K140559

SECHRIST
INDUSTRIES, INC.

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510(k) SUMMARY

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1. Submitter Device Information

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2. Device Information

Trade/Proprietary Name	Model 3300H/HR Monoplace Hyperbaric Oxygen Chamber Model 3600H/HR Monoplace Hyperbaric Oxygen Chamber
Device Common Name	Monoplace Hyperbaric Chamber
Classification Name	Hyperbaric Chamber (21 CFR 868.5470, Product Code CBF)

3. Predicate Device Information

Legally marketed device to which we are claiming equivalence is the Sechrist Model 4100H/HR Hyperbaric Chamber originally cleared under 510(k) K100268

4. General Description

A hyperbaric oxygen chamber is a pressure vessel and control system that is designed to provide patient exposure to a very high oxygen concentration at higher than normal atmospheric pressure. Titration of the oxygen exposure is controlled by selecting the pressure achieved within the pressure vessel. Pressurization and de-pressurization rates are selected to minimize patient discomfort while increasing and decreasing the chamber pressure. Typical monoplace chambers are capable of pressurizing to 3 ATA (29.4 psig above atmospheric pressure). The typical pressurization and de-pressurization rates are in the range of 0.4 to 5.0 psig/minute.

The Sechrist Models 3300H/HR and 3600H/HR Hyperbaric Chambers are monoplace pressure chambers designed to administer 100% oxygen at pressure greater than ambient, up to 3 atmospheres absolute (30 psig) of pressure. These hyperbaric chambers consist of a mechanical and pneumatic system capable of controlling the operator defined pressurization profiles.

These Hyperbaric Chambers are constructed with a horizontal seamless acrylic viewport which varying internal diameter sizes.

Models	Internal Diameter
3300H/HR Hyperbaric Chambers	32.50 inches (83 cm)
3600H/HR Hyperbaric Chambers	35.50 inches (90 cm)

Each model is equipped with a clear anodized aluminum cover on one end and the other end with a hard anodized door assembly, with access ports available for patient interface (such as patient monitoring, delivery of intravenous fluids, etc.) locking mechanism and interlocking safety device.

The cylinder, end cover and the door assembly are assembled together with stainless steel tie rods/nuts and hinge assembly. Each Hyperbaric Chamber Model comes in two configurations designated with a suffix of "H" and "HR". The suffix "H" is the Standard configuration where the control panel is located on the left of the chamber when facing the door and the door opens from left to right. The suffix "HR" is the Reverse configuration where the control panel is located on the right side of the chamber and the door opens from right to left.

The functional performance system and the safety features incorporated in the Models 3300H/HR and 3600H/HR Hyperbaric Chambers are the same that have been incorporated into the design of the Model 4100H/HR predicate device.

A pressurization cycle counter is provided to maintain a record of the number of pressurization cycles the chamber experienced.

A two-way intercommunication system is used to maintain contact between patient and attendant.

5. Statement of Intended Use

The intended use of the Sechrist Model 3300H/HR and Model 3600H/HR Hyperbaric Chambers are to administer 100% oxygen at pressure greater than ambient, up to 3 atmospheres absolute (30 psi) of pressure.

Specific indication for use of the hyperbaric chambers have been established by the Committee on Hyperbaric Oxygen Therapy of the Undersea and Hyperbaric Medical Society (founded in 1967 to foster exchange of data on the physiology and medicine of commercial and military diving). The committee is comprised of practitioners and scientific investigations in the fields of internal medicine, infectious diseases, pharmacology, emergency medicine, general surgery, orthopedic surgery and aerospace medicine. The committee is responsible for continually reviewing research and clinical data in determining the safety and efficacy of hyperbaric oxygen. Currently, there are thirteen indications that are approved by the committee; these thirteen indications were accepted based on sound physiologic rationale, in vivo or in vitro studies that demonstrate effectiveness, controlled animal studies, prospective controlled clinical studies and extensive clinical experience from multiple hyperbaric medicine centers. These thirteen indications have been recommended for third-party reimbursements and most insurance carriers have established reimbursement policy based on these recommendations.

The thirteen indications are:

1. Air or Gas embolism
2. Carbon Monoxide Poisoning
   Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
3. Clostridial Myonecrosis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemia's
5. Decompression Sickness
6. Arterial Insufficiencies
   Central Retinal Artery Occlusion
   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. Comprised Grafts and Flaps
13. Thermal Burns

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

6.1. CHAMBER CONTROLS

The Models 3300H/HR and 3600H/HR Hyperbaric Chambers both use the same control panel knobs and switches as used in the predicate device 4100H/HR.

