DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 22, 2017

OxyHeal Medical Systems, Inc.
Edward J. Chomas
VP, Regulatory Affairs
3224 Hoover Ave
National City, California 91950

Re: K163109
Trade/Device Name: OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: Class II
Product Code: CBF
Dated: February 22, 2017
Received: February 23, 2017

Dear Edward Chomas:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163109

Device Name
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family

Indications for Use *(Describe)*

The following indications which are listed on the Undersea & Hyperbaric Medical Society (UHMS) web site: www.uhms.org are approved uses of hyperbaric oxygen therapy as defined by the Hyperbaric Oxygen Therapy Committee.

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning
a. Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
3. Clostridial Myositis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Ischemias
5. Decompression Sickness
6. Arterial Insufficiencies
a. Central Retinal Artery Occlusion
b. Enhancement of Healing in Selected Problem Wounds
7. Severe Anemia
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections
10. Osteomyelitis (Refractory)
11. Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
12. Compromised Grafts and Flaps
13. Acute Thermal Burn Injury

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 008– 510(k) Summary
for
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family

Device Name: OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family

1. Submission Sponsor

OxyHeal® Medical Systems, Inc.
3224 Hoover Avenue
National City, CA 91950
Phone: 619.336.2022
Fax: 619.336.2017
Contact: W. T. 'Ted' Gurneé, President & CEO

2. Submission Correspondent

OxyHeal® Medical Systems, Inc.
3224 Hoover Avenue
National City, CA 91950
Phone: 619.336.2022
Fax: 619.336.2017
Contact: Edward J. Chomas, VP Regulatory Affairs
Email: echomas@oxyheal-international.com

3. Date Prepared

28 October 2016

4. Device Name

Trade/Proprietary Name:	OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
Common/Usual Name:	Multiplace Hyperbaric Chamber
Classification Name:	Chamber, Hyperbaric
Classification Regulation:	21 CBF 868.5470
Classification Panel:	Anesthesiology
Product Code:	CBF
Device Class:	II

FDA Establishment Registration #: 1000519737

5. Predicate Device

OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family (K152223)

6. Device Description

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family is comprised of a multiplace hyperbaric chamber and a number of major subsystems that support the overall system operation, control, and monitoring.

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber is a pressure vessel for human occupancy (PVHO) that is designed in a horizontally orientated cylindrical geometry. Chamber configurations vary based on the needs of the end user, and may be designed and manufactured in one (1), two (2), or three (3), compartment configurations. Patient capacities may range anywhere from four (4) to twenty-four (24) dependent on chamber size, number of compartments, or the direction provided by the customer to meet their needs. Lastly, maximum operating pressures range from 3ATA (~30psi) to 6ATA (~73.5psi), with each of the compartments designed to operate independently.

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System is regulated by the same codes and standards as the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System, predicate device K152223.

1. NFPA 99 (2012 Edition): National Fire Protection Agency - Standard for Health Care Facilities Chapter 14 – Hyperbaric Chambers
    - FDA recognized consensus standard: (Recognition Number 1-67)
2. ANSI/ASME PVHO-1 (2012 Edition): American National Standards Institute/American Society of Mechanical Engineers – Safety Standard for Pressure Vessels for Human Occupancy.
    - FDA recognized consensus standard: (Recognition Number 1-78)
3. ISO 14971 (2012 Edition): International Standard Organization, Medical Devices – Application of Risk Management to Medical Devices
    - FDA recognized consensus standard: (Recognition Number 5-40)

OxyHeal® Medical Systems, Inc. complies with the ASME/PVHO-1 the FDA recognized consensus code and standard requirements for materials, design, fabrication, and testing of the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber. This includes: overall PVHO design, joint design, welding, non-destructive examination (NDE), viewports, penetrations, material reinforcement, pressure relief devices, piping, electrical outfitting, inspections, testing, risk analysis, documentation, and marking (labeling).

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System design also complies with the hyperbaric facilities requirements specified in the FDA recognized consensus standard NFPA 99 and satisfies the requirements for protection against electrical, explosive, and fire hazards and associated facilities used for medical procedures at gauge pressures within the ranges: 0psi to 100psi.

OxyHeal® Medical Systems, Inc.'s design control processes for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System are the same as those employed for the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System, predicate device K152223. These processes conform to the requirements of 21 CFR 820.30 and comply with the ISO 14971 FDA recognized consensus standard.

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chambers consists of the hyperbaric chamber itself and the major subsystems briefly described below. Each subsystem is substantially equivalent to that which is contained in the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family predicate device (K152223).

6.1 Compressed Air System.

The compressed air system consists of two (2) rotary screw compressors capable of producing pressurized air that is then stored in an air receiver, which in turn is used to pressurize the hyperbaric chamber. Air is filtered prior to entering the hyperbaric chamber, resulting in a breathable quality, Compressed Gas Association (CGA) Grade "E" air as required by NFPA 99. Details of the parts and components comprising the compressed air system are identified and described in Table 1, Sub-table 1-3, Compressed Air System.

