

MAY 3 0 2000

K993010

510(k) SUMMARY

**Environmental Tectonics Corporation's
BARA-MED® Acrylic Monoplace Hyperbaric Chamber**

SUBMITTER'S NAME AND ADDRESS

Environmental Tectonics Corporation ("ETC")
Hyperbaric Division
125 James Way
Southampton, PA 18966

CONTACT PERSON AND TELEPHONE/FACSIMILE NUMBERS

Micheal W. Allen
Director, Hyperbaric Division
Environmental Tectonics Corporation
125 James Way
Southampton, PA 18966

Phone: (215) 355-9100, Ext. 373
Facsimile: (215) 357-4000

DATE PREPARED: September 3, 1999

NAME OF DEVICE

Trade of Proprietary Name: BARA-MED® Clinical Acrylic
Monoplace Hyperbarid Chamber

Common Name: Hyperbaric Chamber

Classification Name: Hyperbaric chamber, 21 C.F.R. § 868.5470

PREDICATE DEVICES

- ◆ Dixie Manufacturing Co.'s Dixie 800-45 (pre-amendment device)
- ◆ Perry Baromedical's Sigma I (pre-amendment device)
- ◆ Sechrist Industry's Sechrist 2500 (pre-amendment device)
- ◆ Sechrist Industry's Sechrist 2500E (K934164)
- ◆ Sechrist Industry's Sechrist 3200 (K950386)

DEVICE DESCRIPTION/SUBSTANTIAL EQUIVALENCE

The BARA-MED® and its predicate devices have the same intended use: to promote the movement of oxygen into a patient's tissues by causing him to respire oxygen at a pressure that is greater than that of the earth's atmosphere (*i.e.*, 1 ATA). Specifically, the BARA-MED® and the predicate devices are indicated for air or gas embolism; carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning; clostridial myositis and myonecrosis (gas gangrene); crush injury, compartment syndrome, and other acute traumatic ischemias; decompression sickness; enhancement of healing in selected problem wounds; exceptional blood loss (anemia); intracranial abscess; necrotizing soft tissue infections; refractory osteomyelitis; delayed radiation injury (soft tissue and bony necrosis); compromised skin grafts and flaps; thermal burns. These indications for use are in accordance with the recommendations made by the Undersea and Hyperbaric Medical Society for the medical application of hyperbaric chambers.

The BARA-MED® and its 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 electronic system, or indirectly by means of an automatic electronic system. The purposes 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 ETC BARA-MED® is designed and manufactured in accordance with the applicable sections of:

- ASME Boiler and Pressure Vessel Code, Section VII, Rules for Construction of Pressure Vessels, Division 1, 1998 Edition.
- ASME PVHO-1-1997, Safety Standard for Pressure Vessels for Human Occupancy.
- NFPA 99, Standard for Health Care Facilities, Chapter 19, 199 Edition.

In all respects, the BARA-MED® is substantially equivalent to one or more clinical monoplace hyperbaric chambers that are legally marketed for the conduct of hyperbaric oxygen therapy.

PERFORMANCE DATA

Testing was indicated to demonstrate that the device meets the standards referenced above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 3 0 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Environmental Tectonics Corp.
C/O Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004

Re: K993010
Bara-Med, Acrylic Monoplace Hyperbaric Chamber
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: February 28, 2000
Received: March 1, 2000

Dear Mr. Holstein:

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.

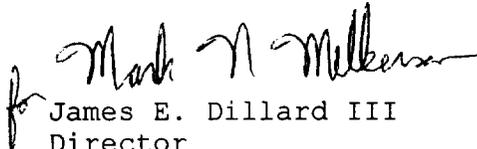
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Howard Holstein

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,

for Mark N. Melker

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 993010

Device Name: BARA-MED® ACRYLIC MONOPLACE CHAMBER

Indications For Use:

All of the contemporary substantially equivalent systems listed in Attachment 12 are used for the same indications as listed in the Hyperbaric Oxygen Therapy: Committee Report, Undersea and Hyperbaric Medical Society, Inc., Revised 1999.

- Air or Gas Embolism
- Carbon Monoxide Poisoning and Carbon Monoxide Poisoning complicated by Cyanide Poisoning
- Clostridial Myositis and Myonecrosis (Gas Gangrene)
- Crush Injury, Compartment Syndrome and other Acute Traumatic Ischemias
- Decompression Sickness
- Enhancement of Healing in Selected Problem Wounds
- Exceptional Blood Loss (Anemia)
- Intracranial Abscess
- Necrotizing Soft Tissue Infections
- Osteomyelitis (Refractory)
- Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
- Skin Grafts and Flaps (Compromised)
- Thermal Burns

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Melburn K 993010

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

510(k) Number K 993010

(Optional Format 3-10-98)