K133169

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DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341 USA

www.dsm.com/medical

## 510(k) SUMMARY

DEC 20 2013

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

**Contact Person:** Brianna Jordan
Regulatory Specialist
E: Brianna.Jordan@dsm.com
P: 484-713-2608
F: 484-713-2903

**Date Prepared:** October 2, 2013

**Device:**

| | |
|---|---|
| Trade Name: | **Meso Tendon Matrix** |
| Common/Usual Name: | Surgical Mesh |
| Classification Name: | Mesh, Surgical |
| Classification Regulation: | 21 CFR 878.3300 |
| Device Class: | Class II |
| Device Code: | OWY |
| Advisory Panel: | General and Plastic Surgery |

**Predicate:** K103787: Medeor Matrix [Kensey Nash Corporation]

**Device Description:**

Meso Tendon Matrix is a resorbable surgical mesh intended to reinforce soft tissue where weakness exists. The implant is derived from porcine mesothelium tissue. 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 Tendon Matrix is intended for use in sports medicine procedures for the reinforcement and repair of soft tissue where weakness exists including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons. Meso Tendon 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.

Meso Tendon Matrix is supplied sterile and for one time use.

**Technological Characteristics:**

The product design and function of Meso Tendon Matrix is substantially equivalent to the FDA cleared predicate device Medeor Matrix (K103787). Meso Tendon Matrix is identical regarding material composition to Kensey Nash ECM Surgical Patch (K094061), cleared May 10, 2010.

| Characteristic | Meso Tendon Matrix | Medeor Matrix (K103787) |
|---|---|---|
| Indications for Use | Meso Tendon Matrix is intended for use in sports medicine procedures for the reinforcement and repair of soft tissue where weakness exists including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons. Meso Tendon 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, | 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; hernia repair; soft tissue reconstructive procedures including plastic and reconstructive surgical applications and for reinforcement of the soft tissues, |

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| Characteristic | Meso Tendon Matrix | Medeor Matrix (K103787) |
|---|---|---|
| | 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. Meso Tendon Matrix is supplied sterile and for one time use. | which are repaired by suture or suture anchors, including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons. The device is not intended to replace normal body structure to 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. The device is provided sterile and for one time use. |
| **Origin** | Porcine tissue | Porcine tissue |
| **Device Characteristics** | Resorbable single layer surgical mesh | Resorbable single layer surgical mesh |
| **Biocompatibility** | Yes | Yes |
| **Reusable** | Single Use Device | Single Use Device |
| **Shelf Life** | 24 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 Tendon Matrix.

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. Testing results indicate that the device is equivalent to the predicate device and meets the requirements for its intended use.

Animal implant studies were performed to confirm the functionality and tissue response characteristics of the 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 Tendon Matrix is substantially equivalent to the predicate device Medeor Matrix (K103787) with regard to material, intended use, principles of operation, 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. Brianna Jordan
Regulatory Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

December 20, 2013

Re: K133169
Trade/Device Name: Meso Tendon Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWY
Dated: October 2, 2013
Received: October 31, 2013

Dear Ms. Jordan:

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,

Joshua C. Nipper -S

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

Enclosure

# Indications for Use

510(k) Number: **K133169**

Device Name: Meso Tendon Matrix

Indications For Use:

Meso Tendon Matrix is indicated for use in sports medicine procedures for the reinforcement and repair of soft tissue where weakness exists including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons.

Meso Tendon 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.

Meso Tendon Matrix 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: K133169