510(k) SUMMARY
(Per 21 CFR 807.92)

MAY 3 1 2013

General Company Information

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

Address: Bacterin International, Inc.
600 Cruiser Lane
Belgrade, MT 59714

Telephone: (406) 388-0480
Fax: (406) 683-9476

Date Prepared May 30, 2013

General Device Information

Product Name: OsteoSelect® Demineralized Bone Matrix Putty
Common Name: Bone Void Filler

Classification: Resorbable calcium salt bone void filler device
21 CFR 888.3045 - Product code: MBP, MQV

Class II

Predicate Devices

OsteoSelect® Demineralized Bone Matrix Putty
Bacterin International, Inc.
510(k) K091321 (use in extremities and pelvis)

DBX® Demineralized Bone Matrix Putty
Musculoskeletal Transplant Foundation
K103784 (use in pelvis and extremities)
K103795 (use in posterolateral spine)

Description

OsteoSelect® DBM 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 (a wax-like material) and phosphate buffered saline (a dispersing agent). OsteoSelect® DBM Putty is virtually odorless, tan in color and can be spread easily with minimal adhesion to surgical gloves.

OsteoSelect® DBM 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 and bone graft substitute for voids or gaps that are not intrinsic to the stability of the bony structure. OsteoSelect® DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone. OsteoSelect® DBM Putty can be used as follows:

- Extremities
- Posterolateral spine
- Pelvis

Substantial Equivalence

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

OsteoSelect® Demineralized Bone Matrix Putty – Bacterin International, Inc. [510(k) K091321]

DBX® Demineralized Bone Matrix Putty – Musculoskeletal Transplant Foundation [510(k) K103784]

The 510(k) Notice contains summaries of manufacturing procedures, physical test results, shelf life testing, functionality (efficacy testing) results and biocompatibility testing that was previously conducted on the OsteoSelect® DBM Putty predicate. 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.

In addition, the Notice contains a report of an *in vivo* study that was conducted to support use of OsteoSelect® DBM Putty in the posterolateral spine.

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

Conclusions

Bacterin International, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the OsteoSelect® DBM Putty. The materials from which the Bacterin device is fabricated have an established history of clinical use, and the device has been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Bacterin International, Incorporated
% Mr. Howard Schrayer
Regulatory Affairs Consultant
600 Cruiser Lane
Belgrade, Montana 59714

Letter dated: May 31, 2013

Re: K130498
Trade/Device Name: OsteoSelect® Demineralized Bone Matrix Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: March 19, 2013
Received: March 20, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130498

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 that are not intrinsic to the stability of the bony strtucture. OsteoSelect® DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.

OsteoSelect® DBM Putty can be used as follows:

- Extremities
- Posterolateral spine
- Pelvis

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)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130498