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Kensey Nash

510(k) Summary

Submitted by: Kensey Nash Corporation
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Date Prepared: February 8, 2012
510(K) #: K112888

Device:
Trade Name: Meso Wound Matrix
Common/Usual Name: Wound Dressing
Proposed Classification: KGN, unclassified

Device Description:
Meso Wound Matrix is composed of porcine collagen from peritoneum tissue. It is an absorbent, white to off- white material supplied as sheet. The device is packaged sterile in a double-layer package.

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Intended Use: Meso Wound Matrix is intended for the management of topical wounds including:

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

Predicate Device:

Manufacturer	**Device**	**510(k)**
Cook Biotech, Inc.	Oasis Wound Matrix	K061711

Technological Characteristics:

Meso Wound Matrix is technologically identical to the cleared KN ECM Surgical Patch (K094061). Like KN ECM Surgical Patch, Meso Wound Matrix consists of terminally sterilized processed lyophilized porcine peritoneum provided in various sizes and packaged in a double layer package.

Performance Data:

Meso Wound Matrix has undergone biocompatibility, hydration, animal, and viral inactivation testing. The following biocompatibility tests were conducted on the finished device according to the requirements of ISO 10993-1:2003, Biological evaluation of medical devices – Part 1:Evaluation and testing. : Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Sub-Chronic Toxicity, Genotoxicity, Implantation, Pyrogenicity and Hemocompatibility.

Substantial Equivalence:

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Based on the material, biocompatibility, bench, and animal testing, and the proposed device labeling, Meso Wound Matrix is substantially equivalent to the identified predicate device in terms of intended use, technological characteristics and principles of operation pursuant to section 510(k).

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

FEB 10 2012

Kensey Nash Corporation
% Ms. Lori Burns, MS, RAC
Manager, Regulatory Affairs
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K112888
Trade/Device Name: Meso Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 30, 2012
Received: February 01, 2012

Dear Ms. Burns:

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

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Indications for Use

510(k) Number (if known): _K112888__

Device Name: Meso Wound Matrix_____

Indications for Use:

Meso Wound Matrix is a resorbable porcine mesothelium derived product intended for the management of topical 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), and draining wounds.

The device is intended for one time use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kessler for MXM

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

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