510(k) Summary
for
OxyBox

FEB 2 4 2003

1. SPONSOR

Oxyfast Corporation
11000 Cedar Avenue, Suite 449
Cleveland, OH 44106

Contact Person: Melvyn Burk
Telephone:216-795-3060

Date Prepared: January 6, 2003

2. Device Name

Proprietary Name: OxyBox
Common/Usual Name: Topical oxygen bandage
Classification Name: Topical oxygen chamber CFR878.5650, Class III

3. PREDICATE DEVICES

O_2Boot™: K971507

4. DEVICE DESCRIPTION

OxyBox is a topical bandage system that incorporates a disposable oxygen concentrator. It consists of three separate component parts: (1) the oxygen concentrator, (2) the sterile cannula and (3) the bandage or wound dressing. Items (2) and (3) are medical grade commercial products that Oxyfast Corporation obtains from device manufacturers or distributors. The oxygen concentrator is a single patient, one time use, disposable, battery-operated device that is capable of delivering 98 to 100 percent oxygen (balance moisture) for seven days at a rate of ~3.0 ml/hour. The cannula conveys the oxygen from the oxygen concentrator to the area beneath the bandage overlying the wound.

5. Indications for Use

The OxyBox System is intended to provide topical oxygen to treat 1) skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions, 2) decubitis ulcers, 3) amputations/infected stumps, 4) skin grafts, 5) burns, and 6) frostbite.

6. Technological Characteristics and Substantial Equivalence

The predicate devices all deliver oxygen to the wound site at very slightly enhanced pressure (1.04 atmosphere). OxyBox delivers oxygen to the wound at ambient pressure (typically 1 atmosphere). The device design is different in the sense that oxygen is generated in situ in the case of the OxyBox, and the predicate devices use an oxygen cylinder to deliver oxygen. The predicate devices as well as the OxyBox deliver near 100 percent pure oxygen to the wound site. Both the OxyBox and the predicate O_2Boot™ are single use devices.

7. Performance Testing

Testing was conducted to validate that the OxyBox performed according to its specifications. In addition, animal testing was conducted that demonstrated that topical oxygen delivered by the OxyBox provides increased epithelialization compared to a control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Oxyfast Corporation
Melvyn Burk
President
University West Building, Suite 449
11000 Cedar Avenue
Cleveland, Ohio 44106 - 3052

FEB 2 4 2003

Re: K023456
Trade/Device Name: OxyBox System
Regulation Number: 878.5650
Regulation Name: Topical Oxygen Chamber
Regulatory Class: Class III
Product Code: KPJ
Dated: October 14, 2002
Received: October 15, 2002

Dear Mr. Burk:

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

Enclosure

510(k) Number (if known): K023456

Device Name: OxyBox System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K023456

Prescription Use Y
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)