Following is description of the chamber controls.

6.1.1. Master Valve

This is a rotary pneumatic valve with three positions. The available positions allow the operator to select the following modes.

a) Vent
b) Off
c) On

Specification

a)	Valve Type:	3-position pneumatic valve rotary selector
b)	Function Positions:	ON, OFF, Emergency Vent
c)	Operating Pressure:	50 - 70 psig

6.1.2. OFF Mode

When the Master Valve is in OFF mode, the hyperbaric chamber will not be capable of developing internal pressure, and the door can be opened and closed.

6.1.3. ON Mode

The ON mode shall not be capable of operation unless the chamber door is closed and in the locked position. When the Master Valve is in ON mode, the hyperbaric chamber shall automatically start developing internal pressure (compressing) up to the Pressure Set point and at a rate established by the Rate Set control provided the door is closed and the Door Safety Interlock is engaged. The chamber door cannot be unlocked if there is more than approximately 1 psig pressure within the hyperbaric chamber.

6.1.4. Emergency Vent Mode

The Emergency Vent Mode allows the operator to depressurize the hyperbaric chamber rapidly to gain rapid access to the patient in an emergency situation. To activate the Emergency Vent, the Emergency Vent Mode is first selected via the Master Valve and the pneumatic push button manually depressed to actuate pneumatic valves to accomplish a decompression at a maximum rate of 30 psig/min.

Specification

(a)	Control Type:	Pneumatic push-button
(b)	Time:	30 psig to 0 psig in 119 sec max

6.1.5. Ventilation (Purge) Flow Rate Control

The Ventilation Flow Rate Control allows the operator to adjust the purge flow rate at which gas exhausts from the hyperbaric chamber during treatment. During treatment, once the chamber reaches desired pressure and oxygen concentration, the high ventilation rate may not be necessary and so to conserve oxygen, flow rate can be reduced. This range is clearly marked near the control valve.

Specification

(a) Control Type:	Single Turn Gate Valve
(b) Ventilation (Purge) Flow Rate:	80 to 400 lpm min @ 15 psig Chamber Pressure
(c) O_2 Conservation Range:	80 to 200 lpm
(d) Tolerance:	± 50 lpm of setting

6.1.6. Pressure Set Control

The desired hyperbaric chamber pressure is adjusted by the rotary Set Pressure Control knob.

Specification

(a) Control Type:	Multi-turn, rotary regulating valve
(b) Range:	1.5 to 30.0 psig or equivalent units
(c) Idle/Default Pressure:	1.5 psig or equivalent units
(d) Resolution:	0.2 psig or equivalent units
(e) Tolerance:	± 0.5 psig of setting

6.1.7. Rate Set Control

The desired pressurization/depressurization rate of the hyperbaric chamber is adjusted by a rotary Rate Set Control knob. The Rate Set is the rate required to reach the desired hyperbaric chamber pressure. The pneumatic system is capable of developing the Set Rate of pressure change within the chamber on a 1:1 ratio.

Specification

(a) Control Type:	Single-turn, rotary valve
(b) Range:	1.0 to 5.0 psig/min
(c) Profile:	Linear
(d) Resolution:	1.0 psig/min
(e) Tolerance:	20% or 0.5 psig/min of setting at range 1.0 to 3.9 psig/min & 40% of setting at range 4.0 to 5.0 psig/min

6.1.8. Intercom

The intercom sub-system is an intercommunication system for two-way private conversation capability between the patient inside the hyperbaric chamber and an attendant outside. It is capable of delivering a single channel (mono) or dual channel (stereo) audio input to the speaker inside the hyperbaric chamber for patient entertainment from an auxiliary source such as but not limited to tape

recorder, cd/mp3 player, DVD player and television. If the handset is picked up for conversation, the auxiliary audio signal shall be temporarily disabled.

Specification

(a)	Supply:	12 VDC nominal
(b)	Audio Power:	½ watt max inside chamber
(c)	Speakers:	Dual 4 ohms or 8 ohms, internal and external
(d)	Internal Microphone:	Electret Condenser type or equivalent
(e)	Volume Controls:	Rotary potentiometers for Volume In & Out CW to increase; CCW to decrease
(f)	Aux. Input Connector:	(2) RCA Phone Jacks or equivalent
(g)	Operator Handset:	Telephone Style or equivalent
(h)	Indicators:	(2) LEDs 1st LED: Green – Main Power ON Black – Main Power OFF 2nd LED: Amber – Low Battery Power

6.2. MEASURED DISPLAYS

6.2.1. Chamber Set Pressure Display

A pneumatic pressure gauge having multiple scales is installed to display the set pressure.

