MAR 15 2006

K053498

5. Traditional 510(k) Pre-market Notification Summary (Per 21CFR807.92)

December 19, 2005

Device Name: HyperOx 101, a Multiplace Hyperbaric Oxygen Treatment Chamber

Common Name: Multiplace Hyperbaric Chamber

Regulation No. 868.5470

Class: II

Code: CBF

Submitted by:
WJO, Inc.
424 Mill Street
Canal's End Plaza
Bristol, PA 19007
William J. O'Brien, D.O., President
Phone: 215-826-8050 Fax 215-826-8053
Contact person: Chris Belletieri, D.O.

Establishment Registration Number: Pending

Manufacturer:
Railway Specialties Corporation (DOD Cage Code 86700)
2979 State Road, P.O. Box 29
Bristol, Pennsylvania 19007-0029
Phone: 215-788-9242, Fax. 215-788-9244
Contact person: Frederic H. Calkins, Jr. - President

Establishment Registration Number: Pending

Predicate Device(s):
Fink Engineering Pty. Ltd Models SL8/DL8/TL20 (K031649)
Pan-American Hyerbarics, Inc. PAH-S1 - K021693
Perry Sigma MP Hyperbaric Chamber – K930748

SUMMARY

The Undersea and Hyperbaric Medical Society (UMHS) defines hyperbaric oxygen therapy as breathing 100% medical oxygen at pressures higher than atmospheric in a hyperbaric chamber. According to the National Fire Protection Association (NFPA), hyperbaric chambers are classified into two categories: Class A (multi-occupant) and Class B (single occupant). The HyperOx Hyperbaric Oxygen Treatment Chamber is a Class A multi-place hyperbaric chamber designed to treat up to 10 patients up to 32 psig. The device will use compressed, dried/chilled air as the pressurization gas and 100% medical oxygen as the treatment gas.

The HyperOx Hyperbaric Oxygen Treatment Chamber is intended to be procured and used by physicians and hospitals to treat a variety of medical conditions that respond to hyperbaric oxygen therapy. Approved conditions responding to hyperbaric oxygen therapy are provided at the end of this summary.

The HyperOx Hyperbaric Oxygen Treatment Chamber is designed and fabricated in strict accordance with the requirements of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code Section VIII, Division 2 using Section II parts A, C and D, Section V, Section IX, ASME-PVHO-1-2002-2003 (American Society of Mechanical Engineers-Pressure Vessels for Human Occupancy) and the National Fire Protection Association (NFPA 99).

Specifications of the HyperOx 101 Hyperbaric Oxygen Treatment Chamber are:

Design Code	ASME Section VIII, Div 1 and ASME-PVHO-1
Operating Pressure	32 psig
Operating Temperature	65 to 95 degrees F
Design Pressure	45 psig
Design Temperature	65 to 95 degrees F
Design Life	70,000 cycles (approx. 30 years)
Hydrostatic Pressure	42.0 psig
Weight	11,200 lbs. (5.6 tons)
Dimensions	72" W X 88" H X 16' 6" L
Doorway Opening Size	30" X 60" clear opening

Lighting	Four (4) external dimmable lights (1) 12" dia. clear view portlight in door (8) 9" dia. clear view portlights in shell
Capacity	Up to 11 occupants
Fire Suppression	IAW NFPA 99
Finish	SSPC-SP-10 shotblast, primed & painted
Controls	Manual electropneumatic pressurization Manual electropneumatic depressurization
Ventilation	Constant airflow
BIBBS with dump	Four
Oxygen Flow Manifold	Twelve feeds to O2 mask
Gas Analysis	Oxygen and carbon dioxide
Communications	Wireless PA
Entertainment (optional)	Wireless internet connection External TV system w/remote & DVD player AM/FM tuner with CD player

WJO, Inc. and Railway Specialties Corporation suggest that the general design approach, method of pressurization and the intended use of the HyperOx Hyperbaric Oxygen Treatment Chamber is substantially equivalent to the Fink Engineering Pty. Ltd models SL8/DL8/TL20 (K031649), Pan-American Hyperbarics, Inc PAH-S1 Chamber (K021693), and Perry Sigma MP Hyperbaric Chamber (K930748) and is proposing them as predicate devices.

INTENDED USE:

Hyperbaric Oxygen Therapy (HBOT) is a painless procedure in which a person is exposed to increased pressure, thus allowing greater absorption of oxygen throughout body tissues. This increased pressure allows more oxygen to reach the cells within the body therefore contributing to the many healing and therapeutic benefits.

When utilizing HBOT, oxygen is forced into the tissues, organs, brain and fluids throughout the body through the pressurization of the hyperbaric chamber.

- Oxygen floods areas that are oxygen starved to stimulate cell growth and regeneration.
- Oxygen displaces toxins and other impurities to assist in detoxification of the patients system.
- Hyperbaric oxygen acts as an anti-viral and anti-bacterial, as bacteria and viruses typically cannot tolerate oxygen.
- Hyperbaric oxygen is an immune modulator, supporting the immune system to bring T and B cells within normal levels.
- Oxygen reduces tumor growth in cancer patients.
- Hyperbaric oxygen increases neural brain function due to oxygen saturation.
- Hyperbaric oxygen provides many other condition specific benefits.

The expressed and intended use of the HyperOx 101 Hyperbaric Oxygen Treatment Chamber is to provide therapy to those patients with selected medical conditions that have been determined to respond to the application of hyperbaric oxygen. As a Class II prescriptive device, it is further intended for physician involvement in their procurement and routine use.

The UHMS is the professional medical organization chartered with setting the standards of care defining the appropriate use of hyperbaric oxygen. More specifically, the UHMS publishes a listing of medical conditions that have been clearly established as appropriate primary or adjunctive use of hyperbaric oxygen (HBO). The disorders on the list have been scientifically validated and verified through extensive data collection.

The conditions listed as appropriate for the use of Hyperbaric Oxygen Treatment are:

- Air or gas embolism
- Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
- Clostridial myositis and myonecrosis
- Crush injury, compartment syndrome and other acute traumatic ischemias
- Decompression sickness
- Enhanced healing of selected problem wounds
- Exceptional blood loss anemia
- Necrotizing soft tissue infections
- Osteomyelitis (refractory)
- Delayed radiation injury (soft tissue and bony necrosis)
- Skin grafts and flaps (compromised)
- Thermal burns
- Intercranial abscess

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Mr. Chris Belletieri
WJO, Incorporated
424 Mill Street at Canal's End Plaza
Bristol, Pennsylvania 19007

Re: K053498
Trade/Device Name: HyperOx Hyperbaric Oxygen Treatment Chamber – Model 101
Regulation Number: 868.5470
Regulation Name: Hyperbaric chamber
Regulatory Class: II
Product Code: CBF
Dated: December 16, 2005
Received: December 16, 2005

Dear Mr. Belletieri :

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 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) 594-4618. 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

Indications for Use

510(k) Number (if known): k053498

Device Name: HyperOx Hyperbaric Oxygen Treatment Chamber - Model 101

Indications For Use:

- Air or gas embolism
- Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
- Clostridial myositis and myonecrosis
- Crush injury, compartment syndrome, and other acute traumatic ischemias
- Decompression sickness
- Enhanced of selected problem wounds
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- Skin grafts and flaps (compromised)
- Thermal burns
- Intercranial abscess

Prescription Use Only
(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)

...Anesthesiology, General Hospital,
...Control Dental Devices

k053498