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)(k) Information

III. 510(k) Summary of Safety and Effectiveness for the O2S, LLC
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

Submitter:

O2S, LLC
1500 Spring Garden Street
Philadelphia, PA 19130

Contact Person:

David E. Petko, P.E.
1500 Spring Garden Street
Philadelphia, PA 19130
Telephone: 215-299-8742
Fax: 215-299-2273
david.petko@o2soxygensystems.com

Summary Preparation Date:

May 8, 2012

2. Names

Device Name:

OxyBand™ Wound Dressing

Classification Name:

Dressing, wound and burn, occlusive

3. Predicate Devices

This device is the exact same device previously approved for our partner OxyBand Technologies, Inc. This device has previously been cleared for marketing under the OxyBand Technologies, Inc. 510(k), number K04063. O2S is filing its own 510(k) application, because O2S plans to produce and sell the same wound dressing to Governmental customers, and will assume the responsibilities of "product owner" under a new O2S 510(k). OxyBand Technologies, Inc. has retained the exclusive right to produce and sell these wound dressing products to non-Governmental customers, and will need to retain the OxyBand Technologies, Inc. original 510(k) for that purpose. See Appendix 2.

The O2S – OxyBand™ Wound Dressing is substantially equivalent to the predicate device and introduces no new indications for use. In addition, the requested indications meet the requirements listed in the "FDA Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing" dated March 31, 1995.

4. Device Description

The OxyBand™ Wound Dressing is made up of a thin polyurethane film commonly used in other wound dressings, with adhesive that seals around the wound at the perimeter of the dressing. An occlusive oxygen barrier film is sealed over the polyurethane film to hold a layer of oxygen over the high oxygen permeability polyurethane film.

510(k) Information

5. Indications for Use

OxyBand™ Wound Dressings are intended to provide a moist, oxygen rich 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. Common applications include: 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 9 2012

O2S, LLC
% Mr. David Petko, P.E.
1500 Spring Garden Street
Philadelphia, Pennsylvania 19130

Re: K121407
Trade/Device Name: O2S OxyBand™ Wound Dressing
Regulation Class: Unclassified
Product Code: FRO
Dated: June 21, 2012
Received: June 25, 2012

Dear Mr. Petko:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121407

Device Name: O2S OxyBand™ Wound Dressing

Indications for Use:

O2S OxyBand™ Wound Dressings assist in managing wound healing. O2S OxyBand™ Wound Dressings can be used to protect light to moderate wounds including skin tears, scrapes, minor pressure sores, abrasions, blisters, lacerations, and minor burns, chafed or irritated skin.

Prescription Use_____ AND/OR Over-The-Counter Use_____X
(Part21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121407

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Prescription Use X AND/OR Over-The-Counter Use
(Part21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
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