Specification

(a)	Display Type:	Pneumatic Pressure Gauge
(b)	Display Range:	0 to 30 psig Nominal, 1.5, 2.0, 2.5, 3.0 ATA 0 to 200 kpa (optional)
(c)	Tolerance:	±5% of reading

6.2.2. Chamber Actual Pressure Display

A pneumatic pressure gauge having multiple scales is installed to display actual hyperbaric chamber pressure.

Specification

(a)	Display Type:	Pneumatic Pressure Gauge
(b)	Display Range:	0 to 30 psig Nominal, 1.5, 2.0, 2.5, 3.0 ATA 0 to 200 kpa (optional)
(c)	Tolerance:	±5% of reading

6.2.3. Chamber Pressure Cycle Counter

A pressure cycle counter is installed to record the total number of hyperbaric chamber pressurization cycles. The pressure cycle counter can be used to keep track of periodic maintenance requirements of the chamber.

Specification

(a)	Display Type:	Pneumatic Mechanical Counter
(b)	Range:	0 to 99,999 cycles min
(c)	Reset:	None

6.3. INDICATORS

6.3.1. Supply Pressure Indicator

An indicator is provided to indicate the existence of the supply pressure.

Specification

(a)	Indicator Type:	Pneumatically operated Green to indicate supply ON Black to indicate supply OFF

6.3.2. Chamber Pressure Indicator

An indicator is provided to indicate the existence of the hyperbaric chamber pressure.

Specification

(a)	Indicator Type:	Pneumatically operated Red to indicate chamber pressure of ~1.5 psig or higher Black to indicate chamber pressure less than 0.5 psig

6.4. SAFETY SYSTEMS

6.4.1. Door Safety Interlock System

The door Safety Interlock System prevents the hyperbaric chamber door from being accidentally opened while the hyperbaric chamber is pressurized. It also prevents the pressurization of the hyperbaric chamber if the door is not in the fully locked position.

Specification

(a)	Activation pressure:	approximately 1.0 psig
(b)	Deactivation pressure:	approximately 0.5 psig

6.4.2. Over-Pressure Relief System

Two over–pressure relief valves are installed to prevent hyperbaric chamber from exceeding its maximum allowable working pressure. If the relief valve malfunctions and causes rapid decompression of the hyperbaric chamber pressure, the Manual Shut-Off Valve is also be available to prevent the rapid decompression.

3300H/HR:

(a) Relief Valve Set Pressure:	35 psig maximum
(b) Tolerance:	±2 psig
(c) Manual Shut-Off Valve:	Sealed open with a soft wire seal

3600H/HR:

(a) Relief Valve Set Pressure:	36 psig maximum
(b) Tolerance:	±2 psig
(c) Manual Shut-Off Valve:	Sealed open with a soft wire seal

6.4.3. Emergency Shutoff and Automatic Vent

The Emergency Shutoff system allows the operator to automatically shut off the gas supply and depressurizes the hyperbaric chamber. This system is activated using a toggle switch protected by a cover to prevent accidental activation.

Specification

(a) Control Type:	Pneumatic Toggle Switch
(b) Decompression Time:	30 psig to 0 psig in 119 sec max

7. TABLE OF COMPARISON

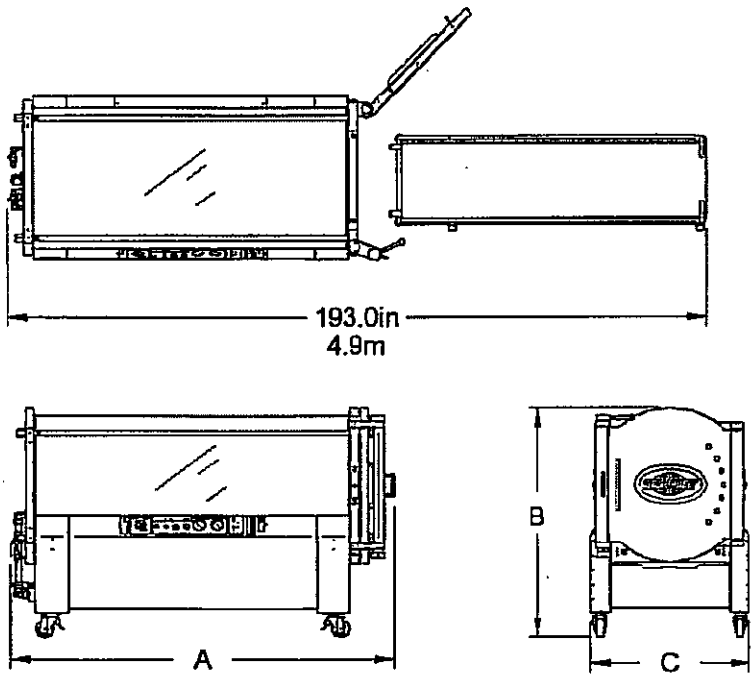
There are no changes in the intended use and there are no significant changes in performance specifications or principal of operation of the two the Models 3300H/HR and 3600H/HR Hyperbaric Chambers, as compared to the predicate device Sechrist Model 4100H/HR Hyperbaric Chamber. Existing technology, consistent with that used in comparative chambers, has been incorporated into the design of this device.

