510(k) Summary
as required by 807.92(c)
Date: 12/30/2010

Product: Monoplace Hyperbaric Chamber
Model: RSI 4200 (™)
510K Number: K102831

General Information:

Classification: Class II, CBF
AN (73), Anesthesiology Panel
(Title 21, CFR 868.5470)

Trade Name: Chamber, Hyperbaric

Owner: Reimers Systems Inc.
8210-D Cinder Bed Rd.
Lorton VA 22079
703-952-0240

Contact: Nayil Alam
Electrical Engineer
703-952-0240
nayil@reimerssystems.com

Performance Standards:

A performance standard under Section 514 has not been promulgated for this device type. However, the device is designed and manufactured in accordance with the following industry standards:

- ASME Boiler and Pressure Vessel Code, Section VIII, Division 1
- ASME PVHO-1 Pressure Vessels for Human Occupancy Standard
  Regulation Number: 868.5470
- NFPA 99 Safety Standard for Health Care Facilities, Chapter 20
  Regulation Number: 868.5470

Predicate Devices: 807.92(a)(3)

i. Sechrist Industries Model 2500B (K934164)
ii. Millennium 2000, 2001, 2002, 2003, 2004, 2005 (K041007)

Device Description: 807.92(a)(4)

The model RSI4200 (™) hyperbaric chamber is a monoplace (one person) pressure chamber designed to be pressurized with air while patient breathes pure oxygen at treatment pressure (between 1 and 3 atmospheres absolute, ATA).

The chamber comes with fixed tray system with comfortable custom mattress. The patient tray system is designed to accommodate a lying or sitting patient during a hyperbaric treatment. The chamber is designed to administer all of the standard treatment protocols for 3 ATA or less. The chamber includes the following sub systems:

1. Pressurization, Depressurization and Ventilation:
This system includes pneumatically controlled valves and components. These valves and controls are used to control the pressurization rate and depressurization rate, the steady state pressure and the ventilation rate.

2. Communications and Entertainment:
The chamber is equipped with a system to facilitate clear and easy communication between the patient and chamber operator. The communication system also permits the use of an auxiliary audio input for patient entertainment. Patient entertainment is automatically muted when the operator lifts the hand set from its cradle.

3. Windows:
The chamber windows are positioned and sized to provide a feeling of comfort and spaciousness to the patient.

4. Oxygen Breathing System:
The chamber is equipped with the necessary controls to administer oxygen to the patient whereby the patient wears a standard medical oxygen hood or mask.

Indications For Use:

Specific indications for use of hyperbaric chambers have been established by the Committee on Hyperbaric Oxygen Therapy of the Undersea and Hyperbaric Medical Society. The current specific indications are:

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning and Smoke Inhalation, Carbon Monoxide Complicated by Cyanide Poisoning
3. Clostridial Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias
5. Decompression Sickness
6. Enhancement of Healing in Selected Problem Wounds
7. Exception Blood Loss (Anemia)
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections (Subcutaneous Tissue, Muscle, Fascia)
10. Osteomyelitis (Refractory)
11. Radiation Tissue Damage (Osteoradionecrosis)
12. Skin Grafts and Flaps (Compromised)
13. Thermal Burns

Summary of Substantial Equivalence:

RSI considers the following design characteristics to be substantially equivalent to previously listed devices. While this device is not entirely like any of the predicate devices, it is a compilation of the sub-systems from the predicate devices. Each of the major sub-systems used on the model RSI$^{4200(™)}$ has been shown to be safe and effective on predicate devices. These sub-systems are described below:

1. Vessel Construction: The construction of the model RSI$^{4200\,(™)}$ hyperbaric chamber is similar to the Millenium 2000, 2001, 2002, 2003, 2004, 2005 (K041007) in that it is a welded metal pressure vessel with commonly used shapes and windows. The design and construction of the pressure shell is in accordance with the very commonly used and accepted ASME Boiler and Pressure vessel code, section VIII, division 1. Windows are designed to meet the applicable sections of PVHO (pressure vessel for human occupancy) standard.

2. Pressure Controls: The pressure controls are very similar to the pneumatic pressure controls of the Sechrist 2500B (K934164) and the Millenium 2000, 2001, 2002, 2003, 2004, 2005 (K041007) . However, RSI$^{4200\,(™)}$ chamber controls are simpler and easy to use.

3. Communications System: The communication system is designed to meet the requirements of NFPA 99 Chapter 20 for hyperbaric facilities. The chamber interior microphone and speaker arrangement and operation is similar to that of Sechrist 2500B (K934164) chamber.

4. Oxygen Breathing System: The chamber is equipped with the necessary controls to administer oxygen to the patient whereby the patient wears a standard medical oxygen hood or mask

5. General: The RSI$^{4200\,(™)}$ has been designed, built and tested in compliance with all of the applicable requirements of the performance standards listed herein. Each predicate device with a similar function must also meet these requirements.

RSI accepts that the model RSI$^{4200\,(™)}$ is substantially equivalent to the predicate devices and is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Nayil Alam
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Reimers System, Incorporated
8210 – D Cinder Bed Road
Lorton, Virginia 22079

AUG 19 2011

Re: K102831
Trade/Device Name: RSI 4200
Regulation Number: 21 CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: August 8, 2011
Received: August 18, 2011

Dear Mr. Alam:

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 D. 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): K102831

Device Name: RSI 4200

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11. Radiation Tissue Damage (Osteoradionecrosis)
12. Skin Grafts and Flaps (Compromised)
13. Thermal Burns

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102831