DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 29, 2016

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

Re: K152223
Trade/Device Name: OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: Class II
Product Code: CBF
Dated: March 18, 2016
Received: March 21, 2016

Dear Mr. 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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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)*
K152223

Device Name
OxyHeal 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family

Indications for Use *(Describe)*
The following indications which are listed on the Undersea and Hyperbaric Medical Society (UHMS) website: 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.

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Section 6 – 510(k) Summary for OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

26 April 2016

4. Device Name

Trade/Proprietary Name:	OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family
Common/Usual Name:	Rectangular 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 Devices

Fink Engineering PTY LTD SL8, DL8, and TL20 Hyperbaric Oxygen Facility (K031649)
OxyHeal Health Group®, Inc. OxyHeal® 2000 Hyperbaric Chamber Series (K011866)

6. Device Description

The OxyHeal® 5000, Rectangular Multiplace Hyperbaric Chamber System is comprised of a multiplace hyperbaric chamber and a number of major subsystems that support the overall system operation, control, and monitoring.

An OxyHeal® 5000 multiplace hyperbaric chamber is a pressure vessel for human occupancy that is designed in a rectangular geometry. Configurations vary based on the needs of the end user and may consist of two (2), three (3), or more compartments. Capacities may range anywhere from six (6) to twenty-four (24) patients or more, dependent on chamber size, the number of compartments, or the direction of 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.

Each OxyHeal® 5000 multiplace hyperbaric chamber is designed, fabricated, inspected, tested, marked and stamped to meet the standards defined in the American Society of Mechanical Engineers / Pressure Vessel for Human Occupancy (ASME/PVHO-1). These chambers comply with the National Fire Protection Agency (NFPA) 99, Health Care Facilities.

The OxyHeal 5000, Rectangular Multiplace Hyperbaric Chamber System consists of the hyperbaric chamber itself and the major subsystems briefly described below:

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, Grade "E" air as required by NFPA 99.

6.2 Fire Suppression System.

The fire suppression system 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.

6.3 Bulk Oxygen System

A bulk oxygen (O_2) system is the primary source for supplying O_2 to the patients' breathing hoods inside the chamber. The bulk O_2 is typically supplied by the end users of this device.

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.

6.5 HP Gas System

The HP gas system is used to supply O_2 and medical air back-up in the event of an emergency resulting in the loss of primary breathing air and O_2. Mixed gasses (e.g. helium, nitrogen, and helium-oxygen /nitrogen-oxygen mixes) may also be supplied as required by the end users. All gasses are connected to the hyperbaric chamber through appropriate piping, a gas manifold, and appropriately filtered.

6.6 Environmental Control System (ECS)

The environmental control system is used to manage the temperature (heating and cooling) of the hyperbaric chamber.

6.7 Control Console

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. 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).

7. Intended Use

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

8. Technological Characteristics and Substantial Equivalence

The following tables provide a comparison of OxyHeal's Rectangular Multiplace Hyperbaric Chamber Systems Family of Products to that of the predicate device with respect to intended use, technological characteristics and principles of operation; thereby providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 1 compares the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family to the Fink Engineering PTY LTD Double Lock (DL8) and Tripe Lock (TL20) Hyperbaric Treatment Facility, and the OxyHeal® 2000 Hyperbaric Chamber System which are the predicate devices.

Comparison Table 1. OxyHeal 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Compared to the Fink Engineering DL8 and TL20 Hyperbaric Treatment Facilities and the OxyHeal 2000 Hyperbaric Chamber System

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
510(k) Number	K152223	K031649	K011866	K152223
Product Code	CBF	CBF	CBF	Identical
Regulation Number	21 CFR 868.5470	21 CFR 868.5470	21 CFR 868.5470	Identical
Regulation Name	Hyperbaric Chamber	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 1999	As defined in the Hyperbaric Oxygen Therapy Committee Report, dated 1999	Substantially equivalent
Hyperbaric Chamber Code Design	1. ASME: Boiler and Pressure Code 2. ASME PVHO-1: Safety Standard for Pressure Vessels for Human Occupancy	1. ASME Section VIII, Div. 1 2. ASME PVHO-1. Safety Standard for Pressure Vessels for Human Occupancy	1. ASME Section VIII, Div. 1 2. ASME PVHO-1. Safety Standard for Pressure Vessels for Human Occupancy	Substantially equivalent
Hyperbaric Chamber System Design	NFPA 99, Chapter 14 – Hyperbaric Facilities	NFPA 99, Chapter 19 – Hyperbaric Facilities	NFPA 99, Chapter 19 – Hyperbaric Facilities	Substantially equivalent
Operating Pressure	3.0ATA – 6.0ATA	6.0 ATA	3.0 ATA	OxyHeal 5000 Product Family Chambers and the Fink DL8 and TL20 are substantially equivalent.