6.2 Fire Suppression System.

The fire suppression system (FSS) consists of both a fire deluge system (primary) and hand line system (secondary). Water (potable) for both systems is stored in pressure vessels manufactured to ASME standards. The fire deluge system is activated in the event of a fire in the hyperbaric chamber; while the hand line system is activated manually. This complies with NFPA 99:2012, Standard for Health Care Facilities Chapter 14 – Hyperbaric Facilities. Details of the parts and components comprising the FSS are identified and described in Table 1, Sub-table 1-4, Fire Suppression System.

6.3 Oxygen Delivery System

An oxygen (O_2) delivery system is the primary source for supplying O_2 to patients' breathing hoods inside the chamber. OxyHeal® Medical Systems, Inc. (OMS) provides the end user with the requirements needed for an OxyHeal® 4000 hyperbaric chamber system, and it is the end user's responsibility for supplying a system meeting these requirements. Examples of two types of O_2 delivery systems and associated piping are identified and described in Table 1, Sub-table 1-5, Oxygen Delivery Requirements.

6.4 Built-in Breathing System

The built-in breathing system (BIBS) is capable of supplying each individually seated patient with breathing gas via standard oxygen hoods or free-flow masks. Breathing gasses can be O_2, medical air, or a gas mixture. Details of the parts and components comprising the BIBS are identified and described in Table 1, Sub-table 1-6, Built-in Breathing System (BIBS).

6.5 Environmental Control System

The environmental control system (ECS) is used to manage the temperature (heating and cooling) and relative humidity (RH) of the hyperbaric chamber. Details of the parts and components comprising the ECS are identified and described in Table 1, Sub-table 1-7, Environmental Control System (ECS).

6.6 Control Console

The control console serves as the central location where a qualified hyperbaric chamber technician (CHT) is capable of controlling and monitoring an OxyHeal® 4000 product family hyperbaric chamber system. The Human-Machine Interface (HMI) touch screen control system installed in the operator control console is the primary location from which a hyperbaric chamber operator is able to initiate and monitor patient hyperbaric oxygen therapy (HBOT) treatments. Manual back-up control systems are built into the system for control of pressurization and depressurization from both inside and outside the hyperbaric chamber in the event that the automatic feature is inoperable for any reason.

From the HMI touchscreen, the operator is also able to control the following:

a. Administer BIBS gasses
b. Analyze / monitor O_2
c. Analyze/ monitor carbon dioxide (CO_2) [option]
d. Analyze / monitor relative humidity inside the hyperbaric chamber
e. Control and monitor the temperature in the hyperbaric environment
f. Open and close doors in any hyperbaric chamber compartment
g. Turn ON/OFF and adjust the intensity of hyperbaric chamber lighting; and
h. Perform administrative functions.

The FSS is activated from the control console. A communications system is installed at the control console allowing a CHT to communicate to patients and inside attendants within the hyperbaric chamber. The equipment used for the analysis of chamber and BIBS line gasses is mounted at the control console. Chamber lighting is managed at the control console. The control console also contains equipment used to visually monitor patients inside of the hyperbaric chamber from a CCTV, and initiate and adjust patient audio and visual entertainment (radio, CD, DVD, and TV). Details of the parts and components comprising the control console are identified and described in Table 1, Sub-table 1-8, Control Console.

Comparison Table 1.
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
Compared to the
OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family

1-1 Regulatory Info			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
510(k) Number	K163109	K152223	Unique K numbers for each product family have been assigned.
Product Code	CBF	CBF	Identical
Regulation Number	21 CFR 868.5470	21 CFR 868.5470	Identical
Regulation Name	Hyperbaric Chamber	Hyperbaric Chamber	Identical
Indications for use:	As defined in the Hyperbaric Oxygen Therapy Committee Report, dated 2008	As defined in the Hyperbaric Oxygen Therapy Committee Report, dated 2008	Identical

1-2 Hyperbaric Chamber			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
Hyperbaric Chamber Code Design	1. ASME: Boiler and Pressure Code 2. ASME PVHO-1: Safety Standard for Pressure Vessels for Human Occupancy. FDA consensus standard recognition no. 1-78.	1. ASME: Boiler and Pressure Code 2. ASME PVHO-1: Safety Standard for Pressure Vessels for Human Occupancy. FDA consensus standard recognition no. 1-78.	Regardless of PVHO geometry: • Rectangular: OxyHeal® 5000 [non-uniform distribution of pressure (worst case)] • Cylindrical: OxyHeal® 4000 [uniform distribution of pressure] Codes and standards defining requirements for PVHO materials, design, fabrication, and testing are identical.
- **Calculations**	ASME Section VIII, Div. 1	ASME Section VIII, Div. 1	Identical

