JUL 22 1998

K972908

Sands Hyperbaric Systems

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AMENDED 510 (k) SUMMARY

§807.92 (a) (1).

Submitted by: Sands Hyperbaric Systems

510 (k) Number: K972908

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Original Preparation Date: August 4, 1997
Revision Date ***September 23, 1997***
Revision Date ***April 30, 1998***
Prepared by: Lachlan W. Sands

§807.92 (a) (2).

Trade Name: Sands Series III Clinical Chamber
Common Name: HYPERBARIC OXYGEN CHAMBER
Classification Name: HYPERBARIC OXYGEN CHAMBER
C.F.R. No.: 868.5470
510 (k) Number: K972908

§807.92 (a) (3).

Equivalent Device #1 Reneau Unit (*since renamed the PROTEUS CHAMBER*)*
510 (k) No.: K840841
Decision Date: 08/07/84

Equivalent Device #2 Sechrist Model 3200P/3200PR Hyperbaric Chamber
510 (k) No.: K950386
Decision Date: 06/13/95

* see Exhibit A

DESCRIPTION OF THE DEVICE

A hyperbaric oxygen treatment ("HBOT") chamber is a pressure vessel that is large enough to accommodate a person or persons. It is capable of being energized with a gas, either air, oxygen, or a mix of the two. Therapeutic pressures are rarely more than 100 PSIG.

The chamber itself can be fabricated from steel, acrylic or any substance designed to cope with the designed working pressure of the chamber.

A HBOT chamber normally has the following features*:

① at least one doorway large enough to permit entry and exit,

② a number of windows which permit observation of the occupants,

③ a pressurization and depressurization system which also serves to ventilate the interior of the chamber,

④ a way of providing 100% oxygen to the patient, either by way of breathing the compartment gas when the HBOT chamber is energized by oxygen or by a mask.