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
				The OxyHeal 2000 is designed to operate at the lower pressure range as noted.
Operating Temperature	50°F-125°F	62°F – 100°F	Capable of operating within design temperature ranges; however from a practical standpoint, ranges based on maintaining patient comfort.	Substantially equivalent
Design Temperature	50°F – 125°F	62°F – 100°F	50°F – 120°F	Substantially equivalent
Design Pressure	30psig – 75psig	80.0 psi	30psig	OxyHeal 5000 Product Family Chambers and the Fink DL8 and TL20 are substantially equivalent. The OxyHeal 2000 is designed to operate at the lower pressure range as noted.
Design Life	90,000 cycles or 60 years, which ever happens first	≥ 30 years	≥ 30 years	All hyperbaric chambers listed have life expectancy of ≥ 30 years: Substantially equivalent
Hydrostatic Pressure	39psi - 97.5psi	104.0 psi	45psi	OxyHeal 5000 Product Family Chambers and the Fink DL8 and TL20 are substantially equivalent. The OxyHeal 2000 is designed to operate at the lower pressure range noted.

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
Inspection Authority	Independent 3rd Party ASME Authorized Inspector (AI). Affix ASME Stamp on chamber data plate	ASME "U" Stamp	Independent 3rd Party ASME Authorized Inspector (AI). Affix ASME Stamp on chamber data plate	Substantially equivalent
Weight (lbs.)	15,000lbs to 120,000lbs	Ranges Stated: ~26,400 to ~110,231	~ 7,000	Weights of the OxyHeal 5000 Product Family Chambers and the Fink DL8 and TL20 are substantially equivalent. The OxyHeal 2000 is a significantly smaller chamber.
Dimensions **Main Compartment (Lock) (ML)** **Transfer Compartment (Lock) (EL)** **Inner Compartment (Lock) (IL)**	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.	 **Ranges stated:** 8.1'W x 7'H x 11'L to 10.3'W x 7'H x 19.3'L **Ranges stated:** 8.1'W x 7'H x 4.5'L to 7.8'W x 7'H x 10.8'L 7.8'W x 7'H x 10.8'L	Dia. = 6'; H = 7'	The dimensions of the OxyHeal 5000 Product Family chamber and the Fink DL8 and TL20 are substantially equivalent. The OxyHeal 2000 is intentionally designed as a smaller cylindrical hyperbaric chamber and no transfer compartment.
Volume **Main Compartment (Lock) (ML)**	 Rectangular geometry from 600ft³ to 2600ft³	 **Ranges stated:** 614.5ft³ to 1,536.2ft³	 197.8ft³	The OxyHeal 5000 Product Family chamber volumes and the Fink DL8 and TL20 are substantially equivalent.

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
Transfer Compartment (Lock) (EL) **Inner Compartment (Lock) (IL)**		**Ranges stated:** 254.3ft^3 to 529.7ft^3 480.3ft^3		The OxyHeal 2000 is intentionally designed as a smaller cylindrical hyperbaric chamber.
Total Volume	6,00ft³ to 2,600ft ³	**Ranges stated:** 868.7ft^3 to 2,546.2ft^3	197.8ft^3	Total volumes of the OxyHeal 5000 Product Family chamber and the Fink DL8 and TL 20 are substantially equivalent. The OxyHeal 2000 is intentionally designed as a smaller cylindrical hyperbaric chamber with much smaller total volumes.
Medical Lock	Cylindrical Min: 10 inch diameter Max: 16 inch diameter	13.8” x 13.8” x 19.7”	10” ID x 10”L	Substantially equivalent
Main Doorway Size	Minimum door frame size: 44” x 80, Maximum 52” x 80”	39.4” x 75.6”	32” x 83”	The OxyHeal 5000 Product Family and the Fink DL8 and TL20 chamber main doorway sizes are substantially equivalent. The doorways of the OxyHeal 5000 compared to the 2000 Product Family chambers and the Fink DL8 and TL20