1-2 Hyperbaric Chamber			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
- **Joint Design**	Design and fabrication shall be in accordance with specified Divisions of Section VIII of the ASME Code and the following requirements of ASME/PVHO-1, para. 1-7.1 (a) through (c)	Design and fabrication shall be in accordance with specified Divisions of Section VIII of the ASME Code and the following requirements of ASME/PVHO-1, para. 1-7.1 (a) through (c)	Identical
- **ASME PVHO-1 Material**	SA 516 Grade 70	SA 516 Grade 70	Identical
- **Stress Allowance**	Per ASME Section II	Per ASME Section II	Identical
- **Non-Destructive Examinations (NDE)**	NDE shall be performed in accordance with ASME/PVHO-1, para. 1-7.3	NDE shall be performed in accordance with ASME/PVHO-1, para. 1-7.3	Identical
- **Hydrostatic Test**	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section UG-99 @ 1.3 times max. allowable working pressure.	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section UG-99 @ 1.3 times max. allowable working pressure.	Identical
Hyperbaric Chamber System Fire Safety Design	NFPA 99, Chapter 14 – Hyperbaric Facilities. FDA consensus standard recognition no. 1-76.	NFPA 99, Chapter 14 – Hyperbaric Facilities. FDA consensus standard recognition no. 1-76.	Regardless of PVHO geometry: • Rectangular: OxyHeal® 5000 • Cylindrical: OxyHeal® 4000 This standard defining requirements for protection against electrical, explosive, and fire hazards in hyperbaric facilities is identical
Operating Pressure	3.0ATA – 6.0ATA	3.0ATA – 6.0ATA	Identical
Operating Temperature	50°F - 125°F	50°F - 125°F	Identical
Design Temperature	50°F – 125°F	50°F – 125°F	Identical

1-2 Hyperbaric Chamber			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
Design Pressure	30psig – 75psig	30psig – 75psig	Identical
Design Life	90,000 cycles or 60 years, which ever happens first	90,000 cycles or 60 years, which ever happens first	Identical
Hydrostatic Pressure	39psi - 97.5psi	39psi - 97.5psi	Identical
Inspection Authority	Independent 3rd Party ASME Authorized Inspector (AI). Affix ASME Stamp on chamber data plate	Independent 3rd Party ASME Authorized Inspector (AI). Affix ASME Stamp on chamber data plate	Identical Reference FDA recognized consensus standard: ASME PVHO-1 (Recognition Number 1-78)
Weight (lbs.)	12,600lbs to 100,000lbs	15,000lbs to 120,000lbs	Substantially equivalent
Dimensions **Main Compartment (Lock) (ML)** **Transfer Compartment (Lock) (EL)** **Inner Compartment (Lock) (IL)**	For all compartments, the following min/max apply Min: 60” Diameter x 10’L Max: 120” Diameter x 20’L Semi-elliptical or flat heads, cylindrical or semi-cylindrical shell, and circular or rectangular door frames	For all compartments, the following min/max apply Min: 8’ W x 7’ H x 10’L Max: 11’W x 8’H x 20’L Flat Heads, Rectangular Shell, and Rectangular Door Frames.	Substantially equivalent
Total Volume	From 567 ft³ to 2434 ft³	600 ft³ to 2,600 ft³	Substantially equivalent
Medical Lock	Cylindrical Min: 10 inch diameter Max: 16 inch diameter	Cylindrical Min: 10 inch diameter Max: 16 inch diameter	Identical
Main Doorway Size	Rectangular Door Min: 39.5” W x 65” H Max: 47.75” W x 75.5” H Cylindrical Door	Rectangular Door Min: 44” W x 80” H Max: 52” W x 80” H	Substantially equivalent

1-2 Hyperbaric Chamber			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
	Min: 33.5" D Max: 90" D		
Penetrators	Maximum of 30 Penetrations of 2" x 12" blocks.	Maximum of 30 Penetrations of 2" x 12" blocks.	Identical
Viewports (PVHO-1)	Minimum: One (1) per hyperbaric chamber. Maximum: Six (6) per compartment. Minimum: 8" Diameter, Maximum: 30" Diameter.	Minimum: One (1) per hyperbaric chamber. Maximum: Six (6) per compartment. Minimum: 8" Diameter, Maximum: 30" Diameter.	Identical
Compartment Relief	One (1) ASME certified pressure relief valve per compartment. 30 psig to 75 psig	One (1) ASME certified pressure relief valve per compartment. 30 psig to 75 psig	Identical
Compartment Drain	Minimum One (1) manual drain in each compartment	Minimum One (1) manual drain in each compartment	Identical
Finish - Chamber	Sandblasted and finished with 2-part high quality epoxy paint with glossy finish.	Sandblasted and finished with 2-part high quality epoxy paint with glossy finish.	Identical
Capacity Main Compartment	4 Patients Up to 24 Patients	4 Patients Up to 24 Patients	Identical
Hyperbaric Chamber Interior			
Lighting Subsystem	LED lights Min: 4 Max: 15 Chamber illumination complies with paragraph 14.2.3 of NFPA 99 (FDA consensus std. recognition no. 1-67).	LED lights Min: 4 Max: 15 Chamber illumination complies with paragraph 14.2.3 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Identical
BIBS with Overboard Dump	Four (4) to Twenty-Four (24), on demand gas delivery.	Four (4) to Twenty-Four (24), on demand gas delivery.	Identical
Hoods with Overboard Dump	Four (4) to Twenty-Four (24) 1-100LPM delivery flow meters. Minimum	Four (4) to Twenty-Four (24) 1-100LPM delivery flow meters. Minimum	Identical

