



Food and Drug Administration  
10903 New Hampshire Avenue  
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Prosidyan Incorporated  
% Ms. Janice Hogan  
Regulatory Counsel  
Hogan Lovells US LLP  
1835 Market Street, 29<sup>th</sup> Floor  
Philadelphia, Pennsylvania 19103

November 10, 2015

Re: K151154

Trade/Device Name: FIBERGRAFT™ BG Morsels - Bone Graft Substitute  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: Class II  
Product Code: MQV  
Dated: September 18, 2015  
Received: September 18, 2015

Dear Ms. Hogan:

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 Parts 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 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 on last page

510(k) Number (if known)  
K151154

Device Name

FIBERGRAFT™ BG Morsels - Bone Graft Substitute

Indications for Use (Describe)

FIBERGRAFT™ BG Morsels - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Morsels must be used with autogenous bone marrow aspirate and autograft in the posterolateral spine.

FIBERGRAFT™ BG Morsels is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

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

Prescription Use (Part 21 CFR 801 Subpart D)  
Subpart C)

Over-The-Counter Use (21 CFR 801

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 510(k) SUMMARY

### Prosidyan's FIBERGRAFT™ BG Morsels

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

Prosidyan, Inc.  
30 Technology Drive  
Warren, NJ 07059  
Phone: (908) 517-3666  
Facsimile: (908) 325-0058  
Contact Person: Charanpreet S. Bagga

Date Prepared: October 28, 2015

#### Name of Device and Name/Address of Sponsor

FIBERGRAFT™ BG Morsels Bone Graft Substitute

#### Common or Usual Name

Bone Void Filler

#### Classification Name

Resorbable Calcium Salt Bone Void Filler, 21 CFR 888.3045, product code MQV

#### Predicate and Reference Devices

Predicate Devices: NovaBone Products, LLC's NovaBone Putty (K112773) (Primary Predicate); Prosidyan Inc., FIBERGRAFT™ BG Morsels Bone Graft Substitute (K141956, K132805)

Reference Device: NovaBone Resorbable Bone Graft Substitute (K052494)

#### Intended Use / Indications for Use

FIBERGRAFT™ BG Morsels - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT™ BG Morsels must be used with autogenous bone marrow aspirate and autograft in the posterolateral spine.

FIBERGRAFT™ BG Morsels is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

## Technological Characteristics

The technological characteristics of the FIBERGRAFT™BG Morsels have not changed since the prior clearances of the product. The FIBERGRAFT™BG Morsels provide an osteoconductive, resorbable, biocompatible bone graft substitute that is to be gently packed into defect sites. The FIBERGRAFT™BG Morsels are made from crystalline 45S5 bioactive glass. Each granule of BG Morsels is created from a matrix of bioactive glass fibers and microspheres. Bioactive glass is defined as a group of glasses that has a compositional range that allows the formation of hydroxyapatite (HA) as a surface layer when exposed to an aqueous phosphate-containing solution such as simulated body fluid. The HA layer that forms in an aqueous phosphate-containing solution plays a significant role in forming a strong bond with natural bone. The granules provide an ultra-porous scaffold for desired biological response and improved handling characteristics, while optimizing radiopacity and resorption. BG Morsels are generally spherical in appearance and provided in granular form. The matrix is flash sintered to form a porous shell at its surface, which creates the generally spherical structure of the granules, while maintaining a level of porosity within each granule.

## Performance Data

Physical property evaluations, functional animal studies, and biocompatibility tests were performed for the FIBERGRAFT™BG Morsels device. Specifically, simulated distribution, whole package integrity and seal strength were tested on the defined packaging configuration. Accelerated and real time aging tests were also performed with passing results. The biocompatibility of the BG Morsels is demonstrated by ISO 10993 testing and the long history of clinical use of the bioactive glass material for the same intended use. In addition, the BG Morsels is composed of the same bioactive glass material with the same chemical composition and the same type and duration of patient contact as the NovaBone predicates. The physical functions and bioactivity of the BG Morsels were also evaluated, and results met the testing requirements. The device is considered bioactive based on *in vitro* studies that show apatite layer formation on the surface of the implant following immersion in simulated body fluid (SBF). These results have not been correlated to clinical performance.

Animal testing demonstrated evidence of new bone formation in critical size defects, consistent with FDA's recommendations for Class II synthetic bone graft substitutes. Two separate animal studies were conducted. The Prosidyran FIBERGRAFT™ BG Morsels product was evaluated and compared to a positive control, the predicate device (NovaBone Putty), and to a negative sham control (untreated defect) in an ovine model. The animal study evaluated the device performance in critical sized cancellous bone defects in the lateral distal femurs from 58 skeletally mature sheep, including radiographic, histological, histomorphometric, and biomechanical data. Testing of the BG Morsels in the ovine model is representative of the indications for use and range of anatomical sites proposed for the subject device. In addition, the study was conducted for a duration of 24 weeks with several interim evaluation points (i.e., 4, 8, 12, and 24 weeks), including a minimum of 3 animals per time point per treatment group. The results of the study demonstrated that the FIBERGRAFT™BG Morsels device performs as safely and as effectively as the predicate device, and any differences between the results of the device groups do not raise new types of safety or effectiveness concerns.

In addition, the FIBERGRAFT BG Morsels product was also evaluated in a rabbit study to further support device performance for its indications for use. The FIBERGRAFT™ BG Morsels product was compared to its predicate device as well as autograft (positive) control. The animal study evaluated device performance in a rabbit posterolateral spine fusion

model with 41 skeletally mature rabbits, including radiographic, histological, histomorphometric, and biomechanical data. Testing of the FIBERGRAFT™ BG Morsels in the rabbit model is representative of the indications for use and range of anatomical sites proposed for the subject device. The results of the study through 26 week follow up demonstrated that the FIBERGRAFT™ BG Morsels device performs substantially equivalently to the predicate device, and any minor technological differences between the device groups do not raise new types of safety or effectiveness concerns. The device was compared to autograft in animal performance testing in order to demonstrate substantial equivalence to the predicate. ISO 10993-6 testing was also conducted, and results supported substantial equivalence of the FIBERGRAFT BG Morsels compared to its predicate. Fluid absorbability testing further confirmed the use of BMA and the shelf life of the product.

Therefore, performance testing demonstrated that the FIBERGRAFT™ BG Morsels device functions as intended and meets the requirements of class II bone void fillers as compared to the predicate devices.

### **Substantial Equivalence**

As demonstrated in performance testing, the FIBERGRAFT™ BG Morsels product is substantially equivalent to its predicate devices. FIBERGRAFT™ BG Morsels has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. Thus, FIBERGRAFT™ BG Morsels is substantially equivalent.

### **Conclusions**

FIBERGRAFT™ BG Morsels is an osteoconductive, resorbable, biocompatible bone graft substitute composed of bioactive glass. The product is substantially equivalent to its predicate devices for its intended use as a synthetic bone void filler and bone graft extender. Performance testing, including bench and in vivo data, demonstrated that the device functions as intended without raising new safety or effectiveness questions.