K061030

510(k) Summary

MAY - 9 2006

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

Contact Person: Deborah A. Racioppi, RA Compliance Manager
Ph: 610-594-4389 Fax: 610-524-0265

Date Prepared: March 22, 2006

510(k) #:

Device:

Trade Name: BioBlanket™ Surgical Mesh

Common/Usual Name: Surgical Mesh, Tissue Repair Biomaterial

Proposed Classification: Surgical Mesh
21 CFR Part 878.3300 (79 FTM) Class II

Device Description:
BioBlanket™ Surgical Mesh is comprised of a single layer porous, cross-linked collagen patch that is supplied sterile and for one-time use.

Intended Use:
BioBlanket™ Surgical Mesh 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, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture line reinforcement and reconstructive procedures. The device is also intended for reinforcement of the soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery. The device is intended for one time use.

Substantial Equivalence:
In terms of Section 510(k) substantial equivalence, BioBlanket™ Surgical Mesh is similar to the predicate collagen-based surgical mesh devices listed below previously cleared for commercial distribution. The BioBlanket™ Surgical Mesh is substantially equivalent in terms of intended use, technological characteristics, performance and material.

Manufacturer	Device	510(k)	ProCode
Kensey Nash Corp.	BioBlanket™ Surgical Mesh	K043259	FTM
Kensey Nash Corp.	BioBlanket™ Surgical Mesh	K041923	FTM

Performance Data:
BioBlanket™ Surgical Mesh has been subjected to biocompatibility, integrity, in-vitro and in-vivo performance tests. The device passed the requirements of all tests.

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
% Ms. Deborah A. Racioppi
RA Compliance Manager
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K061030
Trade/Device Name: BioBlanket™ Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXB, OXE, OXH, OWY, PAI, PAJ
Dated: April 12, 2006
Received: April 14, 2006

Dear Ms. Racioppi:

This letter corrects our substantially equivalent letter of May 9, 2006.

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

Indications For Use Statement

510(k) Number (if known): K061030

Device Name: BioBlanket™ Surgical Mesh

Indications for Use:
BioBlanket™ Surgical Mesh 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, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture line reinforcement and reconstructive procedures. The device is also intended for reinforcement of the soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery. The device is intended for one time use.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061030