August 23, 2022

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

Re: K213803
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: July 19, 2022
Received: July 19, 2022

Dear Janice 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement on last page

510(k) Number *(if known)*
K213803

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., the 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® Aeridyan™ Matrix must be used with autogenous bone marrow aspirate and autograft in posterolateral spine. FIBERGRAFT® Aeridyan™ Matrix must be hydrated with saline or blood for pelvis and extremity applications.

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® Aeridyan™ Matrix – Bone Graft Substitute

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

Prosidyan, Inc.
41 Spring Street #107
New Providence, NJ 07974
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Contact Person: Gina M. Nagvajara, PhD

Date Prepared: July 19, 2022

Name of Device and Name
FIBERGRAFT® Aeridyan™ Matrix Bone Graft Substitute

Common or Usual Name
Filler, Bone Void, Calcium Compound

Classification Name/CFR Regulation/Product Code
Resorbable Calcium Salt Bone Void Filler, 21 CFR 888.3045, product code MQV

Predicate Device
- Prosidyan Inc, FIBERGRAFT BG Matrix (K180080)

Reference Devices
- NovaBone Products LLC, NovaBone MacroFORM (K140946)
- Prosidyan, Inc., FIBERGRAFT® AERIDYAN Matrix (K182670)

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., the 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® Aeridyan™ Matrix must be used with autogenous bone marrow aspirate and autograft in posterolateral spine. FIBERGRAFT® Aeridyan™ Matrix must be hydrated with saline or blood for pelvis and extremity applications.

Device Description

FIBERGRAFT® Aeridyan™ Matrix product is composed of 45S5 bioactive glass (M-45 granules), boron bioactive glass (MS-B microspheres/Borospheres™) and bovine type I collagen. After hydration with saline, blood or 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 posterolateral spine fusion applications, the product is intended to be hydrated with bone marrow aspirate (BMA) and mixed with autograft in a recommended 1:1 ratio. In pelvis and extremity applications, the product must be hydrated with saline or blood.

The FIBERGRAFT® AERIDYAN Matrix product was previously cleared in K182670. There have been no technological changes to the device since this last clearance - the formulation, raw materials and critical raw material suppliers remain the same. The intent of this submission is to expand the indication in the pelvis and extremities based on completion of an additional functional animal study.

Technological Characteristics

The FIBERGRAFT Aeridyan Matrix is of the same composition as the previously cleared FIBERGRAFT Aeridyan Matrix in K182670; and also similar in composition to the previously cleared FIBERGRAFT BG Matrix (K180080). All products are resorbable, osteoconductive, bioactive bone void filler devices that are composed of bioactive glass and bovine collagen. The comparison among the devices is shown in the table below.

	Prosidyan's FIBERGRAFT® Aeridyan™ Matrix (Subject Device)	**Prosidyan's FIBERGRAFT® BG Matrix (K180080) (Predicate Device)**	**NovaBone MacroFORM (K140946) (Reference Device)**	**Prosidyan's FIBERGRAFT® AERIDYAN Matrix (K182670) (Reference Device)**
Intended Use	Bone void filler for orthopedic applications	Bone void filler for orthopedic applications	Bone void filler for orthopedic applications	Bone void filler for orthopedic applications
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., the 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® Aeridyan™ Matrix must be used with autogenous bone marrow aspirate and autograft in posterolateral spine. FIBERGRAFT® Aeridyan™ Matrix must be hydrated with saline or blood for pelvis and extremity applications.	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.	NovaBone MacroFORM bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroFORM is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NovaBone MacroFORM must be hydrated with autogenous bone marrow prior to implantation. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.	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.
Target Population	Individuals with surgically created osseous defects or osseous defects due to traumatic injury to bone.	Individuals with surgically created osseous defects or osseous defects due to traumatic injury to bone.	Individuals with surgically created osseous defects or osseous defects due to traumatic injury to bone.	Individuals with surgically created osseous defects or osseous defects due to traumatic injury to bone.
Anatomical Placement	Posterolateral spine, Extremities and Pelvis	Posterolateral spine, Extremities and Pelvis	Extremities and Pelvis	Posterolateral spine

	Prosidyan's FIBERGRAFT® Aeridyan™ Matrix (Subject Device)	**Prosidyan's FIBERGRAFT® BG Matrix (K180080) (Predicate Device)**	**NovaBone MacroFORM (K140946) (Reference Device)**	**Prosidyan's FIBERGRAFT® AERIDYAN Matrix (K182670) (Reference Device)**
Primary Component	45S5 Bioactive Glass, Boron bioactive glass	45S5 Bioactive Glass	45S5 Bioactive Glass	45S5 Bioactive Glass, Boron bioactive glass
Collagen composition	Type I Collagen from bovine	Type I Collagen from bovine	Type I Collagen from bovine	Type I Collagen from bovine
Osteoconductive	Yes	Yes	Yes	Yes
Bioactive	Yes	Yes	Yes	Yes
Resorbs	Yes	Yes	Yes	Yes
Sterility	Sterile	Sterile	Sterile	Sterile
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible
Packaging	Thermo-form tray	Thermo-form tray	Thermo-form tray and sealed cups	Thermo-form tray

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 has been 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 posterolateral spine fusion study to support device performance for its indications for use in the spine. The FIBERGRAFT® Aeridyan Matrix product was compared to the FIBERGRAFT® BG Matrix predicate device 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 weeks of 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.

The FIBERGRAFT® Aeridyan Matrix product has also been evaluated in a rabbit femoral condyle defect study in skeletally mature rabbits to further support device performance for its indications for use in extremities and pelvis applications. The FIBERGRAFT® Aeridyan Matrix product was compared to the BG Matrix and NovaBone MacroFORM predicate and reference devices. The animal study evaluated device performance in critical sized defects in the distal femur of 44 skeletally mature rabbits. The performance was evaluated using radiographic, histological, and histomorphometric 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 weeks of follow up demonstrated that the FIBERGRAFT® Aeridyan Matrix device performs substantially equivalently to the predicate and reference devices, and any minor technological differences between the device groups do not adversely impact performance.

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 device and reference 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 and reference devices. The minor technological differences between Aeridyan Matrix and its predicate device do not raise any new issues of safety or effectiveness. The data demonstrated that Aeridyan Matrix is substantially equivalent to the predicate device.

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 and reference devices for its intended use as a synthetic bone void filler. Performance

testing, including *in vivo* data, demonstrated that the device functions as intended, supporting substantial equivalence.