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DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341 USA

www.dsm.com/medical

510(k) SUMMARY

Submitted By: DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Susan Pileggi
Regulatory Specialist
E: Susan.Pileggi@dsm.com
P: 484-713-2100
F: 484-713-2903

OCT 30 2013

Date Prepared: May 28, 2013

Device:

Trade Name:	**Meso Bilayer Surgical Mesh**
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical
Classification Regulation:	21 CFR 878.330
Device Class:	Class II
Device Code:	FTM, OXH
Advisory Panel:	General and Plastic Surgery

Predicate: K094061: Kensey Nash ECM Surgical Patch [Kensey Nash Corporation]

Device Description:

Meso Bilayer Surgical Mesh is a resorbable surgical mesh intended to reinforce soft tissue where weakness exists. The implant is derived from porcine tissue and a synthetic absorbable polymer. The material is supplied sterile in double-layer packages. The implant is packaged dry and prior to use is hydrated with saline or autologous body fluids such as blood, bone marrow aspirate, or blood concentrates such as platelet rich plasma.

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Intended Use:

Meso Bilayer Surgical Mesh is intended for implantation to reinforce soft tissues where weakness exists in patients requiring soft tissue repair and reinforcement in plastic and reconstructive surgery 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.)

Meso Bilayer Surgical Mesh is supplied sterile and for one time use.

Technological Characteristics:

The intended use, product design, material, and function of Meso Bilayer Surgical Mesh is substantially equivalent to the FDA cleared predicate device Kensey Nash ECM Surgical Patch (K094061).

Characteristic	Meso Bilayer Surgical Mesh	Kensey Nash ECM Surgical Patch
Indications for Use	Meso Bilayer Surgical Mesh is intended for implantation to reinforce soft tissues where weakness exists in patients requiring soft tissue repair and reinforcement in plastic and reconstructive surgery 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.) Meso Bilayer Surgical Mesh is supplied sterile and for one time 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, 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, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, and sacrocolposuspension. The device is supplied sterile and intended for one time use.

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Characteristic	Meso Bilayer Surgical Mesh	Kensey Nash ECM Surgical Patch
Origin	Porcine tissue	Porcine tissue
Device Characteristics	Resorbable double layer surgical mesh	Resorbable single layer surgical mesh
Biocompatibility	Yes	Yes
Reusable	Single Use Device	Single Use Device
Shelf Life	6 months	36 months
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Packaging	Double peel packages	Double peel packages

Biocompatibility and Performance Data:

Biocompatibility testing, biomechanical bench testing, characterization testing and in vivo performance testing have been conducted to evaluate the biological safety and biomechanical performance characteristics of Meso Bilayer Surgical Mesh.

Biocompatibility testing was completed on the finished sterile device in accordance with the requirements of *ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.* Testing included Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Genotoxicity, Hemocompatibility, Subacute Systemic Toxicity, and Chronic Systemic Toxicity. Other safety testing included a viral inactivation study and residual chemical assessment. Results indicate that the device's biocompatibility profile is acceptable.

Biomechanical testing included tensile strength burst testing, wet tear testing, and suture retention. Testing results indicate that the device is equivalent to the predicate device and meets the requirements for its intended use.

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Animal implant studies were performed to confirm the functionality and tissue response characteristics of proposed device. Results indicate a normal tissue healing response and confirm the device's remodeling capability.

Substantial Equivalence:

Performance testing has confirmed that the Meso Bilayer Surgical Mesh is substantially equivalent to the predicate device with regard to materials, intended use, operation, and function, 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

Kensey Nash Corporation dba DSM Biomedical
Ms. Susan Pileggi
Regulatory Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

October 30, 2013

Re: K132025
Trade/Device Name: Meso Bilayer Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXH
Dated: October 17, 2013
Received: October 18, 2013

Dear Ms. Pileggi:

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 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. 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 -S

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

Enclosure

Indications For Use Statement

510(k) Number: K132025

Device Name: Meso Bilayer Surgical Mesh

Indications For Use:

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Meso Bilayer Surgical Mesh is supplied sterile and for one time use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132025