DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGID/ANDB
WO66 RM2532
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6274

Premarket Notification 510(k) Review

Date: February 13, 2017

Reviewer: Neel (CDRH) Patel

Subject: Special 510(k)# K163109

Applicant: Oxyheal Medical Systems, Inc.	**Device Trade Name:** Oxyheal 4000 Multiplace Hyperbaric Chamber Family
Contact Name: Edward Chomas	**Contact Title:** VP, Regulatory Affairs
Correspondent Firm: Oxyheal Medical Systems, Inc.	**Phone:** (619) 336-2022 **Email:** echomas@oxyheal-international.com
Received Date: November 7, 2016	**Due Date:** February 16, 2017
Pro Code(s): CBF **Class:** II **Reg #:** 868.5470	**Reg Name:** Hyperbaric Chamber

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K152223	CBF	Rectangular Multiplace Hyperbaric Chamber System Product Family With Touchscreen Control System	Oxyheal Medical Systems, Inc.

(b)(5)

Review Team

Lead Reviewer: Neel (CDRH) Patel (CDRH/ODE/DAGRID/ANDB)

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Digital Signature Concurrence Table	
Reviewer Sign-Off	Neel J. Patel -S 2017.02.13 19:36:56 -05'00'

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

K163109
Oxyheal Medical Systems, Inc.
Device Trade Name: Oxyheal 4000 Multiplace Hyperbaric Chamber Family
Contact Name: Edward Chomas

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

DEFICIENCY LIST

(b)(4)

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K161309 Date Received by DCC: Nov 7, 2016

Lead Reviewer: Neel Patel

Branch: ANDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments:		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments:		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	X	
Comments:		

Does the submission meet all 4 criteria above?

- (●) Yes, submission meets criteria for a Special 510(k). Continue checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	X		
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)*	X				
6) Submission is a Class III 510(k) device.			X		
7) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
8) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			X		
9) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
10) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
11) A description of all device modification(s) including rationale for each modification.		X		X	
(b)(4)					
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X			X	
a) Submission includes a list of all components and accessories to be marketed with the subject device.		X			
b) Submission includes a description (as detailed in item 10(a), 10(b) and 10(d) above) of each component or accessory.		X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.		X			
(b)(4)					
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:				X	
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
(b)(4)					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*				X	
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
(b)(4)					
D. Design Control Activities					
15) Design Control Activities Summary includes all of the following:				X	
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components **AND** the results of the analysis.		X			
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.		X			
c) Declaration of conformity with design controls. All 3 must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30. iii. Statement is signed by the individual responsible for these activities.	X				
(b)(4)					
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
16) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X			X	
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.		X			
(b)(4)					
17) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	X				

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Neel J. Patel -S 2016.11.22 11:33:22 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Todd D. Courtney -S 2016.11.22 12:16:45 -05'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

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

K163109
Oxyheal Medical Systems, Inc.
Device Trade Name: Oxyheal 4000 Multiplace Hyperbaric Chamber Family
Contact Name: Edward Chomas

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

(b)(4)

From: Stringfellow, Michelle * [Michelle.Stringfellow@fda.hhs.gov]
Sent: 1/17/2017 10:42:59 PM
To: echomas@oxyheal-international.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K163109/S001 Acknowledgment Notification
Attachments: S001.pdf

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

Acknowledgment Letter

1/17/2017

EDWARD J. CHOMAS, VP, REGULATORY AFFAIRS
OXYHEAL MEDICAL SYSTEMS, INC.
3224 HOOVER AVE
NATIONAL CITY, CA 91950
UNITED STATES

Dear EDWARD J. CHOMAS:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K163109/S001
Received: 1/17/2017
Applicant: OXYHEAL MEDICAL SYSTEMS, INC.
Device: OxyHeal 4000 Multiplace Hyperbaric Chamber Family

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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."

February 15, 2017</br></br> We have reviewed your submission K163109/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K163109/S001 to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is August 14, 2017. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Neel Patel, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
CDRH/ODE/DAGID/ANDB
WO66 RM2530
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6371

Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: March 17, 2017

Reviewer: Todd Courtney

Subject: Special 510(k)# K163109/S002

Applicant: Oxyheal Medical Systems, Inc.	**Device Trade Name:** Oxyheal 4000 Multiplace Hyperbaric Chamber Family
Contact Name: Edward Chomas	**Contact Title:** VP, Regulatory Affairs
Correspondent Firm: Oxyheal Medical Systems, Inc.	**Phone:** (619) 336-2022 **Email:** echomas@oxyheal-international.com
Received Date: February 23, 2017	**Due Date:** March 25, 2017
Pro Code(s): CBF **Class:** II **Reg #:** 868.5470	**Reg Name:** Hyperbaric Chamber

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K152223	CBF	Rectangular Multiplace Hyperbaric Chamber System Product Family With Touchscreen Control System	Oxyheal Medical Systems, Inc.

(b)(5)

Recommendation

I recommend that the Oxyheal 4000 Multiplace Hyperbaric Chamber Family is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer Todd Courtney (CDRH/ODE/DAGID/ANDB)

(b)(5)

(b)(5)

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(b)(5)

(b)(5)

Digital Signature Concurrence Table	
Reviewer Sign-Off	Todd D. Courtney -S 2017.03.20 16:26:10 -04'00'

K163109

OxyHeal® Medical Systems, Inc.
Special 510(k)
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
K-Number Unknown

Section 004 –510(k) OMS Cover Letter

03 November 2016

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

This Special 510(k) submittal contains the information for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family for Pre-Market Notification. The CD provided with the submission package is the official electronic copy of the submission; this electronic copy is an exact duplicate of this submission.

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family in this 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 to the predicate device (K152223) which 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. 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.

(b)(4)

We are offering this OxyHeal® 4000 Special 510(k) in order to obtain current FDA 510(k) clearance to bring this modified device family into current regulatory compliance.

The following contains the regulatory information for the contents of this submission supporting the device's market clearance.

