K111436

OCT 14 2011

Attachment 8

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

SUBMITTER INFORMATION

a.	Company Name:	Brennen Medical, LLC
b.	Company Address:	1290 Hammond Road St. Paul, MN 55110
c.	Company Phone: Company Facsimile:	(651) 429-7413 (651) 429-8020
d.	Contact Person:	Kenneth B. Herland V.P. Regulatory Affairs/QA
e.	Date Summary Prepared:	September 8, 2011

DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	Porcine Dermal Matrix (TBD)
b.	Regulation Number :	21 CFR 878.3300
c.	Regulation Name :	Surgical Mesh
d.	Device Class :	II
e.	Product Code :	FTM

IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Brennen Medical	Porcine Surgical Mesh	K081272	07/31/2008
Brennen Medical	Porcine Surgical Mesh	K030460	03/07/2003

DEVICE DESCRIPTION

Porcine Dermal Matrix is a prescription, sterile, single use, hydrated, non-crosslinked, porcine skin that has both the epidermal and subdermal sides removed leaving only the dermis. The product is available in several sizes.

SUBSTANTIAL EQUIVALENCE

Porcine Dermal Matrix is substantially equivalent to Brennen's Porcine Dermal Matrix Surgical Mesh. Porcine Dermal Matrix is substantially equivalent in intended use, mode of action, and design to the predicate devices. The size and thickness is basically the same as

the predicate on K030460 and the intended use is identical to the Porcine Surgical Mesh on K081272. The introduction of this product does not raise any new issues of safety or effectiveness.

INTENDED USE

Intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. Specifically indicated for: Plastic and reconstructive surgery; Muscle flap reinforcement; Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias; Suture-line reinforcement; Reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Porcine Dermal 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.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are identical to the predicate devices (Porcine Surgical Mesh and DermMatrix). The following Biocompatability testing was conducted per ISO 10993-1: ISO MEM Elution Assay, Bacterial Mutagenicity Test, ISO Acute Systemic Injection, ISO Guinea Pig Maximization Sensitization, ISO Intracutaneous Reactivity Test, Materials Mediated Rabbit Pyrogen, Eight week Intramuscular Implant, Thirteen Week Intramuscular Implant, Six-Month Intramuscular Implant. The product met all of the stated requirements of each test.

Bench testing has demonstrated that the device is safe and effective for its intended use, and that its performance is substantially equivalent to the predicate devices.

CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission. Test evaluations of Porcine Dermal Matrix show that the device performs as intended and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Brennen Medical, LLC
% Mr. Kenneth B. Herland
VP, RA/QA
1290 Hammond Road
Saint Paul, Minnesota 55110

OCT 14 2011

Re: K111436
Trade/Device Name: Porcine Dermal Matrix Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: October 12, 2011
Received: October 13, 2011

Dear Mr. Herland:

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 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/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,

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

Enclosure

Indications for Use

510(k) Number (if known): K111436

Device Name: Porcine Dermal Matrix Surgical Mesh

Indications for Use:

Intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including but not limited to: Plastic and reconstructive surgery; Muscle flap reinforcement; Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias; Suture-line reinforcement; Reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Porcine Dermal 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, quadraceps, 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.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111436