K011312

JUL 1 8 2001

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

Prepared: 25 April 2001

TRADE NAME: Khrunichev BLKS-303 MK Monoplace Hyperbaric System

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)
Tampa Hyperbarics "T.H.E." Chamber (K981938)
HyperTec 3200 (K002795)

ADDRESS OF MANUFACTURER:

Khrunichev State Research and Space Production Center
Novozavodskaja Street, 18
Moscow, 121309
Russia
Tele/fax: +7 (095) 145-9616

CONTACT PERSON: Evgeny Vinogradski

EXECUTIVE SUMMARY

The Undersea and Hyperbaric Medical Society (UHMS) defines hyperbaric oxygen therapy as breathing 100% oxygen at pressures higher than 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 Khrunichev BLKS-303 MK Monoplace Hyperbaric System is a Class B monoplace hyperbaric chamber designed to treat a single patient at up to a maximum operating pressure of 4 Atmospheres Absolute (ATA) or 44.1 pounds per square inch gauge (psig). The chamber uses 100% oxygen as the pressurization and hyperbaric treatment gas which is not to be administered at a pressure equivalent greater than 3 ATA or 29.4 psig.

The Khrunichev BLKS-303 MK Monoplace Hyperbaric System is 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; enhanced healing of selected problem wounds; exceptional blood loss anemia; necrotizing soft tissue infections; ostemyelitis (refractory); delayed radiation injury (soft tissue and bony necrosis); compromised skin flaps and grafts; thermal burns; and, intracranial abscess. Aggressive research into the beneficial effects of hyperbaric oxygen, when appropriately applied, will result in additional medical conditions being added to the list of indications by the UHMS.

The Khrunichev BLKS-303 MK Monoplace Hyperbaric System is designed, fabricated and tested in accordance with the engineering and manufacturing safety and quality assurance requirements of the Russian Federation, the European Community (CE Marking) and the following FDA recognized standards of the United States:

- ANSI/ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, Pressure Vessels
- ANSI/ASME-PVHO-1 (American Society of Mechanical Engineers-Safety Standard for Pressure Vessels for Human Occupancy)
- NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities

The chamber shell is constructed of aluminum with six (6) large, acrylic window inserts for ease of patient viewing. The 770-pound chamber has an external width of 42 inches (3.5 feet), an external length of 94 inches (7.83 feet), and an internal diameter of 28.7 inches (2.39 feet). When combined, these features allow for state of the art treatment of a single patient in comfort. Large acrylic windows create a more open atmosphere than other predominately metal monoplace chambers available thus helping reduce patient claustrophobia. The pressurization and treatment gas is 100% oxygen thus eliminating the need for patient breathing masks or hoods. A penetrator plate is provided in the chamber door to allow user supplied intravenous lines, medical monitoring leads, etc., to be used as required.

Patient ingress and egress is enhanced by a portable gurney that connects to a retractable chamber bed. The gurney is connected to the chamber; the chamber bed is removed from the chamber to allow the patient to be placed onto the bed's surface. Once secure, the patient is then rolled into the chamber for treatment.

A low-voltage (9 volt) patient intercommunication system designed and installed in accordance with NFPA 99, Chapter 19 provides effective communication between the patient in the chamber and the outside chamber operator or physician. The intercommunications handset is located on top of the chamber for easy operator access. A combined speaker/microphone is located inside the chamber so the patient can have "hands-free" communication with the outside operator or physician.

Single operator chamber pressure control is achieved via a simple, reliable pneumatic control panel located atop of the chamber. Both the rates of pressurization and depressurization are variable to facilitate patient comfort and minimize physiological reactions during controlled pressure changes. An emergency depressurization circuit is provided to allow for prompt patient access and egress during any emergency situation.

Intended Use:

It is the expressed, intended use of the Khrunichev BLKS-303 MK Monoplace Hyperbaric System 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 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) 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 Khrunichev BLKS-303 MK Monoplace Hyperbaric System is designed to be installed and operated in medical facilities as defined by the NFPA 99, Health Care Facilities, Chapter 19, 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 1 8 2001

Mr. W. T. Workman
Khrunichev State Research and Production Space Center
c/o Workman Hyperbaric Services, Inc.
18111 Copper Ridge Drive
San Antonio, TX 78259-3612

Re: K011312
BLK-303 MK Monoplace Hyperbaric System
Regulation Number: 868.5470
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: April 25, 2001
Received: April 30, 2001

Dear Mr. Workman:

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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011312

Device Name: KHRUNICHEV BLKS-303 MK MONOPLACE HYPERBARIC SYSTEM

Indications For Use:

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11. Skin grafts and flaps (compromised)
12. Thermal burns
13. Intracranial abscess

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011312

(Optional Format 3-10-98)