47

OxyHeal® Medical Systems, Inc.
Special 510(k)
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
K-Number Unknown

Type of 510(k) Submission:	Special
Device Name:	OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
Submission is Completed by:	Ed Chomas VP Regulatory Affairs OxyHeal® Medical Systems, Inc. 3224 Hoover Ave. National City, CA 91950
On Behalf of:	OxyHeal® Medical Systems, Inc. 3224 Hoover Ave. National City, CA 91950
Contact Person:	Ed Chomas, VP Regulatory Affairs
e-mail:	echomas@oxyheal-international.com
Office Number:	(619) 336-2022
Facility Registration No.:	1000519737

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact OxyHeal® Medical Systems, Inc. at (619) 336-2022 or by email at wtg@oxyheal.com.

Sincerely,

(b)(6)

W.T. Garnee
President & CEO
OxyHeal® Medical Systems, Inc.
3224 Hoover Ave.
National City, CA 91950

03 November 2016
Date

From: Le, Ponleiy * [Ponleiy.Le@fda.hhs.gov]
Sent: 11/7/2016 8:06:49 PM
To: echomas@oxyheal-international.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K163109 ACK LETTER
Attachments: Acknowledgment%20Letter (2).pdf

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

Acknowledgment Letter

11/7/2016

EDWARD J. CHOMAS, VP, REGULATORY AFFAIRS
OXYHEAL MEDICAL SYSTEMS, INC.
3224 HOOVER AVE
NATIONAL CITY, CA 91950
UNITED STATES

Dear EDWARD J. CHOMAS:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K163109
Received: 11/7/2016
Applicant: OXYHEAL MEDICAL SYSTEMS, INC.
Device: OxyHeal 4000 Multiplace Hyperbaric Chamber Family

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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 ft^3 to 2434 ft^3	600 ft^3 to 2,600 ft^3	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).

Section 014 – Items Required Under Paragraph 807.87

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Proposed Label / Labeling

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Attachment (1)

"Red-Lined" Instructions for Use (IFU) Manual

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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

OxyHeal Medical Systems, Inc.
Edward 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,

LETTER SHOULD BE DATED BEFORE SIGNING, AND MUST BE SIGNED OUT OF CTS ON THE DATE INDICATED ON THE LETTER.

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 & 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.

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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.

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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 ft^3 to 2434 ft^3	600 ft^3 to 2,600 ft^3	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).

K163109/S002

OxyHeal® Medical Systems, Inc.
Special 510(k)
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
K163109/S001

22 February 2017

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Reference: (a) FDA e-mail and attached File: Subject: K163109/S001 is on Hold Pending Your Response Dated 15 February 2017

Subject: OxyHeal® Medical Systems, Inc. Response to FDA Hold Letter Regarding K163109/S001

Dear Mr. Patel:

This letter is OxyHeal® Medical Systems, Inc.'s (OMS's) response to the.pdf attachment (file name: K163109-S001.Deficiencies.AINN.pdf) contained in the reference (a) e-mail.

This submittal consists of two copies of our response (1 eCopy and 1 paper copy). The contents of the eCopy is an exact duplicate of the paper copy.

OMS has structured its response to your reference (a) FDA Hold Letter by repeating each FDA comment and responding to that comment immediately below. Where applicable, OMS has updated certain Sections of the previous submittal and referenced the name of the hard copy tab and eCopy file names in its responses.

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Lastly and for your convenience, we have attached a copy of "only" the Section 008 and Section 014 pages which have changed (track change features enabled) to make it easier for you to identify.

If you have any questions regarding this submittal, please contact me directly by phone: (619) 336-2022 or e-mail: echomas@oxyheal-international.com.

Sincerely,

(b)(6)

Edward J. Chomas
Vice President, Regulatory Affairs
OxyHeal® Medical Systems, Inc.

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

OxyHeal® Medical Systems, Inc.
Special 510(k)
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
K163109/S001

22 February 2017

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Reference: (a) FDA e-mail and attached File: Subject: K163109/S001 is on Hold Pending Your Response Dated 15 February 2017

Subject: OxyHeal® Medical Systems, Inc. Response to FDA Hold Letter Regarding K163109/S001

Dear Mr. Patel:

This letter is OxyHeal® Medical Systems, Inc.'s (OMS's) response to the.pdf attachment (file name: K163109-S001.Deficiencies.AINN.pdf) contained in the reference (a) e-mail.

This submittal consists of two copies of our response (1 eCopy and 1 paper copy). The contents of the eCopy is an exact duplicate of the paper copy.

OMS has structured its response to your reference (a) FDA Hold Letter by repeating each FDA comment and responding to that comment immediately below. Where applicable, OMS has updated certain Sections of the previous submittal and referenced the name of the hard copy tab and eCopy file names in its responses.

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If you have any questions regarding this submittal, please contact me directly by phone: (619) 336-2022 or e-mail: echomas@oxyheal-international.com.

Sincerely,

(b)(6)

Edward J. Chomas
Vice President, Regulatory Affairs
OxyHeal® Medical Systems, Inc.

(b)(4)

Special 510(k) Summary (b)(4)

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Items Required Under Para. 807.87 Rev (b)(4)

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March 22, 2017</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Todd Courtney.

 *** This is a system-generated email notification ***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGID/ANDB
WO66 RM2532
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6274

Premarket Notification 510(k) Review

Date: February 13, 2017

Reviewer: Neel (CDRH) Patel

Subject: Special 510(k)# K163109

Applicant: Oxyheal Medical Systems, Inc.	**Device Trade Name:** Oxyheal 4000 Multiplace Hyperbaric Chamber Family
Contact Name: Edward Chomas	**Contact Title:** VP, Regulatory Affairs
Correspondent Firm: Oxyheal Medical Systems, Inc.	**Phone:** (619) 336-2022 **Email:** echomas@oxyheal-international.com
Received Date: November 7, 2016	**Due Date:** February 16, 2017
Pro Code(s): CBF **Class:** II **Reg #:** 868.5470	**Reg Name:** Hyperbaric Chamber

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K152223	CBF	Rectangular Multiplace Hyperbaric Chamber System Product Family With Touchscreen Control System	Oxyheal Medical Systems, Inc.

(b)(5)

Review Team

Lead Reviewer: Neel (CDRH) Patel (CDRH/ODE/DAGRID/ANDB)

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K163409/S001

OxyHeal® Medical Systems, Inc.
Special 510(k)
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
K163109

13 January 2017

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

(b)(4)

Subject: OxyHeal® Medical Systems, Inc. Response to FDA RTA Comments Regarding K163109

Dear Mr. Patel:

(b)(4)

This submittal consists of two copies of our response (1 eCopy and 1 paper copy). The contents of the eCopy is an exact duplicate of the paper copy.

