K081506

JUL 25 2008

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

Prepared: May 26, 2008

TRADE NAME: Hyperbaric America, LLC, Presidential Monoplace Hyperbaric Chamber Systems

COMMON NAME OF DEVICE: Monoplace Hyperbaric Chamber

CLASSIFICATION: 73 CBF, 21 CFR 868.5470

ESTABLISHMENT REGISTRATION NUMBER: Pending

CLAIMED PREDICATE DEVICE(S):

Sechrist 2500 (K934164)
Sechrist 2800 (K950386)
Sechrist 3200 (K950386)
Perry Sigma 1 (K832127)
Perry Sigma 34 (K990927)
ETC BaraMed (K993010)
Pan America Hyperbarics PAH-S1 (K021693)
HyperTec 3200 (K002795)

ADDRESS OF MANUFACTURER:

284 Ridge Road
Hinckley, OH 44233

CONTACT PERSON: Joe Adkins
(216) 849-7847

SUMMARY

The Hyperbaric America Presidential Monoplace Hyperbaric Chamber Systems (Model HA-34 and HA-38) are Class B monoplace hyperbaric chambers designed to treat one patient at up to a maximum operating pressure of 3 Atmospheres Absolute (ATA) or 29.4 pounds per square inch gauge (psig). The chamber uses 100% oxygen as the pressurization gas and patient breathes the oxygen contained inside the chamber as the hyperbaric treatment gas. Air pressurization with oxygen delivery by mask is optional

The Presidential Hyperbaric Oxygen Systems are 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, 2007 Edition); and, NFPA 99, Health Care Facilities, Chapter 20, Hyperbaric Facilities, 2005 Edition. The overall external length of both models is 92 inches. The internal diameter of Model HA-34 is 33.5 inches and of Model HA-38 is 38 inches. The chamber is constructed by half-steel and half-acrylic tube. A low-voltage patient intercommunication system designed and installed in accordance with NFPA 99, Chapter 20 and provides communications between the patients in the chamber and the outside chamber operator.

The system consists of an operator control panel that contains all of the controls and connection points. Single operator chamber pressure control is achieved via a simple manual pneumatic control. Spare penetrators are provided to allow user supplied medical monitoring leads, etc., to be used as required. Patient is loaded and unloaded by a retractable gurney. When loading, patient lies down on the fire retardant foamed bunk, aligned to the rails of the chamber and fixes four wheels of the gurney, then push the bunk into the chamber. Unloading the patient with an opposite procedure. The chamber is also equipped with safety switch for pressurization. There is no gas supply for pressurization before the chamber's door is closed and secured thoroughly.

Intended Use:

It is the expressed, intended use of the Hyperbaric America, LLC, Presidential Hyperbaric Chamber Systems 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 its procurement and routine use.

The conditions listed as appropriate for the use of HBO by the Undersea & Hyperbaric Medical Society's 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 healing 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

The Hyperbaric America, LLC, Presidential Hyperbaric Chamber Systems are 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 operation 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

JUL 31 2008

Mr. Tom Workman
Hyperbaric America, LLC
1811 Copper Ridge Drive
San Antonio, TX 78259-3612

Re: K081506
Trade/Device Name: Hyperbaric America, LLC, Presidential Monoplace Hyperbaric Chamber Systems
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: May 12, 2008
Received: May 2, 2008

Dear Mr. Workman:

This letter corrects our substantially equivalent letter of July 25, 2008.

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 (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.

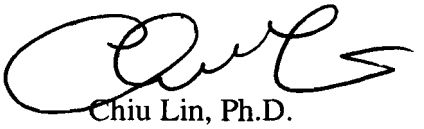
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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 continue 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-***[see OC organization structure below for correct phone extension].*** 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 (240) 276-3150 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): Pending

Device Name: Hyperbaric America, LLC, Presidential Monoplace Hyperbaric Chamber Systems

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Prescription Use XX (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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