K061208

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I. 510(K) SUMMARY

LifeCell Dural Substitute Matrix

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

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08869

Phone: (908) 947-1114
Facsimile: (908) 947-1095

Contact Person: Rey Librojo

Date Prepared: April 28, 2006

Name of Device and Name/Address of Sponsor

LifeCell Dural Substitute Matrix

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Common or Usual Name

Dura Substitute

Device Classification

Class II

Regulation Number

21CFR § 882.5910

Product Code:

GXQ

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Classification Name

Dura Substitute

Predicate Devices

Integra LifeSciences' DuraGen® Dural Regeneration Matrix (K043427)
Bio-Vascular's DuraGuard® Dural Repair Patch (K982282)

Intended Use / Indications for Use

LifeCell Dural Substitute Matrix is indicated as a dural substitute for the repair of dura mater.

Technological Characteristics

The LifeCell Dural Substitute Matrix, like the predicate devices made from a biological material, is made from donated human cadaver skin. The donated allograft human dermis is processed to remove cells and freeze-dried to remove moisture while preserving the general structure of the dermal matrix. The LifeCell Dural Substitute Matrix is terminally sterilized using e-beam irradiation and packaged in a double-pouch configuration. The freeze-dried matrix is rehydrated prior to implantation. After implantation, the graft is revascularized and repopulated with cells. The LifeCell Dural Substitute Matrix is packaged in a double-pouch configuration – an inner (Tyvek) peel-pouch and an outer foil pouch.

Performance Data

The mechanical and preclinical animal testing has demonstrated that the LifeCell Dural Substitute Matrix will meet its intended function as a dura substitute. Clinical data has shown that it is an adequate dura substitute used for the repair of dura mater.

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Substantial Equivalence

The LifeCell Dural Substitute Matrix is as safe and effective as the DuraGen Dural Regeneration Matrix and the DuraGuard Dural Repair Patch. The LifeCell Dural Substitute Matrix has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The technological difference between the LifeCell Dural Substitute Matrix and its predicate devices raises no new issues of safety or effectiveness. Performance data demonstrates that the LifeCell Dural Substitute Matrix is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LifeCell Corporation
% Mr. Rey Librojo
Manager, Regulatory Affairs
One Millenium Way
Branchburg, New Jersey 08876

JAN - 3 2007

Re: K061208
Trade/Device Name: LifeCell Dural Substitute Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura substitute
Regulatory Class: II
Product Code: GXQ
Dated: October 13, 2006
Received: October 16, 2006

Dear Mr. Librojo:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K061208

I. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K061208

Device Name: LifeCell Dural Substitute Matrix

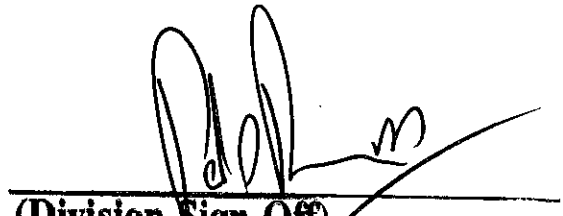
Indications for Use:

LifeCell Dural Substitute Matrix is indicated as a dural substitute for the repair of dura mater.

Prescription Use ✓ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (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 K061208