Modifications made to the device do not affect the intended use or alter the fundamental scientific technology of the device. Therefore, the modified device is substantially equivalent to the cleared device.

The chart below compares the modifications listed above to the predicate device.

Description	Model 4100H/HR (Predicate)	Model 3600H	Model 3300H
Operational Control			
	Pneumatic Only	No Change	No Change
Modes			
Emergency Vent	Included	No Change	No Change
OFF	Included	No Change	No Change
ON	Included	No Change	No Change
Emergency Shutoff and Automatic Vent	Included	No Change	No Change
Displays			
Chamber Pressure Gauge	Mechanical Gauge	No Change	No Change
Pressure Set Gauge	Mechanical Gauge	No Change	No Change
Pressure Cycle Counter	Mechanical/Pneumatic type	No Change	No Change
Alarms/Indicators			
Supply Pressure Indicator	Pneumatic	No Change	No Change
Chamber Pressure Indicator	Pneumatic	No Change	No Change
AC Power Indicator	LED	No Change	No Change
Battery Charging Indicator	LED	No Change	No Change
Low Battery Warning/Caution	LED	No Change	No Change
Accessories			
Intercom System	Included	No Change	No Change
Purge Rate Adjustment	Included	No Change	No Change
Materials			
Pressure bearing Materials	Aluminum	No Change	No Change
	Stainless Steel	No Change	No Change
	Alloy Steel	No Change	No Change
	Acrylic	No Change	No Change

Description	Model 4100H/HR (Predicate)	Model 3600H	Model 3300H
Specifications			
Maximum Operating Pressure	30.0 psig 3.0 ATA 2.1 kg/cm^2 206.8 kPa at ambient	No Change	No Change
Operating Temperature Range	50° – 100° F (10°– 38° C)	No Change	No Change
Operating Humidity Range	30% to 90% at 77° F	No Change	No Change
Supply Pressure	50.0 to 70.0 psig (3.5 to 4.9 kg/cm^2) (344.8 to 482.7 kPa)	No Change	No Change
Supply Pressure Flow Rate	42 SCFM	34 SCFM	32 SCFM
Rate Set	1– 5.0 psig/min	No Change	No Change
Pressure Set	1.5 – 30 psig	No Change	No Change
Purge Rate	80 to 400 LPM with the chamber pressure set at 15 psig	No Change	No Change
Emergency Vent Rate	30 psig to 0 psig in 119 seconds maximum (0.25 – 0.5 psig/second)	No Change	No Change
Relief valves	Quantity (2) Set at 36.00 psig	Quantity (2) Set at 36.00 psig	Quantity (2) Set at 35.00 psig
Electrical Power			
A.C. Input range	90 to 264 VAC	No Change	No Change
A.C. Input Frequency	47 to 33 Hz	No Change	No Change
D.C Output Voltage	+12 VDC Nominal	No Change	No Change
D.C. Output Current	3.3 A Maximum	No Change	No Change
Cylinder Dimensions (reference Drawing A)			
Cylinder Internal Diameter	41.00 Inches (104 cm)	35.50 Inches (83 cm)	32.50 Inches (90 cm)
Internal Length	91.00 Inches (231 cm)	91.00 Inches (231 cm)	91.00 Inches (231 cm)
External Length(A)	106.00 Inches (269 cm)	106.00 Inches (269 cm)	106.00 Inches (269 cm)
External Height (B)	69.75 Inches (177 cm)	63.00 Inches (160 cm)	59.00 Inches (150 cm)
External Width (C)	46.75 Inches (119 cm)	44.50 Inches (113 cm)	44.50 Inches (113 cm)
Chamber Weight	3,500 lbs (1591 kg)	2,220 lbs (1009 kg)	2,030 lbs (923 kg)
Supported Patient Weight	700 lbs standard (318 kg)	700 lbs standard (318 kg)	500 lbs standard (227 kg); 700 lbs optional (318 kg)