OMS has structured its response to your RTA letter by repeating each comment contained in the Acceptance Checklist for Special 510(k)s, responding to that comment immediately below, and referring you to attachments which revise sections of our original submission that further address your comments. (b)(4) The table provided below provides a cross reference between the eCopy and the paper copy.

RTA Special 510(k) Checklist: Section / Paragraph No.	Paper Copy Response	eCopy Response File Name
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If you have any questions regarding this submittal, please contact me directly by phone: (619) 336-2022 or e-mail: echomas@oxyheal-international.com.

Sincerely,

(b)(6)

Edward J. Chomas
Vice President, Regulatory Affairs
OxyHeal® Medical Systems, Inc.

From: Johnson, Tanitta * [Tanitta.Johnson@fda.hhs.gov]
Sent: 2/23/2017 6:59:56 PM
To: echomas@oxyheal-international.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K163109/S002 Acknowledgment Notification
Attachments: S002.pdf

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

Acknowledgment Letter

2/23/2017

EDWARD J. CHOMAS, VP, REGULATORY AFFAIRS
OXYHEAL MEDICAL SYSTEMS, INC.
3224 HOOVER AVE
NATIONAL CITY, CA 91950
UNITED STATES

Dear EDWARD J. CHOMAS:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K163109/S002
Received: 2/23/2017
Applicant: OXYHEAL MEDICAL SYSTEMS, INC.
Device: OxyHeal 4000 Multiplace Hyperbaric Chamber Family

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

OxyHeal® Medical Systems, Inc.
Special 510(k)
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
K163109

13 January 2017

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

(b)(4)

Subject: OxyHeal® Medical Systems, Inc. Response to FDA RTA Comments Regarding K163109

Dear Mr. Patel:

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OMS has structured its response to your RTA letter by repeating each comment contained in the Acceptance Checklist for Special 510(k)s, responding to that comment immediately below, and referring you to attachments which revise sections of our original submission that further address your comments. (b)(4) The table provided below provides a cross reference between the eCopy and the paper copy.

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Sincerely,

(b)(6)

Edward J. Chomas
Vice President, Regulatory Affairs
OxyHeal® Medical Systems, Inc.

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K161309 Date Received by DCC: 1/17/2017

Lead Reviewer: Neel Patel

Branch: ANDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments:		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments:		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	X	
Comments:		

Does the submission meet all 4 criteria above?

- (●) Yes, submission meets criteria for a Special 510(k). Continue checklist below.
- ( ) No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	X		
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)*	X				
6) Submission is a Class III 510(k) device.			X		
7) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
8) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			X		
9) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
10) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
11) A description of all device modification(s) including rationale for each modification.	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 10(a), 10(b) and 10(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Design Control Activities					
15) Design Control Activities Summary includes all of the following:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components **AND** the results of the analysis.	X				
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	X				
c) Declaration of conformity with design controls. All 3 must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30. iii. Statement is signed by the individual responsible for these activities.	X				
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
16) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	X				
17) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	X				

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Neel J. Patel -S 2017.01.31 14:21:56 -05'00'
Branch Chief Sign-Off (digital signature optional)*	Todd D. Courtney -S 2017.02.01 08:25:17 -05'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with with decision required. Branch and Division digital signature optional.

November 22, 2016</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K163109. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K163109, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Heath

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by May 21, 2017, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Neel Patel, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

 *** This is a system-generated email notification ***

Section 015 – Design Control Activities

Concise Summary of the Design Control Activities

The OxyHeal® Medical Systems, Inc. (OMS) performance in the design, fabrication, outfitting, testing, and installation of each OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product in the product family is guided by the following three (3) FDA recognized consensus standards:

a. 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)

b. 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)

a. ISO 14971 (2007 Edition): International Standard Organization, Medical Devices – Application of Risk Management to Medical Devices
   - FDA recognized consensus standard: (Recognition Number 5-40)

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family design process complies with the requirements outlined in the Code of Federal Regulations (CFR) Title 21, Part 820, Subpart 820.30 Design Controls. These are the identical processes which the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family (K152223) predicate device was designed under.

(b)(4)

(b)(4)

Identification of Risk Analysis Methods.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Identification and Description of the V&V Test Methods

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.

1. Non-destructive Testing (Examination)

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.

2. Hydrostatic Testing

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.

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.

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).

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

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 to ensure they are consistently safe and effective and operate. 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

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).

4. Declaration of Conformity

A declaration of conformity for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product follows.

Manufacturer's Declaration of Conformity for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber Product Family

This Declaration of Conformity is issued by ***OxyHeal® Medical Systems, Inc.,*** the manufacturer of the medical device family identified herein.

OxyHeal® Medical Systems, Inc. hereby declares that the product listed below meets the relevant provisions of the applicable directives and declares with sole responsibility, that the product has been designed, fabricated, and tested within our ISO 13485 compliant quality management system (QMS).

Trade/Proprietary Name:	OxyHeal 4000, Cylindrical Multiplace Hyperbaric Chamber 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 510(k) Number:	To be assigned

FDA Establishment Registration #: 1000519737

Manufacturer: OxyHeal® Medical Systems, Inc. (OMS)
3224 Hoover Avenue
National City, CA 91950
Contractor and Government Entity (CAGE): 5NS24

This device is governed by the following recognized industry and FDA consensus standards:

a. 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)
b. 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)
c. ISO 14971 (2007 Edition): International Standard Organization, Medical Devices – Application of Risk Management to Medical Devices

- FDA recognized consensus standard: (Recognition Number 5-40)

This manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

There have been no violated inspection reports issued to the facility, the product, or OMS processes.

All verification and validation activities have been performed by undersigned individuals who were responsible for such efforts and the results demonstrated that the predetermined acceptance criteria were met.

Performed by:

(b)(6)

A. Garay
Vice President, Manufacturing

13 January 2017
Dated

(b)(6)

E. Chomas
Vice President, Regulatory Affairs

13 January 2017
Dated

5. Sterilization, Biocompatibility, and Expiration Date, etc.

The sterilization, biocompatibility, and expiration for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family is identical to the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family (refer to K152223).

