax)
Date of Preparation:	March 18, 2004

Device Name:	Mobile Oxygen Storage Tank
Common Trade Name:	MOST
Classification Name:	Portable Oxygen Generator with accessories
Device Classification:	868.5440 (Class II)
Product Code:	CAW
Panel:	Anesthesiology and Respiratory Therapy Devices

Predicate Legally Marketed Device Equivalence

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

K020330 – Deployable Oxygen Concentration System (DOCS)
K003939 – Venture IOH 200 Home Fill II Complete Home Oxygen System by Invacare Corporation

Both the DOCS and the Home Fill 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.

The Home Fill II predicate includes a proprietary cylinder to be filled from an oxygen generation system. The DOCS when used with the MOST as an accessory will have the same intended use and technological characteristics as the Invacare unit.

These predicate devices use an oxygen-generating process to fill cylinders that can be transported to where the oxygen is needed. The DOCS system also has this same cylinder filling capability, but with the addition of the MOST there is another option for deploying the oxygen in the field.

Safe Medical Devices Act (SMDA) Statement

The oxygen supplied by the MOST 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.

Description of Device

The Mobile Oxygen Storage Tank (MOST) is an oxygen storage and distribution system consisting of lightweight, high strength, high-pressure composite wound brass lined cylinders and a distribution manifold secured within a rugged waterproof case. The MOST contains 10,000 liters of oxygen when filled to 2,250 psig. The MOST has a maximum flow capability of 225 LPM, which is equivalent to 75 LPM per Oxygen Output fitting (3 fittings per MOST).

The MOST's small footprint, relatively light weight and easy carrying system make it optimal for military deployments. Eight handles, two on each long side of the MOST and two on the top at each end are provided for ease of transportation. The MOST contains the Apparatus Kit, which includes the equipment required to distribute the oxygen to up to three patients concurrently. The exterior dimensions of the MOST are: a length of

37.25", a width of 27.18", and height of 15.44." The MOST weighs approximately 184 pounds when fully charged to 2250 psig.

Intended Use of Device

The Mobile Oxygen Storage Tank (MOST) is intended to provide 93% oxygen at 50 psig nominal pressure for supplemental oxygen use only. The MOST is intended to be filled from the Expeditionary Deployable Oxygen Concentration System (E-DOCS) only. The MOST is intended for military use only.

Device Labeling

The MOST, is clearly labeled "93% Oxygen".

The MOST has labels clearly showing contraindications.

The MOST is clearly labeled "For Use With EDOCS Only".

The MOST is labeled as "Rx Only"

The system is not sold or labeled as sterile.

Comparison of Technological Characteristics

The MOST consists fundamentally of two cylinders, a manifold that connects to the EDOCS system for filling, as it does not have its own oxygen generating capability. In this lack of filling capability, the MOST is an accessory to the DOCS system and together they have the same technological characteristics as the Home Fill II systems. The MOST system is simpler and at least as safe and effective as both the DOCS and the Home Fill II systems. The technology is well established and has been used in other legally marketed products.

As with the Home Fill II system, the MOST is filled only from the DOCS system, which conforms to the USP 24-NF19 standard.

Summary of Performance Testing

Verification and validation testing activities were conducted to establish the performance, reliability and safety characteristics of the MOST, to demonstrate performance as intended. Testing involved the following areas:

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

Acceptance criteria were based on USAF specifications (AFMESA), DOT-CFFC, NASA and MIL-STD-810F.

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 MOST 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2004

Mr. Tarik Naheiri
Director of Technology and Engineering
Pacific Consolidated Industries, LLP
3430 West Carriage Drive
Santa Ana, CA 92704

Re: K040738
Trade Name: Mobile Oxygen Storage Tank (MOST)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: March 18, 2004
Received: March 25, 2004

Dear Mr. Naheiri:

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.

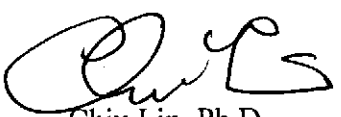
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Statement of Indications for Use

Name: **Mobile Oxygen Storage Tank (MOST)**

The Mobile Oxygen Storage Tank (MOST) is intended to provide 93% oxygen at 50 psig nominal pressure for supplemental oxygen use only. The MOST is intended to be filled from the Expeditionary Deployable Oxygen Concentration System (E-DOCS) only. The MOST is intended 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 X
(Per 21 CFR 801.109)

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

510(k) Number: K640738