



Food and Drug Administration  
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July 2, 2015

LifeCell Corporation  
Ms. Linda Scamardella  
Regulatory Affairs Specialist  
One Millennium Way  
Branchburg, New Jersey 08876

Re: K150712  
Trade/Device Name: LTM-Perforated Surgical Mesh  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: Class II  
Product Code: FTM  
Dated: June 3, 2015  
Received: June 4, 2015

Dear Ms. Scamardella:

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" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

K150712

Device Name

LTM-Perforated Surgical Mesh

Indications for Use (Describe)

LTM-Perforated Surgical Mesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

LTM-Perforated Surgical Mesh is intended for single patient one-time use only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

### 1. SUBMITTER

#### Name and Address of Submitter

LifeCell Corporation  
One Millennium Way  
Branchburg, NJ 08876

#### Contacts:

Linda Scamardella  
Regulatory Affairs Specialist  
Phone: (908) 947-1661  
Fax: (908) 947-1095

Mira Leiwant  
Director, Quality Engineering and Regulatory Affairs  
Phone: (908) 809-7747  
Fax: (908) 947-1095

#### Prepared by and Date:

Linda Scamardella  
March 18, 2015

### 2. DEVICE

Name of Device:	LTM-Perforated Surgical Mesh
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh (21 C.F.R. §878.3300)
Device Class:	Class II
Product Code:	FTM

### 3. PREDICATE DEVICE

#### Predicate Device:

LTM-Surgical Mesh (K070560) - LifeCell Corporation  
This predicate has not been subject to a design-related recall

#### Reference Devices:

Biodesign® Hernia Graft, Cook Medical (K974540)  
Collamend™ FM Implant, Davol Inc. - subsidiary of C.R. Bard (K082687)  
SurgiMend™ e, TEI Biosciences Inc. (K083898)

#### **4. DEVICE DESCRIPTION**

LTM-Perforated Surgical Mesh is a surgical mesh that is derived from porcine dermis and then processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers. The device is designed to perform as a surgical mesh for soft tissue repair. The device consists of a terminally sterilized sheet of processed porcine dermal matrix provided in prescribed geometric configurations and thicknesses. The device is packaged in a double pouch configuration, and is sterilized via electron beam irradiation. The device is considered a single use device which is to be used in a healthcare facility or hospital.

The subject device shares the same underlying scientific design as a porcine derived acellular dermal matrix, and has the same Intended Use, Indications for Use, and principles of operation as the cleared predicate device, LTM-Surgical Mesh (K070560). This 510(k) premarket notification describes a new design feature of the subject device, which introduces a pre-defined pattern of perforations throughout the tissue matrix.

#### **5. INDICATIONS FOR USE**

LTM-Perforated Surgical Mesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and /or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

LTM-Perforated Surgical Mesh is intended for single patient one-time use only.

#### **6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The subject device, LTM-Perforated Surgical Mesh, and the predicate device, LTM-Surgical Mesh (K070560), are both derived from porcine dermis and then processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers. The material type for both devices can be described as a porcine acellular dermal matrix. Both devices consist of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and thicknesses. Both are packaged in a double pouch configuration and sterilized via electron beam irradiation.

The subject device, LTM-Perforated, and the predicate device, LTM-Surgical Mesh (K070560) share the same underlying scientific design as a porcine derived acellular dermal matrix, and have the same Intended Use, Indications for Use, and principles of operation. The predicate introduces a new design feature, a pre-defined pattern of perforations in the tissue matrix. The spacing and size of the perforations were specifically designed to maintain mechanical properties and meet the same established performance specifications as the predicate device, LTM-Surgical Mesh. The subject device utilizes the existing manufacturing processes of the predicate LTM-Surgical Mesh. Perforations are added to the tissue during the final die cutting stage at the time the device is cut to its final dimensions.

## 7. PERFORMANCE

The predicate device, LTM-Surgical Mesh (K070560) has undergone appropriate biocompatibility testing, animal testing, and viral inactivation testing. The data demonstrates that the device is biocompatible and that the manufacturing process is capable of viral inactivation. The subject device, LTM- Perforated Surgical Mesh and the predicate device, LTM-Surgical Mesh (K070560) utilize the same raw materials (porcine dermis), processing components/solutions and manufacturing processes, and are identical except for the presence of perforations. Therefore, no further biocompatibility testing, animal testing, or viral inactivation testing was performed given that the presence of perforations does not change the biochemical or material properties of the surgical mesh.

### **Bench Testing:**

Bench testing was performed on the subject LTM-Perforated Surgical Mesh device to support substantial equivalence. Testing and/or evaluations included relevant elements of the FDA “*Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh*” issued March 2, 1999. **Table 1** includes the applicable product characterization criteria used to demonstrate substantial equivalence.

<b>Table 1: Substantial Equivalence Criteria</b>	
Bench Testing /Evaluation	Applicable Standard
Mesh Thickness	N/A
Tensile Strength	N/A
Device Stiffness	N/A
Suture Pull-Out Strength	N/A
Tear Resistance	ASTM D5735-95
Burst Strength	ASTM D6797-07

Performance data demonstrates that LTM-Perforated maintains similar mechanical properties and meets the established specifications as the predicate device. In addition, the LTM-Perforated Surgical Mesh shares the technological characteristics of perforations with other legally marketed reference devices. This new technological characteristic does not affect safety and efficacy of the device or raise new questions of safety or efficacy. LTM-Perforated Surgical Mesh meets the requirements to perform its intended use as a soft tissue patch and is substantially equivalent to the predicate device, LTM-Surgical Mesh (K070560).

### **Clinical Testing:**

No clinical testing was included in this submission.

## 8. CONCLUSIONS

The subject device, LTM-Perforated Surgical Mesh, meets the requirements to perform its intended use as a soft tissue patch and is substantially equivalent to the legally marketed predicate device, LTM-Surgical Mesh (K070560).