February 5, 2024

Bone Solutions, Inc.
% Kevin A. Thomas, Ph.D.
VP & Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K234013
Trade/Device Name: Mg OSTEOINJECT™; Mg OSTEOREVIVE™; Mg OSTEOCRETE™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV, OIS
Dated: December 18, 2023
Received: December 19, 2023

Dear Dr. Thomas:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234013

Device Name

Mg OSTEOINJECT™; Mg OSTEOREVIVE™; Mg OSTEOCRETE™

Indications for Use *(Describe)*

Mg OSTEOINJECT™
Mg OSTEOINJECT™ is intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.
Mg OSTEOINJECT™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis.
Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process.
Mg OSTEOINJECT™ is intended to be placed into bony voids either before or after final fixation.
Mg OSTEOINJECT™ is resorbed and replaced with bone during the healing process.
Mg OSTEOINJECT™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Mg OSTEOREVIVE™
Mg OSTEOREVIVE™ is intended for bony voids or defects of the extremities, posterolateral spine, intervertebral disc space, and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.
Mg OSTEOREVIVE™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis.
Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process.
Mg OSTEOREVIVE™ is intended to be placed into bony voids either before or after final fixation.
Mg OSTEOREVIVE™ is resorbed and replaced with bone during the healing process.
Mg OSTEOREVIVE™ must be used with morselized autograft bone in the posterolateral spine.
When used in intervertebral body fusion procedures Mg OSTEOREVIVE™ must be used with morselized autograft bone with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
Mg OSTEOREVIVE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Mg OSTEOCRETE™
Mg OSTEOCRETE™ is intended for bony voids or defects of the extremities, posterolateral spine, intervertebral disc space, and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.
Mg OSTEOCRETE™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis.
Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process.
Mg OSTEOCRETE™ is intended to be placed into bony voids either before or after final fixation.
Mg OSTEOCRETE™ is resorbed and replaced with bone during the healing process.
Mg OSTEOCRETE™ must be used with morselized autograft bone in the posterolateral spine.
When used in intervertebral body fusion procedures Mg OSTEOCRETE™ must be used with morselized autograft bone with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
Mg OSTEOCRETE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

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.

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:

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510(k) Summary
K234013
Mg OSTEOINJECT™, Mg OSTEOREVIVE™, Mg OSTEOCRETE™
Bone Solutions, Inc.

January 31, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Bone Solutions, Inc. 5712 Colleyville Boulevard, Suite 210 Colleyville, Texas 76034 Telephone +1 817-809-8850
Official Contact	Drew Diaz, CEO
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Mg OSTEOINJECT™, Mg OSTEOREVIVE™, Mg OSTEOCRETE™
Common Name	Filler, bone void, calcium compound
Regulation Number	21 CFR 888.3045
Regulation Name	Resorbable calcium salt bone void filler device
Regulatory Class	Class II
Product Code	MQV
Secondary Product Code	OIS
Classification Panel	Orthopedic
Reviewing Office	Office of Health Technology 6 (Orthopedic Devices)
Reviewing Division	Division of Health Technology 6 C (Restorative, Repair and Trauma Devices)

PREDICATE DEVICE INFORMATION

Predicate Devices
K232315, Catalyst Bone Void Filler, OssDsign AB
K231528, Bonalive Orthopedics granules, Bonalive Biomaterials, Ltd.

Reference Devices
K071004, OsteoCrete™ Bone Void Filler, Bone Solutions Inc.
K212991, OSTEOREVIVE™, Bone Solutions Inc.

INDICATIONS FOR USE STATEMENT

Mg OSTEOINJECT™

Mg OSTEOINJECT™ is intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.
Mg OSTEOINJECT™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis.
Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process.
Mg OSTEOINJECT™ is intended to be placed into bony voids either before or after final fixation.
Mg OSTEOINJECT™ is resorbed and replaced with bone during the healing process.
Mg OSTEOINJECT™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Mg OSTEOREVIVE™

Mg OSTEOREVIVE™ is intended for bony voids or defects of the extremities, posterolateral spine, intervertebral disc space, and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.
Mg OSTEOREVIVE™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis.
Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process.
Mg OSTEOREVIVE™ is intended to be placed into bony voids either before or after final fixation.
Mg OSTEOREVIVE™ is resorbed and replaced with bone during the healing process.
Mg OSTEOREVIVE™ must be used with morselized autograft bone in the posterolateral spine.
When used in intervertebral body fusion procedures Mg OSTEOREVIVE™ must be used with morselized autograft bone with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
Mg OSTEOREVIVE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Mg OSTEOCRETE™

