

2-24-99

K983648



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January 15, 1999

**Amended 510(k) K983648 SUMMARY**  
**Page 1 of 3**

**Food and Drug Administration**  
**Center for Devices and Radiological Health**  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Attention: Document Control Clerk

Subject: **SIGMA Plus / II** Multiplace Hyperbaric Chamber Summary of Safety & Effectiveness Information - Amended as of January 15, 1999

Gentlemen:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Substantial Equivalence:** The Perry Baromedical Corporation **SIGMA Plus / II** Multiplace Hyperbaric Chamber is substantially equivalent to the Perry Baromedical Corporation **SIGMA II** Dualplace Hyperbaric Chamber, [510(k) K862198/A]. The **SIGMA Plus / II** has the same intended use and the same technological characteristics as the **SIGMA II** predicate device. The scope and operation of the **SIGMA Plus/ II** is identical to that of the **SIGMA II** in the following areas:

- 1 The critical component of both systems consists of an ASME pressure vessel that is designed, fabricated, and tested in accordance with the requirements of the ASME Boiler and Pressure Vessel Code, Section VIII, Division I; and ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy.
- 2 The pressure vessel consists of certified metal components constructed of materials in conformance with the ASME Boiler and Pressure Vessel Code, Section II - Materials. In addition to the metal parts, the pressure retaining boundary consists of an acrylic plastic cylinder, designed and constructed to the requirements of ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy.
- 3 The pressure vessel is protected from accidental over pressurization by an ASME "UV" stamped pressure relief valve.

- 4 The medium used for pressurization of the chamber is compressed breathing quality air.
- 5 Treatment capacity of the chamber is two (2) patients.
- 6 Communication between the patients / attendants is through an intrinsically safe communications system.
- 7 The **SIGMA II** and **SIGMA Plus/ II** chambers are used to provide Hyperbaric Oxygen Therapy, prescribed by a licensed physician, where medical grade oxygen is administered to patients while under pressure, by the patient breathing oxygen from a breathing hood or breathing mask with the chamber pressurized with breathing air. The breathing of oxygen at elevated pressure promotes the movement of oxygen into the patient's tissues.
- 8 The chamber pressurization and depressurization control system is completely pneumatic, with no electrical or electronic components.
- 9 Both chambers are Class "A" multiplace hyperbaric systems, with Fire Suppression Systems and independent hand line fire extinguishing systems.

Differences do exist between the **SIGMA Plus/ II** and the **SIGMA II** Dualplace chamber; they include:

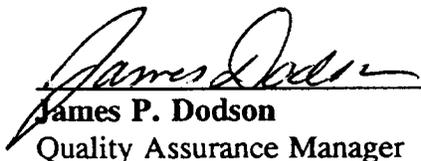
- 1 The PVHO-1 acrylic cylinder in the **SIGMA Plus / II** chamber is 40" inside diameter and 65" long, and the PVHO-1 acrylic cylinder in the **SIGMA II** chamber is 40" inside diameter by 85" long. Both acrylic cylinders are designed with a 20 to 1 safety factor.
- 2 The pneumatic controls for the **SIGMA Plus / II** chamber are mounted in a control box that is suspended from a moveable arm, allowing use from either side of the chamber; while the pneumatic controls for the **SIGMA II** chamber are mounted in a console panel mounted on one side of the chamber.

- 3 The **SIGMA Plus/ II** Multilace Hyperbaric Chamber has painted fiberglass cosmetic covers on the sides and ends of the chamber; the **SIGMA II** Dualplace Hyperbaric Chamber has aluminum side cosmetic covers.
- 4 The Built-In Breathing System controls for the **SIGMA Plus / II** are mounted in a pedestal mounted moveable control panel, allowing positioning to suit the operator location. The **SIGMA II** Built-In Breathing System controls are mounted in the control console positioned at the side of the chamber.
- 5 The **SIGMA II** Dualplace chamber is available with an Entry Lock and a Medical Lock feature, which are not offered with the **SIGMA Plus / II**.

The changes to the **SIGMA II** system resulting in the **SIGMA Plus/ II** Dualplace Hyperbaric Chamber enhance its ease of operation, and do not adversely effect the safety and effectiveness of the device. **The basic treatment method is identical, only the chamber acrylic window length size has been changed**

None of the above information is confidential and all may be made available to the public upon written request.

**Perry Baromedical Corporation**

  
James P. Dodson  
Quality Assurance Manager

1-15-99  
Date



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 24 1999

Mr. James P. Dodson  
Perry Baromedical Services  
7555 Garden Road  
Riviera Beach, FL 33404-3411

Re: K983648  
SIGMA Plus/II Multiplace Hyperbaric Chamber  
Regulatory Class: II (two)  
Product Code: 73 CBF  
Dated: January 26, 1999  
Received: February 2, 1999

Dear Mr. Dodson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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## INDICATIONS FOR USE

The **SIGMA Plus / II** Multiplace hyperbaric System is indicated for use for the following clinical medical conditions in accordance with guidelines established by the Undersea and Hyperbaric Medical Society, as follows:

1. Air or Gas Embolism
2. Carbon Monoxide / Smoke Inhalation
3. Compromised Skin Grafts and Flaps
4. Crush Injuries / Acute Traumatic Ischemias
5. Decompression Sickness
6. Enhanced Healing in Selected Problem Wounds
7. Exceptional Blood Loss (Anemia)
8. Gas Gangrene (Clostridial Myonecrosis)
9. Intracranial Abscess
10. Necrotizing Soft Tissue Infections
11. Radiation Tissue Damage (Osteoradionecrosis)
12. Refractory Osteomyelitis
13. Thermal Burns

Prescription Device

*M Kramer*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K983648