April 6, 2018

Prosidyan, Inc.
% Janice M. Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K180080
Trade/Device Name: FIBERGRAFT® BG Matrix 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: January 10, 2018
Received: January 10, 2018

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 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K180080

Device Name

FIBERGRAFT® BG Matrix Bone Graft Substitute

Indications for Use *(Describe)*

FIBERGRAFT® BG Matrix - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® BG Matrix 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 Matrix must be used with autogenous bone marrow aspirate and autograft in posterolateral spine.

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

X Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

Prosidyan, Inc.'s FIBERGRAFT® BG Matrix – Bone Graft Substitute

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

Prosidyan, Inc.
30 Technology Drive
Warren, NJ 07059
Phone: (610)-945-5640
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Contact Person: Charanpreet S. Bagga

Date Prepared: March 7, 2018

Name of Device and Name

FIBERGRAFT® BG Matrix Bone Graft Substitute

Common or Usual Name

Bone Void Filler

Classification Name/CFR Regulation/Product Code

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

Predicate Devices

- Novabone Products LLC, Novabone MacroFORM (K140946) (Primary predicate device)
- Prosidyan Inc, FIBERGRAFT BG Matrix (K171284) (Reference device)
- Prosidyan Inc, FIBERGRAFT BG Putty (K143533, K170306) (Reference device)

Intended Use / Indications for Use

FIBERGRAFT® BG Matrix - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® BG Matrix 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 Matrix must be used with autogenous bone marrow aspirate and autograft in posterolateral spine.

Device Description

FIBERGRAFT® BG Matrix product is composed of 45S5 bioactive glass components (M-45 granules, MS-45 microspheres) and bovine type I collagen. The BG Matrix after hydration with saline or blood can be applied to the defect site or can be molded into the desired shape and gently packed into the defect site as a non-setting putty. In the posterolateral spine fusion

applications, the product is intended to be hydrated with bone marrow aspirate (BMA) and mixed with autograft in a 1:1 ratio.

The FIBERGRAFT® BG Matrix product was previously cleared in K171284. There has not been any change to the device since the last clearance.

Technological Characteristics

FIBERGRAFT® BG Matrix is a bioactive osteoconductive, resorbable, biocompatible bone graft substitute. The product is composed of 45S5 bioactive glass components (M-45 granules, MS-45 microspheres) and bovine type I collagen. The BG Matrix hydrated with saline or blood can be applied to the defect site or can be used as a moldable and malleable material that can be placed at the defect site. In addition, for posterolateral spine fusion applications, the product can be mixed with autograft.

The addition of collagen creates a single piece bone graft in a shape and size that is clinically relevant for ease of use during implantation.

Performance Data

The performance of the FIBERGRAFT® BG Matrix has been established by undertaking physical and chemical property evaluation studies, functional performance animal studies and biocompatibility tests. The physical and chemical property studies confirmed the *in vitro* functionality and bioactivity of the BG Matrix. The *in vitro* bioactivity test results have not been correlated to clinical performance. The biocompatibility of the FIBERGRAFT® BG Matrix 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 Matrix is composed of the same bioactive glass material and the same type and duration of patient contact as the predicates. Packaging evaluations, shelf life testing and real time aging testing were performed with passing results. Bacterial endotoxin testing was performed using the limulus amebocyte lysate (LAL) method and showed that the device meets the endotoxin limits of established guidelines.

The FIBERGRAFT® BG Matrix product was evaluated in a rabbit posterolateral spine fusion study to further support device performance for its indications for use in posterolateral spine. The FIBERGRAFT® BG Matrix product was compared to its predicate device as well as controls. The animal study evaluated device performance in critical sized cancellous bone in the posterolateral spine of 53 skeletally mature rabbits. The performance was evaluated using radiographic, histological, histomorphometric, and biomechanical data. Testing of the FIBERGRAFT® BG Matrix 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 the performance of the FIBERGRAFT® BG Matrix device.

The FIBERGRAFT® BG Matrix product was also evaluated in a critical size distal femur defects in skeletally mature rabbits to further support device performance for its indications for use in extremities and pelvis applications. The FIBERGRAFT® BG Matrix product was compared to its predicate device as well as controls. The animal study evaluated device performance in critical sized defects in the distal femur of 42 skeletally mature rabbits. The performance was evaluated using radiographic, histological, histomorphometric, and biomechanical data. Testing of the FIBERGRAFT® BG Matrix 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 Matrix device performs substantially equivalently to the predicate device and positive control, and any minor technological differences between the device groups do not raise new types of safety or effectiveness concerns.

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

Substantial Equivalence

As demonstrated in performance testing, the FIBERGRAFT® BG Matrix has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between BG Matrix and its predicate devices do not raise any new issues of safety or effectiveness. The data demonstrate that BG Matrix is substantially equivalent to the predicate devices.

Conclusion

FIBERGRAFT® BG Matrix is an osteoconductive, resorbable, biocompatible bone graft substitute composed of bioactive glass, mixed with Type I collagen. The FIBERGRAFT® BG Matrix is substantially equivalent to its predicate device for its intended use as a synthetic bone void filler. Performance testing, including *in vivo* data, demonstrated that the device functions as intended without raising new safety or effectiveness questions.