Fig. 1

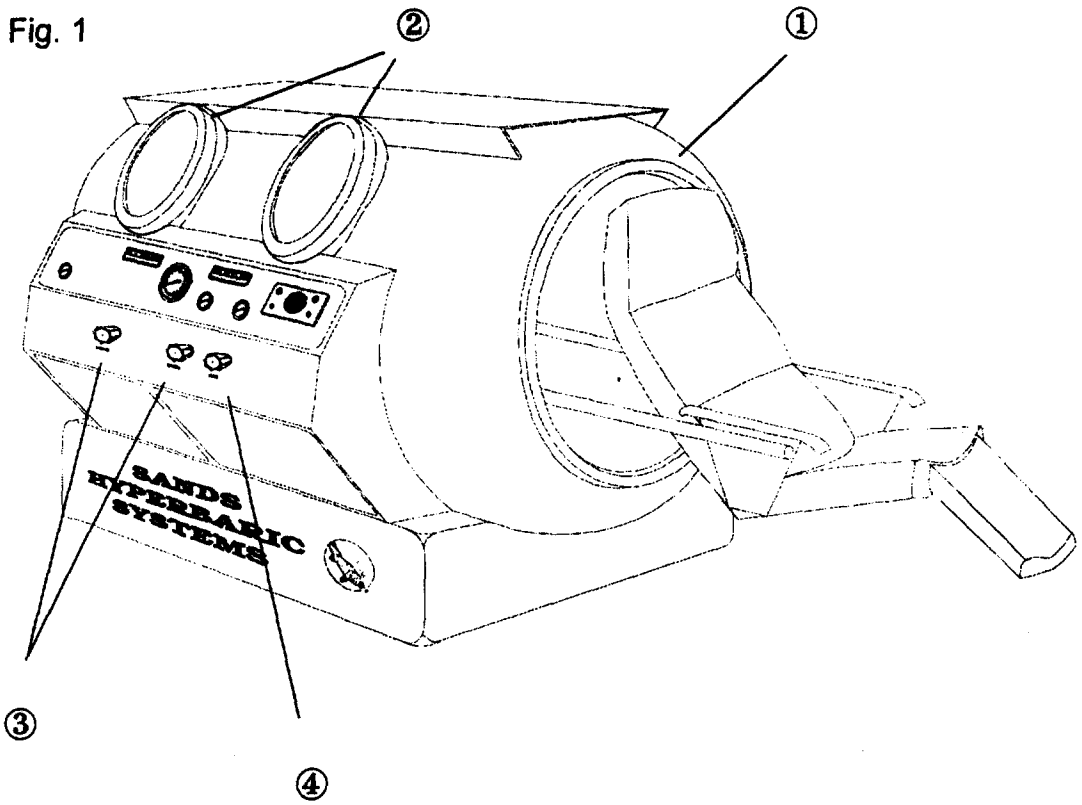


Fig. 1 This is the HBOT chamber that is the subject of this 510(k) summary. It is fabricated from stainless steel.

* Fifteen HBOT currently have 510(k) numbers assigned. All have these features.

INTENDED USE OF THE DEVICE

There are more than 400 HBOT chambers being used in the US, mostly installed in hospital acute care facilities.

Treatment consists of placing the patient entirely in the HBOT chamber. Pressure is then elevated to a treatment pressure selected by the physician. The patient then breathes 100% oxygen for ninety (:90) minutes while at that pressure.

The table below describes the maladies for which hyperbaric oxygen therapy is prescribed:

APPROVED USES AND THRESHOLD LEVELS FOR THE NUMBER OF HYPERBARIC TREATMENTS

(As published by the Undersea and Hyperbaric Medical Society's (UHMS) Oxygen Committee 1992)

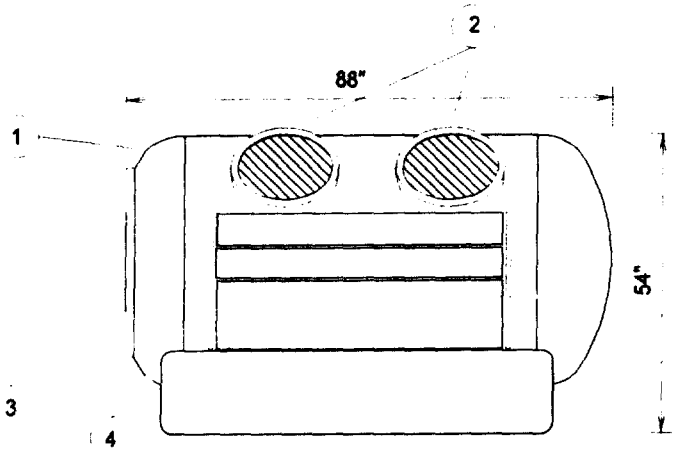
INDICATIONS	Threshold Levels
1. Air or Gas Embolism	14
2. Carbon Monoxide Poisoning and Smoke Inhalation	10
3. Clostridial Myonecrosis (Gas Gangrene)	5* - 10
4. Crush Injury, Compartment Syndrome and Other Acute traumatic Ischemias	3* - 12
5. Decompression Sickness	Until improvement plateaus or 14 days
6. Enhanced Healing in Selected Problem Wounds	10* - 60
7. Exceptional Blood Loss (anemia)	Until HCT 22.9%
8. Necrotizing Soft Tissue Infections (Subcutaneous Tissue, Muscle, Fascia)	5* - 30
9. Osteomyelitis (refractory)	20* - 60
10. Radiation Tissue Damage (Osteoradionecrosis)	10* - 60
11. Skin Grafts and Flaps (compromised)	6* - 40
12. Thermal Burns	5* - 45

* Lower thresholds. If the patient receives less than the indicated lower treatment threshold, a Q/A review should be triggered. In these disorders, too few treatments are unlikely to have any effect and potentially are a waste of money and resources. Reasons for early termination of HBO treatment may include: death, misdiagnosis, claustrophobia, deterioration or failure to perceive improvement

