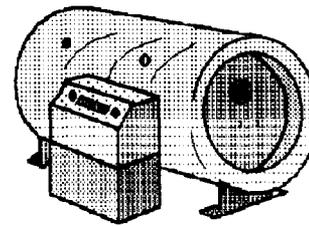


Tampa Hyperbaric Enterprise
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Office of Device Evaluation

Division of Cardiovascular, Respiratory, and Neurological Devices

9200 Corporate Blvd.

Rockville, MD 20850

updated December 4, 1996

Trade name: Tampa Hyperbaric Chamber

Common Name of device: Hyperbaric Chamber (or Recompression Chamber)

Classification: 21 CFR 868.5470 Pro code #73CBF

Establishment registration number: 9024206

Address of Manufacturer: 700 West Waters Avenue, Tampa, FL 33604

Contact person: Michael Capria

510(k) Number **K960389**

DEC - 5 1996

Section 2

Summary of device effectiveness: This device raises the absolute air pressure to a level that has been documented to double the partial pressure of oxygen in breathing quality air. This effectively raises the available partial pressure of oxygen during normal inspiration. With the addition of higher percentages of oxygen via oronasal mask the partial pressure of oxygen in body tissues can be increased 10 times above natural atmospheric conditions. This hyperbaric device has passed clinical trial tests to verify that it does indeed raise the available partial pressure of oxygen in body tissues.

Safety and effectiveness: This hyperbaric chamber is generally safe and effective when used within documented parameters relative to decompression table times for repetitive use. The intake and exhaust valves are sized ($\frac{1}{2}$ ") to slow the time required for full compression and decompression. This provides a fail-safe method for filling the chamber with air and alternately releasing the air prior to egress. It requires 15 minutes to fill the chamber to the optimum working pressure (15 psig) and 8 minutes to depressurize the chamber. While this is slower than most chambers already on the market the longer time is actually more comfortable for the patients. Incidental temporary side-effects (i.e. eardrum pain or damage and psychological anxiety) are rare if contraindications are screened and the attendant monitors the

occupant. While some more serious side-effects (i.e. collapsed lung and oxygen toxicity) were documented in other similar hyperbaric chambers, those problems were evoked at greater pressures with the increased risk of those type medical misadventures. On the other hand, this device has the relief valve designed to limit pressure to 21 psig. This added feature effectively limits risk and assures overall safety to hyperbaric chambers already in commercial use.

The chamber uses an in-swinging steel hatch door with a rubber "O" ring in the contacting face. There is no latch or other device to lock. A reasonable push against the hatch while the air pressure rises will initiate hatch closure. Air pressure holds the hatch securely closed. There are no high voltage devices placed inside this hyperbaric chamber. There are no new technological materials used. There are manual air pressure valves to prevent inadvertent or unauthorized changes. There are no exposed sharp edges in tank construction. The construction is mechanically stable and has no exposed moving parts. The hyperbaric chamber is secure from vibration and offers 3/8 inch thick steel protection to the occupants in the unlikely event of an outside catastrophe. The occupants have an internal emergency release valve for additional security. The tank construction is coated to withstand fluid spills. The chamber is certified to operate within specifications up to 150° F and has been hydrostatically tested to assure performance. The surface temperature of the chamber does not increase during its operation. No toxic materials come into contact with the patient, operator or attendant. The air is certified pure breathing quality. There are no wires in the device that could risk strangulation. This device is intended to have operator assistance to monitor the activity inside and outside the hyperbaric chamber.

There are four small chairs bolted inside the chamber along a certified welded angle iron. This allows patients to sit during the hyperbaric sessions. There is adequate room for these four chairs to be removed and replaced with two cots bolted along the same angle iron without welding any new metal to the chamber (new welds would void certification). There are two certified viewports for visual inspection of the occupants.

The intended use of this device is discussed by the "Indications for Use" section and includes: Decompression sickness; Carbon monoxide with or without cyanide poisoning; Smoke inhalation; Exceptional blood loss; Clostridial myonecrosis; Crush injury, compartment syndrome and acute traumatic ischemias; Selected Problem Wounds; Compromised skin grafts; Osteomyelitis; Osteoradionecrosis; Thermal burns; Necrotizing soft tissue infections.