Mg OSTEOCRETE™ is intended for bony voids or defects of the extremities, posterolateral spine, intervertebral disc space, and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.
Mg OSTEOCRETE™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis.
Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process.
Mg OSTEOCRETE™ is intended to be placed into bony voids either before or after final fixation.
Mg OSTEOCRETE™ is resorbed and replaced with bone during the healing process.
Mg OSTEOCRETE™ must be used with morselized autograft bone in the posterolateral spine.
When used in intervertebral body fusion procedures Mg OSTEOCRETE™ must be used with morselized autograft bone with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
Mg OSTEOCRETE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

SUBJECT DEVICE DESCRIPTION

This submission includes three devices with three separate trade names bundled into the single 510(k) application. The purpose of this application is to expand the indications to include specific language for the use of all three devices for benign bone cysts and tumors (in adults), and to expand the indications for use of two of the devices (Mg OSTEOREVIVE™ and Mg OSTEOCRETE™) to include use with intervertebral body fusion device cleared by FDA for use with a bone void filler. The subject devices are a magnesium-based synthetic bone void filler that is moldable, injectable, drillable, resorbable, adhesive/cohesive, radiopaque, and osteoconductive. The subject devices comprises a powder component (magnesium-based compound) and a mixing solution (buffered saline). Once the components are mixed intra-operatively prior to implantation, an acid-base reaction happens to form a

cohesive paste. Once the product is placed into the bony void, the paste will adhere to the adjacent bone during the curing process. The devices are provided sterile to the end user for single-use only in various sizes from 3 cc to 15 cc.

PERFORMANCE DATA

Non-clinical testing data according to the guidance documents *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device* (issued June 2003) and *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 2016) were referenced from K212991. The non-clinical testing data leveraged from K071004 to demonstrate substantial equivalence included: chemical composition, physical properties, sterilization, sterile barrier shelf life, product shelf life, and biocompatibility. Performance testing data also leveraged from K212991 demonstrated that the subject device is drillable, and may be used as an adjunct to conventional rigid hardware during the surgical procedure (only when used in the extremities and pelvis). Animal testing data were leveraged from K212991 and K071004.

Bacterial endotoxin testing has been performed to ensure the device meets pyrogen limit specifications. The *Limulus* amebocyte lysate (LAL) test, kinetic turbidimetric method, was performed according to USP *<85> Bacterial Endotoxins Test*. The LAL testing met the limit acceptance criterion of ≤ 20 EU/device, based upon the recommendations for implanted devices in the FDA guidance document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*, issued January 21, 2016 (Section V, A, 4).

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject devices and the predicate devices have the same intended use, the same product classification, product codes (MQV), and have similar Indications for Use statements, with the additions to the subject device Indications for Use described above. Although the subject devices and the predicate devices have slightly different Indications for Use language, these differences in language do not change the intended use as a bone void filler.

Differences among the subject devices and the predicate device include the exact indications for use language, the mineral components, and the scaffold or binder material (K232315). These minor differences do not raise new issues of safety or effectiveness, and therefore, do not impact substantial equivalence.

CONCLUSION

The subject devices and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject devices and predicate devices encompass the same range of physical dimensions (volumes), are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate device and the reference devices listed above.