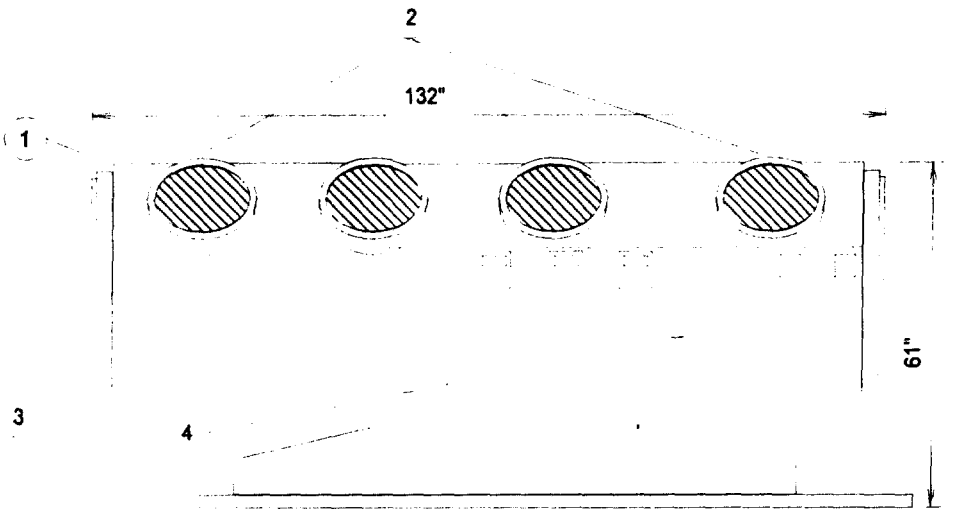
TECHNOLOGICAL CHARACTERISTIC COMPARISON

The subject device is identical to the predicate devices in all technical areas except dimension, weight and configuration.

Fig. 2



proposed equivalent 510(k) device -- side view



Predicate device 510(k) No. K840841 -- side view

Drawings to size perspective scale

Equivalent table

①	Both HBOT chambers have stainless steel pressure vessels built to full ANSI/ASME- PVHO1 codes (Exhibit B) §807.87 (e)
②	Both HBOT chambers have acrylic 14" windows built to full ANSI/ASME PVHO1 codes (Exhibit C) §807.87 (e)
③	Both HBOT chambers have a view window incorporated in the door.
④	Both HBOT chambers have similar pressurization, ventilation and patient breathing systems.

TECHNOLOGICAL CHARACTERISTIC COMPARISON

The subject device is not identical to the secondary predicate device except in the gas delivery to the patient.

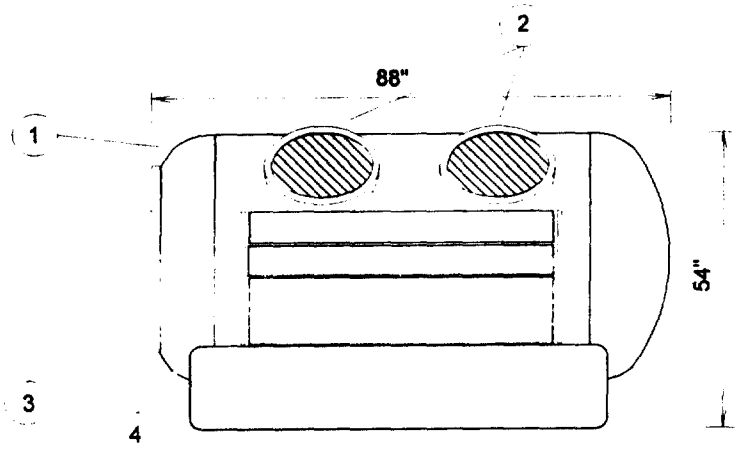
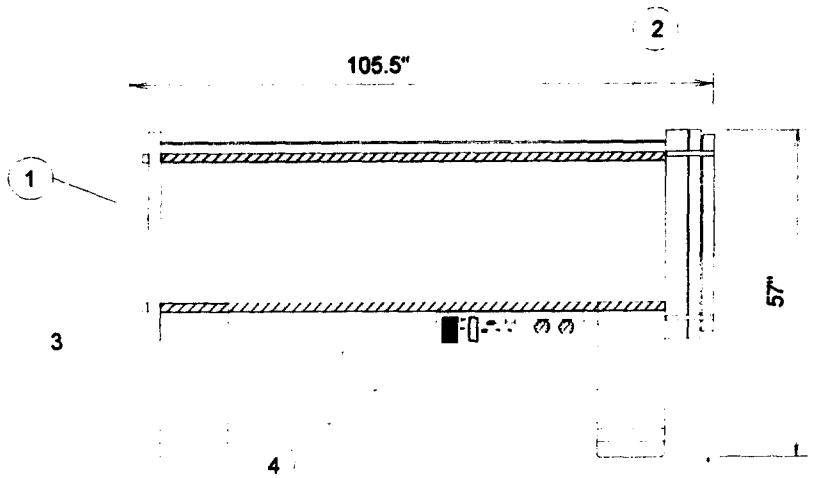


