DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2004

Mr. Rick Ryder
Owner
Hyperbaric for Life, LLC
3206 West State Avenue
Phoenix, Arizona 85051

Re: K041007
Trade/Device Name: Millennium 2000, 2001, 2002, 2003, 2004, 2005
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: October 25, 2004
Received: October 25, 2004

Dear Mr. Ryder:

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) 276-0115. 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

Section 2	Indications for Use

510(k) Number: K _041007_____ (To be assigned)

Device Name: Millennium 2000,2001,2002,2003,2004,2005

Indications for Use:
The conditions listed as appropriate for the use of Hyperbaric Oxygen Therapy in the current edition of the Undersea and Hyperbaric and Medical Society (UHMS)Hyperbaric Oxygen Therapy Committee Report (1998) are as follows

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 bone necrosis)

Skin grafts and flaps (compromised)

Thermal burns

Intracranial abscess

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

510(k) Number: K041007

Prescription Use X **or** **Over-the-counter use __**
(Per CFR 801.109)