K113866 page 1/2

MAR 2 3 2012

SECTION 16: 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.

16.1 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:	December 28, 2011

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Porcine Dermal Xenograft (TBD)
b. Regulation Number :	N/A
c. Regulation Name :	Porcine Dermal Xenograft
d. Device Class :	Unclassified
e. Product Code :	KGN

16.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Brennen Medical	Porcine Surgical Mesh	K111436	10/12/2011
Lifecell's	LTM Wound Dressing	K082103	10/08/2008
TEI Biosciences	PriMatrix	K083440	12/12/2008

16.4 DEVICE DESCRIPTION

Porcine Dermal Xenograft is an acellular, sterile, porcine dermal xenograft for use in treatment of topical wounds. The product is available in several sizes.

16.5 SUBSTANTIAL EQUIVALENCE

Porcine Dermal Xenograft is substantially equivalent to TEI's PriMatrix and Lifecells ATM Wound Dressing along with Brennen's Porcine Surgical Mesh. Porcine Dermal Xenograft is equivalent in intended use, mode of action, and design to the predicate devices. The introduction of this product does not raise any new issues of safety or effectiveness.

16.6 INTENDED USE

Porcine Dermal Xenograft is intended for the management of wounds that include: Partial and full thickness wounds; Pressure, diabetic, and venous ulcers; Chronic vascular ulcers; Second-degree burns; Surgical wounds-donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence; Trauma wounds-abrasions, lacerations, and skin tears; Tunneled/undermined wounds; Draining wounds. The Porcine Dermal Xenograft provides an environment that supports wound healing and control of minor bleeding. The device is intended for single patient, one time use only.

16.7 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are identical to the predicate devices (Porcine Surgical Mesh, PriMatrix and LTM Wound Dressing). The ISO 10993-1 required Biocompatibility testing was conducted on the product. 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.

16.8 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 Xenograft 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 Herland
VP Regulatory Affairs/QA
1290 Hammond Road
Saint Paul, Minnesota 55110

MAR 2 3 2012

Re: K113866
Trade/Device Name: Porcine Dermal Xenograft
Regulatory Class: Unclassified
Product Code: KGN
Dated: February 13, 2012
Received: February 14, 2012

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

INDICATION FOR USE

510(k) Number:

Device Name: **Porcine Dermal Xenograft**

Indications for Use: Porcine Dermal Xenograft is intended for the management of wounds that include: Partial and full thickness wounds; Pressure, diabetic, and venous ulcers; Chronic vascular ulcers; Second-degree burns; Surgical wounds-donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence; Trauma wounds-abrasions, lacerations, and skin tears; Tunneled/undermined wounds; Draining wounds. The Porcine Dermal Xenograft provides an environment that supports wound healing and control of minor bleeding. The device is intended for single patient, one time use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Daniel Kanz for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K139666