K031649

DEC - 5 2003

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

Prepared: 26 May 2003

**TRADE NAME:** SL8 Hyperbaric Oxygen Treatment Facility
DL8 Hyperbaric Oxygen Treatment Facility
TL20 Hyperbaric Oxygen Treatment Facility

**COMMON NAME OF DEVICE:** Multiplace Hyperbaric Chamber

**CLASSIFICATION:** 73 CBF, 21 CFR 868.5470

**ESTABLISHMENT REGISTRATION NUMBER:** Pending

**CLAIMED PREDICATE DEVICE(S):**

Perry Sigma MP Multiplace Hyperbaric Chamber – K930748
Gulf Coast Multiplace Hyperbaric Chamber – K950957
Reimers T Class Hyperbaric Chamber – K954387

**ADDRESS OF MANUFACTURER:** Fink Engineering PTY LTD
100 Talinga Road
Cheltenham
Victoria 3192
Australia
Tele: 03-9585-2966

**CONTACT PERSON:** Eric Fink, Managing Director

## 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 SL8/DL8 and TL20 Hyperbaric Oxygen Treatment Facilities are Class A multiplace hyperbaric chambers designed to treat up to 8 (SL/DL8) or 20 (TL20) patient at up to a maximum operating pressure of 3 Atmospheres Absolute (ATA) or 29.4 pounds per square inch gauge (psig) for the SL8 and up to 6 ATA or 73.5 psig for the DL8 and TL20. Each model uses compressed air as the pressurization gas and 100% oxygen as the hyperbaric treatment gas.

The SL/DL8 and TL20 Hyperbaric Oxygen Treatment Facilities are intended to be procured and used by physicians to treat a variety of medical conditions that respond to hyperbaric oxygen. The 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 smoke inhalation; clostridial 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; osteomyelitis (refractory); radiation tissue damage (osteoradionecrosis); 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 SL/DL8 and TL20 Hyperbaric Oxygen Treatment Facilities are designed and fabricated in accordance with the requirements of the ANSI/ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, Pressure Vessels; ANSI/ASME-PVHO-1 (American Society of Mechanical Engineers-Pressure Vessels for Human Occupancy); and, NFPA 99, Health Care Facilities, Chapter 19 (Chapter 20, 2002 Edition), Hyperbaric Facilities.

The SL/DL8/TL20 rectangular hyperbaric chamber(s) include as a key component a new and very user-friendly rectangular chamber designed and manufactured specifically for the medical community to be used for hyperbaric oxygen treatment. The design of this unique ASME PVHO chamber has been driven by comments from hyperbaric physicians, technicians and nurses who require their equipment to be simple, easy to use and to simulate as closely as possible clinical conditions found elsewhere in their working environment.

The SL/DL8/TL20 facilities place major emphasis on patient comfort and user-friendly operator controls and incorporate several innovative and unique features including:

- A large, comfortable rectangular hyperbaric chamber that has been outfitted t appear like any other clinical room in a hospital to reduce patient anxiety
- A rectangular medical lock with a unique locking system enabling single-handed operation
- Large walk-trough rectangular sliding doors that fit flush with the floor so that patients can be wheeled into the chamber without bumping over a door jam
- An easy to use control panel with large VDU display to monitor the treatment profile including the internal chamber pressure, temperature, humidity, oxygen and carbon dioxide parameters
- An oxygen delivery system with venturi assisted overboard exhaust to eliminate the possibility of "shrink wrapping" patients with their oxygen hoods
- Whisper quiet ventilation system to pneumatically control temperature, humidity and upper oxygen limit without the need for internal electrical blowers
- Aesthetically pleasing external chamber cladding

Specifications of the SL8 Hyperbaric Oxygen Treatment Facility are as follows:

| | |
|---|---|
| Design Code | ASME Section VIII, Div 1 and ASME PVHO-1 |
| Operating Pressure | 3.0 ATA |
| Operating Temperature | 62°F to 100°F |
| Design Pressure | 32.3 psi |
| Design Temperature | 62°F to 100°F |
| Design Life | 70,000 cycles (30 years) |
| Hydrostatic Pressure | 42.0 psi |
| Inspection Authority | ASME "U" Stamp |
| Weight | ~15,432 lbs |
| Dimensions | 8.1ftW X 7ftH X 10.8 ft L |
| Volume | 586 $ft^3$ |
| Medical Lock | 13.8 in X 13.8 in X 19.7 in |
| Doorway Size | 32.2 in X 75.6 in |

| | |
|---|---|
| Lighting | Four external dimmable lights |
| 13 in ID viewports | Two PVHO |
| 5.9 in ID viewport | One PVHO |
| Capacity | Eight seated persons |
| Fire Suppression | IAW NFPA 99 |
| Finish | Shotblasted and Painted |
| Life Support Controls | Manual electropneumatic pressurization |
| | Manual electropneumatic depressurization |
| Environmental Control | Heating |
| Ventilation | Constant airflow |
| BIBS with overboard dump | Four |
| Hoods with overboard dump | Four |
| Depth Measurement | Digital with analog backup |
| Gas Analysis | Oxygen and carbon dioxide |
| Communications | Internal/external PA System |
| | Sound powered phone backup |
| Entertainment | Individual four-channel selection for eight persons |
| TV System | External color with remote control |
| | AM/FM Tuner/CD & DVD Player |

