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December 24, 1997

510(k) SUMMARY

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*** Monoplace Hyperbaric Chamber Summary of Safety & Effectiveness Information

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*** Monoplace Hyperbaric Chamber is substantially equivalent to the Perry Baromedical Corporation **SIGMA I** Monoplace Hyperbaric Chamber, [510(k) K832127]. The **SIGMA *Plus*** has the same intended use and the same technological characteristics as the **SIGMA I** predicate device. The scope and operation of the **SIGMA *Plus*** is identical to that of the **SIGMA I** 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 either compressed pure oxygen or compressed breathing air.

5 Treatment capacity of the chamber is one (1) patient.

6 Communication between the patients / attendants is through an intrinsically safe communications system.

7 The **SIGMA I** and **SIGMA *Plus*** chambers are used to provide Hyperbaric Oxygen Therapy, prescribed by a licensed physician, where medical grade oxygen is administered to patients while under pressure; either by the patient breathing the chamber atmosphere, (when pressurized with oxygen), or by the patient breathing oxygen from a breathing hood or breathing mask, (when 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.

Differences do exist between the **SIGMA *Plus*** and the **SIGMA I** Monoplace chamber; they include:

1 The PVHO-1 acrylic cylinder in the **SIGMA *Plus*** chamber is 40" inside diameter, and the PVHO-1 acrylic cylinder in the **SIGMA I** chamber is 25.25" inside diameter. Both acrylic cylinders are designed with a 20 to 1 safety factor.

2 The pneumatic controls for the **SIGMA *Plus*** 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 I** chamber are mounted in a panel on one side of the chamber.

3 The **SIGMA *Plus*** Monoplace Hyperbaric Chamber has painted fiberglass cosmetic covers on the sides and ends of the chamber; the **SIGMA I** Monoplace Hyperbaric Chamber has a wheeled aluminum support chassis.

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The changes to the **SIGMA I** system resulting in the **SIGMA *Plus*** Monoplace 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 size has been increased.**

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

Perry Baromedical Corporation

James Dodson 12-24-97

James P. Dodson Date
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1998

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

Re: K974868
SIGMA Plus Monoplace Hyperbaric Chamber
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: April 3, 1998
Received: April 6, 1998

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 (Premarket 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

Attachment 3A

PERRY
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Riviera Beach FL 33404
(561) 840-0395

Operations & Maintenance Manual Addenda

April 1, 1998

Subject: **FDA Indications for Use Statement**

The monoplace hyperbaric chamber is indicated for use for the following clinical medical cpndconditions 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

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974868

✓ Prescription Use