1-2 Hyperbaric Chamber			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
	flow for hoods: 40-lpm.	flow for hoods: 40-lpm.	
Depth Measurement	Digital with analog backup	Digital with analog backup	Identical
Pressure Transmitter	Ranges: Minimum = 0 psig Maximum = 75 psig	Ranges: Minimum = 0 psig Maximum = 75 psig	Identical
Temperature Sensor	75°F ± 5°F	75°F ± 5°F	Identical
Relative Humidity Sensor	0% - 100%	0% - 100%	Identical
Television (TV) System	24VDC LED TV Monitors. Customer specified. Two (2) or four (4) per treatment compartment	24VDC LED TV Monitors. Customer specified. Two (2) or four (4) per treatment compartment	Identical

1-3 Compressed Air System			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
Air Compressors	Qty. two (2) rotary screw Operating range: Rated Power: 208V ±10%, 3-ph, 60Hz - 460V ±10%, 3-ph, 60Hz Max Working Pressure: 125psig – 217psig Air Delivery 155 CFM - 288 CFM	Qty. two (2) rotary screw Operating range: Rated Power: 208V ±10%, 3-ph, 60Hz - 460V ±10%, 3-ph, 60Hz Max Working Pressure: 125psig – 217psig Air Delivery 155 CFM - 288 CFM	Identical
Air Receiver	Ranges: Qty. 1 – Qty.5 depending on space and location within client facility.	Ranges: Qty. 1 – Qty.5 depending on space and location within client facility.	Substantially equivalent
- **Design Code**	ASME Boiler and Pressure Code	ASME Boiler and Pressure Code	Identical
- **Calculations**	ASME Section VIII, Div. 1	ASME Section VIII, Div. 1	Identical
- **Joint Design**	Joint design and fabrication shall be performed in	Joint design and fabrication shall be performed in	Identical

1-3 Compressed Air System			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
	accordance with UW-12 and Table UW-12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	accordance with UW-12 and Table UW-12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	
- **Non-Destructive Examinations (NDE)**	Radiographic examination and ultrasonic examination shall be performed in accordance with UW-51 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII Ultrasonic examination shall be performed in accordance with UW-53 and Appendix 12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	Radiographic examination and ultrasonic examination shall be performed in accordance with UW-51 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII Ultrasonic examination shall be performed in accordance with UW-53 and Appendix 12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	Identical
- **Hydrostatic Test**	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section UG-99 @ 1.3 times maximum allowable working pressure.	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section UG-99 @ 1.3 times maximum allowable working pressure.	Identical
Pressure Vessel Relief	One (1) pressure relief satisfying the requirements of ASME Boiler and Pressure Vessel Code, Section UG-125. Rated at 200 psig	One (1) pressure relief satisfying the requirements of ASME Boiler and Pressure Vessel Code, Section UG-125. Rated at 200 psig	Identical
Filters			
- Liquid Separator	Removes moisture from air using centrifugal force	Removes moisture from air using centrifugal force	Identical
- Prefilter Filter	5 micron element	5 micron element	Identical
- Coalescing Filter	1 micron element	1 micron element	Identical
- Active Carbon Filter	Charcoal element	Charcoal element	Identical

1-3 Compressed Air System			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
- Particulate Filter	3 micron element	3 micron element	Identical
- High Efficiency Filter	.01 micron element	.01 micron element	Identical
Piping	ASTM B88	ASTM B88	Identical
Testing	OMS Factory Acceptance Test (FAT)	OMS Factory Acceptance Test (FAT)	Substantially Equivalent

1-4 Fire Suppression System			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
Fire Suppression System Design Code	Fire Protection complies with paragraph 14.2.5 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Fire Protection complies with paragraph 14.2.5 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Identical
Fire Deluge Tank	Quantity ranges based on number of chamber compartments: 1 Compartment: Qty. 1 2 Compartment: Qty. 2 3 Compartment: Qty. 3 Fire deluge system complies with paragraph 14.2.5.2 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Quantity ranges based on number of chamber compartments: 1 Compartment: Qty. 1 2 Compartment: Qty. 2 3 Compartment: Qty. 3 Fire deluge system complies with paragraph 14.2.5.2 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Identical
- **Design Code**	ASME Boiler and Pressure Code, Section VIII Division I	ASME Boiler and Pressure Code, Section VIII Division I	Identical
- **Calculations**	ASME Section VIII, Div. 1	ASME Section VIII, Div. 1	Identical
- **Joint Design**	Joint design and fabrication shall be performed in accordance with UW-12 and Table UW-12 of	Joint design and fabrication shall be performed in accordance with UW-12 and Table UW-12 of	Identical

