JUN 2 6 2002

K020974

510(K) SUMMARY

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

SUBMITTER'S NAME AND ADDRESS

Environmental Tectonics Corporation ("ETC")
BioMedical Systems Group
125 James Way
Southampton, PA 18966-3877

CONTACT PERSON AND TELEPHONE / FACSIMILE NUMBERS

Michael W. Allen
Vice-President, BioMedical Systems Group
Environmental Tectonics Corporation
125 James Way
Southampton, PA 18966-3877

DATE PREPARED: 26 March 2002

NAME OF DEVICE

Trade of Proprietary Name: BARA-MED® Acrylic Monoplace Hyperbaric 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: as a prescription device intended for the whole-body administration of oxygen to a patient at pressures not exceeding 3 ATA.

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 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 ETC BARA-MED® 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, 1998 Edition.
- ASME PVHO-1, Safety Standard For Pressure Vessels For Human Occupancy, 1997 Edition
- NFPA 99, Standard For Health Care Facilities, Chapter 19, Hyperbaric Facilities, 1999 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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Environmental Tectonics Corporation
c/o Mr. Michael W. Allen
BioMedical Systems Group
125 James Way
Southampton, PA 18966-3877

Re: K020974
BARA-MED® Acrylic Monoplace Hyperbaric Chamber
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: March 26, 2002
Received: March 26, 2002

Dear Mr. Allen:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. While this concern has existed with devices of this type prior to the submission of this premarket notification, we believe that eliminating references to the specific medical conditions for which this device is to be used, from the indications for use statement, could exacerbate the situation. Although, we could attempt to address this concern by identifying and requiring a limitation on the use of the device to appear in the device labeling, this would require that we identify each use that could result in patient harm; a task that is clearly not

practical. To more effectively address this concern, in accordance with Section 513(i)(1)(E), if you label this device for any specific indications for use, your labeling, instructions for use (including company sponsored training programs), as well as any bibliography that accompanies your device, is limited to the following medical conditions:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myositis and myonecrosis
4. Crush injury, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness
6. Enhanced healing of selected problem wounds
7. Exceptional blood loss anemia
8. Necrotizing soft tissue infections
9. Osteomyelitis (refractory)
10. Delayed radiation injury (soft tissue and bone necrosis)
11. Skin grafts and flaps (compromised)
12. Thermal burns
13. Intracranial abscess.

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); 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.

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

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Bernard E. Statland, M.D.,Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

Indications for Use
Page 1 of 1
510(k) Number (if known): K020974
Device Name: BARA-MED Acrylic Monoplace Hyperbaric Chamber
Indications for Use:

The BARA-MED Monoplace Hyperbaric Chamber is a prescription device intended for the whole body administration of oxygen to a patient at pressures not exceeding 3 ATA (Atmospheres Absolute).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)
(Posted July 1, 1998)
Back to the Indications for Use Page

Division of Cardiovascular & Respiratory Devices
510(k) Number K020974

Prescription Use ✓
(Per 21 CFR 801.109)