K022028

DEC 17 2002

Attachment 3

510(K) SUMMARY

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.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Vascular One, Inc.
8711 E. Pinnacle Peak Road
Suite 306
Scottsdale, AZ 85255-3517

Contact: Mr. Edward Lisinski, President

Date Summary Prepared: June 20, 2002

2. Name of the Device:

VX-400 Topical Hyperbaric Oxygen Chamber

3. Predicate Device Information:

- O_2 Boot, GWR Medical, LLP, Chadds Ford, PA, K#971507
- Topox Topical Sacral Hyperbaric Oxygen Chamber, Topox, Inc. North Attleboro, MA, K#920948
- The Topical Hyperbaric Oxygen Extremity Chamber, Advanced Hyberbaric Technologies, Inc., Farmingdale, NJ. (Grandfathered, Pre-Amendment Status).

4. Device Description:

The VX-400 Topical Hyperbaric Oxygen Chamber is a small, portable system that provides oxygen, at prescribed pressure for a prescribed duration, to a patient's limb. It is used at home or a clinical setting to help speed wound healing. The system consists of five (5) major components:

1. The Blue/Clear Plastic Chamber
2. The Control Unit
3. The Hand Held Controller
4. The Silicone Sleeve
5. Power Cube (Power Supply)

The VX-400 is a rectangular, yet rounded (10 x 24 x 16) rigid plastic shell constructed of two plastic half-panels, to which epoxy is applied and then heat-sealed together along the edges to form one chamber.

The chamber is a rigid plastic sleeve into which the patient places their limbs. There are two (2) hose barbs on the chamber, one for oxygen tubing that fills the chamber, and one for tubing to a pressure sensor. The controller consists of a plastic box with two (2) pieces of attached clear flexible tubing; these connect to the two (2) barbs on the chamber. The controller has a hose connected from the 50-psi oxygen source, a connector for a "power cube" that plugs into an AC wall outlet, and a cable that connects to the hand controller. The controller also incorporates a flowmeter. The hand-held controller can be programmed by the clinician to the prescribed time and pressure therapy, and then set to allow the patient to only turn the unit on and then off; it has a small 2 line LCD alphanumeric display and several push buttons.

5. **Intended Use:**

For Treatment of open acute or chronic wounds, e.g.,

- Skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions
- Decubitus ulcers
- Amputations/infected stumps
- Skin grafts
- Burns
- Frostbite

6. **Comparison to Predicate Devices:**

Both the VX-400 Topical Hyperbaric Oxygen and the Advanced Hyperbaric Technologies Topical Hyperbaric Oxygen Extremity Chamber are constructed of enclosed, rigid plastic to allow for pressures of up to 50 mmHg of the extremities. The VX-400 device is constructed of materials similar to the Advance Hyperbaric device and is used in an identical manner for the treatment of chronic skin and pressure sores of the extremities. The GWR O_2 Boot device employs a disposable sleeve, and is flexible in construction. All of the devices are constructed of transparent materials to allow the wounds to be viewed and monitored during set-up and treatment. The VX-400 device and the predicates use the hospital wall oxygen or tank oxygen supplies. The prescribed oxygen pressures are maintained and controlled at all times. The VX-400 device is software driven. The GWR device is not.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:**

Performance testing to confirm the operations by setting several treatment combinations, and checking time and pressure (clock) was conducted in order to show that the device meets product specifications.

Testing information demonstrating safety and effectiveness of the VX-400 Topical Hyperbaric Oxygen Chamber in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

A Contract Testing Laboratory conducted the following testing:

a. Operation at 5 +5°C and at +40°C, 90- 95% relative humidity (to assure that the device operates normally in the environment of use)

b. Storage at -20°C and at +60°C, 90-95% relative humidity (storage resistance)

c. Sinusoidal vibration

d. Leakage current and dielectric withstand of power cube (electrical safety)

e. Thermal Safety

Vascular One, Inc. conducted Impact (drop) resistance testing.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazard. It was the contract testing laboratory and Vascular One, Inc.'s conclusion that the VX-400 device samples(s) tested met all relevant requirements of the aforementioned test.

8. **Discussion of Clinical Tests Performed:**

Not applicable

9. **Conclusions:**

The subject device, The Vascular One VX-400 Topical Hyperbaric Oxygen Chamber, has the same intended use and similar characteristics as the predicate devices. Moreover, bench tenting contained in our submission and non-clinical testing supplied demonstrates that there are no differences in their technological characteristics, thereby not raising any new questions of safety or effectiveness. Thus, the VX-400 Topical Hyperbaric Oxygen Chamber is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2002

Vascular One, Inc.
Susan D. Goldstein-Falk
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K022028
Trade/Device Name: VX-400 Topical Hyperbaric Oxygen Chamber
Regulation Number: 878.5650
Regulation Name: Topical oxygen chamber for extremities
Regulatory Class: Class III
Product Code: KPJ
Dated: September 18, 2002
Received: September 23, 2002

Dear Ms. Goldstein-Falk:

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 (301) 594-4659. 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" (21CFR 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 022028

Attachment #2

510(k) Number (if known): K#022028

Device Name VX-400 Topical Hyperbaric Oxygen Chamber

Indications For Use:

For Treatment of open acute or chronic wounds, e.g.,

- Skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions
- Decubitus ulcers
- Amputations/infected stumps
- Skin grafts
- Burns
- Frostbite

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022028