

K100268

APR 23 2010

510(K) SUMMARY

Sechrist Industries, Inc., 4100H/HR Hyperbaric Chamber (K100268)

Submitter: Sechrist Industries, Inc.
4225 E. La Palma Ave.
Anaheim, CA 92807

Date Prepared: March 3, 2010

Contact: Victor Arellano, Director, Quality Assurance & Regulatory Affairs
Phone: 714-579-8344 Fax: 714-579-8424

Trade Name : Model 4100H/HR Hyperbaric Chamber

Common Name : Hyperbaric Chamber

Classification Name : Chamber, Hyperbaric (Title 21, C.F.R. § 868.5470)

Product Code : CBF

Predicate Device : Sechrist Industries, Inc., Model 3200P/PR Hyperbaric Chamber (K950386)

Intended Use

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. Comprised Grafts and Flaps
13. Thermal Burns

Technological Characteristics

The Sechrist Model 4100H/HR Hyperbaric Chamber is a monoplace pressure chamber designed to administer 100% oxygen at pressure greater than ambient, up to 3 atmospheres absolute (30 psi) of pressure. The hyperbaric chamber is a mechanical and pneumatic system capable of controlling the operator defined pressurization profiles.

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). Typical pressurization and de-pressurization rates are in the range of 0.4 to 5.0 psig/minute.

The Model 4100H/HR is constructed with a horizontal 41 inch internal diameter seamless acrylic cylinder. One end is equipped with a hard anodized aluminum cover 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. The Model 4100 comes in two configurations (4100H and 4100HR). In the Standard configuration—4100H—the control panel is located on the left of the chamber when facing the door. In the Reverse configuration—4100HR—the control panel is located on the right side of the chamber.

Performance Data

Performance testing conducted confirms the device operates as designed. The Model 4100H/HR Hyperbaric Chamber functioned as intended per its approved specifications.

A performance standard regulation Section 514 of the Food, Drug and Cosmetic Act has not been promulgated for this device type.

However, the device is designed and manufactured in accordance with the following industry standards:

- Section VIII, Division 1 of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code
- ASME PVHO-1 Pressure Vessels for Human Occupancy Standard
- NFPA 99 Safety Standard for Health Care Facilities, Chapter 20

The following quality assurance measures were applied to the development of the 4100H/HR Hyperbaric Chamber - Requirements specifications reviews, performance testing and validation, environmental testing, electrical safety/EMC testing manufacturing process control procedures, process validation, and design controls.

Substantial Equivalence

The Model 4100H/HR Hyperbaric Chamber is as safe and effective as the Model 3200P/PR Hyperbaric Chamber. The Model 4100H/HR Hyperbaric Chamber has the same intended uses, similar technological characteristics, and similar principles of operation as its predicate device. The minor technological differences between the Model 4100H/HR Hyperbaric Chamber Neptune and its predicate device raise no new questions of safety or effectiveness. Thus, the Model 4100H/HR Hyperbaric Chamber Ventilator is substantially equivalent.



APR 23 2010

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

Mr. Victor Arellano
Director Quality Assurance & Regulatory Affairs
Sechrist Industries, Incorporated
4225 East La Palma Avenue
Anaheim, California 92807

Re: K100268
Trade/Device Name: Sechrist Model 4100H/HR Hyperbaric Oxygen Chamber
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: April 9, 2010
Received: April 12, 2010

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100268

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5. Decompression Sickness

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

L Schultze

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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Indications for Use

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 Central Retinal Artery Occlusion
 Enhancement of Healing In Selected Problem Wounds
7. Severe Anemia
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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