Drawing A

8. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Summary of Technological Changes

Similarities

The modifications made to the existing Model 4100H/HR Hyperbaric Oxygen Chamber do not affect the indications for use or theory of operation, and do not change the hyperbaric pressure technology used in the design of the chamber. There has been no change in the science involved with providing hyperbaric oxygen therapy in a monoplace chamber. The weight and dimensions of the two models created by the change are decreased due to the reduction in the size of the acrylic viewport window and pressure retaining metal components. The pressure bearing components and materials have not been changed and comply with the ASME Boiler & Pressure Vessels Code Section VIII Division 1 and ASME PVHO-1 Safety Standard for Pressure Vessels for Human Occupancy. The control panel used for each model is the same as found on the Model 4100H/HR Hyperbaric Chamber with the operational controls remaining the same.

The pressure related safety features of the two Models 3300H/HR and 3600H/HR Hyperbaric Chambers, including the door interlock system, and the door safety switch have not been changed from the Model 4100H/HR Hyperbaric Chamber.

Differences (Changes)

The only changes to the Model 4100H/HR resulting in the two Models 3300H/HR and 3600H/HR Hyperbaric Chambers are as follows:

A. Acrylic Cylinder Size

Model 3600H/HR Hyperbaric Chamber

This Hyperbaric Chamber model has a smaller internal diameter, external height and external width when compared to the Model 4100H/HR Hyperbaric Chamber (predicate). These difference in sizes from the Model 4100H/HR Hyperbaric Chamber (predicate device) can be seen in the Engineering Drawings (see Section 12 - Attachment A).

Description	Model 4100H/HR (Predicate)	Model 3600H
Cylinder Internal Diameter	41.00 Inches (104 cm)	35.50 Inches (83 cm)
External Height (B)	69.75 Inches (177 cm)	63.00 Inches (160 cm)
External Width (C)	46.75 Inches (119 cm)	44.50 Inches (113 cm)
Chamber Weight	3,500 lbs (1591 kg)	2,220 lbs (1009 kg)

The effects of the modification to this model (i.e., smaller cylinder internal diameter, external height and external widths) results in a reduction of the overall chamber weight when compared to that of the predicate device. This reduction in cylinder size does not affect the operation of the device and its ability to function to the same specifications as the predicate device.

Model 3300H/HR Hyperbaric Chamber

This Hyperbaric Chamber model has a smaller internal diameter, external height and external width when compared to the Model 4100H/HR Hyperbaric Chamber (predicate). These difference in sizes from the Model 4100H/HR Hyperbaric Chamber (predicate device) can be seen in the Engineering Drawings (see Section 12 - Attachment A).

Description	Model 4100H/HR (Predicate)	Model 3300H
Cylinder Internal Diameter	41.00 Inches (104 cm)	32.50 Inches (90 cm)
External Height (B)	69.75 Inches (177 cm)	59.00 Inches (150 cm)
External Width (C)	46.75 Inches (119 cm)	44.50 Inches (113 cm)
Chamber Weight	3,500 lbs (1591 kg)	2,030 lbs (923 kg)

The effects of the modification to this model (i.e., smaller cylinder internal diameter, external height and external widths) results in a reduction of the overall chamber weight when compared to that of the predicate device.

B. Relief Valve

This Hyperbaric Chamber model has two over–pressure relief valves installed to prevent the hyperbaric chamber from exceeding its maximum allowable working pressure which is the design pressure. However, the maximum working pressure is still limited to 30 psi or 3 ATA. The Model 3300H/HR has a setting that differs from the predicate device while the Model 3600H/HR has the same setting as the predicate device. The pressure setting of this model is the same as a previous device (Model 3200) for which the 3300H/HR will eventually replace.

Description	Model 4100H/HR (Predicate)	Model 3600H	Model 3300H
Relief valves	Quantity (2) Set at 36.00 psig	Quantity (2) Set at 36.00 psig	Quantity (2) Set at 35.00 psig

C. Gas Supply Flow rate

The Hyperbaric Chamber requires a gas supply source with a flow rate measured in standard cubic feet per minute (SCFM) units capable of supplying a gas supply pressure within a range of 50–70 psig. The required SCFM is based on the volume requirements during peak flow conditions for each model Hyperbaric Chamber.

