October 22, 2025

Prosidyan, Inc.
% Dr. Mehdi Kazemzadeh-Narbat
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, DC 20001 USA

Re: K253417
Trade/Device Name: FIBERGRAFT™ BG Putty GPS Bone Graft Substitute FIBERGRAFT™ BG Putty Bone Graft Substitute FIBERGRAFT™ AERIDYAN™ Matrix Bone Graft Substitute 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: September 25, 2025
Received: September 25, 2025

Dear Dr. Mehdi Kazemzadeh-Narbat:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.10.22 14:18:37 -04'00'

Jesse Muir, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253417

Please provide the device trade name(s).

FIBERGRAFT™ BG Putty GPS Bone Graft Substitute
FIBERGRAFT™ BG Putty Bone Graft Substitute
FIBERGRAFT™ AERIDYAN™ Matrix Bone Graft Substitute
FIBERGRAFT™ BG Matrix Bone Graft Substitute

Please provide your Indications for Use below.

FIBERGRAFT™ BG Putty GPS:
"FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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 Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler. FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization."

FIBERGRAFT™ BG Putty:
"FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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 Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler. FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization."

FIBERGRAFT™ AERIDYAN™ Matrix Bone Graft Substitute:
"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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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:
"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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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."

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

K253147

510(k) Summary

Manufacturer:	Prosidyan, Inc. 41 Spring Street Suite 107 New Providence, NJ 07974
Contact:	Mehdi Kazemzadeh-Narbat, PhD, PMP Director, Regulatory Affairs 803 7th Street NW, Floor 3 Washington, DC 20001 Office: 202.552.6011 Email: mkazemzadeh@mcra.com
Prepared By:	MCRA an IQVIA business Mehdi Kazemzadeh-Narbat, PhD, PMP Director, Regulatory Affairs 803 7th Street NW, Floor 3 Washington, DC 20001Office: 202.552.6011 Email: mkazemzadeh@mcra.com
Date Prepared:	October 7, 2025
Device Trade Name:	FIBERGRAFT™ BG Putty Bone Graft Substitute FIBERGRAFT™ BG Putty GPS Bone Graft Substitute FIBERGRAFT™ AERIDYAN™ Matrix Bone Graft Substitute FIBERGRAFT™ BG Matrix Bone Graft Substitute
Device Common Name:	Resorbable calcium salt bone void filler device
Classification:	21 CFR 888.3045 Class II
Product Codes:	MQV

Indications for Use:

"FIBERGRAFT™ BG Putty GPS - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty GPS is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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 Putty GPS must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty GPS must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler. FIBERGRAFT™ BG Putty GPS is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization."

"FIBERGRAFT™ BG Putty - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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 Putty must be used with autograft in the posterolateral spine. When used in intervertebral body fusion procedures, FIBERGRAFT™ BG Putty must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler. FIBERGRAFT™ BG Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization."

"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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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™ 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 osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of 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."

Predicate Devices:

FIBERGRAFT™ BG Putty GPS (K222276)
FIBERGRAFT™ BG Putty (K222276)
FIBERGRAFT™ AERIDYAN™ Matrix Bone Graft Substitute (K213803)
FIBERGRAFT™ BG Matrix Bone Graft Substitute (K180080)

Reference Devices:

GlassBone Granules (K242782)
MONTAGE Settable, Resorbable Bone Putty, MONTAGE-QS Settable, Resorbable Bone Putty, MONTAGE Flowable Settable, Resorbable Bone Paste, MONTAGE-XT Settable, Resorbable Hemostatic Bone Putty (K243526)

Device Description:

FIBERGRAFT™ BG Putty GPS is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty GPS is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable/polymeric carrier to form a cohesive material. FIBERGRAFT™ BG Putty GPS is to be provided in a spindle drive syringe and is compatible with the GPS Cannula product.

FIBERGRAFT™ BG Putty is an osteoconductive, resorbable, biocompatible bone graft substitute to be gently packed into defect sites and to be used as non-structural scaffolds. The FIBERGRAFT™ BG putty is made from 45S5 bioactive glass, where the bioactive glass components are mixed with an absorbable/polymeric carrier to form a cohesive material.

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.

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, blood, or bone marrow aspirate (BMA) 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 BMA and mixed with autograft in a 1:1 ratio.

Purpose of this Submission:

The purpose of this Special 510(k) is to expand the indications for use statement (IFUS) of the FIBERGRAFT™ BG Putty and FIBERGRAFT™ BG Putty GPS Bone Graft Substitute (K222276), FIBERGRAFT™ AERIDYAN™ Matrix Bone Graft Substitute (K213803), and FIBERGRAFT™ BG Matrix Bone Graft Substitute (K180080), to include the statement "benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old)" to the current IFUS. Besides the addition of this statement, there is no change in the subject device materials, manufacturing process, sterilization, and packaging process.

Substantial Equivalence and Predicate Devices:

The subject device is substantially equivalent to its reference devices in terms of added language to the Indications for Use; "benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old)" and identical to predicate devices in terms of materials, manufacturing process, sterilization, and packaging process. All pre-clinical testing conducted to support the previous 510(k) clearances are applicable to the subject device. The only modification proposed in this Special 510(k) is to include the statement "benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old)" to the current IFUS.

Conclusion:

The subject FIBERGRAFT™ bone substitutes are substantially equivalent to its predicates with respect to intended use, technological characteristics, and performance.