March 5, 2024

BONESUPPORT AB
℅ Scott Bruder, MD, PhD
Founder and CEO
Bruder Consulting & Venture Group
268 Glen Place
Franklin Lakes, New Jersey 07417

Re: K240459
Trade/Device Name: Cerament Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: February 16, 2024
Received: February 16, 2024

Dear Dr. Bruder:

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.

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,

Sara S. Thompson -S

For

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

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 below.

510(k) Number *(if known)*
K240459

Device Name
CERAMENT BONE VOID FILLER

Indications for Use *(Describe)*
CERAMENT BONE VOID FILLER is a ceramic bone graft substitute intended for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure.
CERAMENT BONE VOID FILLER is indicated to be injected, or placed, into bony voids or gaps in the skeletal system, i.e. extremities, pelvis, posterolateral spine (only during open surgery in spine), and intervertebral disc space. These defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 9 years old), or osseous defects created as a result of either surgery or traumatic injury to the bone. When used in intervertebral body fusion procedures, CERAMENT BONE VOID FILLER must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
CERAMENT BONE VOID FILLER resorbs and is replaced by bone during the healing process.
CERAMENT BONE VOID FILLER can augment hardware and support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process. CERAMENT BONE VOID FILLER can be drilled and screws can be placed through it.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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Date Prepared
February 16, 2024

Device

Trade Name	CERAMENT BONE VOID FILLER
Common Name	Bone void filler
Regulation	21 CFR 888.3045 Resorbable calcium salt bone void filler device
Classification	Class II
Product Code	MQV
Panel	Orthopedic

Predicates

Primary Predicate	NuVasive - Attrax Putty (K203714)
Secondary Predicate	Prosidyan - Fibergraft™ BG Putty (K222276)
Reference Device (K201535)	BONESUPPORT AB - CERAMENT® BONE VOID FILLER

Device Description
CERAMENT BONE VOID FILLER is composed of hydroxyapatite, calcium sulfate hemihydrate, and calcium sulfate dihydrate, and it identical to the device cleared in K201535. This submission expands the device's indication to include use in the intervertebral space.

Indications for Use Statement
CERAMENT BONE VOID FILLER is a ceramic bone graft substitute intended for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure.

CERAMENT BONE VOID FILLER is indicated to be injected, or placed, into bony voids or gaps in the skeletal system, i.e. extremities, pelvis, posterolateral spine (only during open surgery

in spine), and intervertebral disc space. These defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 9 years old), or osseous defects created as a result of either surgery or traumatic injury to the bone. When used in intervertebral body fusion procedures, CERAMENT BONE VOID FILLER must be used on its own with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

CERAMENT BONE VOID FILLER resorbs and is replaced by bone during the healing process.

CERAMENT BONE VOID FILLER can augment hardware and support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process. CERAMENT BONE VOID FILLER can be drilled and screws can be placed through it.

Substantial Equivalence
The intended use is the same for subject and predicate devices. The subject device and predicates are all cleared for use as bone void fillers in the intervertebral body space.
There are differences in the device's material composition, but these do not raise different questions of safety and effectiveness. The effect of differences in material composition is addressed in the prior functional animal model performance.

Performance
The subject device has been previously cleared under K201535, which serves as a Reference Device. This submission is leveraged to support the device's sterility, shelf-life, endotoxin, pyrogenicity, biocompatibility, and characterizations/bench performance as recommended in FDA's *Class II Special Controls Guidance Document for Resorbable Calcium Salt Bone Void Filler Devices*. The device's performance in the intervertebral body space was supported by a robust analysis of bone grafting materials in the prior posterolateral spine fusion studies.

Summary
The subject device and predicates have the same intended use, and the same specific indications for use in the intervertebral body space. Any differences in technological characteristics between the subject device and predicate do not raise different questions of safety and effectiveness. Based on the clinical analysis, the device is substantially equivalent to the predicates.