6. 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 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).

Section 014 – Items Required Under Paragraph 807.87

Rational for Modifying a Rectangular Shaped Geometry Chamber to a Cylindrical Shaped Geometry Chamber

OMS reiterates that the predicate device for this Special 510(k) submittal is the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family (K152223) and that the only modification is in the dimensional specification; e.g. from a rectangular geometry a cylindrical geometry. We also confirm that the intended use, technological characteristics, and the performance data of all subsystems are the same as the predicate device (K152223).

(b)(4)

Description of Modified Device.

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) patients or more, 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.

The design control processes employed for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System is the same used 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.

Representative comparative illustrations of the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System single, double, and triple compartment product family to the substantially equivalent OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System, predicate device K152223 are provided below.

(b)(4)

OxyHeal® 4000 Single Compartment Cylindrical Chamber Compared to and OxyHeal® 5000 Single Compartment Rectangular Chamber

(b)(4)

OxyHeal® 4000 Double Compartment Cylindrical Chamber Compared to and OxyHeal® 5000 Double Compartment Rectangular Chamber

(b)(4)

OxyHeal® 4000 Triple Compartment Cylindrical Chamber Compared to and OxyHeal® 5000 Triple Compartment Rectangular Chamber

OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber Sub-systems

An OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System encompasses the hyperbaric chamber itself and a number of major subsystems. A representative illustration showing the OxyHeal® 4000 cylindrical hyperbaric chamber and associated subsystems system installed in a hyperbaric facility (Figure 1) compared to the OxyHeal® 5000 rectangular hyperbaric chamber predicate device (K152223) with associated subsystems (Figure 2).

Each subsystem is substantially equivalent to those associated with the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family predicate device (K152223). A brief description of these subsystems is provided immediately following Figure 2.

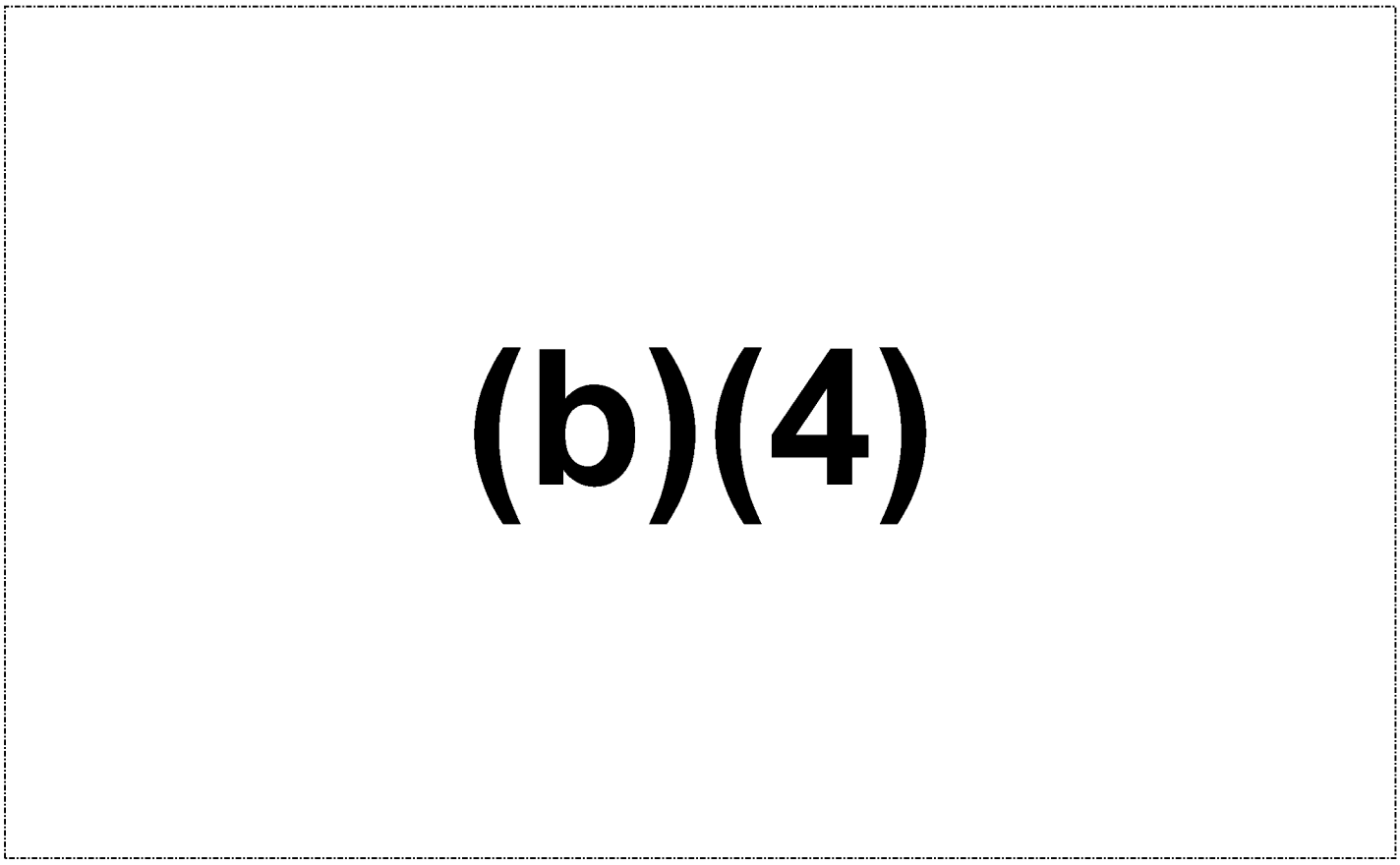


Figure 1. OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Representative Hyperbaric System Facility Layout.

