October 16, 2020

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

Re: K201535
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: June 8, 2020
Received: June 8, 2020

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 (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,

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201535

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, and posterolateral spine (only during open surgery in spine). 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Manufacturer:	BONESUPPORT AB Scheelevägen 19 IDEON Science Park SE-223 70 LUND, SWEDEN + 46 46 286 53 70
Contact:	Blerta Shuka blerta.shuka@bonesupport.com + 46 70 330 27 68 (direct phone)
Prepared by:	MCRA, LLC 1050 K Street, NW, Suite 1000 Washington, DC 20001 +1.202.552.5800
Date prepared:	October 9, 2020

Device Information

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

Device Description

CERAMENT| BONE VOID FILLER is a fast-setting, injectable and moldable ceramic bone graft substitute intended for filling bone voids/gaps. The material consists of a powder and a liquid component. The major constituents of the powder are hydroxyapatite and calcium sulfate hemihydrate. The liquid component (C-TRU) contains iohexol as a radio-opacification enhancer. Mixing the components with the combined mixing injection (CMI) device, results in a viscous material intended to set *ex vivo* or *in vivo*.

By combining hydroxyapatite and calcium sulfate, an optimal balance is achieved between implant resorption rate and bone ingrowth rate. Calcium sulfate acts as a resorbable carrier for hydroxyapatite. Hydroxyapatite has a slow resorption rate, high osteoconductivity, promoting bone ingrowth and gives long term structural support to the newly formed bone.

The ceramic bone graft substitute is placed into the bone defect under direct visualization or under radiographic monitoring during open or percutaneous surgery. The paste may be injected into the defect, molded by hand and digitally placed into the defect, or used to prepare beads that are placed into the defect. The accompanying injection device (ID) and Tip Extenders may be used to facilitate filling the bone defect.

When fully set *in vivo*, CERAMENT | BONE VOID FILLER is drillable and can be used to augment hardware during the surgical procedure.

Indications for Use

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, and posterolateral spine (only during open surgery in spine). 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.

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.

Predicate Devices

510(k) number	**Trade name**	**Manufacturer**	**Predicate**
K073316	CERAMENT | BONE VOID FILLER	Bonesupport AB	Primary predicate
K090871	CERAMENT | BONE VOID FILLER (High Contrast)	Bonesupport AB	Reference device
K132656, K113871	PRO-DENSE Bone Graft Substitute	Wright Medical Technology, Inc.	Reference device
K102722	Norian Drillable Inject and Norian Drillable Fast Set Putty	Synthes	Reference device

Comparison of Technological Characteristics with the Predicate Device

The table below summarizes the differences between the technological characteristics of the primary predicate device (CERAMENT| BONE VOID FILLER, K073316) and the subject device.

Table 1. Comparison between the device and its primary predicate device (CERAMENT | BONE VOID FILLER, K073316)

Feature	Any difference between the primary predicate device and the new device
Powder component	No difference
Liquid component	No difference
Mixing of paste	No difference
Delivery of paste to patient	Two plastic Tip Extenders have been added to the device. They may be connected to the CERAMENT|ID to facilitate paste injection
Indications	Indications have been expanded to include use in: • filling benign bone cysts and tumors in adults and pediatric patients ≥ 9 years old, • augmenting hardware and supporting bone fragments during a surgical procedure, and • ability to drill and place screws through the material.

Performance Testing

The previously provided performance testing demonstrates the substantial equivalence of CERAMENT| BONE VOID FILLER. The prior testing was conducted in accordance with the Guidance for Industry and FDA Staff (Class II Special Controls Guidance Document: Resorbable calcium salt bone void filler device; Guidance for Industry and FDA (issued June 2, 2003)).

Additional testing has been conducted to demonstrate that CERAMENT | BONE VOID FILLER can be used to augment hardware and support bone fragments during a surgical procedure, and that the material can be drilled and screws placed through it.

Biocompatibility

Previously conducted biocompatibility testing demonstrates that CERAMENT | BONE VOID FILLER is biocompatible.

Conclusions

Based on the information provided in this premarket notification, CERAMENT| BONE VOID FILLER is substantially equivalent to the predicate device in intended use, materials, technological characteristics, principles of operation, and function. Testing and engineering analyses showed that CERAMENT | BONE VOID FILLER met the pre-determined acceptance criteria identified in the Design Control Activities Summary. Additionally, CERAMENT | BONE VOID FILLER is in compliance with pyrogenicity testing requirements for orthopedic implants.