Fig. 2A

proposed equivalent 510(k) device -- side view



Predicate device 510(k) No. K950386 -- side view

Drawings to size perspective scale

①	Proposed device, stainless steel, ALL components built to full ANSI/ASME PVHO1 Codes (Exhibit B) §807.87 (e)
①	Predicate device , alloy and sheet metal, ANSI/ASME PVHO1 PARTIAL data report. (Exhibit B1) §807.87 (e)
②	Proposed device, with 5 acrylic windows built to Case-5 Addenda of the 1993 PVHO-1. (Exhibit C) §807.87 (e)
②	Predicate device, has a cylindrical window, in-house certification. (Exhibit B1) §807.87 (e)
③	Doors on both devices entirely different. (see page 7 "Weight Difference")
④	Both HBOT chambers have similar pressurization, ventilation and patient breathing systems. (next table, page 6)

	Proposed 510(k) device K972908	Equivalent 510(k) device* K950386
Maximum operating pressure	60 PSIG	30 PSIG
Operating Room Temperature	70°F - 100° F	50°F - 100° F
Operating relative Room Humidity	40% - 90% @ 77°F	40% - 90% @ 77°F
Supply Pressure	90 - 150 PSIG	50 - 90 PSIG
Purge Rate	280 – 800 liters per minute (chamber pressure 30 PSI)	240 – 400 liters per minute (chamber pressure 15 PSI)
Emergency Vent Rate	0.5 to 1.5 psi/sec	0.4 to 1.0 psi/sec.
Relief Valve	One, set at 60 PSI	Two, set at 35 PSI
Pressure Ret Set	1.0 to 6.5 psi/min	1.0 to 5.0 psi/min

* Data taken from Sechrist Industries, Inc. *User's Manual*, Monoplace hyperbaric Chamber Model 3200 and 3200R P/N 100196 Rev.5

§807.92 (b) (1).

ASSESSMENT OF NON-CLINICAL PERFORMANCE DATA

Not applicable to this summary.

§807.92 (b) (2).

ASSESSMENT OF CLINICAL PERFORMANCE DATA

Not applicable to this summary.

§807.92 (b) (3).

CONCLUSIONS FROM NON-CLINICAL AND CLINICAL PERFORMANCE DATA

Not applicable to this summary.

OTHER INFORMATION -- Weight Difference

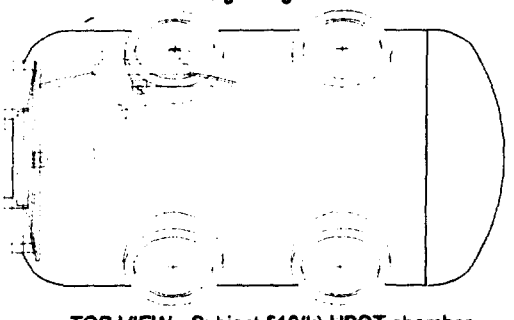
The subject 510(k) HBOT chamber weighs approximately 1200 lbs. The predicate #1 HBOT chamber weighs approximately 5200 lbs. The weight difference is caused by a number of factors. However, the primary factor is the door swing on each chamber.

Internal doors (chamber doors that swing inwards into the chamber) are common to large multi-person chambers (e.g. K950957) are held shut by internal compartment pressure. No door locking devices are required. Further, the domed end-walls (heads) are lightweight, as is the hull and the door itself. This is because the design calculations take into account the moment and deformation potential of the already pressure-contoured chamber (pressure vessel).

Conversely, external opening doorways (chamber doors that open into the room housing the chamber) require thicker hulls to anchor the door hinge and cope with the weight of a much heavier door and locking mechanism.