Table of Substantial Equivalence

Features / Comparisons	Subject Device K234013 Mg OSTEOINJECT™, Mg OSTEOREVIVE™, Mg OSTEOCRETE™ Bone Solutions Inc.	Primary Predicate Device K232315 Catalyst Bone Void Filler OssDsign AB	Predicate Device K231528 Bonalive Orthopedics granules Bonalive Biomaterials, Ltd.
Indications for Use Statement	Mg OSTEOINJECT™ is intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. Mg OSTEOINJECT™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Mg OSTEOINJECT™ is intended to be placed into bony voids either before or after final fixation. Mg OSTEOINJECT™ is resorbed and replaced with bone during the healing process. Mg OSTEOINJECT™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.	Catalyst Bone Void Filler is indicated for filling bone voids or defects of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, extremities, and pelvis) that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or as a result of traumatic injury to the bone. Catalyst Bone Void Filler is a bone graft putty that is resorbed and replaced with bone during the healing process. Catalyst Bone Void Filler must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine. When used in intervertebral body fusion procedures, Catalyst Bone Void Filler must be used with morselized autograft bone at a ratio of 1: 1 by volume with an intervertebral body fusion device cleared by FDA for use with a bone void filler.	Bonalive® Orthopedics granules is an implant intended to fill bony voids or gaps of the skeletal system (i.e., 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 and are not intrinsic to the stability of the bony structure. Bonalive® Orthopedics granules resorbs and is replaced with bone during the healing process.
	Mg OSTEOREVIVE™ is intended for bony voids or defects of the extremities, posterolateral spine, intervertebral disc space, and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. Mg OSTEOREVIVE™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Mg OSTEOREVIVE™ is intended to be placed into bony voids either before or after final fixation. Mg OSTEOREVIVE™ is resorbed and replaced with bone during the healing process. Mg OSTEOREVIVE™ must be used with morselized autograft bone in the posterolateral spine. When used in intervertebral body fusion procedures Mg OSTEOREVIVE™ must be used with morselized autograft bone with an intervertebral body fusion device cleared by FDA for use with a bone void filler. Mg OSTEOREVIVE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.		
	Mg OSTEOCRETE™ is intended for bony voids or defects of the extremities, posterolateral spine, intervertebral disc space, and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. Mg OSTEOCRETE™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure only in the extremities and pelvis. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Mg OSTEOCRETE™ is intended to be placed into bony voids either before or after final fixation. Mg OSTEOCRETE™ is resorbed and replaced with bone during the healing process. Mg OSTEOCRETE™ must be used with morselized autograft bone in the posterolateral spine. When used in intervertebral body fusion procedures Mg OSTEOCRETE™ must be used with morselized autograft bone with an intervertebral body fusion device cleared by FDA for use with a bone void filler. Mg OSTEOCRETE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.		

Features / Comparisons	Subject Device **K234013** **Mg OSTEOINJECT™, Mg OSTEOREVIVE™,** **Mg OSTEOCRETE™** **Bone Solutions Inc.**	Primary Predicate Device **K232315** **Catalyst Bone Void Filler** **OssDsign AB**	Predicate Device **K231528** **Bonalive Orthopedics granules** **Bonalive Biomaterials, Ltd.**
Reason for Predicate/Reference Device	*Not applicable – Subject Device*	Indications for use	Indications for use
Product Codes	MQV, OIS	MQV	MQV
Intended Use	Bone void filler for skeletal system; extremities, pelvis, and posterolateral spine, and with an intervertebral body fusion device FDA cleared for use with a bone void filler	Bone void filler for skeletal system; extremities, pelvis, and posterolateral spine, and with an intervertebral body fusion device FDA cleared for use with a bone void filler	Bone void filler for skeletal system; Extremities and pelvis
Design			
Form	Powder and liquid components; after mixing and placement the device sets in the surgical site; can be injected in the surgical site	5.8 wt% silicon-substituted calcium phosphate granules suspended in a resorbable polymer gel	Amorphous, non-porous, random-shaped particles
Materials			
Mineral component Calcium/other salts	β -tricalcium phosphate (8%) Magnesium oxide (41%) Monopotassium phosphate (44%) Monosodium phosphate (3%)	5.8 wt% silicon-substituted calcium phosphate (granules 30 wt% of final device)	SiO_2, Na_2O, CaO , P_2O_5
Scaffold/Binder	None	Polymer gel (70 wt% of final device)	None
Indicated for Use in Extremities and Pelvis	Yes	Yes	Yes
Mix with autograft bone prior to use	No Not indicated for mixing with autograft in extremities or pelvis	No Not indicated for mixing with autograft in extremities or pelvis	No Not indicated for mixing with autograft in extremities or pelvis
Indicated for Use in Posterolateral Spine	Yes	Yes	No
Mix with autograft bone prior to use	Required to mix with autograft 1:1 by volume for use in the posterolateral spine	Required to mix with autograft 1:1 by volume for use in the posterolateral spine	Not applicable – not indicated for use in posterolateral spine
Indicated for Use in the intervertebral disc space	Yes	Yes	Not applicable – not indicated for use in the intervertebral disc space
Mix with autograft bone prior to use	Required to mix with autograft 1:1 by volume for use in with an intervertebral body fusion device cleared by FDA for use with a bone void filler	Required to mix with autograft 1:1 by volume for use in with an intervertebral body fusion device cleared by FDA for use with a bone void filler	Not applicable
How Provided			
Sizes	Kits of powder and liquid components for volumes of: 3 cc, 5 cc, 10 cc, and 15 cc	Volumes of 1 cc, 2.5 cc, 5 cc, 10 cc	Volumes of 1 cc, 2.5 cc, 5 cc, 10 cc
Sterility	Provided sterile to end user	Provided sterile to end user	Provided sterile to end user
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use