The typical treatment cycle of a hyperbaric chamber consists of three phases:

1. Peak Flow – defined as increase from ambient to the prescribed treatment pressure at worst condition.
2. Steady Flow – defined as pressure hold at treatment level.
3. Minimum Flow – defined as exhaust from treatment pressure to ambient.

The required Gas Supply Flow Rates for the Models 3600H/HR and 3300H/HR Hyperbaric Chambers as compared to the predicate model is provided in the table below. The table illustrates the flow rates required for the Model 3600H/HR and Model 3300H/HR are lower than the predicate device Model 4100H/HR Hyperbaric Chamber.

Description	Model 4100H/HR (Predicate)	Model 3600H/HR	Model 3300H/HR
Gas Supply Flow Rate	42 SCFM	34 SCFM	32 SCFM

9. TESTING & PERFORMANCE EVALUATION

The Table below summarizes the tests required to validate/verify design changes based on the risk analysis. Design Validation & Verification, Electrical Safety/EMC and Performance test reports are provided in Appendix VIII.

SYSTEM VALIDATION MATRIX

Device Change	Device Requirement Reference	Testing Performed	Acceptability Criteria	Test Reference
Decreased Acrylic Window Size, Length and Width	Device specification	System Design Validation	Performs to requirements	2009-0010
	ASME Authorized Pressure Vessel Facility	ASME Boiler & Pressure Vessels Code Section VIII Division 1	ASME Authorization	ASME "U" Certificate of Authorization
	PVHO-1 Pressure Bearing Testing	PVHO-1 Safety Standard for Pressure Vessels for Human Occupancy	Tested at 1.1 x MAWP	PVHO-1 Appendix I, Enclosure 4
Over Pressure Relief valve pressure change	1. Device Specification 2. Final Test and Calibration Procedures Model 3300H/HR, 3600H/HR, 4100H/HR Series	1. System Design Validation 2. Activation pressure of valves	Performs to requirements	Document No. 150156, Section 5
Gas supply flow rate	1. Device Specification 2. Final Test and Calibration Procedures Model 3300H/HR, 3600H/HR, 4100H/HR Series	1. System Design Validation 2. Device performs to specification after calibration.	Performs to requirements	1. 2009-0010 2. Doc. No. 150156

10. DETAILED DESCRIPTION OF MODIFICATIONS

The modifications resulting in the Model 3300H/HR Hyperbaric Chamber and Model 3600H/HR Hyperbaric Chamber as compared with the Model 4100H/HR Hyperbaric Chamber (predicate) are provided in the following sections and associated tables.

10.1. Smaller Acrylic Cylinder Size

Design Requirement:

The internal diameter of the Model 3300H/HR acrylic cylinder was decreased to 32.50 inches and the internal diameter for the Model 3600H/HR acrylic cylinder was decreased to 35.50 inches from the internal diameter of 41.0 inches of the Model 4100H/HR (predicate device) to provide the most commonly used size of chamber for the most common patient population size on the market and reduce the space necessary to house the hyperbaric chambers.

Design Modification:

The decrease in the internal diameter of the cylinder from 41.0 inches (Model 4100H/HR) to 32.50 inches (Model 3300H/HR) was made to meet customer requests for a Hyperbaric

Chamber that would accommodate the most common patient size and weight seeking clinical treatment in the market and reduce the space necessary to house the hyperbaric chambers. The reduction in the internal diameter also resulted in reduction of external height and width of the cylinder.

Hazard / Risk:

Change does not pose a risk to the operator or patient.

Validation:

The decrease in acrylic viewport size was validated by testing the Model 3300H/HR and Model 3600H/HR Hyperbaric Chambers ability to operate to their approve product specifications. The data indicates the change does not affect the devices ability to perform to its product specifications and performs equivalently to the Model 4100H/HR Hyperbaric Chamber (predicate device).

Item	Description	Model 4100H/HR (Predicate)	Model 3600H	Model 3300H
1	Cylinder Internal Diameter	41.00 Inches (104 cm)	35.50 Inches (83 cm)	32.50 Inches (90 cm)
2	External Height (B)	69.75 Inches (177 cm)	63.00 Inches (160 cm)	59.00 Inches (150 cm)
3	External Width (C)	46.75 Inches (119 cm)	44.50 Inches (113 cm)	44.50 Inches (113 cm)

10.2. Relief Valve Pressure Change

Design Requirement:

The Relief Valve Pressure for the Model 3300H/HR Hyperbaric Chamber was changed to 35 psig from the pressure of 36 psig offered on the predicate device Model 4100H/HR Hyperbaric Chamber (predicate device). This change was made to offer the same pressure relief option as the Sechrist Model 3200 released by 510(k) K950386.

