June 28, 2022

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

Re: K221256
Trade/Device Name: Mg OSTEOINJECT™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV, OIS
Dated: May 2, 2022
Received: May 2, 2022

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Mg OSTEOINJECT™

Indications for Use *(Describe)*

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 defects 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.

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
K221256
Mg OSTEOINJECT™
Bone Solutions, Inc.

June 28, 2022

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™
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

Primary Predicate Device
K212991, OSTEOREVIVE™, Bone Solutions, Inc.

Reference Device
K140375, MASTERGRAFT® Strip; MASTERGRAFT® Putty, Medtronic Sofamor Danek USA, Inc.

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 defects 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.

SUBJECT DEVICE DESCRIPTION

Mg OSTEOINJECT™ is a magnesium-based synthetic bone void filler that is drillable, resorbable, radiopaque, and osteoconductive. The Mg OSTEOINJECT™ Kit contains powder (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 device is provided sterile to the end user for single-use only in two sizes, 3 cc and 5 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 referenced to demonstrate substantial equivalence included: chemical composition, physical properties, sterilization, sterile barrier shelf life, product shelf life, and biocompatibility. Performance testing data also referenced 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).

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 device is substantially equivalent in indications and design principles to the primary predicate device K212991 and the reference device K140375. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device and the primary predicate device.

The primary predicate device is K212991, for the identical formulation, packaging, and sterilization as the subject device. The subject device differs from K212991 in terms of the indications for use; the subject device is indicated only for use in the extremities and pelvis.

The reference device K140375 is for support of substantial equivalence of the subject device provided in a kit with a volume of 3 cc. The reference device K140375 includes the same indications for use in the extremities and pelvis and includes a range of volumes from 0.75 cc to 9 cc.

The subject device and the primary predicate device K21299 have the same intended use, the same product classification and product codes (MQV and OIS), and have similar Indications for Use statements. The subject device, the primary predicate device, and the reference device are indicated for use as bone void fillers in the extremities and pelvis. Although the subject device, the primary predicate device, and the reference device 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, and the reference device all incorporate calcium phosphate materials that are mixed to form a solid after setting (subject device and primary predicate device) or are within a polymeric binder or scaffold (reference device). The subject device and primary predicate device have identical materials and formulation and are mixed intra-operatively. The subject device, the primary predicate device, and the reference device are all provided in comparable volumes, sterilized by irradiation, and are for single-patient, single-use.

Differences among the subject device, the primary predicate device, and the reference device include the exact indications for use (including use in the posterolateral spine for the primary predicate and reference device), the mineral components, and the scaffold or binder material (bovine collagen in the reference device K140375). The minor differences among the subject device, the primary predicate device, and the reference device do not raise new issues of safety or effectiveness, and therefore, do not impact substantial equivalence.

CONCLUSION

The subject device, the primary predicate device, and the reference device have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and the primary predicate device are manufactured from identical materials. The subject device, the primary predicate, and the reference device 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 device listed above.

Table of Substantial Equivalence

Features / Comparisons	Subject Device	Primary Predicate Device
	Mg OSTEOINJECT™ Bone Solutions Inc.	K212991 OSTEOREVIVE™ Bone Solutions Inc.
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 defects 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. 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	OSTEOREVIVE™ is intended for bony voids or defects of the extremities, posterolateral spine, and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created by traumatic injury to the bone. OSTEOREVIVE™ can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. OSTEOREVIVE™ is intended to be placed into bony voids either before or after final fixation. OSTEOREVIVE™ is resorbed and replaced with bone during the healing process. OSTEOREVIVE™ must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine. OSTEOREVIVE™ is not intended to treat large defects that in the surgeon's opinion would fail to heal spontaneously.
Reason for Predicate/Reference Device	*Not applicable – Subject Device*	Identical or similar indications for use, formulation, packaging, and sterilization
Product Codes	MQV, OIS	MQV, OIS
Intended Use	Bone void filler for skeletal system; extremities and pelvis	Bone void filler for skeletal system; extremities, pelvis, and posterolateral spine
Design		
Form	Powder and liquid components; after mixing device is injectable and sets in the surgical site	Powder and liquid components; after mixing device is injectable and sets in the surgical site
Granule Size	Not applicable, non-porous solid after mixing and setting	Not applicable, non-porous solid after mixing and setting
Porosity	Not applicable, non-porous solid after mixing and setting	Not applicable, non-porous solid after mixing and setting
Materials		
Mineral component Calcium/other salts	β-tricalcium phosphate (8%) Magnesium oxide (41%) Monopotassium phosphate (44%) Monosodium phosphate (3%)	β-tricalcium phosphate (8%) Magnesium oxide (41%) Monopotassium phosphate (44%) Monosodium phosphate (3%)
Scaffold/Binder	None	None
Indicted for Use in Extremities and Pelvis	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
Indicated for Use in Posterolateral Spine	No	Yes
Mix with autograft bone prior to use	*Not applicable – not indicated for use in posterolateral spine*	Required to mix with autograft 1:1 by volume for use in the posterolateral spine

Table of Substantial Equivalence

Features / Comparisons	Subject Device	Primary Predicate Device
	Mg OSTEOINJECT™ Bone Solutions Inc.	K212991 OSTEOREVIVE™ Bone Solutions Inc.
How Provided		
Sizes	Kits of powder and liquid components for volumes of: 3 cc and 5 cc	Kits of powder and liquid components for volumes of: 5 cc, 10 cc, and 15 cc
Sterility	Provided sterile to end user	Provided sterile to end user
Sterilization	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use