MAY 28 1997

K952545/53

Wright INDUSTRIES

C. Wright Industries
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Gardena, CA. 90249
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Contact: Charles Wright
Date:4-15-1997

510(k) Summery

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFC-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: 510 (k) Notification
Document control # ~~K95245~~ K952545
Proprietary Name: Wright 1000 Mono Hyperbaric Chamber.
Common Name: Hyperbaric Chamber.
Calssification Name: (PVHO) Pressure Vessel for Human Occupancy.
73 CBF, CFR 868.5470
Predicate Device: HYOX System Limited 510(k) No. K874107

Attention: Christy Foreman

Sincerly Yours

Charles Wright
Owner/Operator
C. Wright Industries

HYPERBARIC TREATMENT:

Hyperbaric oxygen therapy (HBO)is a medical treatment where a patient is placed in a specially designed vessel and placed under pressure greater then sea level and breathes 100% oxygen intermittently. Alveolar oxygen pressure is increased causing a rise in plasma oxygen content which results in enhanced tissue oxygen delivery. the amount of pressure increases and the length of time under pressure are determined by the condition being treated. Treatment pressures are usually between 2 and 3 times atmospheric. treatment usually lasts from 1 to 2 hours at full pressure.

The following are approved indications:

1: Air or gas embolism.

2: Carbon monoxide poisoning and smoke inhalation.
Carbon monoxide complicated by cyanide poisoning.

3: Clostridial myonecrosis (Gas gangrene).

4: Crush injury, Compartment syndrome, and other acute traumatic ischemias.

5: Decompression sickness.

6: Enhancement of healing in selected problem wounds.

7: Exceptional blood loss (Anemia)

8: Necrotizing soft tissue infections (Subcutaneous tissue, Muscle, Fascia).

9: Osteomyelitis (Refractory).

10: Radiation tissue damage (Osteoradionecrosis).

11. Skin grafts and flaps (Compromised).

12. Thermal burns.

13. Adjunctive hyperbaric oxygen in intracranial abscess.

CONTRAINDICATIONS:

Only previously listed indications are approved all others are considered contraindications.

REFERANCES:

1: HYPERBARIC MEDICINE PROCEDURES. 1996
2: HYPERBARIC OXYGEN THERAPY: A COMMITTEE REPORT. 1996
3: MONOPLACE HYPERBARIC CHAMBER SAFTY GUIDELINES. 1991

The Wright 1000 Mono Hyperbaric Camber:

*Max operational pressure 30 PSIG.

*Constructed out of SA516-70N steel

*The 4 Large 14" Windows Constructed out of PVO Acrylic

*Hydrostatic tested at 45 PSIG.

*Welds are X-rayed

*Welds magna Flux tested after hydrostatic test.

*Manufactured by a ASME approved house and certified by ASME. Certification No. 28,352

*Manufactured under PVHO guidelines

*Manufactured under NFPA Guidelines

*Registered with National Board Of Pressure Vessel Inspectors.

*Wiring to National Electrical code.

*Electrical Testing: Electromagnetic and Safety testing Conducted.

*Spacious interior

*2 Way Communications

*Pressure and Oxygen monitoring With alarms.

*Programmable Treatment Pressure Alarms

*Variable ventilation

*Comfortable reclining chair

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1997

Mr. Charles Wright
Wright Industries
13760 South Gramercy Place
Gardena, California 90249

Re: K952545
Wright 1000 Mono Hyperbaric Chamber
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: April 15, 1997
Received: April 21, 1997

Dear Mr. Wright:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4646. 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health