K130817 page 1/2

APR 17 2013

510(k) Summary
LTM-Laparoscopic Surgical Mesh

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Contact Person:
John Blewitt
Senior Regulatory Affairs Associate
Phone: (908) 947-1432
Fax: (908) 947-1095

Date Prepared:
March 21, 2013

Name of Device and Name and Address of Sponsor
LTM-Laparoscopic Surgical Mesh—Strattice Reconstructive Tissue Matrix (RTM)
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Common or Usual Name
Surgical Mesh

Classification Name
Surgical Mesh—(21 C.F.R. §878.3300)

Device Class
II

Product Code
OXK, FTM

Predicate Devices
LTM-Laparoscopic Surgical Mesh (K121289)—LifeCell Corporation

Intended Use/ Indications for Use

LTM-Laparoscopic 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 during open or laparoscopic procedures.

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

Device Description and Technological Characteristics

LTM-Laparoscopic Surgical Mesh is a surgical mesh that is derived from porcine dermis and is processed and preserved in a phosphate buffered aqueous solution containing matrix stabilizers. This device is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient. The device consists of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and thicknesses and is packaged in a double pouch configuration. The proposed device has the same scientific technology, principles of operation, Intended Use, and Indications for Use as the cleared predicate device, LTM-Laparoscopic Surgical Mesh (K121289).

The only change described in this submission is a minor modification to the Instructions for Use. There have been no changes made to the physical LTM-Laparoscopic Surgical Mesh device. The Instructions for Use have been modified to describe fixation of the device by sutures and surgical tacks, according to surgeon preference. The Instructions for Use previously provided as part of the cleared predicate device (K121289) described suturing LTM-Laparoscopic Surgical Mesh into position.

Performance Data

The addition of language in the device Instructions for Use describes fixation the device using sutures and surgical tacks. Additional validation of the design was performed to ensure fixation using surgical tacks could be achieved. Testing included laparoscopic fixation of LTM-Laparoscopic Surgical Mesh by surgical tacks under simulated conditions, and the results have demonstrated that this method of fixation did not affect safety and efficacy of the device or raise any new questions of safety or efficacy .Thus, the proposed LTM-Laparoscopic Surgical Mesh continues to perform its intended use as a soft tissue patch to reinforce soft tissue where weakness exists and for the repair of damaged or ruptured soft tissue membranes and is substantially equivalent to the predicate device LTM-Laparoscopic Surgical Mesh (K121289).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

LifeCell Corporation
% Mr. John Blewitt
Senior Regulatory Affairs Associate
One Millennium Way
Branchburg, New Jersey 08876

April 17, 2013

Re: K130817
Trade/Device Name: LTM – Laparoscopic Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXK, FTM
Dated: March 22, 2013
Received: March 25, 2013

Dear Mr. Blewitt:

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

Peter D. Rumm -S

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

Enclosure

510(k) Number (if known): K130817

Device Name: LTM-Laparoscopic Surgical Mesh

Indications For Use:

LTM-Laparoscopic 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 during open or laparoscopic procedures.

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

Prescription Use (21 CFR Part 801 Subpart D)	_XX_	AND/OR	Over the Counter Use 21 CFR Part 801 Subpart C	___

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

___Concurrence of CDRH, Office of Device Exemption (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130817