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510(k) Summary

Submitted by: Kensey Nash Corporation dba DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Lori Burns, MS, RAC
Manager Regulatory Affairs
Ph: (484) 713-2100
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Date Prepared: June 13, 2014
510(K) #: K094061

Device:
Trade Name: Kensey Nash ECM Surgical Patch
Common/Usual Name: Surgical Mesh
Proposed Classification: 21 CFR 878.3300
FTM, OXH, OXE, PAJ, PAG
Class II

Device Description:
The Kensey Nash ECM Surgical Patch is a resorbable porcine-peritoneum-derived collagen surgical mesh intended for reinforcement of soft tissues. The device is supplied sterile in double-layer packages. The product is packaged dry (lyophilized) to be hydrated prior to use.

Predicate Devices:

Manufacturer	Device	510(k)#
Cook, Inc.	SurgiSiS	K992159
Cook, Inc.	SurgiSiS	K034039
Cook, Inc.	SurgiSiS	K062697
Organogenesis Inc.	FortaFlex	K011025
Organogenesis Inc.	FortaFlex	K020049

Intended Use:
The Kensey Nash ECM Surgical Patch is intended for implantation to reinforce soft tissues where weakness exists in patients requiring soft tissue repair, reinforcement in plastic and reconstructive surgery, and in the urological, gynecological (excluding transvaginal repair of pelvic organ prolapse), and gastroenterological anatomy including but not limited to the following procedures: reinforcement of primary closure such as suture line reinforcement and muscle flap reinforcement; hernia repair (e.g., hiatal, femoral, paracolostomy, umbilical), urethral and vaginal prolapse repair (excluding transvaginal repair of pelvic organ prolapse), colon prolapse repair, rectal prolapse repair (excluding rectocele) using an abdominal approach, reconstruction of the pelvic floor using an abdominal approach (excluding transvaginal repair of pelvic organ prolapse), bladder support, and sacrocolposuspension.

The Kensey Nash ECM Surgical Patch is supplied sterile and intended for one time use.

Performance Data:
Mechanical testing performed with KN ECM demonstrated equivalence of the device to legally marketed predicate devices. Mechanical test reports were completed for the following:

- Tensile Testing

- Suture Retention

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, Intracutaneous Reactivity, Systemic Toxicity, Sub-Chronic Toxicity, Genotoxicity, Implantation, Pyrogenicity and Hemolysis.

The device was evaluated in two *in vivo* studies; defects were repaired and evaluated in a sheep model and a rabbit study was performed to evaluate tissue reactions.

The Kensey Nash ECM Surgical Patch passed the requirements of all tests.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 16, 2014

Kensey Nash Corporation d.b.a. DSM Biomedical
Ms. Lori Burns
Manager, Regulatory Affairs
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K094061
Trade/Device Name: Kensey Nash ECM Surgical Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXE, OXH, PAG, PAJ
Dated: April 29, 2010
Received: April 30, 2010

Dear Ms. Burns:

This letter corrects our substantially equivalent letter of May 18, 2010.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K094061

Device Name
Kensey Nash ECM Surgical Patch

Indications for Use *(Describe)*
The Kensey Nash ECM Surgical Patch is intended for implantation to reinforce soft tissues where weakness exists in patients requiring soft tissue repair, reinforcement in plastic and reconstructive surgery, and in the urological, gynecological (excluding transvaginal repair of pelvic organ prolapse), and gastroenterological anatomy including but not limited to the following procedures: reinforcement of primary closure such as suture line reinforcement and muscle flap reinforcement; hernia repair (e.g., hiatal, femoral, paracolostomy, umbilical), urethral and vaginal prolapse repair (excluding transvaginal repair of pelvic organ prolapse), colon prolapse repair, rectal prolapse repair (excluding rectocele) using an abdominal approach, reconstruction of the pelvic floor using an abdominal approach (excluding transvaginal repair of pelvic organ prolapse), bladder support, and sacrocolposuspension.

The Kensey Nash ECM Surgical Patch is supplied sterile and intended for one time use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."