

K061711

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Attachment 4 (Modified 18 July 2006)

SPECIAL 510(K) SUMMARY

JUL 19 2006

Submitted By: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn,
VP Quality Assurance & Regulatory Affairs
Tel: (765) 497-3355
Fax: (765) 497-2361
July 18, 2006

Names of Device:

Trade Name: OASIS[®] Wound Matrix
Common/Usual Name: Animal-derived, extracellular matrix wound care product
Classification:

Unclassified

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended Use:

The OASIS[®] Wound Matrix device's intended use is for the management of wounds including:

- **partial and full-thickness wounds,**
- **pressure ulcers,**
- **venous ulcers,**
- **diabetic ulcers,**
- **chronic vascular ulcers,**
- **tunneled/undermined wounds,**
- **surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence),**
- **trauma wounds (abrasions, lacerations, second-degree burns, and skin tears),**
- **draining wounds.**

The device is supplied sterile and is intended for one-time use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2006

Cook Biotech, Inc.
% Mr. Perry W. Guinn
Vice President, Quality Assurance
and Regulatory Affairs
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K061711
Trade/Device Name: Oasis Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 16, 2006
Received: June 19, 2006

Dear Mr. Guinn:

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.

Page 2 -- Mr. Perry W. Guinn

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with some initials and a small mark below the name.

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

Enclosure

K061711

Indications for Use

510(k) Number (if known): K061711

Device Name: Oasis Wound Matrix

Indications For Use:

The Oasis Wound Matrix is intended for the management of wounds including:

- Partial and full thickness wounds;
 - Pressure ulcers;
 - Venous ulcers;
 - Diabetic ulcers;
 - Chronic vascular ulcers;
 - Tunneled, undermined wounds;
 - Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence);
 - Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears);
 - Draining wounds.

The device is intended for one-time use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Puchner for MCM

(Division Sign-Off)

**Division of General, Restorative
and Neurological Devices**

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