1-4 Fire Suppression System			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
	ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	
- **Non-Destructive Examinations (NDE)**	Radiographic examination and ultrasonic examination shall be performed in accordance with UW-51 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII Ultrasonic examination shall be performed in accordance with UW-53 and Appendix 12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	Radiographic examination and ultrasonic examination shall be performed in accordance with UW-51 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII Ultrasonic examination shall be performed in accordance with UW-53 and Appendix 12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	Identical
- **Hydrostatic Test**	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section VIII, UG-99 @ 1.3 times max. allowable working pressure.	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section VIII, UG-99 @ 1.3 times max. allowable working pressure.	Identical
Pressure Vessel Relief	One (1) pressure relief satisfying the requirements of ASME Boiler and Pressure Vessel Code, Section UG-125. Rated at 200 psig	One (1) pressure relief satisfying the requirements of ASME Boiler and Pressure Vessel Code, Section UG-125. Rated at 200 psig	Identical
Hand Line Tank	Hand Line system complies with paragraph 14.2.5.3 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Hand Line system complies with paragraph 14.2.5.3 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Identical
- **Design Code**	ASME Boiler and Pressure Code, Section VIII Division I	ASME Boiler and Pressure Code, Section VIII Division I	Identical
- **Calculations**	ASME Section VIII, Div. 1	ASME Section VIII, Div. 1	Identical
- **Design Code**	Joint design and fabrication shall be performed in	Joint design and fabrication shall be performed in	Identical

1-4 Fire Suppression System			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
	accordance with UW-12 and Table UW-12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	accordance with UW-12 and Table UW-12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	
- **Joint Design**	Radiographic examination and ultrasonic examination shall be performed in accordance with UW-51 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII Ultrasonic examination shall be performed in accordance with UW-53 and Appendix 12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	Radiographic examination and ultrasonic examination shall be performed in accordance with UW-51 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII Ultrasonic examination shall be performed in accordance with UW-53 and Appendix 12 of ASME Boiler and Pressure Vessel Code, Division, I, Section VIII	Identical
- **Non-Destructive Examinations (NDE)**	NDE shall be performed in accordance with ASME/PVHO-1, para. 1-7.3	NDE shall be performed in accordance with ASME/PVHO-1, para. 1-7.3	Identical
- **Hydrostatic Test**	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section UG-99 @ 1.3 times max. allowable working pressure.	Hydrostatic testing to be performed in accordance with ASME Boiler and Pressure Vessel Code, Section UG-99 @ 1.3 times max. allowable working pressure.	Identical
Pressure Vessel Relief	One (1) pressure relief satisfying the requirements of ASME Boiler and Pressure Vessel Code, Section UG-125. Rated at 200 psig	One (1) pressure relief satisfying the requirements of ASME Boiler and Pressure Vessel Code, Section UG-125. Rated at 200 psig	Identical
Piping	ASTM B88	ASTM B88	Identical
Testing	OMS Factory Acceptance Test (FAT)	OMS Factory Acceptance Test (FAT)	Substantially Equivalent

1-5 Oxygen Delivery Requirements			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
Facility Supplied Ground Storage and Bulk Liquid O_2	(Customer Provided) Ranges: Gallons: 500-13,000 SCF: 50K – 1.3M 100psi – 150PSI Permitted by Authority Having Jurisdiction (AHJ)	(Customer Provided) Ranges: Gallons: 500-13,000 SCF: 50K – 1.3M 100psi – 150PSI Permitted by Authority Having Jurisdiction (AHJ)	Identical
or			
Microbulk	(Customer Provided) Ranges: Gallons: 230-715 SCF: 5,658 – 66,592 100psi – 150PSI Permitted by Authority Having Jurisdiction (AHJ)	(Customer Provided) Ranges: Gallons: 230-715 SCF: 5,658 – 66,592 100psi – 150PSI Permitted by Authority Having Jurisdiction (AHJ)	Identical
Piping	ASTM B819	ASTM 819	Identical

1-6 Built In Breathing System (BIBS)			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
HP Oxygen	Cylinder Size: K Pressure: 3000 psig CGA 346	Cylinder Size: K Pressure: 3000 psig CGA 346	Identical
HP Medical Air	Cylinder Size: K Pressure: 3000 psig CGA 346	Cylinder Size: K Pressure: 3000 psig CGA 346	Identical
HP Mixed Gas (e.g.) - **Nitrogen** - **Nitrox** - **Helium**	Cylinder Size: K Pressure: 3000 psig - CGA 580 - CGA 326 - CGA 580	Cylinder Size: K Pressure: 3000 psig - CGA 580 - CGA 326 - CGA 580	Identical
Piping	ASTM B819	ASTM B819	Identical
Testing	OMS Factory Acceptance Test (FAT)	OMS Factory Acceptance Test (FAT)	Substantially Equivalent

