K052735

DEC 2 8 2005

510(K) SUMMARY

LifeCell Corporation's AlloCraft™ DBM

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

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08869

Phone: (908) 947-1115
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Contact Person: Lorraine T. Montemurro

Date Prepared:December 14, 2005,

Name of Device and Name/Address of Sponsor

AlloCraft™ DBM

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08869

Common or Usual Name

Bone graft material

Classification

Class II

Regulation Number

21 CFR §888.3045

Product Codes

MBP and MQV

Classification Name

Resorbable calcium salt bone void filler

Predicate Devices

Musculoskeletal Transplant Foundation's DBX® Demineralized Bone Matrix
Wright Medical's AlloMatrix®
Exactech's Resorbable Bone Paste

Intended Use / Indications for Use

AlloCraft is intended for use as bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. AlloCraft can be used to fill bone voids in the posterolateral spine. It is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury.

AlloCraft is intended for single patient use only.

Technological Characteristics

AlloCraft, like all bone graft materials containing demineralized bone matrix, is a bone void filler that may be packed or placed within osseous defects that are not intrinsic to the stability of the bony structures. AlloCraft is packaged in two separate syringes, one containing the demineralized bone matrix and a second containing acellular dermal matrix resuspended in sterile saline. When mixed, the two tissues form a putty-like mixture that can be molded or handled by the surgeon, or placed directly into the osseous defect site.

Performance Data

LifeCell has assessed the osteoconductive and osteoinductive properties of AlloCraft in valid animal models. The Company also establishes the osteoinductive potential of each lot of the DBM component of AlloCraft in a valid animal model. In all instances, AlloCraft functioned as intended and the bone formation observed was as expected.

Substantial Equivalence

AlloCraft is as safe and effective as the DBX and Allomatrix bone graft materials. AlloCraft has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between AlloCraft and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrates that AlloCraft is as safe and effective as the predicate devices. Thus, AlloCraft is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2005

Ms. Lorraine T. Montemurro
Manager, Regulatory Affairs
LifeCell
One Millennium Way
Branchburg, New Jersey 08876

Re: K052735 S1
Trade/Device Name: AlloCraft™DBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MBP, MQV
Dated: December 14, 2005
Received: December 16, 2005

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 Office of Compliance at (240) 276-0120 . 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bucher

Mark N. Melkerson,
Acting 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):____K052735_ _____

Device Name: AlloCraft™ DBM

Indications for Use:

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AlloCraft is intended for single patient use only

Prescription Use ___✓___ (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)

Barbara Brelwood for Ryan

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

510(k) Number K052735