K052866

DEC 13 2005

Hyperbaric Technologies Inc.

Abbreviated 510(k) NOTIFICATION SUMMARY
(Per 21 CFR 807.92)

Prepared: 3 March 2005

Trade Name: OxyHeal 1000 Monoplace Hyperbaric chamber

Common Name of Device: Monoplace Hyperbaric Chamber

Classification: 73 CBF, 21 CFR 868.5470

Establishment Registration Number: 2029408

Claimed Predicate Device(s)

Environmental Tectonics Corp. 'Bara-Med" (K020974)
Hyperbaric Technologies, Inc. 'OxyHeal 2000' (K011866)

ADDRESS OF MANUFACTURER:

OxyHeal Health Group
P.O. Box 1987
La Jolla, CA 92038

CONTACT PERSON:

DAVE HEANEY
Director, Quality Assurance
OxyHeal Health Group
3224 Hoover Avenue
National City, CA 91950
(619) 336-2022

EXECUTIVE SUMMARY

The Undersea and Hyperbarics Medical Society (UHMS) defines Hyperbaric oxygen therapy as breathing 100% oxygen at pressures higher that 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 OxyHeal 1000 series is a Class B monoplace hyperbaric chamber system designed to treat 1 patient to a maximum operating pressure of 3 Atmospheres Absolute (ATA) or 30 pounds per square inch gauge (psig). The chamber uses compressed 100% oxygen as the pressurization gas as well as the hyperbaric treatment gas.

The OxyHeal 1000 monoplace hyperbaric chamber series are intended to be procured and used by physicians to treat a variety of medical conditions that respond to hyperbaric oxygen. The Undersea and Hyperbaric Medical Society (UHMS) produces a list of medical conditions that have been identified for the appropriate primary or adjunctive use of hyperbaric oxygen. These approved conditions include: air or gas embolism; carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning; clostridial myositis and myonecrosis (gas gangrene) ; crush injury, compartment syndrome and other acute traumatic ischemias; decompression sickness; enhancement of healing in selected problem wounds; exceptional blood loss anemia; Intracranial abscess; necrotizing soft tissue infections; osteomyelitis (refractory); delayed radiation injury (soft tissue and bony necrosis); skin flaps and grafts (compromised); and, thermal burns. Aggressive research into the beneficial effects of hyperbaric oxygen, when appropriately applied, will result in additional medical conditions being added to the host of indications by the UHMS.

The Oxyheal 1000 monoplace hyperbaric chamber series is designed and fabricated in accordance with the requirements of the ANSI/ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, Pressure Vessels, ANSI/ASME-PVHO-1 (American Society of Mechanical Engineers-Pressure Vessels for Human Occupancy); and NFPA 99, Health Care Facilities, Chapter 20, Hyperbaric Facilities. The overall external length of the chamber is 105" inches. Its internal diameter is 33.5" inches. These features allow for the state of the art treatment of one (1) patient in comfort. The large cylindrical window create an open atmosphere thus reduce patient confinement anxiety. Pressurization and ventilation is continuously provided by compressed 100% oxygen. The patient breathes the chamber atmosphere directly. An air-break assembly using a regulated medical air source and mask is available.

A low-voltage patient intercommunication system designed and installed in accordance with NFPA 99, Chapter 20 provides communications between the patient in the chamber and the outside chamber operator. It also provides the patient with audio program content from external sources such as TV's, cassette players, radios, etc. A television screen is mounted externally to provide yet another dimension of entertainment.

Single operator chamber pressure control is achieved via a simple industrial adjustable controller with output and input feedback. A pneumatic, manually operated control system is provided for double control redundancy. The rate and direction of pressure change, time at a particular pressure, ventilation rate, fire suppression system, mechanical ventilator and air break assembly are controlled from a single point by the chamber operator, either indirectly with an automatic electronic system or directly by a pneumatic system. A series of penetrators are provided in the vessel end caps wall to allow user supplied intravenous lines, suction, medical monitoring leads, etc., to be used as required.

OxyHeal has concluded that the OxyHeal 1000 Monoplace Hyperbaric Chamber series and its predicate devices have very similar principles of operation. Specifically, the general design approach, method of pressure control and intended use of the OxyHeal 1000 monoplace hyperbaric chamber series are substantially equivalent to the Environmental Tectonics Corp. 'ETC Bara-Med' Monoplace Hyperbaric Chamber (K020974), and the Hyperbaric Technologies, Inc. 'OxyHeal 2000' (K011866) and is proposing them as predicate devices for the Oxyheal 1000 Monoplace Hyperbaric Chamber series.

Intended Use:

It is the expressed, intended use of the Oxyheal 1000 Monoplace Hyperbaric Chamber series 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 the 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. It should be noted

that the list is dynamic. Based on the strength of the scientific data, disorders are both added and removed from the list, depending on the outcomes of scientific pursuit.
The conditions listed as appropriate for the use of HBO in the current edition of the Hyperbaric Oxygen Therapy Committee report (2003) are as follows:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myositis and myonecrosis
4. Crush injury, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness.
6. Enhanced of healing in selected problem wounds
7. Exceptional blood loss (anemia)
8. Intracranial abscess
9. Necrotizing soft tissue infections
10. Osteomyelitis (refractory)
11. Delayed radiation injury (soft tissue and bony necrosis)
12. Skin Grafts and flaps (compromised)
13. Thermal burns

The Oxyheal 1000 Monoplace Hyperbaric chamber series is designed to be installed and operated in medical facilities as defined by the NFPA 99, Health Care Facilities, Chapter 20, Hyperbaric Facilities. Further, this system is intended to be operated only by medical personnel specifically trained in the appropriate use of HBO and the safe operations of all related equipment such as the hyperbaric chamber.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2005

Mr. David M. Heaney
Director, Quality Assurance
OxyHeal Health Group
3224 Hoover Avenue
National City, California 91950

Re: K052866
Trade/Device Name: OxyHeal 1000 Monoplace Hyperbaric Chamber
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: October 5, 2005
Received: October 14, 2005

Dear Mr. Heaney:

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.

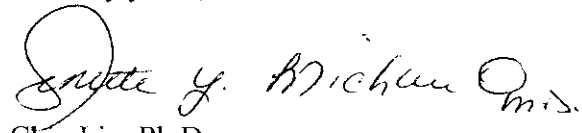
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.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

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning
   Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
3. Clostridal Myositis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias
5. Decompression Sickness
6. Enhancement of Healing in Selected Problem Wounds
7. Exceptional Blood Loss (Anemia)
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections
10. Osteomyelitis (Refractory)
11. Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
12. Skin Grafts & Flaps (Compromised)
13. Thermal Burns

Prescription Use ✓ 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)

K052846