The Relief Valve Pressure for the Model 3600H/HR Hyperbaric Chamber remains unchanged from the Model 4100H/HR Hyperbaric Chamber (predicate device).

Design Modification:

The Relief Valves relief pressure was adjusted by the supplier to trigger at 35 psig ± 2 psig.

Hazard / Risk:

The identified hazard of excessive chamber pressure could potentially result in patient barotrauma risk. The identified hazard of chamber pressurization exceeding design pressure could potentially result in catastrophic structural failure risk.

Validation

The activation of the Relief Valve Pressure valves were validated by testing the Model 3300H/HR and Model 3600H/HR Hyperbaric Chambers ability to activate the Relief Valves at their respective preset activation pressures. Each Relief Valve is tested prior to installation during the manufacturing of the Hyperbaric Chamber. . This data is recorded in the "Final Test and Calibration Procedures Model 3300H/HR, 3600H/HR, 4100H/HR Series" (Document 150156).

The data indicates that the Model 3300H/HR and Model 3600H/HR Hyperbaric Chambers activates the Relief Valves at the activation pressures as outlined in the product specifications and performs equivalently to the Model 4100H/HR Hyperbaric Chamber (predicate device).

Item	Description	Model 4100H/HR (Predicate)	Model 3600H	Model 3300H
1	Relief Valve Pressure (activation pressure)	36 psig ± 2 psig	36 psig ± 2 psig	35 psig ± 2 psig

10.3. Gas Supply Flow Rate Change

The Hyperbaric Chamber requires a gas supply source with a flow rate measured in standard cubic feet per minute (SCFM) units capable of supplying a gas supply pressure within a range of 50-70 psig. The required SCFM is based on the volume requirements during peak flow conditions for each model Hyperbaric Chamber.

The typical treatment cycle of a hyperbaric chamber consists of three phases:

1. Peak Flow – defined as increase from ambient to the prescribed treatment pressure.
2. Steady Flow – defined as pressure hold at treatment level.
3. Minimum Flow – defined as exhaust from treatment pressure to ambient.

The required Gas Supply Flow Rates for the Models 3600H/HR and 3300H/HR Hyperbaric Chambers as compared to the predicate model is provided in the table below.

Description	Model 4100H/HR (Predicate)	Model 3600H	Model 3300H
Gas Supply Flow Rate	42 SCFM	34 SCFM	32 SCFM

Design Requirement:

The Gas Supply Flow Rate for the Model 3300H/HR Hyperbaric Chamber was reduced to 32 SCFM from the predicate device of 42 SCFM. The Model 3600H/HR Hyperbaric Chamber Gas Supply Flow Rate was also reduced to 34 SCFM from the predicate device of 42 SCFM. The SCFM required to operate each device is based on the volume requirements of each Hyperbaric Chamber model. The Gas Supply Flow Rate required during peak flow conditions is used to establish the minimum SCFM for each model.

Design Modification:

The Model 3600H/HR and the Model 3300H/HR Hyperbaric Chamber have a lower volume than the Model 4100H/HR Hyperbaric Chamber (predicate device). The Model 3600H/HR requires 34 SCFM to ensure operation to its approved specifications and Model 3300H/HR Hyperbaric Chamber requires 32 SCFM to ensure operation to its approved specifications.

Hazard / Risk:

The identified potential hazard of fluctuations in gas supplies may lead a risk of the inability to compress Hyperbaric Chamber.

Validation

The decrease in Gas Supply Flow Rates were validated by testing the Model 3300H/HR and Model 3600H/HR Hyperbaric Chambers ability to operate to their approve product specifications. Each model is tested 100% using the recommended supply pressure settings during manufacturing to ensure it will perform to its approved specification. This data is recorded in the "Final Test and Calibration Procedures Model 3300H/HR, 3600H/HR, 4100H/HR Series" (Document 150156). The data indicates the change does not affect the devices ability to perform to its product specifications and performs equivalently to the Model 4100H/HR Hyperbaric Chamber (predicate device).