1-7 Environmental Control System (ECS)			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
Environmental Control System	Chamber temperature and humidity control complies with paragraph 14.2.4.3 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Chamber temperature and humidity control complies with paragraph 14.2.4.3 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Identical
Environmental Control Unit (ECU)	Quantity ranges based on number of chamber compartments: 1 Compartment: Qty. 1 2 Compartment: Qty. 2 3 Compartment: Qty. 3	Quantity ranges based on number of chamber compartments: 1 Compartment: Qty. 1 2 Compartment: Qty. 2 3 Compartment: Qty. 3	Identical
ECU Physical Dimensions	24"L X 24"W X 36"H	24"L X 24"W X 36"H	Identical
ECU Heat Load (Heat Mode)	~ 12000 BTU/HR	~ 12000 BTU/HR	Identical
ECU Heat Load (Heat Mode)	~ 16000 BTU/HR	~ 16000 BTU/HR	Identical
ECU Coolant Pump Motor	2.2 AMPS	2.2 AMPS	Identical
ECU Coolant Pump Flow Rate	4.2 GPM @ 24 FT HEAD	4.2 GPM @ 24 FT HEAD	Identical
Testing	OMS Factory Acceptance Test (FAT)	OMS Factory Acceptance Test (FAT)	Substantially Equivalent

1-8 Control Console			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
HMI Touchscreen Monitor	Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 1-2 3 Comp: Qty. 2-3 • Primary method of controlling chamber • Primary means for monitoring chamber system status	Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 1-2 3 Comp: Qty. 2-3 • Primary method of controlling chamber • Primary means for monitoring chamber system status	Identical
Life Support Controls	Automatic pressurization & depressurization with manual back-up from both inside and outside each chamber compartment.	Automatic pressurization & depressurization with manual back-up from both inside and outside each chamber compartment.	Identical
Emergency Depressurization	Chamber depressurization complies with paragraph 14.2.4.5 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Chamber depressurization complies with paragraph 14.2.4.5 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Identical
Ventilation	Automatic chamber ventilation with manual back-up. Ranges are as follows: - Min = 6 cfm/min - Max = 48 cfm/min ± 1 FSW stability Chamber ventilation complies with paragraph 14.2.4.1 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Automatic chamber ventilation with manual back-up. Ranges are as follows: - Min = 6 cfm/min - Max = 48 cfm/min ± 1 FSW stability Chamber ventilation complies with paragraph 14.2.4.1 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Identical
Programmable Logic Controller (PLC)	Controls the operator initiated actions at the HMI touch screen by communicating with various	Controls the operator initiated actions at the HMI touch screen by communicating with various	Identical

1-8 Control Console			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
	devices managing the performance of chamber subsystems	devices managing the performance of chamber subsystems	
Keyboard and Mouse #1 and #2	Alternate method for providing input to control hyperbaric chamber Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 1-2 3 Comp: Qty. 2-3	Alternate method for providing input to control hyperbaric chamber Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 1-2 3 Comp: Qty. 2-3	Identical
Patient Monitor, Quad Screen	Visual method for monitoring patients undergoing HBOT Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 1-2 3 Comp: Qty. 2-3	Visual method for monitoring patients undergoing HBOT Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 1-2 3 Comp: Qty. 2-3	Identical
Fire Suppression System (FSS) Activation Pushbutton	When depressed, activates FSS and illuminates green Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 2 3 Comp: Qty. 3	When depressed, activates FSS and illuminates green Quantity ranges based on number of chamber compartments (Comp): 1 Comp: Qty. 1 2 Comp: Qty. 2 3 Comp: Qty. 3	Identical
Communications System	Primary: Wireless telephone Secondary: Intercom Tertiary: (OPTION) Sound powered backup	Primary: Wireless telephone Secondary: Intercom Tertiary: (OPTION) Sound powered backup	Identical
Gas Analysis System	Determines the O_2 and CO_2 from within a treatment compartment or from the BIBS gases. Analox SDA Oxygen	Determines the O_2 and CO_2 from within a treatment compartment or from the BIBS gases. Analox SDA Oxygen	Identical

1-8 Control Console			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
	Monitor w/ SDA Carbon Dioxide Monitor (OPTION add on) O_2 @ 0% - 100% ± 1% CO_2 @ 0 – 5250 NOTE parts per million (ppm) ± 25ppm. Oxygen monitoring complies with paragraph 14.2.8.4 of NFPA 99 (FDA consensus std. recognition no. 1-67).	Monitor w/ SDA Carbon Dioxide Monitor (OPTION add on) O_2 @ 0% - 100% ± 1% CO_2 @ 0 – 5250 NOTE parts per million (ppm) ± 25ppm. Oxygen monitoring complies with paragraph 14.2.8.4 of NFPA 99 (FDA consensus std. recognition no. 1-67).	
Flowmeters	Controls the flow of gas to the gas analyzer so as not to damage the analyzers internal parts. Two (2) per compartment	Controls the flow of gas to the gas analyzer so as not to damage the analyzers internal parts. Two (2) per compartment	Identical
Selector Switch	User adjustable and used for selecting between zero gas, calibration gas or gas flow from the chamber compartment. One (1) per compartment	User adjustable and used for selecting between zero gas, calibration gas or gas flow from the chamber compartment. One (1) per compartment	Identical
Patient Entertainment System	Components as listed below.	Components as listed below.	Identical
– **Television (TV) System**	Displays digital video on chamber interior mounted TVs	Displays digital video on chamber interior mounted TVs	Identical
– **DVD Player**	Provides digital video to patient entertainment monitor inside chamber	Provides digital video to patient entertainment monitor inside chamber	Identical
– **CD Player**	Provides digital audio to speaker of patient headphones inside chamber	Provides digital audio to speaker of patient headphones inside chamber	Identical
– **AM/FM Tuner**	Provides audio to patient headphones inside chamber	Provides audio to patient headphones inside chamber	Identical

