K072427

JUN 11 2008

Perry Baromedical Corporation **July 12, 2007**

510(k) SUMMARY

1.	Submitter Information	Perry Baromedical Corporation ("PBC") 3660 Interstate Parkway, Riviera Beach, Florida 33404
2.	Contact Information	John Crocker, Quality Manager Tel: (561) 840-0395 Ext. 206 Fax: (561) 840-0398
3.	Trade Name	**SIGMA *Elite* XX** Monoplace Hyperbaric Chamber Where XX can be 34, 36, or 40
4.	Common Name	Hyperbaric Chamber
5.	Device Class	Class II
6.	Product Code	CBF
7.	Product Classification	per 21 CFR § 868.5470
8.	Classification Panel	Anesthesiology
9.	Predicate Devices	Perry Baromedical's, SIGMA 34 (K990927) Sechrist Industry's, Sechrist 3300E/ER (K052713) Environmental Techtonics' BARA-MED (K020974)
10.	Device Description	The **SIGMA *Elite*** Series Hyperbaric Chambers and their predicate devices have the same intended use; as a prescription device intended for the whole body administration of oxygen to a patient at pressures not exceeding 3 ATA. The **SIGMA *Elite*** Series Hyperbaric Chambers and their predicate devices have very similar general principles of operation. All of these chambers are pressurized and ventilated continuously with pure oxygen, and the patient breathes the chamber atmosphere. Also, in each of the chambers, the pressure-time profile (i.e. the rate and direction of pressure change and the time held at any particular pressure), as well as the oxygen ventilation rate of any treatment, are controlled by the chamber's operator, either directly by means of a pneumatic or an automatic electronic system. The purpose of such controls are to be able to conduct the particular hyperbaric oxygen treatment prescribed by the physician in a way that is safe and comfortable for the patient, and to be able to respond appropriately and effectively to any contingency circumstance.

The **SIGMA *Elite*** Series of Hyperbaric Chambers is designed and manufactured in accordance with the applicable sections of:

- ASME Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Pressure Vessels, Division 1, 2003 Edition
- ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy, 2002 Edition
- NFPA 99, Standard for Health Care Facilities, Chapter 19, Hyperbaric Facilities, 2005 Edition
- CAN/CSA C22.2 60601-1-1-02 Safety Requirements for Medical Electrical Systems, 2002 Edition EN60601-1-2:2002
- EMC Standard for Medical Devices, 2002 Edition

11.	Intended Use	These devices are to be used by properly trained personnel to deliver hyperbaric oxygen therapy as prescribed by the attending physician.
12.	Performance Data	Testing was indicated to demonstrate that the devices meet the standards referenced above.
13.	Clinical Tests	None
14.	Conclusion	In all respects, the **SIGMA *Elite*** Series of Hyperbaric Chambers are substantially equivalent to one or more clinical monoplace hyperbaric chambers that are legally marketed for the conduct of hyperbaric oxygen therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2008

Mr. John Crocker
Quality Manager
Perry Baromedical Corporation
3660 Interstate Parkway
Riviera Beach, Florida 33404

Re: K072427
Trade/Device Name: SIGMA Elite 34, 36, and 40
Regulation Number: 21CFR 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: May 29, 2008
Received: June 2, 2008

Dear Mr. Crocker:

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.

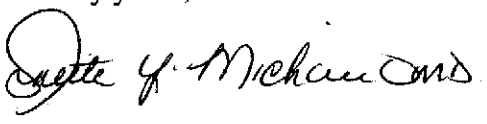
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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 Statement

510(k) Number K072427

Device Name SIGMA Elite 34, 36, and 40

Indications for Use

The **SIGMA Elite** 34, 36 and 40 Monoplace Hyperbaric Chambers are intended 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 Ischemia
5. Decompression Sickness
6. Enhanced Healing in Selected Problem Wounds
7. Exceptional Blood Loss (Anemia)
8. Gas Gangrene (Clostridia Myonecrosis)
9. Intracranial Abscess
10. Necrotizing Soft Tissue Infections
11. Radiation Tissue Damage (Osteoradionecrosis)
12. Refractory Osteomyelitis
13. Thermal Burns

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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

510(k) Number: K072427

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)