1st Comparison Table Information:

Predicate Device	Our Device
Proteus Dual-Place Hyperbaric Chamber # K862198 Perry Baromedical, Inc. FDA # 1036464	Tampa Hyperbaric Chamber #K960389 Tampa Hyperbaric Enterprise FDA # 9024206
Labeling	Labeling
Has required labels along with control panel labels	Has required labels along with control panel labels
Intended Use	Intended Use
Has all the prior listed indications plus air or gas embolism	All the prior listed indications except air or gas embolism
Physical Characteristics	Physical Characteristics
Stainless steel; supine patient position on gurney; airlock for a seated attendant; pressurized with a combination of bottled oxygen and nitrogen; gas analysis meters to monitor environment; viewports to directly see interior / exterior activity with audio system for communication.	Carbon steel; seated or supine patient position; seated attendant without airlock; pressurized with compressed air derived from oil-less compressed certified pure, filtered air; gas analysis meters to monitor environment; audio-video system to see interior / exterior activity for communication. Water deluge system for fire safety.
Anatomical Sites	Anatomical Sites
Entire body	Entire body
Performance Testing	Performance Testing
Certified by the American Society of Mechanical Engineers - Pressure Vessel for Human occupancy	Certified by the American Society of Mechanical Engineers - Pressure Vessel for Human occupancy
Safety Characteristics	Safety Characteristics
Direct monitoring at a work station attached to the device. Electric controls to valves with electric meters to regulate pressure. Externally swung hatch with <i>auto-clave</i> type secure closure. Warning alarms for toxic gas or fire hazards.	Direct monitoring at a work station attached to the device. Manual control valves with direct pressure meters to regulate pressure. Internally swung hatch manually seals itself against inside of tank. Warning alarms for toxic gas or fire hazards. Water deluge system for fire safety.

2nd Comparison Table Information:

Predicate Device	Our Device
Proteus Multi-Place Hyperbaric Chamber # K930748 Perry Baromedical, Inc. FDA # 1036464	Tampa Hyperbaric Chamber #K960389 Tampa Hyperbaric Enterprise FDA # 9024206
Labeling	Labeling
Has required labels along with control panel labels	Has required labels along with control panel labels
Intended Use	Intended Use
Has all the prior listed indications plus air or gas embolism	All the prior listed indications except air or gas embolism

Physical Characteristics

Stainless steel; standing, seated or supine patient positions with airlock for attendant; pressurized with a combination of bottled oxygen, nitrogen and compressed air derived from oil-less compressed certified pure, filtered air; gas analysis meters to monitor environment; viewports and audio-video system to directly see interior / exterior activity for communication. Water deluge system for fire safety.

Anatomical Sites

Entire body

Performance Testing

Certified by the American Society of Mechanical Engineers - Pressure Vessel for Human occupancy Includes hydrostatic pressure testing to 1½ working pressure, tank magnaflux testing, and X-ray testing of all welds.

Safety Characteristics

Direct monitoring at a work station attached outside the device. Electric controlled valves with electric meters to regulate pressure. Tank hatch swing inside to manually seal itself against tank.

Physical Characteristics

Carbon steel; seated or supine patient position; seated attendant without airlock; pressurized with compressed air derived from oil-less compressed certified pure, filtered air; gas analysis meters to monitor environment; audio-video system to see interior / exterior activity with audio system for communication. Water deluge system for fire safety.

Anatomical Sites

Entire body

Performance Testing

Certified by the American Society of Mechanical Engineers - Pressure Vessel for Human occupancy

Safety Characteristics

Direct monitoring work station attached outside the device. Manual control brass valves, direct pressure gas gauges to regulate pressure. Tank hatch swings inside to manually seal itself against tank.

Truth and Accuracy Statement: The undersigned certifies the statements made in this submission are true and accurate with respect to his knowledge of the facts contained herein.

signed Michael Capria

Michael Capria (computer font signature for fax transmission)