K091321

SEP 11 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: Bacterin International, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

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Date Prepared May 4, 2009

General Device Information

Product Name: OsteoSelect™ Demineralized Bone Matrix Putty

Classification: "Osteoinductive Bone Void Filler W/O Human Growth Factor",
21 CFR 888.3045 - Product code: MBP
Class II

Predicate Devices

DBX® Demineralized Bone Matrix Putty
Musculoskeletal Transplant Foundation
510(k) K040262

Grafton® DBM
Osteotech, Inc.
510(k) K051195

Description

OsteoSelect™ Demineralized Bone Matrix Putty is processed human bone that has been demineralized and combined with an absorbable carrier that is biocompatible and biodegradable. The combination of demineralized bone and the absorbable carrier results in a putty-like consistency for ease and flexibility of use during surgical application. The carrier material is a mixture of carboxymethylcellulose and phosphate

buffered saline. OsteoSelect™ Putty is virtually odorless, tan in color and can be spread easily with minimal adhesion to surgical gloves.

OsteoSelect™ DMB Putty is intended for use as a filler for voids or gaps that are not intrinsic to the stability of the bony structure. The putty will be absorbed within a period of 90 days.

Intended Use (Indications)

OsteoSelect™ DBM Putty is indicated for use as a bone void filler for voids or gaps in the extremities and pelvis that are not intrinsic to the stability of the bony structure. It is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.

Substantial Equivalence

This submission supports the position that OsteoSelect™ Demineralized Bone Matrix Putty is substantially equivalent to a number of pre-enactment and previously cleared devices, including:

DBX® Demineralized Bone Matrix Putty - Musculoskeletal Transplant Foundation [510(k) K040262]

Grafton® DBM - Osteotech, Inc. [510(k) K051195]

The 510(k) Notice contains summaries of physical test results, functionality (efficacy testing) results and biocompatibility testing. The methods used for processing the DBM used in the device have been tested and validated for viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes was evaluated. The processing methods were determined to provide significant viral inactivation potential for a wide range of viruses.

OsteoSelect™ DBM Putty is osteoconductive and has been shown to have osteoinductive potential in an athymic rat model. Every final lot of OsteoSelect™ DBM Putty is tested in an *in vivo* rat model for osteoinductive potential. It is unknown how the osteoinductivity potential in the rat model correlates with human clinical performance.

The data presented demonstrate that the device is biocompatible and is suitable for its indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Bacterin International, Inc.
% Mr. Howard L. Schrayer
600 Cruiser Lane
Belgrade, Montana 59714

SEP 11 2009

Re: K091321
Trade Name: OsteoSelect™ Demineralized Bone Matrix Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler
Regulatory Class: II
Product Code: MQV, MBP
Dated: July 9, 2009
Received: July 14, 2009

Dear Mr. Schrayer:

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: OSTEOSELECT™ Demineralized Bone Matrix Putty

Indications For Use:

OsteoSelect™ (DBM) Putty is indicated for use as a bone void filler and bone graft substitute for voids or gaps in the extremities and pelvis that are not intrinsic to the stability of bony structure. It is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.

Prescription Use_____X____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091321