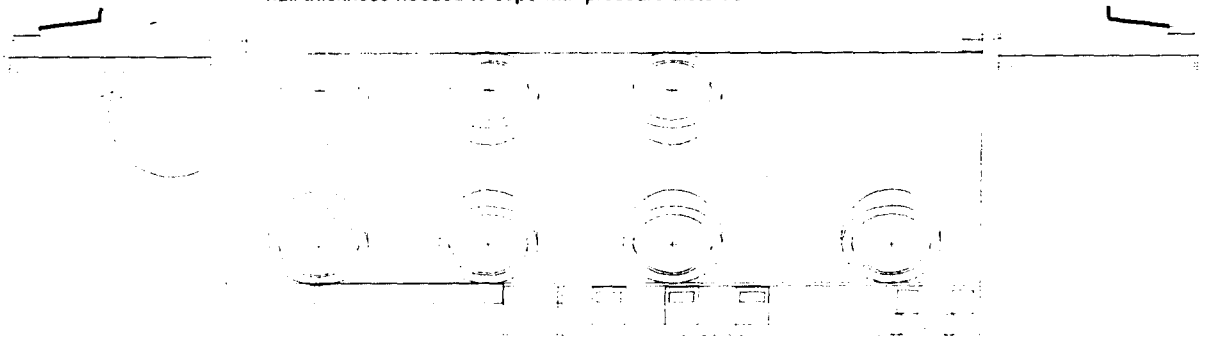
Fig. 3

Door opens inwards. Held shut by internal pressure.
Lightweight hull and door built to ASME-PVHO-1 calculations and codes.



TOP VIEW - Subject 510(k) HBOT chamber

Door opens outwards. Robust locking mechanism requried to avoid opening under pressure. Heavyweight hull thickness needed to cope with pressure distortion.



TOP VIEW - predicate K840841 HBOT chamber

The subject 510(k) HBOT chamber has an internal door. Comment is made on the ASME "U-1A" certificate (Exhibit B) and the ASME PVHO-1 "U-4" certificate, Item #12 remark (Exhibit D).

OTHER INFORMATION – National Fire Protection Agency (NFPA) section 99

The subject 510(k) HBOT chamber is classified as a Class B chamber under the NFPA-99 regulations relating to HBOT chambers in medical facilities (see "U-4" certificate, Item #12 remark - Exhibit D)

Additional information on the subject 510(k) HBOT chamber where it conforms with NFPA-99 is included in Exhibit F.

OTHER INFORMATION – Safety Information, Over-pressure of HBOT Chamber

The potential for bursting of the pressure vessel because the design pressure is removed by the permanent fixture of an over-pressure relief valve. The subject 510(k) HBOT chamber is fitted with a 60 PSIG relief valve, certified by COMBRACO in accordance with ASME Boiler Pressure Vessel Code, Section 1, Section VIII, and UG-125 through UG-136 (Division 1). (See comments ASME "U-1A" certificate - Exhibit B)

In repeated tests, (Pages 10 -12 – Exhibit E) the over-pressure valves tripped (audible "murmur") at 56 PSIG and fully opened at 59 PSIG. Pressure flows of up to 12 SCFM could not override the over-pressure valves which vented with a loud audible signal (120 dB) and stayed in the open-vent position after all oxygen supply lines were closed.

OTHER INFORMATION – Communication System

As the patient is isolated within the chamber, all hyperbaric chambers must use an electronic communication device. All include internal speakers and microphones for the patients. The electronic module and power supply are on the exterior of the chamber.

The physical problem to overcome within the chamber is that the density of the gas rises as the chamber pressure increases, thereby creating an environment where normal speaker cones lose their ability to vibrate and produce good quality sound. More powerful speakers for this environment have been developed but they require a higher wattage and defeat our intent to have no electrical current within the chamber. We chose not to use internal speakers.

In the instance of predicate devices #1 and #2, both use high current internal speakers.

By avoiding internal speakers in the instance of the subject 510(k) HBOT chamber, there are no electrical leads penetrating into the chamber, thus this potential for fire ignition is completely avoided.

The subject 510(k) HBOT chamber utilizes the acoustic properties of its stainless steel shell, using external transducers for both sound input and output. These are powered by an "AMCOM 1" communicator, designed and built by AMRON Industries of Escondido, California.