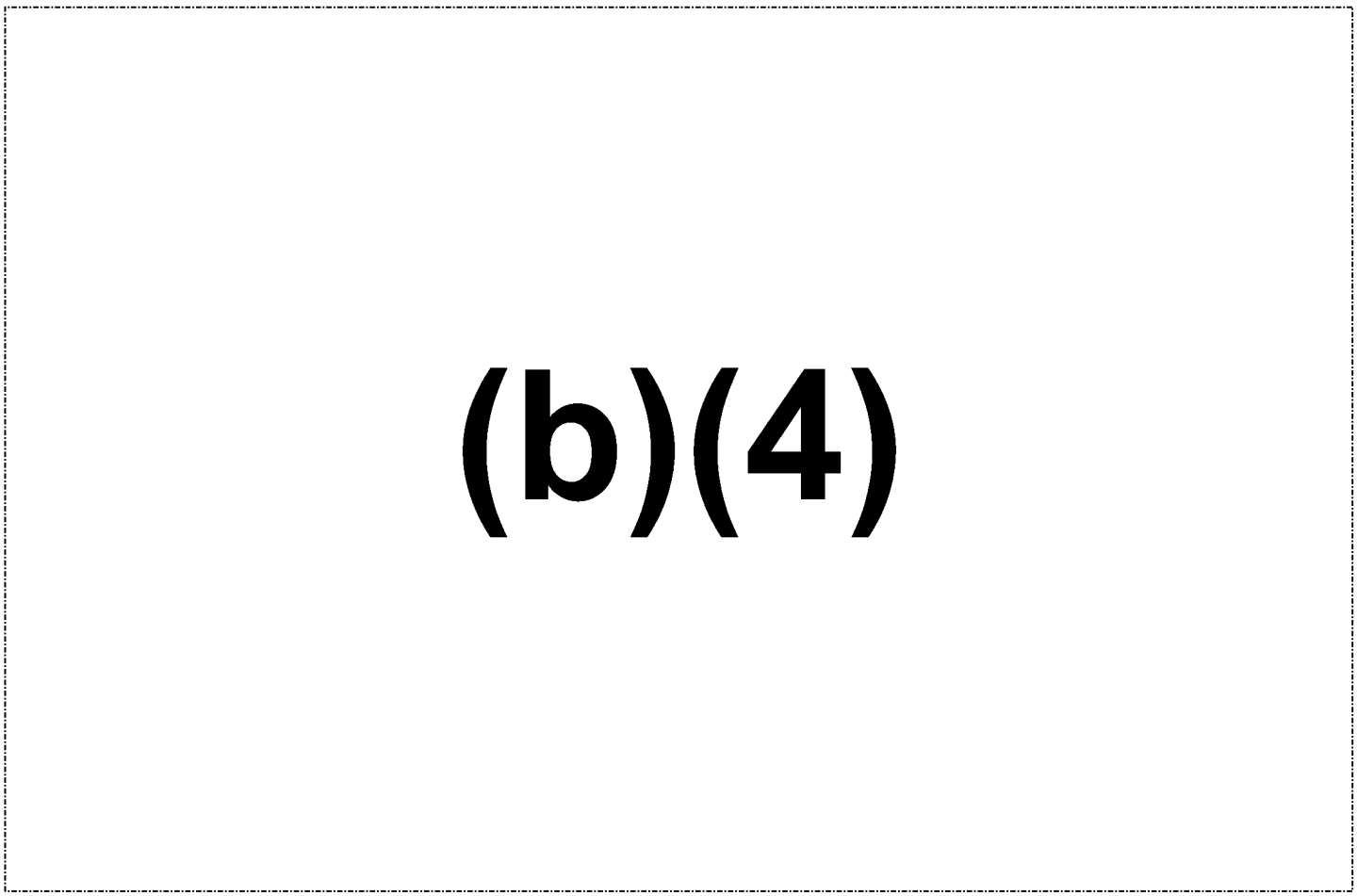


Figure 2. OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Representative Hyperbaric System Facility Layout.

Sub-system Descriptions

- **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.

- **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.

- **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.

- **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).

- **Environmental Control System (ECS)**

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).

- **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 of Device Listed in This Special 510(k) Submission to Predicate Device Cleared Under K152223.

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.

Comparison Table 1
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
Compared to the
OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family (K152223)

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
- **Joint Design**	Design and fabrication shall be in accordance with	Design and fabrication shall be in accordance with	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)**	
	specified Divisions of Section VIII of the ASME Code and the following requirements of ASME/PVHO-1, para. 1-7.1 (a) through (c)	specified Divisions of Section VIII of the ASME Code and the following requirements of ASME/PVHO-1, para. 1-7.1 (a) through (c)	
- **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 ft^3 to 2434 ft^3	600 ft^3 to 2,600 ft^3	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

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)**	
– **AM/FM Tuner**	Provides audio to patient headphones inside chamber	Provides audio to patient headphones inside chamber	Identical
– **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

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.

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.

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.

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.

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).

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

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. 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

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).

Intended Use of the Device.

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

Proposed Label / Labeling
The intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s).

The labeling requirements for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family are identical to that of the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family (K152223) predicate. Labeling requirements are described below.

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

The OxyHeal® 4000 is operated by trained and qualified personnel who are familiar with the use and safety procedures for the OxyHeal 4000.

A combination of ASME and PVHO nameplates (labels) are used to identify the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family. Nameplates are permanently affixed to the hyperbaric chamber and each of the individual pressure vessels tanks after completion of the hydrostatic pressure test process, and formal sign-off by an independent 3rd party ASME accredited Authorized Inspector (AI). A sample (blank) of each label is provided below. A definition of information required on each nameplate is contained alongside the label.

EXAMPLE OF ASME NAMEPLATE

Certified by: Stamp National Board (NB) symbol and NB number. NOTE – NB stamp only supplied by the National Board to accredited manufacturers; such as OxyHeal® Medical Systems, Inc. (OMS).

MAWP: Maximum Allowable Working Pressure stated in psi (pounds per square inch) and degrees Fahrenheit (°F)

MDMT: Maximum Design Metal Temperature (°F)

Serial Number: Chronologically assigned by OMS manufacturing.

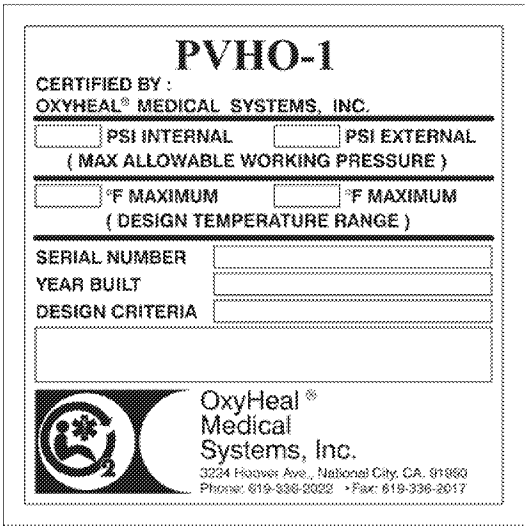
Year Built: Enter CY. NOTE – ASME Code may change from year-to-year. Date manufactured is associated with edition of code chamber is fabricated to.

