K080353
Page 1/2

510(K) SUMMARY

LifeCell Corporation's LTM Surgical Mesh

APR - 3 2008

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

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876
Phone: (908) 947-1115
Facsimile: (908) 947-1095

Contact Person: Lorraine T. Montemurro, R.N., R.A.C.
Date Prepared: February 08, 2008

Name of Device and Name/Address of Sponsor

LTM Surgical Mesh

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Common or Usual Name

Surgical Mesh

Classification Name

Surgical Mesh

Classification

Class II

Product Code

FTM

Predicate Devices

LifeCell Corporation's LTM Surgical Mesh (K070560)
Pegasus Biologics, Inc.'s OrthADAPT™ (K071065)

Intended Use / Indications for Use

The LifeCell Tissue Matrix (LTM) Surgical Mesh is intended for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Indications for use also include the repair of body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

The device 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. 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.

LTM is intended for single patient, one time use only.

Technological Characteristics

The LTM is a surgical mesh that is derived from porcine skin. The LTM device consists of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and thicknesses, and packaged in double pouch configuration.

Performance Data

The LTM has undergone extensive biocompatibility testing, animal testing, viral inactivation testing, and biomechanical testing. The data indicate that the device is biocompatible and that the manufacturing process is capable of inactivating any viral components that may come with the starting material. The biomechanical data show that the LTM matrix possesses sufficient strength and suture retention for the intended use.

Substantial Equivalence

LTM is substantially equivalent to the legally marketed predicate devices, LifeCell Corp.'s LTM Surgical Mesh (K070560) and Pegasus Biologics, Inc.'s OrthADAPT™ (K071065) surgical mesh devices. LTM has the same intended uses and the same or similar indications, technological characteristics, and principles of operation as these predicate devices. Performance data demonstrate that LTM functions equivalently to the predicate devices. Thus, LTM is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LifeCell Corporation
% Ms. Lorraine T. Montemurro, R.N., R.A.C.
Manager, Regulatory Affairs
One Millennium Way
Branchburg, New Jersey 08876-3876

APR - 3 2008

Re: K080353
Trade/Device Name: LTM Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 8, 2008
Received: February 11, 2008

Dear Ms. Montemurro:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080353

Device Name: LTM Surgical Mesh

Indications for Use:

The LifeCell Tissue Matrix (LTM) Surgical Mesh is intended for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Indications for use also include the repair of body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

The device 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. 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.

LTM is intended for single patient, one time use only.

Prescription Use X (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil A.P. Ogden for MXM

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

510(k) Number K080353