While this communicator does not have "UL" listing, it must be pointed out that the manufacturers supply communicators to the U.S. Navy and this communicator is currently used and approved on the transportable recompression chamber system that the Navy is deploying fleet-wide. It is also appropriate to point out that this Navy chamber was designed by the same individual who designed the subject 510(k) HBOT chamber.

There are no measurable values of current leakage at (1) the location of the communication system, (2) at the sites of the transponders, (3) within the chamber interior, and (4) at the primary chamber grounding lead.

OTHER INFORMATION – Electromagnetic Compatibility Testing

There are no electronic monitors included in the design or function of the subject 510(k) chamber. Therefore, no electromagnetic compatibility testing has been performed.

OTHER INFORMATION – PVHO-1 windows

The PVHO-1 Case 5 Addenda of 1993 was selected because it was the only option at the time of the design of the SHS Series III Hyperbaric Chamber. At that time no U.S. manufacturer of chamber windows held the ASME PVHO-1 certificate. Code 5 says in part:

> The PVHO manufacturer or owner/user shall be responsible for the evaluation and qualification of the window fabricator's quality assurance program to assure the quality control programs are established and implemented in accordance with Section 3, Article 4 of PVHO-1. On-site window fabricator evaluation is required prior to procurement of windows. All window fabricator activities shall be audited at least annually.

The windows of any PVHO-1 are a primary pressure boundary. In the last two decades their have been a number of window failures which caused fatalities of both patients and attendants, particularly in device K 934164. Also, we note that predicate device #2 K950386 was built to the 1993 PVHO-1 (the same as the subject 510(k) chamber) but excludes the cylindrical window (its largest pressure boundary) from the *Form U-4 Manufacturer's Data Report Supplementary Sheet (Exhibit B1, page 2).* Additionally, predicate device #2 K950386, does not perform a hydrostatic test on the window and chamber but a pneumatic test.

In view of the above and with a surfeit of caution, after finite element analysis of the window designs and careful choice of a window manufacturer (Plastic Supply and Fabrication of New Orleans – primary supplier of pressure windows to the US Navy) we chose to adopt the more stringent (and expensive) Case 5 Addenda. We used the independent services of Professional Engineer, Mr. Vern Rez, to travel to the manufacture's facility to perform an evaluation and audit prior to manufacture.

Additionally, a stringent hydrostatic pressure test of each window occurs with the testing of the chamber. This test is for one hour at 90 PSIG and 90° F (Exhibit E, pages 3 &4)

However, the 1996 Addenda to PVHO-1 has largely superceded 1993 Case 5. All future chamber windows for the Series III chamber will be manufactured to the latest PVHO-1 Addenda.

OTHER INFORMATION – Proposed Marketing Material

All proposed marketing material has been abandoned. New Marketing material will be issued when the national marketing of the chamber commences

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 1998

Mr. Lachlan Sands
Sands Hyperbaric Systems
709 East Washington Boulevard
Los Angeles, CA 90021-3106

Re: K972908
Sands Series III Clinical Chamber
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: April 30, 1998
Received: May 4, 1998

Dear Mr. Sands:

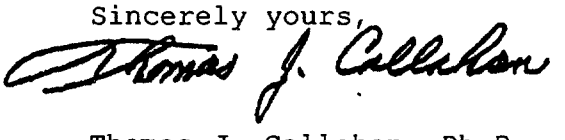
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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

510(k) Number (if known):

Device Name: K 972908
HYPERBARIC CHAMBER

Indications For Use:

APPROVED USES AND THRESHOLD LEVELS FOR THE NUMBER OF HYPERBARIC TREATMENTS
(As published by the Undersea and Hyperbaric Medical Society's (UHMS) Oxygen Committee 1995)

INDICATIONS	Threshold Levels
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10. Radiation Tissue Damage (Osteoradionecrosis)	10* - 60
11. Skin Grafts and Flaps (compromised)	6* - 40
12. Thermal Burns	5* - 45

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use X (Per 21 CFR 801.109) Over-The-Counter Use

510(k) Number

(Optional Format 1-2-96)