



October 13, 2025

Bone Solutions, Inc.  
% Kevin Thomas  
VP & Director of Regulatory Affairs  
PaxMed International, LLC  
1925 Palomar Oaks Way  
Suite 210  
Carlsbad, California 92008

Re: K251522

Trade/Device Name: Mg OSTEONJECT™; 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, MBP, OIS

Dated: September 12, 2025

Received: September 15, 2025

Dear Kevin 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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Robert M.  
Stefani -S**

Digitally signed by  
Robert M. Stefani -S  
Date: 2025.10.13 19:24:49  
-04'00'

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

## Indications for Use

510(k) Number: K251522

### Device Name

Mg OSTEONJECT™, Mg OSTEOREVIVE™; Mg OSTEOCRETE™

### Indications for Use (Describe)

#### Mg OSTEONJECT™

Mg OSTEONJECT™ 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 and pediatric patients  $\geq 6$  years old), may be surgically created osseous defects or osseous defects created by traumatic injury to the bone.

Mg OSTEONJECT™ 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 OSTEONJECT™ is intended to be placed into bony voids either before or after final fixation.

Mg OSTEONJECT™ is resorbed and replaced with bone during the healing process.

Mg OSTEONJECT™ 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 and pediatric patients  $\geq 6$  years old), 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 and/or allograft bone in the posterolateral spine.

When used in intervertebral body fusion procedures Mg OSTEOREVIVE™ must be used with morselized autograft and/or allograft 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 and pediatric patients  $\geq 6$  years old), 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 and/or allograft bone in the posterolateral spine.

When used in intervertebral body fusion procedures Mg OSTEOCRETE™ must be used with morselized autograft and/or allograft 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.**

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

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**510(k) Summary**  
**K251522**  
**Mg OSTEONJECT™, Mg OSTEOREVIVE™, Mg OSTEORETE™**  
**Bone Solutions, Inc.**  
October 10, 2025

**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 Rebecca E. Kattan, PhD PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone +1 858-792-1235 Email kthomas@paxmed.com flarson@paxmed.com rkattan@paxmed.com

**DEVICE NAME AND CLASSIFICATION**

Trade/Device Name	Mg OSTEONJECT™, Mg OSTEOREVIVE™, Mg OSTEORETE™
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 Codes	MBP, 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**

Primary Predicate Device  
K242372, Mg OSTEOREVIVE™, Mg OSTEORETE™, Bone Solutions Inc.  
Reference Devices  
K234013, Mg OSTEONJECT™, Mg OSTEOREVIVE™, Mg OSTEORETE™, Bone Solutions Inc.  
K231528, Bonalive Orthopedics granules, Bonalive Biomaterials, Ltd.

## 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 and pediatric patients  $\geq 6$  years old), 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 and pediatric patients  $\geq 6$  years old), 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 and/or allograft bone in the posterolateral spine.

When used in intervertebral body fusion procedures Mg OSTEOREVIVE™ must be used with morselized autograft and/or allograft 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 and pediatric patients  $\geq 6$  years old), 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 and/or allograft bone in the posterolateral spine.

When used in intervertebral body fusion procedures Mg OSTEOCRETE™ must be used with morselized autograft and/or allograft 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 (3) devices with 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 use in pediatric patients  $\geq 6$  years old. The subject devices are a magnesium-based synthetic bone void filler that is moldable, drillable, resorbable, adhesive/cohesive, radiopaque, and osteoconductive. The subject devices consist of 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 occurs 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 2024) were referenced from K242372 and K234013. The non-clinical testing data leveraged to demonstrate substantial equivalence included: chemical composition, physical properties, sterilization, sterile barrier shelf life, product shelf life, and biocompatibility. Performance testing data also leveraged 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 to support the indications for use as a bone void filler also were referenced in K242372 and K234013.

Additional non-clinical data provided to support the indication for use in pediatric patients included a toxicological risk assessment, and an animal model to demonstrate that serum magnesium levels in animals implanted with the subject device did not significantly increase over time, and were not significantly different from control animals.

Bacterial endotoxin testing has been performed to ensure the device meets pyrogen limit specifications. The *Limulus* ameobocyte lysate (LAL) test, kinetic turbidimetric method, was performed according to USP <85> *Bacterial Endotoxins Test*. The LAL testing met the limit acceptance criterion of  $\leq 20$  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 2024), Section V, A, 4.d.

No clinical data were included in this submission.

## EQUIVALENCE TO MARKETED DEVICES

The subject device, the primary predicate device K242372, and the reference devices K234013 and K231528 have the same intended use, the same product classification, product codes (MQV for all, MBP for K242372, and OIS for K242372 and K234013), and have similar Indications for Use statements, with the additions to the subject device Indications for Use described above. Although the subject device, the primary predicate device, and the reference devices have slightly different Indications for Use language, these differences in language do not change the intended use as a bone void filler. The subject device, the primary predicate device K242372 and the reference device K234013 are made of identical materials, provided in the same range of physical dimensions (volumes), are packaged in identical materials, and are sterilized using identical methods.

Differences between the subject device and the reference device K231528 include the exact indications for use language, the mineral components, and the range of sizes (volumes). These minor differences do not raise new issues of safety or effectiveness, and therefore, do not impact substantial equivalence.

## CONCLUSION

The subject device, the primary predicate device K242372, and the reference device K234013 have the same intended use, have identical technological characteristics, and are made of identical materials. The subject device, the primary predicate device K242372, and the reference device K234013 encompass the same range of physical dimensions (volumes), are packaged in identical materials and are sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the primary predicate device and the reference devices listed above.