March 13, 2024

BoneSupport AB
Blerta Shuka
Sr. Regulatory Affairs Specialist
Scheelevagen 19
Ideon Science Park
SE-223 70
Lund, Sweden

Re: K234008
Trade/Device Name: Cerament G
Regulation Number: 21 CFR 888.3046
Regulation Name: Resorbable Calcium Salt Bone Void Filler Containing A Single Approved Aminoglycoside Antibacterial
Regulatory Class: Class II
Product Code: QRR
Dated: December 19, 2023
Received: December 19, 2023

Dear Blerta Shuka:

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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2024.03.13 13:49:35 -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

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)*
K234008

Device Name
CERAMENT G

Indications for Use *(Describe)*
CERAMENT G is a resorbable, gentamicin-eluting ceramic bone void filler intended for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to bone infection and open fractures.

By eluting gentamicin, CERAMENT G can reduce the occurrence and reoccurrence of bone infection from gentamicin-sensitive microorganisms in order to protect bone healing.

CERAMENT G can augment provisional hardware to help 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 G resorbs and is replaced by bone during the healing process.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Device Trade Name:	CERAMENT® G
Manufacturer:	BONESUPPORT AB Scheelevägen 19, Ideon Science Park, SE-223 70 Lund, Sweden
Contact:	Blerta Shuka Sr. Regulatory Affairs Specialist +46703302768
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	February 20, 2024
Regulation:	21 CFR 888.3046 Resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial.
Classification:	Class II
Product Code:	QRR
Primary Predicate:	CERAMENT G (DEN210044)

Indications For Use:

CERAMENT G is a resorbable, gentamicin-eluting ceramic bone void filler intended for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to bone infection and open fractures.

By eluting gentamicin, CERAMENT G can reduce the occurrence and reoccurrence of bone infection from gentamicin-sensitive microorganisms in order to protect bone healing.

CERAMENT G can augment provisional hardware to help 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 G resorbs and is replaced by bone during the healing process.

Device Description:

CERAMENT G is an implantable bone void filler (device/ drug combination product) indicated for use as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) where there is a need for supplemental bone graft. It is composed

of hydroxyapatite, calcium sulfate and gentamicin, and is identical to the device cleared in DEN210044.

This submission expands the device's indication to include use in patients with open fractures in need for bone void filling.

Performance Testing Summary:

The subject device was granted under DEN210044, which serves as the predicate device. This submission is leveraged to support the device's sterility, shelf-life, endotoxin, biocompatibility, and characterizations/bench performance as recommended in FDA's Class II Special Controls listed in DEN210044 and the "Resorbable Calcium Salt Bone Void Filler Devices" guidance document including:

- Bench testing of finished combination product
    - Dissolution
    - pH
    - Setting reaction temperature
    - Force required to transfer paste from mixing syringe to delivery syringe
    - Compressive strength
    - Working time
    - Setting time
    - Augmentation of hardware and bone alignment
- Bench testing of drug components and drug constituent parts
    - Compliance with current monograph of Gentamicin Sulfate
    - Antimicrobial activity
    - Elution study
- Stability of gentamicin
- Sterility
- Biocompatibility
- Pyrogenicity testing
- Animal Testing
    - Serum levels of gentamicin
    - Osteoconductivity
    - Resorbable properties

Clinical Performance of CERAMENT G:

Clinical data on the performance of CERAMENT G were collected on a consecutive series of 81 patients with Gustilo-Anderson IIIB fractures who were treated by the Manchester Orthoplastic

Group between June 2013 and April 2021.[1] This Real World Evidence from the Manchester Cohort support the substantial equivalence of CERAMENT G as evidenced by:

- ***Low Rate of Deep Infection:*** CERAMENT G demonstrated an extremely low rate of deep infection (i.e., 3.7%) which compares favorably to the standard of care infection rates which range from 5.3% to 33.6%, with a weighted mean infection rate of 14.5%.
- ***Limb Salvage:*** Patients who received CERAMENT G demonstrated a high rate of limb salvage (i.e., 96.3%). These results compare favorably to the limb salvage rates for the SOC group which ranged from 93.2% to 98.2%.
- ***Bone Union:*** Patients who received CERAMENT G demonstrated high rates of limb union (96%). These results demonstrate that CERAMENT G supports formation of new bone, and they compare favorably to the rates of union for the SOC group which ranged from 71.4% to 94.7%.

Substantial Equivalence:

The CERAMENT G which is the subject of this 510(k) is identical to the product granted in DEN210044.

The technology and intended use for the product are the same as the predicate product, CERAMENT G (DEN210044). The predicate indications (i.e., use as a resorbable, gentamicin-eluting ceramic bone void filler intended for use in defects in the extremities as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to bone infection). The subject indications (i.e., use as a resorbable, gentamicin-eluting ceramic bone void filler intended for use in defects in the extremities as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to open fractures) differ slightly from the predicate indications; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate.

Real World Evidence demonstrates that patients who received CERAMENT G as part of the treatment of their open fracture achieved a low rate of deep infection; a high rate of limb salvage; and a high rate of bone union. As summarized in the "Clinical Performance of CERAMENT G," these clinical results compare favorably to the results for the standard of care.

These results demonstrate that CERAMENT G is as safe, as effective, and performs as well as the predicate device.

[1] Henry JA, Ali A, Elkhidir IH, Reid A, Wong J, Pillai A. Long-Term Follow-Up of Open Gustilo-Anderson IIIB Fractures Treated With an Adjuvant Local Antibiotic Hydroxyapatite Bio-Composite. Cureus. 2023 May 16;15(5):e39103. doi: 10.7759/cureus.39103. PMID: 37332443; PMCID: PMC10270668.