Head Thickness: Thickness expressed in inches.
NOTE – Heads refer to the ends of the chamber.

Shell Thickness: Thickness expressed in inches
NOTE – Shell refer to the body of the chamber.

Vertical Rectangle (Shown as "blank space")
Place ASME Stamp. NOTE – American Society of Mechanical Engineers (ASME) symbol (stamp) only supplied to accredited manufacturers; such as OMS.

Horizontal Rectangle (Shown as "blank space")
Stamp chamber family "short" title (name); e.g. OxyHeal 4000-XX, where "XX" represents maximum number of patients the chamber is designed to accommodate.



EXAMPLE OF PVHO-1 NAMEPLATE

PSI Internal: Stamp Maximum Allowable Working Pressure (MAWP) expressed in pounds per square inch (psi).

PSI External: Stamp external pressure in psi.

Design Temperature Range: Enter minimum and maximum design temperature range in degrees Fahrenheit (°F).

Serial Number: Chronologically assigned by OMS manufacturing.

Year Built: Enter CY.

Design Criteria: Enter PVHO-1 Code chamber is manufactured to. NOTE – PVHO-1 code may change from year-to-year. "Year Built" is associated with edition of code hyperbaric chamber is fabricated to.

Horizontal Rectangle (Shown as "blank space")
Stamp chamber family "short" title (name); e.g. OxyHeal 4000-XX, where "XX" represents maximum number of patients that the chamber is designed to accommodate.

Advertisements for the Device
Refer to the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family product brochure in the pages which follow.

WE HEAL WITH OXYGEN

OxyHeal® Medical Systems, Inc.

Cost Efficient • Light Weight and Designed for Your Needs

OxyHeal® 4000

Cylindrical Multiplace Hyperbaric Chamber

OxyHeal Medical Systems, Inc.

• Phone: 1-619-336-2022 • Fax: 1-619-336-2017
• E-mail: sales@oxyheal-international.com
• Website: www.oxyheal-international.com

OxyHeal® Medical Systems, Inc.'s 4000 series hyperbaric systems are available in fully cylindrical or semi-cylindrical dual or triple compartment configurations. The cylindrical shape is the most economical—the semicylindrical configuration doesn't need a deep floor pit as it has no bilge volume, which would otherwise need regular disinfection & cleaning.

OMS' door designs include our wide round doors or swinging rectangular doors. Patient comfort is ensured by proprietary seats equipped with headrests & leg supports and allowing full 60° recline. Clearance through the chamber during loading is provided by our proprietary sliding-base design. Seating sections are removeable.

Seating sections are easily moved to accommodate any combination of seating, gurneys & wheelchairs. OMS utilizes industrial controllers automated with non-Windows® based controls and OMS proprietary software, ensuring stable operations, spares and support through the life of the equipment.

The OxyHeal® Medical Systems, Inc.'s 4000 series cylindrical hyperbaric chamber systems offer a variety of sizes and configurations to suit our client's needs. These economical chambers are designed incorporating the lessons learned from over 42 years of operational clinical experience. Our own engineers have been clinical CHT's with hands-on experience before turning their passions to developing the next generation of Hyperbaric technology. Other models, such as the Semi-Cylindrical Omega and larger Rectangular chambers are available to accommodate you as well. Call us to customize your system.

Since 1982, OMS multiplace hyperbaric chambers have been used by the staff of its affiliated companies to staff and manage Wound Healing & Hyperbaric Medicine Centers of Excellence throughout the USA. In fact, OMS systems have operated for over 20 years in hospitals without a single down day in which patients could not be treated.

OMS works closely with renowned hospital physicians board certified in hyperbaric medicine to provide full service management, clinical operation, and hyperbaric research.

Directions for Use

The OxyHeal® 4000 is operated by trained and qualified personnel who are familiar with the use and safety procedures for the OxyHeal 4000.

An Instructions for Use (IFU) Manual has been red-lined to identify the modifications made to the IFU Manual for Predicate Device (K152223) to reflect the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family. This red-lined manual is provided as Attachment 1 to this section.

The intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s).

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).

Attachment (1)

"Red-Lined" Instructions for Use (IFU) Manual

(b)(4)

February 1, 2017</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K163109/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Neel Patel.

 *** This is a system-generated email notification ***

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 ft^3 to 2434 ft^3	600 ft^3 to 2,600 ft^3	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).

SECTION 001

MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
Oxyheal Medical Systems Inc 3224 Hoover Ave National City CA 91950 US	William Gurnee
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****6790	2.1 E-MAIL ADDRESS wtg@oxyheal.com 2.2 TELEPHONE NUMBER (include Area code) 619-3362022 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) 24-Oct-2016

Form FDA 3601 (10/15)

"Close Window" Print Cover sheet

SECTION 002

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET (FORM FDA 3514)

FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03 November 2016	(b)(4)	Unknown at time of submission

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
OxyHeal Medical Systems, Inc.	2029408		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
N/A	(619) 336-2022		
Street Address	**FAX Number *(including area code)***		
3224 Hoover Ave	(619) 336-2017		
City	**State / Province**	**ZIP/Postal Code**	**Country**
National City	California	91950	USA
Contact Name			
Edward J. Chomas			
Contact Title	**Contact E-mail Address**		
VP, Regulatory Affairs	echomas@oxyheal-international.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
OxyHeal Medical Systems, Inc.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
N/A	(619) 336-2022		
Street Address	**FAX Number *(including area code)***		
3224 Hoover Ave	(619) 336-2017		
City	**State / Province**	**ZIP Code**	**Country**
National City	California	91950	USA
Contact Name			
Edward J. Chomas			
Contact Title	**Contact E-mail Address**		
VP, Regulatory Affairs	echomas@oxyheal-international.com		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify):*

