December 20, 2018

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

Re: K182670
Trade/Device Name: FIBERGRAFT® AERIDYAN 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: September 26, 2018
Received: September 26, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Sarah B. Nelson -S

For 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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K182670

Device Name

FIBERGRAFT® AERIDYAN Matrix Bone Graft Substitute

Indications for Use *(Describe)*

FIBERGRAFT® AERIDYAN Matrix - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® AERIDYAN Matrix is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine). 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® AERIDYAN 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)*

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

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510(k) SUMMARY

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

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

Prosidyan, Inc.
41 Spring St, Suite 107
New Providence, NJ 07974
Phone: (610)-945-5640
Facsimile: (908) 396-1151
Contact Person: Charanpreet S. Bagga

Date Prepared: September 25, 2018

Name of Device and Name

FIBERGRAFT® AERIDYAN 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

- Prosidyan Inc, FIBERGRAFT BG Matrix (K171284, K180080) (Predicate device).
- Stryker/Orthovita Inc, Vitoss Bioactive Bimodal (K103173) (Reference device).

Intended Use / Indications for Use

FIBERGRAFT® AERIDYAN Matrix - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® AERIDYAN Matrix is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine). 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® AERIDYAN Matrix must be used with autogenous bone marrow aspirate and autograft in posterolateral spine.

Device Description

FIBERGRAFT® AERIDYAN Matrix product is composed of 45S5 bioactive glass (M-45 granules), boron bioactive glass (MS-B microspheres) and bovine type I collagen. After hydration with bone marrow aspirate (BMA), the AERIDYAN Matrix can be applied directly to the defect site or 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 BMA and mixed with autograft in a 1:1 ratio.

Technological Characteristics

FIBERGRAFT® AERIDYAN Matrix is a bioactive osteoconductive, resorbable, biocompatible bone graft substitute. The product is composed of 45S5 bioactive glass (M-45 granules), boron bioactive glass (MS-B microspheres) and bovine type I collagen. After hydrated with BMA, the FIBERGRAFT® AERIDYAN Matrix can be applied directly to the defect site or used as a

moldable, and malleable material to be placed at the defect site. In addition, for posterolateral spine fusion applications, the product can be mixed with autograft.

The FIBERGRAFT AERIDYAN Matrix is similar in composition to the previously cleared FIBERGRAFT BG Matrix (K171284, K180080) except that in the AERIDYAN Matrix, the 45S5 bioactive glass microspheres have been replaced by boron glass microspheres (MS-B). The MS-B microspheres share the same principles of operation and similar characteristics as the MS-45 microspheres used in FIBERGRAFT BG Matrix.

Performance Data

The performance of the FIBERGRAFT® AERIDYAN 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 AERIDYAN Matrix. The *in vitro* bioactivity test results have not been correlated to clinical performance. The biocompatibility of the FIBERGRAFT® AERIDYAN 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 AERIDYAN 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® AERIDYAN Matrix product was evaluated in a rabbit study to further support device performance for its indications for use. The FIBERGRAFT® AERIDYAN Matrix product was compared to its predicate devices as well as controls. The animal study evaluated device performance in critical sized cancellous bone in the posterolateral spine of 71 skeletally mature rabbits. The performance was evaluated using radiographic, histological, histomorphometric, and biomechanical data. Testing of the FIBERGRAFT® AERIDYAN 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® AERIDYAN 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® AERIDYAN Matrix 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® AERIDYAN Matrix has the same intended use and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between AERIDYAN Matrix and its predicate devices do not raise any new issues of safety or effectiveness. The data demonstrate that AERIDYAN Matrix is substantially equivalent to the predicate devices.

Conclusion

FIBERGRAFT® AERIDYAN Matrix is an osteoconductive, resorbable, biocompatible bone graft substitute composed of bioactive glass, mixed with Type I collagen. The FIBERGRAFT® AERIDYAN Matrix is substantially equivalent to its predicate devices 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.