Specifications of the DL8 Hyperbaric Oxygen Treatment Facility are as follows:

| | |
|---|---|
| Design Code | ASME Section VIII, Div 1 and ASME PVHO-1 |
| Operating Pressure | 6.0 ATA |
| Operating Temperature | 62°F to 100°F |
| Design Pressure | 80.0 psi |
| Design Temperature | 62°F to 100°F |
| Design Life | 70,000 cycles (30 years) |
| Hydrostatic Pressure | 104.0 psi |
| Inspection Authority | ASME "U" Stamp |
| Weight | ~26,400 lbs |
| Main Lock Dimensions | 8.1ftW X 7ftH X 11ftL |
| Entrance Lock Dimensions | 8.1ftW X 7ftH X 4.5ftL |
| Volume (ML) | 614.5 $ft^3$ |
| Volume (EL) | 254.3 $ft^3$ |
| Total Volume | 868.7 $ft^3$ |
| Medical Lock | 13.8 in X 13.8 in X 19.7 in |
| Main Doorway Size | 39.4 in X 75.6 in |
| Lighting | Six external dimmable lights |
| 13.8 in ID viewports | Two PVHO in ML |
| 5.9 in ID viewports | One PVHO in each lock |
| Main Lock Capacity | Eight seated persons |
| | Four wheelchairs |
| | One hospital gurney |
| Fire Suppression | IAW NFPA 99 |
| Finish | Shotblasted and Painted |
| Life Support Controls | Manual electropneumatic pressurization |
| | Manual electropneumatic depressurization |
| Environmental Control | Heating |
| Ventilation | Constant airflow |
| BIBS with overboard dump | Two |
| Hoods with overboard dump | Six |
| Depth Measurement | Digital with analog backup |
| Gas Analysis | Oxygen and carbon dioxide |
| Communications | Internal/external PA System |
| | Sound powered phone backup |

| | |
|---|---|
| Entertainment | Individual four-channel selection for eight persons |
| TV System | External color with remote control |
| | AM/FM Tuner/CD & DVD Player |
| Compartment Relief | ASME certified relief valve |
| Compartment Drain | One manual drain valve in each lock |

Specifications of the TL20 Hyperbaric Oxygen Treatment Facility are as follows:

| | |
|---|---|
| Design Code | ASME Section VIII, Div 1 and ASME PVHO-1 |
| Operating Pressure | 6.0 ATA |
| Operating Temperature | 62°F to 100°F |
| Design Pressure | 80 psi |
| Design Temperature | 62°F to 100°F |
| Design Life | 70,000 cycles (30 years) |
| Hydrostatic Pressure | 104.0 psi |
| Inspection Authority | ASME "U" Stamp |
| Weight | ~110,231 lbs |
| Main Lock Dimensions | 10.3 ftW X 7ftH X 19.3 ftL |
| Entrance Lock Dimensions | 7.8 ftW X 7 ftH X 10.8ftL |
| Inner Lock Dimensions | 7/8 ftW X 7 ftH X 10.8 ftL |
| Volume (ML) | 1536.2 $ft^3$ |
| Volume (EL) | 529.7 $ft^3$ |
| Volume (IL) | 480.3 $ft^3$ |
| Total Volume | 2546.2 $ft^3$ |
| Medical Lock | 13.8 in X 13.8 in X 19.7 in |
| Main Doorway Size | 39.4 in X 75.6 in |
| Lighting | Fourteen external dimmable lights |
| 23.6 in ID viewports | Four PVHO |
| 13 in ID viewports | Three PVHO |
| 6 in ID viewports | Two PVHO |
| Capacity | Up to twenty persons |
| Fire Suppression | IAW NFPA 99 |
| Finish | Shotblasted and Painted |
| Life Support Controls | Manual electropneumatic pressurization |
| | Manual electropneumatic depressurization |
| Environmental Control | Heating |
| Ventilation | Constant airflow |
| BIBS with overboard dump | Four |
| Hoods with overboard dump | Twenty-two |
| Depth Measurement | Digital with analog backup |
| Gas Analysis | Oxygen and carbon dioxide |
| Communications | Internal/external PA System |
| | Sound powered phone backup |
| Entertainment | Individual four-channel selection for eight persons |
| TV System | External color with remote control |
| | AM/FM Tuner/CD & DVD Player |

Fink Engineering has concluded that the general design approach, method of pressure control, and intended use of the SL8/DL8 and TL 20 Hyperbaric Oxygen Treatment Facilities are substantially equivalent to the Perry Baromedical Services Sigma MP Multiplace Hyperbaric Chamber (K930748), the Gulf Coast Multiplace Hyperbaric Chamber (K950957) and the Reimers Engineering T Class Multiplace Hyperbaric Chamber (K954387) and is proposing them as predicate devices for the SL8/DL8 and TL20 Hyperbaric Oxygen Treatment Facilities.

Intended Use:

It is the expressed, intended use of the Fink Engineering SL8/DL8 and TL20 Hyperbaric Oxygen Treatment Facilities 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 their 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 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2003

Fink Engineering Pty. Ltd.
c/o Mr. W. T. Workman
Workman Hyperbaric Services, Inc.
18111 Copper Ridge Dr.
San Antonio, TX 78259

Re: K031649
Trade/Device Name: Multiplace Hyperbaric Oxygen Treatment Chamber, Models SL8/DL8/TL20
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: September 30, 2003
Received: October 1, 2003

Dear Mr. Workman:

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 (301) 594-4646. 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,

for 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): K031649

Device Name: Fink Engineering PTY LTD, SL8/DL8 and TL20 Hyperbaric Treatment Facilities

Indications For Use:

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 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

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

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K031649