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OCT 0 8 2008

III. 510(K) SUMMARY

LifeCell Corporation's LTM Wound Dressing

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

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Phone: (908) 947-1131
Facsimile: (908) 947-1095

Contact Person: Manal Morcos

Date Prepared: July 24, 2008

Names of Device and Name/Address of Sponsor:

LTM Wound Dressing
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Common or Usual Name

Collagen Wound Dressing

Classification Name

Dressing, Wound, Collagen

Classification:

Unclassified

Product Code:

KGN

Predicate Devices:

Pegasus Biologics, Inc. – Unite Biomatrix (K071425)
LifeCell Corporation – LTM Surgical Mesh (K070560)

Intended Use / Indications for Use

The LTM Wound Dressing is intended for the management of wounds including:

- Partial and full thickness wounds;
- Pressure ulcers;
- Venous ulcers;
- Diabetic ulcers;
- Chronic vascular ulcers;
- Tunneled/undermined wounds;
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence);
- Trauma wounds (abrasions, lacerations, second-degree burns and skin tears);
- Draining wounds
- And other bleeding surface wounds.

The LTM Wound Dressing provides an environment that supports wound healing and control of minor bleeding.

The device is intended for single patient, one time use only.

Technological Characteristics

The LTM Wound Dressing device is identical in materials and construction to the Company's recently cleared LTM Surgical Mesh (K070560). Like the LTM Surgical Mesh, LTM Wound Dressing consists of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and thickness, and packaged in a double pouch configuration.

Performance Data

LifeCell's LTM Wound Dressing is technologically identical to the cleared LTM Surgical Mesh (K070560). The LTM Surgical Mesh has undergone extensive biocompatibility testing, animal testing, viral inactivation testing, and biomechanical testing. The data indicates that the device is biocompatible and that the manufacturing process is capable of inactivating any viral components that may come with the starting material. In all instances, the LTM Surgical Mesh functioned as intended and the performance observed was as expected. As LTM Wound Dressing is the exact same device technologically as the LTM Surgical Mesh, the Company submits that testing conducted on the LTM Surgical Mesh is equally applicable to the LTM Wound Dressing.

Substantial Equivalence

The LifeCell LTM Wound Dressing is as safe and as effective as the legally marketed predicate devices, Pegasus Biologics, Inc.'s Unite Biomatrix (K071425), and LifeCell Corporation's LTM Surgical Mesh (K070560). The LifeCell LTM Wound Dressing has the same intended uses and the same or similar indications, technological characteristics, and principles of operation as its predicate devices. Performance data demonstrates that LifeCell's LTM Wound

Dressing is as safe and effective as the predicate device. Thus, LifeCell's LTM Wound Dressing is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

LifeCell Corporation
% Manal Morcos
Manager, Regulatory Affairs
One Millenium Way
Branchburg, New Jersey 08876

Re: K082103
Trade/Device Name: LTM Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 24, 2008
Received: July 25, 2008

Dear Manal Morcos:

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

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

Enclosure

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II. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082103

Device Name: LTM Wound Dressing

Indications for Use:

The LTM Wound Dressing is intended for the management of wounds including:

- Partial and full thickness wounds;
- Pressure ulcers;
- Venous ulcers;
- Diabetic ulcers;
- Chronic vascular ulcers;
- Tunneled/undermined wounds;
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- And other bleeding surface wounds.

The LTM Wound Dressing provides an environment that supports wound healing and control of minor bleeding.

The device 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)

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

510(k) Number K082103