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 L. Schrayer
600 Cruiser Lane
Belgrade, Montana 59714

August 18, 2015

Re: K150621
Trade/Device Name: OsteoSelect® PLUS 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: MQV, MBP
Dated: June 17, 2015
Received: June 18, 2015

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 [**SELECT ONE:** Part 801 **[or, for IVDs only]** Parts 801 and 809**]**); 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 Industry and Consumer Education 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150621

Device Name
OsteoSelect® PLUS Demineralized Bone Matrix Putty

Indications for Use *(Describe)*
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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Bacterin International, Inc
OsteoSelect® *PLUS* Demineralized Bone Matrix Putty

1.0 Manufacturer Name

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

2.0 Contact

Howard Schrayer
Regulatory Consultant
Phone: 609-924-9510
E-mail: hs.ss@verizon.net

3.0 Date Prepared: August 14, 2015

4.0 Device Name and Classification

Proprietary Name:	OsteoSelect® *PLUS* Demineralized Bone Matrix Putty
Common/Usual Name:	Bone void filler
Classification:	Osteoinductive Bone Void Filler W/O Human Growth Factor
Regulation Number:	21 CFR 888.3045
Device Class:	II
Product Code:	MBP and MQV

5.0 Indications for Use

OsteoSelect® *PLUS* 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® *PLUS* DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone. OsteoSelect® *PLUS* DBM Putty can be used as follows:

- Extremities
- Pelvis
- Posterolateral spine

6.0 Device Description

OsteoSelect® *PLUS* 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® *PLUS* DBM Putty is virtually odorless, tan in color and can be spread easily with minimal adhesion to surgical gloves.

7.0 Predicate Devices

Primary Predicate	OsteoSelect® Demineralized Bone Matrix Putty Bacterin International, Inc. K091321 (use in extremities and pelvis) K130498 (use in posterolateral spine)
References	DBX® MIX Demineralized Bone Matrix Putty Musculoskeletal Transplant Foundation K063676
	Progenix Plus Bone Void Filler Device Medtronic Sofamor Danek K082002

8.0 Comparison to Predicate Devices

The device characteristics and indications for use of the OsteoSelect® *PLUS* DBM Putty are similar or the same as the predicate device.

9.0 Biocompatibility and Performance Testing

The 510(k) Notice contains summaries of manufacturing procedures, physical test results, shelf life testing, functionality (efficacy testing) results and biocompatibility testing previously conducted on the OsteoSelect® DBM Putty predicate. OsteoSelect® *PLUS* DBM Putty was deemed biocompatible based on this prior comprehensive biocompatibility testing performed in accordance with ISO 10993, Biological Evaluation of Medical Devices.

The process used to make Demineralized Bone Matrix for OsteoSelect® DBM Putty was validated for its ability to inactivate and/or clear a panel of model human enveloped and non-enveloped viruses representing DNA- and RNA-containing viruses and various viral shapes and sizes. This testing demonstrated the process provides suitable viral inactivation potential for a wide spectrum of potential human viruses. Other testing and justification was provided in support of an adequate viral inactivation process with successful inactivation potential of the modified particle size formulation. This inactivation potential provides

additional viral contamination risk reduction beyond that provided through donor screening and sterilization.

Based on the change to the DBM particle size distribution, OsteoSelect® PLUS DBM Putty was tested to evaluate extrusion from a syringe, maintenance of consistent handling characteristics for the duration of shelf life, performance under irrigation, cohesiveness while packing behavior into void spaces, and handling without sticking to surgical gloves. The results of these evaluations provide evidence supporting the suitability of the device for its intended use.

Each lot of OsteoSelect® *PLUS* DBM Putty is also tested for osteoinductive potential in a rodent model after gamma sterilization as part of the release criteria.

A comprehensive battery of OsteoSelect DBM Putty non-clinical testing, including chemical, physical, and animal, is additionally referenced and replied upon for the evaluation of the OsteoSelect® *PLUS* DBM Putty.

Testing has provided a reasonable assurance of safety and efficacy for the intended use of the device, and supports a determination of substantial equivalence.

9.0 Conclusion

Bacterin International, Inc. believes that the information provided establishes that the OsteoSelect® *PLUS* DBM Putty device is similar with respect to indications for use, design, function, and fundamental scientific technology to legally marketed devices and that there are no new concerns of safety or efficacy. Therefore, it is concluded that the subject device is substantially equivalent to the predicate.