III. 510(k) Summary of Safety and Effectiveness for the OxyBand Technologies OxyBand ™ Wound Dressing

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

MAR 2 4 2005

Submitter:

OxyBand Technologies
33 Bayview Terrace
Mill Valley, CA 94941

Contact Person:

Maureen O'Connell
5 Timber Lane
North Reading, MA 01864
Telephone: 978-207-1245
Fax: 978-207-1246

Summary Preparation Date:

March 16, 2005

2. Names

Device Name:

OxyBand ™ Wound Dressing

Classification Name:

Dressing, wound and burn, occlusive
Product Code: MGP
Panel: Plastic and Reconstructive Surgery Devices

3. Predicate Devices

The OxyBand ™ Wound Dressing is substantially equivalent to the 3M Medical Products Tegaderm ™ Transparent Dressing (K973036), the Innovative Technologies, Ltd. Transparent Film and Intelligent Film Dressings (K973312) and the Kinetic Concepts, Inc. KCI Wound Cell Transparent Wound Dressing (K020781).

4. Device Description

OxyBand™ is a multilayer wound dressing that keeps out water, dirt and germs, and supplies oxygen to the wound. It is designed to be applied directly over clean skin or wounds for up to 5 days. A study has shown that upon attaching the dressing over a test plate, oxygen levels rise steadily over the device area for the first few hours and then maintain at elevated levels through 5 days as long as the dressing remains intact and secure around the perimeter.

5. Indications for Use

OxyBand ™ Wound Dressings are available as both Prescription and Over-The-Counter products.

The Prescription OxyBand ™ Wound Dressings are intended to provide a moist environment to facilitate the normal wound healing process. OxyBand ™ Wound Dressings can be used to cover and protect wounds and catheter sites, or used as a secondary dressing for other wound products such as gauze, alginates, hydrogels, debridement facilitators, or a protective cover over at risk skin. The OxyBand ™ Wound Dressings are indicated for: clean closed surgical incisions, skin graft donor sites, Stage I or II pressure ulcers, pressure sores, superficial wounds such as abrasions, skin tears, and blisters, lacerations, first and second degree burns, chafed skin, skin continuously exposed to moisture, secondary dressing over gauze, alginates or hydrogels.

The Over-The-Counter OxyBand ™ Wound Dressings are intended to protect light to moderate wounds, including skin tears, scrapes, minor pressure sores, abrasions, blisters, lacerations, minor burns, to protect chafed or irritated skin or skin continuously exposed to moisture, and to create a moist environment for wound healing.

Indications for Use

510(k) Number (if known): K043063

Device Name: OxyBand™ Wound Dressings

Indications For Use:

OxyBand ™ Wound Dressings are intended to provide a moist environment to facilitate the normal wound healing process. OxyBand ™ Wound Dressings can be used to cover and protect wounds and catheter sites, or used as a secondary dressing for other wound products such as gauze, alginates, hydrogels, debridement facilitators, or a protective cover over at risk skin. The OxyBand ™ Wound Dressings are indicated for: clean closed surgical incisions, skin graft donor sites, Stage I or II pressure ulcers, pressure sores, superficial wounds such as abrasions, skin tears, and blisters, lacerations, first and second degree burns, chafed skin, skin continuously exposed to moisture, secondary dressing over gauze, alginates or hydrogels.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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K043063 4 of 4

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Prescription Use _____ AND/OR Over-The-Counter Use ____X___
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Oxyband Technologies, Inc.
c/o Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

Re: K043063
Trade/Device Name: OxyBand™ Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 10, 2005
Received: March 10, 2005

Dear Ms. O'Connell:

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,

for

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043063

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Prescription Use __X__ AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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