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
				predicate chambers are substantially equivalent in terms of safety and effectiveness of operation.
Penetrators	Maximum of 30 Penetrations of 2" x 12" blocks.			
Lighting	LED lights Min: 4 Max: 15	**Ranges stated:** Six (6) to fourteen (14) external dimmable lights	One (1) internally mounted light.	The OxyHeal 5000 Product Family chamber lights, the Fink DL8 and TL20 chamber lights, and the OxyHeal 2000 chamber light comply with NFPA-99 and are substantially equivalent in terms of safety and effectiveness of operation.
Viewports (PVHO-1)	Minimum: One (1) per hyperbaric chamber. Maximum: Six (6) per compartment. Minimum: 8" Diameter, Maximum: 30" Diameter.	**Ranges stated:** **Main Lock (ML):** 13.8" ID - Qty. 2 each to 23.6" ID – Qty. 4 each **Transfer Lock (TL):** 5.9" ID – Qty. 1 each to 13" ID – Qty. 3 each **Inner Lock (IL):** 6" ID - Qty. 2 each	16" ID – Qty. 2 each	The OxyHeal 5000 Product Family and the Fink DL8 and TL20 chamber, and the OxyHeal 2000 viewports are substantially equivalent.
Capacity Main Compartment	4 Patients Up to 24 Patients	**Ranges stated:** From eight (8) seated patients Four (4) wheelchairs	Capable of accommodating up to six (6) upright seated patients	The OxyHeal 5000 Product Family and the Fink DL8 and TL20 chamber main

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
		One (1) hospital gurney to - up to twenty (20) patients	or four (4) upright seated patients and two (2) gurneys.	compartments are substantially equivalent. The OxyHeal 2000 is intentionally designed as a smaller cylindrical hyperbaric chamber with less capacity; however, substantially equivalent in terms of safety and effectiveness of operation.
Fire Suppression	IAW NFPA 99	IAW NFPA 99	IAW NFPA 99	Substantially equivalent
Finish - Chamber	Sandblasted and finished with 2-part high quality epoxy paint with glossy finish.	Shot blasted & painted		Substantially equivalent
Life Support Controls	Automatic pressurization & depressurization with manual back-up from both inside and outside each chamber compartment.	Manual electropneumatic (pressurization) Manual electropneumatic (depressurization)	Automatic pressurization & depressurization with manual back-up from both inside and outside the chamber.	The OxyHeal 5000 Product Family and the OxyHeal 2000 life support controls are substantially equivalent.
Environmental Control	Heating & cooling	Heating	Heating and cooling	The OxyHeal 5000 Product Family and the OxyHeal 2000 environmental controls are substantially equivalent.
Ventilation	Automatic chamber ventilation with manual back-up. Min 6 cfm, Max	Constant air flow	Automatic chamber ventilation with manual back-up.	The OxyHeal 5000 Product Family and the OxyHeal 2000

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
	48cfm with a +/- 1 fsw stability.			ventilation are substantially equivalent.
BIBS with Overboard Dump	Four (4) to Twenty-Four (24), on demand gas delivery.	**Ranges stated:** Two (2) - Four (4)	Four (4)	The BIBS overboard dump system for the OxyHeal 5000 Product Family, the Fink DL8 and TL20 chambers, and the OxyHeal 2000 chamber are substantially equivalent in terms of safety and effectiveness of operation.
Hoods with Overboard Dump	Four (4) to Twenty-Four (24) 1-100LPM delivery flow meters. Minimum flow for hoods: 40-lpm.	**Ranges stated:** Six (6) to Twenty two (22)	Four (4)	The hood overboard dump system for the OxyHeal 5000 Product Family, the Fink DL8 and TL20 chambers, and the OxyHeal 2000 chamber are substantially equivalent in terms of safety and effectiveness of operation.
Depth Measurement	Digital with analog backup	Digital with analog backup	Digital with analog backup	Substantially equivalent
Gas Analysis	Oxygen (O_2) 1-100% and carbon dioxide (CO_2) 0-5000ppm	Oxygen (O_2) and carbon dioxide (CO_2)	Oxygen (O_2) and carbon dioxide (CO_2)	Substantially equivalent
Communications	Primary: Wireless telephone Secondary: Intercom Tertiary: Sound powered backup	Internal/external PA system Sound powered backup	Primary: Wireless telephone Secondary: Intercom	Substantially equivalent

