MAY 22 2009

K082455

Gulf Coast Hyperbarics, Inc. 1100 W. 26th St.
Lynn Haven, FL 32444
(850) 271-1441

510(K) Summary for Gulf Coast Hyperbarics, Inc.
Rectangular Multiplace Hyperbaric Chamber (K082455)

Date: May 22, 2009

To: Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD. 20850

Submitter: Gulf Coast Hyperbarics, Inc.
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Lynn Haven, FL 32444
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Name of Device:

Proprietary name: Rectangular Multiplace Hypebaric Chamber
Common/Usual Name: Hypebaric Chamber

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Equivalent Devices:

Fink Engineering Multiplace Hyperbaric Chamber- K031649
Perry Baromedical Multiplace Hyperbaric Chamber- K930748
Gulf Coast Hyperbarics Multiplace Hyperbaric Chamber – K950957

Device Description

The Gulf Coast Hyperbarics rectangular multiplace hyperbaric chambers are designed and manufactured 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, 2005 Edition. The new Gulf Coast Hyperbaric multiplace rectangular chambers (K082455) are designed and manufactured using the same major components as in the cleared Gulf Coast Hyperbarics multiplace cylindrical chamber (K950957). The rectangular multiplace chamber includes as a key component, a new and user friendly rectangular design which is simple and simulates as closely as possible the clinical conditions found elsewhere in their working environment.

The rectangular chamber(s) place major emphasis on patient and operator safety, and user-friendly operator controls and includes several unique features including:

- A large, comfortable rectangular hyperbaric chamber that has been outfitted to appear like any other clinical room in a hospital to reduce patient anxiety
- Large walk-through rectangular sliding doors that fit flush with the floor so that patients can be wheeled into the chamber without bumping over the doorjamb.
- A large and easy to use control console designed to display all functions of the chamber

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- An oxygen hood supply and exhaust system designed for easy use and eliminates over or under pressurization of the hood and eliminates the possibility of "shrink wrapping" the patient hood.
- Air conditioning system providing controllable cooling and heating of the chamber interior. The temperature and humidity is monitored at the control console.

Specification of the Rectangular Multiplace Hyperbaric Chamber System is as follows:

Design Code	ASME Section VIII, Div. 1 & ASME PVHO-1
Operating Pressure	3.0 ATA
Operating Temperature	62 degrees F to 100 degrees F
Design Pressure	32.3 PSI
Design Temperature	62 degrees F to 100 degrees F
Design Life	70,000 Cycles/30 yrs
Hydrostatic Pressure	42.0 PSI
Inspection Authority	ASME "U" Stamp
Weight	113,000 lbs
Dimensions	9.3'w x 8.3'H x 32'L
Volume	2,423.8f3
Medical Lock	13"dia x 14" long
Doors (all 3)	48"w x 76"H
Lighting	10 External0Dimmable
Viewports/Chamber	18"dia (9 ea)
Viewports (3 doors)	8" dia. (3 ea)
Capacity	12-seated patients
Fire Suppression	Iaw NFPA99- 2005 Edition
Finish	Sand blasted & painted

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Life Support Controls	Manual-Electric
Environmental Control	Cooling & Heating
Ventilation	As Required
BIB w/overboard Dump	3
Hoods w/overboard Dump	12
Depth Measurement	Dual analog both chambers
Gas Analysis	Dual oxygen and single
	Carbon dioxide analyzers
Communications	Internal/External PA system
	Open/Closed communication system
	Sound power phones (3)
	Closed Circuit Television (3)
Entertainment	Individual four-channel Audio for 12 Patients
Television System	Color television-purged
	Main chamber, AM/FM Receiver
	CD & DVD

Gulf Coast Hyperbarics, Inc. has concluded the general design approach, method of pressure control, and intended use of the rectangular chamber multiplace hyperbaric chamber is substantially equivalent to the Perry Baromedical multiplace chamber (K930748), The Fink Engineering multiplace hyperbaric chamber (K031649) and the Gulf Coast Hyperbarics multiplace chamber (K950957) and is proposing them as predicate devices for the Gulf Coast Hyperbarics rectangular multiplace hyperbaric chamber (K085455).

Indications for use:

It is the expressed, intended use of the Gulf Coast Hyperbaric rectangular hyperbaric chamber 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. 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 (1999) is 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 selected problem wounds
7. Exceptional blood loss anemia
8. Necrotizing soft tissue infections
9. Osteomyelitis (refractory)
10. Delayed radiation injury (soft tissue and bony necrosis)
11. Skin grafts and flaps (compromised)
12. Thermal burns
13. Intracranial abscess

INDICATIONS FOR USE:
(As stated on the UHMS website)

The following indications are approved uses of hyperbaric oxygen therapy as defined by the Hyperbaric Oxygen Therapy Committee. The Committee Report can be purchased directly through the UHMS.

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning and 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

Mr. James W. McCarthy
Owner
Gulf Coast Hyperbarics, Incorporated
1100 West 26th Street
Lynn Haven, Florida 32444

Re: K082455
Trade/Device Name: Multiplace Hyperbaric Chamber
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: May 1, 2009
Received: May 12, 2009

Dear Mr. McCarthy:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting 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): K082455

Device Name: MULTIPLACE HYPERBARIC CHAMBER

Indications for Use:

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

510(k) Number: K082455

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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INDICATIONS FOR USE
510(K): K0824455
Device Name: Rectangular Multiplace Hyperbaric Chamber

Indications for Use:

Statement of Indications

It is the expressed, intended use of the Gulf Coast Hyperbarics, Inc. Rectangular Hyperbaric Oxygen Treatment Facilities 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

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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

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In addition, I have included a copy of the most current indications for hyperbaric oxygen therapy from the UHMS website.

Respectfully,

James W. McCarthy, President
Gulf Coast Hyperbarics, Inc.