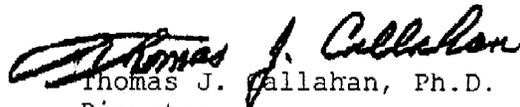


Page 2 - Mr. Michael Capria

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,

  
Thomas J. Callahan, Ph.D.

Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL - 6 1999

Mr. Michael Capria  
Tampa Hyperbaric Enterprise  
700 West Waters Avenue  
Tampa, FL 33604

Re: K981938  
Tampa Hyperbaric Monoplace Chamber  
Regulatory Class: II (two)  
Product Code: 73 CBF  
Dated: April 12, 1999  
Received: April 16, 1999

Dear Mr. Capria:

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.

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Summary comparison of our device to the legally marketed predicate device (continued):

Physical Characteristics	Physical Characteristics
Stainless steel; supine patient position on gurney; eight acrylic viewports on 36" diameter chamber All interior materials cleaned for oxygen service. Certified by the American Society of Mechanical Engineers - Pressure Vessel for Human occupancy	Stainless steel; supine patient position on chamber floor; two acrylic viewports on 30" diameter chamber All interior materials cleaned for oxygen service. Certified by the American Society of Mechanical Engineers - Pressure Vessel for Human occupancy

Intended use of our device is to correct tissue hypoxia for treatment of:

- \*Air or gas embolisms
- \*Decompression sickness
- Carbon monoxide poisoning with or without cyanide complications
- Smoke inhalation
- Exceptional blood loss or anemia
- Clostridial myonecrosis (gangrene)
- Selected problem chronic wounds
- Crush injury, compartment syndrome and acute traumatic ischemias
- Compromised skin grafts
- Osteomyelitis
- Thermal burns
- Osteoradionecrosis (radiation burns)
- Necrotizing soft tissue infections

\*In gas embolism and decompression sickness hyperbaric oxygenation can be used as a primary therapy. In the other indications hyperbaric oxygenation is an adjunctive treatment to further primary medical intervention.

Increases the metabolic activity of the immune system for reducing bacterial infections such as Actinomycosis; controlling bacterial infections associated with clostridia myonecrosis (gangrene) and necrotizing soft tissue infections (severe skin ulcers).

The mechanical effect of higher atmospheric pressure decreases the volume or size of embolism gas trapped in body tissues (Boyle's Law) allowing elimination of the offending gas. This action can reduce air embolism from medical or diving accidents. Additional benefits stem from the vasoconstriction and reduction of swelling that hyperbaric oxygenation provides to reduce histamine mediated inflammation seen with air embolism and related conditions.

Hyperbaric oxygenation produces vasoconstriction while at the same time provides an abundance of available oxygen for cellular metabolism and thus reduces edema after burns or crush injuries while delivering extra oxygen to maintain cellular function. This action has been documented to help reduce tissue damage in osteoradionecrosis (radiation tissue damage) and thermal burns.

Hyperbaric oxygen therapy improves the outcome of compromised skin grafts and can enhance healing in selected problem wounds by the action of better granulation tissue formation. The extra oxygen in hyperbaric therapy diffuses directly into the plasma and can help the outcome in patients with exceptional blood loss and anemia problems.

Hyperbaric oxygen has an anti-bacterial effect on anaerobic bacteria. Also, white blood cells function more effectively to kill pathogenic microbes when oxygen concentrations are optimal. This action helps control infections such as osteomyelitis (unmanageable bone disease).

Summary comparison of our device to the legally marketed predicate device:

**Predicate Device**  
Proteus Dual-Place Hyperbaric Chamber # K862198

**Pressurization Rate**  
Variable control (from maximum 10 psi @ minute)  
slower for less adaptable patients (<1 psi @ minute)  
Maximum intended clinical pressure 75 psi w/air

**Depressurization Rate**  
Varied control (from 0 to 1 psi @ second) with  
an extra emergency (~10 second) release

**Purge Flow Rate**  
Varied control (0 - 50 cfm) with diluent gas or oxygen  
through chamber using valve coordination;  
also, uses patient face mask.

**Our Device**  
Tampa Monoplace Hyperbaric Chamber # K981938

**Pressurization Rate**  
Variable control from maximum 7 psi @ minute  
slower for less adaptable patients, <1 psi @ minute  
Maximum intended clinical pressure 29.4 psi w/oxygen

**Depressurization Rate**  
Varied control (from 0 to 1 psi @ second) with  
an extra emergency (~10 second) release

**Purge Flow Rate**  
Varied control (0 - 1 cfm) with only oxygen through  
chamber using constant automatic pressure regulator;  
no use of face mask. Increased purge volume available  
(1 - 18 cfm) by coordinating intake and exhaust valves.

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K981938

**Summary of 510(k) safety and effectiveness information supporting substantial equivalence**

Tampa Hyperbaric Enterprise

contact: Michael Capria

700 West Waters Avenue

Tampa, Florida 33604

Phone 813-935-4404

Fax 813-932-5392

date prepared May 29, 1998, updated December 11, 1998

Name of Device: Tampa Hyperbaric Monoplace Chamber

Safety: This hyperbaric chamber is generally safe when used with professional supervision within prescribed time limits. The intake and exhaust valves are designed to manage compression and decompression. This provides a reliable method for increasing chamber pressure with oxygen and alternately releasing the oxygen prior to egress. Incidental temporary side-effects (i.e. eardrum pain and psychological anxiety) should be limited by a trained professional monitoring the occupant.

Our monoplace chamber has the added safety feature of a relief valve designed to limit pressure to 30 psig. Normal operating pressure is between 7.5 psi and 22 psi. The stainless steel chamber is designed to support years of normal working pressure compression cycles without structural degradation. The acrylic viewports should be inspected annually and replaced at least every 10 years. The chamber should be hydro-tested when the viewports are replaced. This chamber should be operated in climate controlled room temperatures. Compression causes a slight 10° F rise in temperature that returns to normal once pressure rise ceases. Decompression causes a slight 10° F drop in temperature. These are normal temperature variations. There are no sharp exposed edges and there are no motorized moving parts. There are no toxic materials that come into contact with patients from this device. There are no materials used that could cause strangulation.

Effectiveness: This device raises the absolute oxygen pressure to a level that has been documented to raise the partial pressure of oxygen in body tissues. This effectively raises the available partial pressure of oxygen during normal inspiration between 10 to 20 times above natural atmospheric conditions. Hyperbaric oxygen therapy promotes several physiologic changes:

Displaces accumulated nitrogen in patients with decompression sickness.

Displaces accumulated toxic gases in patients with carbon monoxide poisoning and smoke inhalation with or without cyanide poisoning.

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510(k) Number (if known): **K981938**

Device Name: **Tampa Hyperbaric Monoplace Chamber**

Indications For Use:

- **Carbon monoxide poisoning with or without cyanide complications**
- **Smoke inhalation**
- **Decompression sickness**
- **Exceptional blood loss or anemia**
- **Clostridial myonecrosis (gangrene)**
- **Selected problem chronic wounds**
- **Crush injury, compartment syndrome and acute traumatic ischemias**
- **Compromised skin grafts**
- **Osteomyelitis**
- **Thermal burns**
- **Osteoradionecrosis (radiation burns)**
- **Necrotizing soft tissue infections**
- **Air or Gas Embolism**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \_\_\_\_\_

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)