1-8 Control Console			
Manufacturer	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 4000 Family Summary Comparison to Predicate (K152223)**
Trade Name	**OxyHeal® 4000 Family (K163109)**	**OxyHeal® 5000 Family (K152223)**	
– **4-Zone Mixer**	Individual up to 4-channels. Varies based on customer specification for number of compartments and number of patients to be treated.	Individual up to 4-channels. Varies based on customer specification for number of compartments and number of patients to be treated.	Identical
– **Amplifier**	Amplifies the outputs of the AM/FM tuner, CD/DVD to the chamber interior and the patient headsets	Amplifies the outputs of the AM/FM tuner, CD/DVD to the chamber interior and the patient headsets	Identical
– **Audio / Video Recorder**	Permits customer ability to record patient video and / or audio from within a compartment. OPTION – Customer	Permits customer ability to record patient video and / or audio from within a compartment. OPTION – Customer	Identical
Uninterrupted Power Supply (UPS)	Meets NFPA-99, para. 14.2.5.4.3 for automatic battery back-up. See also NFPA-99: 14.2.5.1.3 (3) for emergency communications and emergency lighting. 14.2.3.3 for emergency lighting. 14.2.5.4.3 for fire deluge	Meets NFPA-99, para. 14.2.5.4.3 for automatic battery back-up. See also NFPA-99: 14.2.5.1.3 (3) for emergency communications and emergency lighting. 14.2.3.3 for emergency lighting. 14.2.5.4.3 for fire deluge	Identical
Testing	OMS Factory Acceptance Test (FAT)	OMS Factory Acceptance Test (FAT)	Substantially Equivalent

7. Intended Use and indications for Use

The intended use of the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family is to administer hyperbaric oxygen therapy (HBOT) to treat patients with any of the below listed indications.

The following indications which are listed on the Undersea & Hyperbaric Medical Society (UHMS) web site: www.uhms.org.are approved uses of hyperbaric oxygen therapy as defined by the Hyperbaric Oxygen Therapy Committee.

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning
    a. Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
3. Clostridial Myositis and Myonecrosis (Gas Gangrene)

4. Crush Injury, Compartment Syndrome and Other Acute Ischemias
5. Decompression Sickness
6. Arterial Insufficiencies
    a. Central Retinal Artery Occlusion
    b. Enhancement of Healing in Selected Problem Wounds
7. Severe Anemia
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections
10. Osteomyelitis (Refractory)
11. Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
12. Compromised Grafts and Flaps
13. Acute Thermal Burn Injury

There is no difference between the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family and the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family in regards to intended use or these indications for use.

8. Technological Characteristics and Substantial Equivalence

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family in this Special 510(k) submittal consists of a minor modification of the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family predicate device (K152223).

The fundamental technology for this minor modification consists of a change in dimensional specifications; i.e. the predicate device (K152223) is a multiplace hyperbaric chamber with a rectangular geometry. The modified device is a multiplace hyperbaric chamber with a cylindrical geometry. This modification does not change the intended use, indications for use, and product labeling. The design of the modified device conforms to the same three FDA recognized standards as the predicate device; two (2) of which are the design and manufacturing standards / codes. The company's design control procedures are the same for the predicate and modified device and conform to the requirements as specified in 21 CFR 820.30.

Table 1 provides a substantially equivalent comparison between the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family and the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family; thereby providing more detailed information regarding the basis for the determination of substantial equivalence.

9. Non-Clinical Testing

In accordance with the requirements of the ASME PVHO-1 standard (the FDA consensus standard recognition number 1-78), the only test methods and /or examinations required for verifying the modification of the pressure vessel for human occupancy [(PVHO) or hyperbaric chamber] from a rectangular to a cylindrical geometry consists of certifying the weld integrity of the joint design and the integrity of the entire PVHO consist of non-destructive testing and hydrostatic testing. These are the identical tests required by the aforementioned standard and also performed on the OxyHeal® 5000 hyperbaric chambers (predicate device K152223). A description of the non-destructive tests and the hydrostatic test conducted for all OxyHeal® 4000 hyperbaric chambers is described below.