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
Entertainment	Individual up to 4-channels. Varies based on customer specification for number of compartments and number of patients to be treated.	Individual 4-channel selection for eight (8) persons	Individual 4-channel selection for up to six (6) persons.	Substantially equivalent
TV System	24VDC LED TV Monitor. AM/FM Tuner/CD, DVD, and Cable TV Tuner. .	External color with remote control AM/FM tuner/CD & DVD player	One (1) internally mounted TV System. AM/FM tuner/CD & DVD player.	The OxyHeal 5000 Product Family TV systems and the Fink DL8 and TL20 TV systems comply with NFPA-99 and are substantially equivalent in terms of safety and effectiveness of operation. The OxyHeal 2000 is intentionally designed as a smaller cylindrical hyperbaric chamber with a TV system that complies with NFPA-99 and is substantially equivalent in terms of safety and effectiveness of operation.
Compartment Relief	One (1) ASME certified pressure relief valve per compartment. 30 psig to 75 psig	ASME certified pressure relief valve	One (1) ASME certified pressure relief valve	Substantially equivalent

Manufacturer	**OxyHeal® Medical Systems, Inc.**	**Fink Engineering PTY LTD**	**OxyHeal® Medical Systems, Inc.**	**OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber Product Family Summary Comparison to Predicates**
Trade Name	**OxyHeal® 5000 Two & Three Compartment Hyperbaric Chamber System**	**DL8 Hyperbaric Treatment Facility & TL20 Hyperbaric Treatment Facility**	**OxyHeal® 2000 Hyperbaric Chamber System**	
Compartment Drain	Minimum One (1) manual drain in each compartment	One (1) manual drain in each compartment	One (1) manual drain	Substantially equivalent

9. Non-Clinical Testing

Refer to paragraphs 9.1 – 9.5

9.1 Structural Testing

The following testing and /or examinations were used in whole or in part for certifying the weld integrity and the integrity of the entire pressure vessel for human occupancy (PVHO) (the hyperbaric chamber):

a. Penetrant Examination (PE)
b. Ultrasonic Testing (UT)
c. Radiographic Examinations (RT)
d. Magnetic Particle Examination (MT)

In accordance with ASME requirements, the entire PVHO is pressure tested hydrostatically. This entails filling the PVHO 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.

9.2 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 National Fire Protection Agency (NFPA) 99, Chapter 14 – Hyperbaric facilities.

9.3 First Operational System TestA 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 5000 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
f. Testing of the chamber pressurization and ventilation gas for meeting requirements for CGA Grade E

9.4 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 to ensure they are consistently safe and effective and operate. This testing includes the following items specified in the OxyHeal 5000 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

9.5 Factory Acceptance Test

A Factory Acceptance Test (FAT) was performed to verify that the system was able to perform all required operational functions. This testing includes the following items specified in the OxyHeal 5000 hyperbaric chamber system product family as defined in the User Design Specification.

a. Pneumatic testing of the low pressure air supply system, Built-in Breathing System (BIBS), and fire suppression system (FSS) at 1.2 times above Maximum Operating Working Pressure
b. Leak testing on all joints and connections
c. Pressure relief valve testing
d. Relative humidity (RH) and Temperature monitoring testing

10. Clinical Testing

There was no clinical testing required to support the OxyHeal 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family.

11. Conclusion

It has been shown in this 510(k) submission that the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family is substantially equivalent to the predicate devices.. The OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family, as designed, manufactured, and tested is determined to be substantially equivalent to the referenced predicate devices.