K984313

OCT 22 1999

510(k) SUMMARY

Hyox Systems, Ltd.'s
HTU3 Hyperbaric Chamber

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Hyox Systems, Ltd.
Pressure Products House
Westhill Industrial Estate, Westhill
Aberdeen, AB32 6TQ
Scotland, United Kingdom

Contact Person:

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Scotland, United Kingdom

Date Prepared: February 3, 1999

Name of Device

HTU3 Hyperbaric Chamber

Common or Usual Name

Hyperbaric Chamber

Classification Name

Hyperbaric Chamber

Predicate Devices

(1) Hyox Systems, Ltd.'s, HTU2 Hyperbaric Chamber
(2) Sechrist Industries's Sechrist 2500E Hyperbaric Chamber
(3) Sechrist Industries's Sechrist 3200 Hyperbaric Chamber

Substantial Equivalence

The HTU3 Hyperbaric Chamber and the predicate devices listed above have the same intended use and very similar principles of operation and technological characteristics. Specifically, the HTU3 and the predicate devices are intended to promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure. The HTU3 is indicated for use in treating: (1) Air or Gas Embolism; (2) Carbon Monoxide Poisoning and Smoke Inhalation, Carbon Monoxide Poisoning Complicated by Cyanide Poisoning; (3) Clostridal Myonecrosis; (4) Crush Injury, Compartment Syndrome, Acute Traumatic Ischemias; (5) Decompression Sickness; (6) Enhancement of Healing in Selected Problem Wounds; (7) Exceptional Blood Loss; (8) Necrotizing Soft Tissue Infections; (9) Osteomyelitis (Refractory); (10) Radiation Tissue Damage; (11) Skin Grafts & Flaps (Compromised); (12) Thermal Burns; and (13) Adjunctive Hyperbaric Oxygen in Intracranial Abscess.

Moreover, the HTU3 is a modified version of the HTU2. To comply with the ASME/PVHO-1 safety standard for pressure vessels for human occupancy, Hyox increased the operating pressure of the Company's hyperbaric therapy unit from two times atmospheric pressure to three times atmospheric pressure, the operating pressure of the Sechrist devices. To facilitate this change, certain minor modifications to the HTU2 were necessary to configure the HTU3, including: (1) an increase in the compression time, as well as an increase in the slow, fast, and emergency decompression times (although the compression and the decompression rates remain unchanged); (2) an increase in the thickness of steel used to manufacture the hyperbaric chamber; (3) an increase in thickness of the device's acrylic windows; and (4) a change from a compressor that functions using a diaphragm unit to a compressor that works using a free piston mechanism. Finally, also to comply with the ASME/PVHO-1 safety standard for pressure vessels for human occupancy, Hyox has made two additional modifications. Hyox has modified the shape of the chamber's acrylic windows and the grade of steel from which the hyperbaric chamber is manufactured.

None of these differences raises new questions of safety or effectiveness. Thus, the HTU3 Hyperbaric Chamber is substantially equivalent to the HTU2, the Sechrist 2500E, and the Sechrist 3200 hyperbaric chambers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

Mr. Edward C. Wilson, Jr.
Hyox Systems, Ltd.
c/o Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K984313
HTU3 Hyperbaric Therapy Unit
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: July 27, 1999
Received: July 27, 1999

Dear Mr. Wilson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Joanne M Whitehead

for Wolf Sapirstein, M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984313

Device Name: **Hyox Systems Ltd.'s HTU3 Hyperbaric Chamber**

Indications for Use:

To promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure, with non critical patients for the treatment of:

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984313

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)