9.1 Non-destructive Testing

There are four different types of non-destructive examinations (NDEs) which are used to verify the integrity of the structural welds comprising the OxyHeal® 4000 hyperbaric chamber structure.

a. **Penetrant Examination (PE)** is a color contrast procedure used to identify surface weld defects. OMS welders apply this liquid penetrant by spraying onto the surface of a root pass (1st pass) weld to ensure that the very base of the weld is without imperfections.

b. **Ultrasonic Testing (UT)** is a technique used to test the integrity of a weld using the propagation of ultrasonic sound waves into the steel material to detect internal flaws. This testing is contracted to an ASME qualified independent 3rd party testing organization who provides a written copy of the results of this testing.

c. **Radiographic Examinations (RT)** is a method employed for weld testing which makes use of X-rays to verify the internal structure and integrity of the welded steel material. This testing is contracted to an ASME qualified independent 3rd party testing organization who provides a written copy of the results of this testing.

d. **Magnetic Particle Examination (MT)** is process which propagates a magnetic field into the welded steel and is used for detecting surface and slightly subsurface discontinuities. This testing is contracted to an ASME qualified independent 3rd party testing organization who provides a written copy of the results of this testing.

9.2 Hydrostatic Testing

A Standard Hydrostatic Test is conducted in accordance with the ASME Section VIII, Division 1 Code paragraph UG-99. This test consists of completely filling the OxyHeal 4000 hyperbaric chamber with water and pressure testing at 1.3 times the maximum allowable working pressure (MAWP) of the PVHO. Each viewport is installed in its location and hydrostatically tested as part of the overall structural test. This test is witnessed by an ASME qualified independent 3rd party authorized inspector (AI). The AI will also review/ approve the nameplate to be affixed on the PVHO to ensure all applicable data, the certification mark, and designator are stamped into the nameplate. Upon successful completion of this testing and review of the nameplate data, the manufacturer (OxyHeal® Medical Systems, Inc.) and the AI will sign the Form U-1 Manufacturer's Data Report for Pressure Vessels as required by the provisions of the ASME Boiler and Pressure Vessel Code Rules, Section VIII, Division 1. Once the Form U-i1 has been signed, OMS is authorized to affix the nameplates to the PVHO.

In parallel, OxyHeal® Medical Systems, Inc. is responsible for signing the FORM PVHO-1 Manufacturer's Data Report for Pressure Vessels for Human Occupancy as required by the provisions of ASME PVHO-1 certifying the design and certification of compliance of the PVHO.

9.3 Other V&V Testing

The validation / verification efforts performed for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family are identical to those performed for the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family (K152223) predicate device.

The following V&V activities listed in this Special 510(k) provide an overview of the V&V activities performed for the predicate device (K152223) and apply to the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family.

9.3.1 Fire Suppression System Testing

A Fire Suppression System (FSS) test was conducted at the completion of the hydrostatic test to ensure that the fire deluge system water spray system and the hand line met the requirements of the FDA recognized consensus standard NFPA 99 (Recognition Number 1-67).

9.3.2 First Operational System Test

A first operational system test (FOST) was performed to verify that the system design met each of the specification requirements. This testing includes the following items specified in the OxyHeal® 4000 hyperbaric chamber system product family as defined in the User Design Specification satisfies the requirements of the FDA recognized consensus standard: ASME PVHO-1 (Recognition Number 1-78).

a. Testing of the minimum and maximum pressurization rates
b. Testing of the minimum and maximum depressurization rates
c. Testing of the minimum and maximum ventilation rates
d. Testing of the conditions under which these rates are to be maintained
e. Testing of the patient gas delivery systems and flow meter range
f. Testing of the chamber pressurization and ventilation gas for meeting requirements for CGA Grade E

9.3.3 Software Validation Testing.

A software validation test was conducted to validate that observed output of designated hyperbaric chamber control functions met the output that they were designed to perform. This testing includes the following items specified in the OxyHeal® 4000 hyperbaric chamber system product family as defined in the User Design Specification.

a. Testing of the minimum and maximum pressurization rates
b. Testing of the minimum and maximum depressurization rates
c. Testing of the minimum and maximum ventilation rates
d. Testing of the conditions under which these rates are to be maintained
e. Testing of the patient gas delivery systems and flow meter range

9.3.4 Factory Acceptance Test

A Factory Acceptance Test (FAT) was performed to verify that the system is able to perform all required operational functions. The FAT is witnessed by and signed off by an independent 3rd party Authorized Inspector (AI). This testing satisfies the requirements of the FDA recognized consensus standards: ASME PVHO-1 (Recognition Number 1-78).and NFPA 99 (Recognition Number 1-67).

10 Conclusion

It has been shown in this Special 510(k) submission that the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family as designed, manufactured, and tested does not raise any different questions regarding its safety and effectiveness, there is no difference in the indications and intended use, is designed to the same FDA recognized consensus standards, and is determined to be substantially equivalent to the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family predicate device (K152223).