K060739

JUL 21 2006

EXHIBIT 2

510(k) Summary

Khrunichev State Research and Production Space Centre
18, Novozavodskaya
121309 Moscow,

February 10, 2006

Contact: Gleb Mitinskiy

1. **Identification of the Device:**
   Proprietary-Trade Name: BLKS-307 MONOPLACE HYPERBARIC OXYGEN TREATMENT SYSTEM
   Classification Names: CBF Hyperbaric Chamber
   Common/Usual Name: Hyperbaric Chamber

2. **Equivalent legally marketed devices:** Khrunichev BLKS-303 MK Monoplace Hyperbaric System, K0011312.

3. **Indications for Use (intended use)** The conditions listed as appropriate for the use of the Hyperbaric Oxygen Therapy in the current edition of Undersea and Hyperbaric Medical Society (UHMS) Hyperbaric Oxygen Therapy Committee Report (1999) 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 bony necrosis)
   - Skin grafts and flaps (compromised)
   - Thermal burns
   - Intracranial abscess

4. **Description of the Device:** The system body is a hermetic cylindrical chamber, which consists of a welded hermetic shell and a quick-to-open cover, made of the AMg6 – ASME Code Case 2403 aluminum alloy. The cover lock ring is made of the SB-211 A92024 material. The hyperbaric oxygen chamber is installed on a base, which is made of carbon steel, with four wheel castors attached to the base bottom. It can be moved within a treatment room if necessary. A control panel is located atop of on the pressure chamber, actuating pneumatic aggregates of the pressure system pneumatic system which are located under the chamber body. A patient's ingress/egress is performed by means of a retractable chamber bed that is wheeled out of the pressure chamber on a portable gurney, which is attached to the chamber at the time the patient

is placed in and out of the chamber. The pressure system overall dimensions BLKS-307-"Khrunichev" without the gurney: length - 100 in, width - 48 in, height - 70.9 in. The pressure system total weight BLKS-307-"Khrunichev" - 1102 lbs. Chamber pressure control is achieved by means of knobs and tumbler switches of a pneumatic control panel located atop of the chamber. Both the rates of pressurization and depressurization are variable to provide patient's comfort while in confined space and with regards to his/her individual tolerance to pressure rate change. The panel is equipped with an emergency decompression push button, which enables fast treatment session termination and egress of a patient in case of an emergency situation. If pressure inside the chamber exceeds maximal operating level of 43.5 PSI, two pressure-relief valves installed on the pressure chamber shell will open. This provides for the patient and personnel safety and prevents the chamber structure damage. In order to exclude possible electric spark formation in an oxygen atmosphere in case of transition of an accumulated electrostatic potential from a patient to the chamber shell, an antistatic bracelet is provided. The bracelet is put on a patient hand or foot. The system is equipped with a grounding cable, which is connected to the treatment room grounding system.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and clinical testing indicates that the new device is as safe and effective as the predicate device.

6. **Substantial Equivalence Chart**

Parameters	Units	Khrunichev BLKS-303MK K011312.	Khrunichev BLKS-307
Internal Diameter	In (mm)	28.7 (730)	42.1 (1080)
Length	In (mm)	93.7 (2380)	90.4 (2300)
Internal Volume	Ft3 (m3)	26.9 (0.95)	56.5 (1.6)
Weight	Lbs (kg)	770 (320)	1102 (500)
Operating Pressure	ATA (Bar)	1 – 4	1 – 4
Compression / Decompression Rate	ATA/min (Bar/min)	0.05 – 0.25	0.05 – 0.25
Emergency Decompression Time from 4 to 1 ATA	Sec	60	90
Maximum Oxygen Consumption			
Isopression (constant pressure) and decompression	l/min	50	52.5
Blowing and compression	l/min	400	400
One hour treatment	l (m3)	6000 (6)	9000 (9)
Lifetime	One-hour treatment sessions	10,000	10,000
Control System		Pneumatic	Pneumatic
Chamber Type		Monoplace	Monoplace
Electronic Patient Vitals and Environment Parameters Indication		Optional	Standard
Chamber Door Lock		Manual	Pneumatic
Material		Aluminum alloy/acrylic glass	Aluminum alloy/acrylic glass
Intercom Device		Standard	Standard

Parameters	Units	Khrunichev BLKS-303MK K011312.	Khrunichev BLKS-307
Built-In-Breathing System		Optional	Optional
Standards and Regulatory Documents Compliant to		FDA 510(k) ASME PVHO NFPA 99 ISO 9001 ISO 13485 TUV National Pressure Vessels Code National Ministry of Healthcare Certificate National Fire Protection Code	ASME PVHO NFPA 99 ISO 9001 ISO 13485 TUV National Pressure Vessels Code National Ministry of Healthcare Certificate National Fire Protection Code

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of Khrunichev State Research and Production Space Centre that the BLKS-307 MONOPLACE HYPERBARIC OXYGEN TREATMENT SYSTEM is as safe and effective as the predicate device, and has few technological differences, thus it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2006

Khrunichev State Research & Production Space Center
C/O Mr. Daniel Kamm
Regulatory Consultant Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K060739
Trade/Device Name: BLKS-307 Monoplace Hyperbaric Oxygen Treatment System
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: CBF
Product Code: II
Dated: June 15, 2006
Received: June 23, 2006

Dear Mr. Kamm:

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) 276-0120. 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/industry/support/index.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): K06

Device Name: BLKS-307 MONOPLACE HYPERBARIC OXYGEN TREATMENT SYSTEM

Indications For Use:
The conditions listed as appropriate for the use of the Hyperbaric Oxygen Therapy in the current edition of Undersea and Hyperbaric Medical Society (UHMS) Hyperbaric Oxygen Therapy Committee Report (1999) are as follows:

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- Skin grafts and flaps (compromised)
- Thermal burns
- Intracranial abscess

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Abraham 7/21/06

...Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control Dental Devices

...) Number K060739