Item	Description	Model 4100H/HR (Predicate)	Model 3600H	Model 3300H
1	Gas Supply Flow Rate	42 SCFM	34 SCFM	32 SCFM

11. VALIDATION / VERIFICATION MEASURES:

The device modification found in the Model 3300H/HR Hyperbaric Chamber and Model 3600H/HR Hyperbaric Chamber are provided in Attachment A.

The Models 3300H/HR and 3600H/HR Hyperbaric Chambers vary in acrylic viewport size and pressure retaining metal components. The control system, piping and performance specifications did not change nor have an impact on the functionality of the device from the Model 4100H/HR Hyperbaric Chamber. The validation documents tested the worst-case scenario which is the larger Model 4100H/HR Hyperbaric Chamber. Functionality of the Models is tested during production as a condition of release.

The Model 4100H/HR Hyperbaric Chamber is considered the worst-case scenario

Device Change	Risk Analysis Reference	Device Requirement Reference	Testing Performed	Acceptability Criteria	Test Reference
Decreased Acrylic Window Size, Length and Width	Items 1, 2, 3	Device specification	System Design Validation	Performs to requirements	2009-0010
		ASME Authorized Pressure Vessel Facility	ASME Boiler & Pressure Vessels Code Section VIII Division 1	ASME Authorization	ASME "U" Certificate of Authorization
		PVHO-1 Pressure Bearing Testing	PVHO-1 Safety Standard for Pressure Vessels for Human Occupancy	Tested at 1.1 x MAWP	PVHO-1 Appendix I, Enclosure 4
Over Pressure Relief valve pressure change	Item 1	Device specification	System Design Validation	Performs to requirements	2009-0010
		Final Test and Calibration Procedures Model 3300H/HR, 3600H/HR, 4100H/HR Series	Activation of Relief Valve verification and Install	Performs to requirements	Document No. 150156
Gas supply flow rate	Item 1	Device specification	System Design Validation	Performs to requirements	2009-0010
		Final Test and Calibration Procedures Model 3300H/HR, 3600H/HR, 4100H/HR Series	Functional performance to specification after calibration.	Performs to requirements	Document No. 150156

12. VALIDATION / VERIFICATION SUMMARY

The validation data indicates the modifications made to the Model 4100H/HR Hyperbaric Chamber (predicate) resulting in the two new Hyperbaric Chamber Models 3300H/HR and 3600H/HR does not affect the Models 3300H/HR and 3600H/HR performance to meet the approved product specifications and these perform as well as and as safe as the predicate device.

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

May 30, 2014

Sechrist Industries, Inc.
Mr. Victor Arellano
Director Regulatory Affairs, Product Safety & Certification
4225 East La Palma Avenue
Anaheim, CA 92807

Re: K140559
Trade/Device Name: Sechrist Models 3300H/HR and 3600H/HR Hyperbaric Chamber
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: April 30, 2014
Received: May 01, 2014

Dear Mr. Arellano:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
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)*
K140559

Device Name
Sechrist Models 3300H/HR Hyperbaric Chamber
Sechrist Models 3600H/HR Hyperbaric Chamber

Indications for Use *(Describe)*

The intended use of the hyperbaric chambers have been established by the Committee on Hyperbaric Oxygen Therapy of the Undersea and Hyperbaric Medical Society (founded in 1967 to foster exchange of data on the physiology and medicine of commercial and military diving). The committee is comprised of practitioners and scientific investigators in the fields of internal medicine, infectious diseases, pharmacology, emergency medicine, general surgery, orthopedic surgery, trauma surgery, thoracic surgery, otolaryngology, oral and maxillofacial surgery and aerospace medicine. The committee is responsible for continually reviewing research and clinical data in determining the safety and efficacy of hyperbaric oxygen. Currently, there are thirteen indications that are approved by the committee; these thirteen indications were accepted based on sound physiologic rationale, in vivo or in vitro studies that demonstrate effectiveness, controlled animal studies, prospective controlled clinical studies and extensive clinical experience from multiple hyperbaric medicine centers. These thirteen indications have been recommended for third-party reimbursement and most insurance carriers have established reimbursement policy based on the recommendations.

The thirteen indications are:

1. Air or Gas embolism
2. Carbon Monoxide Poisoning
   Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
3. Clostridial Myonecrosis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias
5. Decompression Sickness
6. Arterial Insufficiencies
   Central Retinal Artery Occlusion
   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. Compromise Grafts and Flaps
13. Thermal Burns

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Todd D. Courtney -S
2014.05.30 10:26:31 -04'00'

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