The fundamental technology for this minor modification consists of a change in dimensional specifications to the predicate device (K152223) which 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. 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.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed							
1	CBF	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K152223	1	OxyHeal 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family	1	OxyHeal Medical Systems, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Multiplace Hyperbaric Chamber

	Trade or Proprietary or Model Name for This Device		Model Number
1	OxyHeal 4000 Multiplace Hyperbaric Chamber Family	1	OxyHeal 4000
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
CBF	868.5470	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Anesthesiology

Indications *(from labeling)*

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 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.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1000519737	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
OxyHeal Medical Systems, Inc.	2029408
Division Name *(if applicable)*: N/A	Phone Number *(including area code)*: (619) 336-2022
Street Address: 3224 Hoover Ave	FAX Number *(including area code)*: (619) 336-2017

City	State / Province	ZIP Code	Country
National City	California	91950	USA

Contact Name	Contact Title	Contact E-mail Address
Edward J. Chomas	VP, Regulatory Affairs	echomas@oxyheal-international.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ASME/PVHO-1	ASME	Safety Standards for Pressure Vessels for Human Occupancy (FDA Recognition No. 1-78)	2012	05/31/2012
2	NFPA 99	NFPA	Standards for Health Care Facilities, Chapter 14 Hyperbaric Facilities (FDA Recognition No. 1-67)	2012	8/31/2011
3	14971	ISO	International Standards Organization, Medical Devices - Application of Risk Management to Medical Devices (FDA Recognition No. 5-40)	2012	07/31/2012
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

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

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

The burden time for this collection of information is estimated to average 0.5 hour 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
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 control number.

SECTION 003

CERTIFICATIONS OF COMPLIANCE

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2018. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
OxyHeal Medical Systems, Inc

2. Date of the Application/Submission Which This Certification Accompanies
11/03/2016

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
3224 Hoover Avenue

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
National City

State/Province/Region
California

Country
USA

ZIP or Postal Code
91950

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): (619) 336-2022

(Fax): (619) 336-2017

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

OxyHeal 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family, Device Classification: II

Model: OxyHeal 4000, Device Classification: II

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(if number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s):

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
W. T. Gurnee	President & CEO

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	
3224 Hoover Ave	
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City: National City	State/Province/Region: California
Country: USA	ZIP or Postal Code: 91950

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): (619) 336-2022

(Fax): (619) 336-2017

14. Date of Certification

11/03/2016

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

(b)(6)

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 15 minutes and 45 minutes (depending on the type of application/ submission) 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 004

SPECIAL 510(k) OMS COVER LETTER

Section 004 –510(k) OMS Cover Letter

03 November 2016

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

This Special 510(k) submittal contains the information for the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family for Pre-Market Notification. The CD provided with the submission package is the official electronic copy of the submission; this electronic copy is an exact duplicate of this submission.

The OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family in this 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 to the predicate device (K152223) which 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. 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.

(b)(4)

We are offering this OxyHeal® 4000 Special 510(k) in order to obtain current FDA 510(k) clearance to bring this modified device family into current regulatory compliance.

The following contains the regulatory information for the contents of this submission supporting the device's market clearance.

OxyHeal® Medical Systems, Inc.
Special 510(k)
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
K-Number Unknown

Type of 510(k) Submission:	Special
Device Name:	OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family
Submission is Completed by:	Ed Chomas VP Regulatory Affairs OxyHeal® Medical Systems, Inc. 3224 Hoover Ave. National City, CA 91950
On Behalf of:	OxyHeal® Medical Systems, Inc. 3224 Hoover Ave. National City, CA 91950
Contact Person:	Ed Chomas, VP Regulatory Affairs
e-mail:	echomas@oxyheal-international.com
Office Number:	(619) 336-2022
Facility Registration No.:	1000519737

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact OxyHeal® Medical Systems, Inc. at (619) 336-2022 or by email at wtg@oxyheal.com.

Sincerely,

(b)(6)

03 November 2016
Date

W.T. Gumee
President & CEO
OxyHeal® Medical Systems, Inc.
3224 Hoover Ave.
National City, CA 91950

SECTION 005

TABLE OF CONTENTS

Section 005 – Table of Contents

Section **Title**

SECTION 006

SPECIAL 510(k) SCREENING CHECKLIST

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K **Date Received by DCC:**

Lead Reviewer:

Branch: **Division:** **Center/Office:**

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Special 510(k) Criteria The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.			
		Yes	**No**
1.	**510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.**	☑	☐
	Comments: Predicate Device is OxyHeal 5000 Rectangular Multiplace Hyperbaric Chamber Product Family (K152223)		
2.	**Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).**	☑	☐
	Comments: Identical		
3.	**Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).**	☑	☐
	Comments:		
4.	**The submission includes only summary-level information (i.e., NO test reports with performance data).** *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	☑	☐
	Comments:		

Does the submission meet all 4 criteria above?

☑ Yes, submission meets criteria for a Special 510(k). Continue checklist below.

☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☑	☐	16
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☑	☐	See Table of Contents
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☑	☐	1 - 223
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☑	☐	5
Comments:				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)
Submission should be designated RTA if not addressed

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	☑	☐		All

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☑	☐		7
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☑	☐		7
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☑	☐		29
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☑	☐		31
		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☑	☐		53
		Comments:					
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*		☐		☑	
		a.	Contains Class III Summary and Certification	☐	☐	☑	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).				
		Comments Not applicable					
	7.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*		☐	☑		
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☐	☐	☑	
		Comments: No prior submissions for the subject device.					
B.	**Device Description**						
	8.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the		☐		☑	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*					
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	9.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☑	☐		31 & 77
		Comments:					
	10.	The submission includes descriptive information for the device,					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☑	☐		111
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☑	☐		29, 56, 109
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☑	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☑	☐		79 - 80, 112 - 113
		Comments:					
	11.	A description of all device modification(s) including rationale for each modification.		☑	☐		57
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A"is selected, parts a-c below are omitted from the checklist.*		☐		☑	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐	☑		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	Submission includes a description (as detailed in item 10a., 10b., and 10d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☑	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☐	☑		
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)* .	☑	☐		7, 32
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☑	☐		7, 32, 78
		Comments: Predicate K152223 is referenced innumerable times and consistently throughout submission					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☑	☐		35
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☑	☐		37, 83
D.	**Design Control Activities**						
	15.	Design Control Activities Summary includes all of the following:					
		a.	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components **AND** the results of the analysis	☑	☐		218
		b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria	☐	☐		218
		c.	Declaration of conformity with design controls. All 3 below must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.	☑	☐		219, 222

