510(k) Summary

Submitted by: Kensey Nash Corporation
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Date Prepared: May 20, 2009
510(K) #: **K091499**

Device:
Trade Name: Medeor™ Matrix
Common/Usual Name: Surgical Mesh
Proposed Classification: 21 CFR 878.3300, FTM, Class II

Device Description:
Medeor™ Matrix is a resorbable porcine-dermis-derived collagen surgical mesh intended for reinforcement of soft tissues. The device is supplied sterile in double-layer peel-open packages. The product is either packaged dry (lyophilized) to be hydrated prior to use, or can be supplied pre-hydrated, packaged and sterilized in saline.

Predicate Devices:

Manufacturer	Device	510(k)#
Kensey Nash Corporation	BioBlanket™	K061030
LifeCell	Strattice™	K080353

Substantial Equivalence:
Performance Testing has confirmed that Medeor Matrix is substantially equivalent to the predicate devices with regard to materials, intended use, and technological characteristics, pursuant to section 510(k).

Intended Use:

Medeor™ Matrix is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but not limited to; defects of the thoracic wall, suture line reinforcement, and muscle flap reinforcement; urogynecological surgical reinforcement including but not limited to, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernia repair; soft tissue reconstructive procedures including plastic and reconstructive surgical applications, and for reinforcement of the soft tissues, which are repaired by suture or suture anchors, including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons.

Medeor Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures, used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

Medeor Matrix is intended for one time use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 22 2009

Kensey Nash Corporation
% Ms. Alyssa J. Schwarts, MS, RAC
Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K091499
Trade/Device Name: Medeor™ Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: October 12, 2009
Received: October 13, 2009

Dear Ms. Schwarts:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

For Peter R. Rumm
Dep Dir

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

Enclosure

Kensey Nash

Indications For Use Statement

510(k) Number: K091499

Device Name: Medeor™ Matrix

Indications For Use:

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Medeor Matrix is intended for one time use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

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

510(k) Number K091499