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30. iii. Statement is signed by the individual responsible for these activities.				
		Comments:					
E.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	16.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☑	☐		88
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	☑	☐		88, 90-91
		Comments:					
	17.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).		☑	☐		35-36
		Comments:					

Decision: Accept_____ Refuse to Accept_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

SECTION 007

STATEMENT OF INDICATIONS FOR USE

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)*
Unknown

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

SPECIAL 510(k) SUMMARY

(b)(4) – 510(k) Summary

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

(b)(4)

SECTION 009

STANDARDS DATA REPORT FOR 510(k)s
NFPA99

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

NFPA 99, Standards for Health Care Facilities, 8/31/2011

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#1-67	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
NFPA 99, Standards for Health Care Facilities, 8/31/2011

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Chapter 14	Hyperbaric Facilities	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
NONE

DESCRIPTION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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 1 hour 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

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SECTION 010

STANDARDS DATA REPORT FOR 510(k)s
PVHO1

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ASME PVHO 1, Safety Standards for Pressure Vessels for Human Occupancy, 05/31/2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#1-78	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASME PVHO 1, Safety Standards for Pressure Vessels for Human Occupancy, 05/31/2012

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 1	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Conformance is met.

(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 2	Viewports	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Conformance is met.

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 3	Quality Assurance fro PVHO Manufacturers	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Conformance is met.

(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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 1 hour 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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASME PVHO 1, Safety Standards for Pressure Vessels for Human Occupancy, 05/31/2012

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 4	Piping Systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Conformance is met.

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 5	Medical Hyperbaric Systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Conformance is met.

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 6	Diving Systems	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
This section does not apply to Medical Hyperbaric Systems.

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 7	Submersibles	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
This section does not apply to Medical Hyperbaric Systems.

(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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SECTION 011

STANDARDS DATA REPORT FOR 510(k)s
ISO14971

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971, Medical Devices - Application of Risk Management to Medical Devices, 07/31/2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 14971, Medical Devices - Application of Risk Management to Medical Devices, 07/31/2012

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

(b)(4)

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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PRAStaff@fda.hhs.gov

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SECTION 012

TRUTH & ACCURACY STATEMENT

Section 012 - Truth and Accuracy Statement

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as President and CEO of OxyHeal® Medical Systems, Inc., I believe to the best of my knowledge, that all data and information submitted in the Special premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

W. T. Gurnee, Pres/CEO

03 November 2016
Date

To be assigned
Premarket Notification [510(k)] Number

SECTION 013

LEGALLY MARKETED DEVICE UNMODIFIED

Section 013 – Legally Marketed Device Unmodified

Legally Marketed Device Name:	OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family
510(k):	K152223
Trade/Proprietary Name:	OxyHeal® 5000 Hyperbaric Chamber
Common/Usual Name:	Multiplace Hyperbaric Chamber
Classification Name:	Chamber, Hyperbaric
Classification Regulation:	21 CBF 868.5470
Panel:	Anesthesiology Devices
Product Code:	CBF
Device Class:	II

The basis for the decision in pursuing a Special 510(k) submittal is contained in the FDA's Final Guidance published in, "*The New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*" prepared by the Center for Devices and Radiological Health dated March 20, 1998. This decision takes into consideration: intended use; the indications for use; the FDA recognized standards for the classification name, regulation, and device; and the fundamental scientific technology of the medical device

This Premarket, Special 510(k) is submitted for the **OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family**; a modification to OxyHeal® Medical Systems, Inc.'s (OMS's) own device; i.e. the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family. Reference K152223.

Intended Use
Administer hyperbaric oxygen therapy (HBOT) to treat patients with any of the below listed indications.

Indications for 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

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.

FDA Recognized Standards

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)

The FDA recognized standards to the OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family are identical to those of the OxyHeal® 5000 Rectangular Multiplace Hyperbaric Chamber System Product Family predicate device (K152223).

Scientific Technology of the Medical Device

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Attachment (1)
User Design Specification
for the
OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family

User Design Specification

OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Family of Products

Prepared by:

OxyHeal® Medical Systems, Inc.
3224 Hoover Ave.
National City, CA 91950
Phone: +1 (619) 336-2022

Prepared for:

OxyHeal® Medical Systems, Inc.
3224 Hoover Ave.
National City, CA 91950
Phone: +1 (619) 336-2022

Distribution Statement.

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SECTION 014

ITEMS REQUIRED UNDER PARAGRAPH 807.87

Section 014 – Items Required Under Paragraph 807.87

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Proposed Label / Labeling

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Attachment (1)

OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family Brochure

(b)(4)

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Attachment (2)

Instructions for Use (IFU) Manual

for the

OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family Brochure

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SECTION 015

DESIGN CONTROL ACTIVITIES

Section 015 – Design Control Activities

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(b)(4) – 510(k) Summary for OxyHeal® 4000 Cylindrical Multiplace Hyperbaric Chamber System Product Family

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
CDRH/ODE/DAGID/ANDB
WO66 RM2530
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6371

Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: March 17, 2017

Reviewer: Todd Courtney

Subject: Special 510(k)# K163109/S002

Applicant: Oxyheal Medical Systems, Inc.	**Device Trade Name:** Oxyheal 4000 Multiplace Hyperbaric Chamber Family
Contact Name: Edward Chomas	**Contact Title:** VP, Regulatory Affairs
Correspondent Firm: Oxyheal Medical Systems, Inc.	**Phone:** (619) 336-2022 **Email:** echomas@oxyheal-international.com
Received Date: February 23, 2017	**Due Date:** March 25, 2017
Pro Code(s): CBF **Class:** II **Reg #:** 868.5470	**Reg Name:** Hyperbaric Chamber

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K152223	CBF	Rectangular Multiplace Hyperbaric Chamber System Product Family With Touchscreen Control System	Oxyheal Medical Systems, Inc.

(b)(5)

Review Team

Lead Reviewer Todd Courtney (CDRH/ODE/DAGID/ANDB)

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