December 20, 2022

Collagen Matrix, Inc.
Peggy Hansen
SVP, Regulatory and Clinical Affairs
15 Thornton Road
Oakland, New Jersey 07436

Re: K221735
Trade/Device Name: Mineral Collagen Composite Bioactive Moldable
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: November 21, 2022
Received: November 22, 2022

Dear Peggy Hansen:

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 -S

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)*
K221375

Device Name

Mineral Collagen Composite Bioactive Moldable

Indications for Use *(Describe)*

Mineral Collagen Composite Bioactive Moldable is intended for use as a bone void filler for voids or gaps, that are not intrinsic to the stability of the bony structure. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

For spine application Mineral Collagen Composite Bioactive Moldable is combined with either autogenous bone marrow or autograft with saline and can also be used with autograft as a bone graft extender.

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.

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510(k) Number: K221375

510(k) SUMMARY

1. Applicant Information

Applicant Name:	Collagen Matrix, Inc.
Address:	15 Thornton Road Oakland, New Jersey 07436
Telephone:	(201) 405-1477
Fax:	(201) 405-1355
Contact Person:	Peggy Hansen Sr. Vice President, Regulatory and Clinical Affairs phansen@collagenmatrix.com
Date Prepared:	July 18, 2022

2. Name of the Device

Device Trade Name:	Mineral Collagen Composite Bioactive Moldable
Device Common Name(s):	Bone Void Filler Bone Graft Matrix Bone Graft Substitute
Device Classification Name:	Filler, Bone Void, Calcium Compound 888.3045 MQV Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Primary Predicate Device:	Mineral Collagen Composite Bioactive Moldable Collagen Matrix, Inc. K182074
Reference Device:	SIGNAFUSE PUTTY Bioactive Bone Graft Bioventus, Inc. K132071

4. Description of the Device

Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix is composed of anorganic bone mineral, bioactive glass, and type I collagen that can be molded to fit the bone defect. It is an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site. The bone graft matrix is slowly resorbed and replaced by new bone tissue during the natural healing process.

The anorganic bone mineral component of the bone graft matrix is a natural, porous bone graft material produced by removal of all organic components from bovine bone. The composition of the anorganic bone mineral meets ASTM F1581 standard specifications for composition of

anorganic bone for surgical implants. The bioactive glass component of the device is made of 45S5 Bioactive Glass and meets ASTM F1538 standard specifications for glass and glass ceramics biomaterials for implantation. The purified type I collagen is derived from bovine Achilles tendon.

The product is available in various sizes and is provided sterile, non-pyrogenic, and for single use only.

5. Intended Use

Mineral Collagen Composite Bioactive Moldable is intended for use as a bone void filler for voids or gaps, that are not intrinsic to the stability of the bony structure. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

For spine applications, Mineral Collagen Composite Bioactive Moldable is combined with either autogenous bone marrow or autograft with saline and can also be used with autograft as a bone graft extender.

6. Summary/Comparison of Technical Characteristics

This submission expands the indications for use of Mineral Collagen Composite Bioactive Moldable for use in the extremities and pelvis. The subject device has equivalent technological characteristics as the cited legally marketed predicate Mineral Collagen Composite Bioactive Moldable (K182074) device.

Feature	Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix (This submission)	Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix (K182074)	Bioactive Bone Graft Putty SIGNAFUSE PUTTY Reference Device (K132071)
Indications for Use	Mineral Collagen Composite Bioactive Moldable is intended for use as a bone void filler for voids or gaps, that are not intrinsic to the stability of the bony structure. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process. For spine applications, Mineral Collagen Composite Bioactive Moldable is combined with either autogenous bone marrow or autograft with saline and can	Mineral Collagen Composite Bioactive Moldable combined with either autogenous bone marrow or autograft with saline is indicated for bony voids or gaps, that are not intrinsic to the stability of the bony structure; Mineral Collagen Composite Bioactive Moldable can also be used with autograft as a bone graft extender. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.	Bioactive Bane Graft Putty is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Bioactive Bone Graft Putty is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis and posterolateral spine fusion procedures). Bioactive Bone Graft Putty can also be used with autograft as a bone graft extender in the posterolateral spine. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.

Feature	Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix (This submission)	Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix (K182074)	Bioactive Bone Graft Putty SIGNAFUSE PUTTY Reference Device (K132071)
	also be used with autograft as a bone graft extender.		
Physical Form	Strip or Cylindrical matrix (moldable upon hydration)	Strip or Cylindrical matrix (moldable upon hydration)	Putty preloaded into a syringe applicator or Strip (moldable)
Color	White to off-white	White to off-white	White to off-white
Material Composition	• Calcium phosphate (anorganic bone mineral) • Bioactive glass • Type I bovine collagen	• Calcium phosphate (anorganic bone mineral) • Bioactive glass • Type I bovine collagen	• Calcium phosphate (60%HA:40%TCP) • Bioactive glass • Alkylene oxide polymer
Product Sizes	2.5 cc – 40 cc	2.5 cc – 40 cc	2.5 cc – 10 cc
Biocompatibility	Biocompatible ISO 10993	Biocompatible ISO 10993	Biocompatible ISO 10993
Sterility	Sterile, SAL 10^{-6} Gamma irradiation, ISO11137	Sterile, SAL 10^{-6} Gamma irradiation, ISO11137	Sterile, SAL 10^{-6} Gamma irradiation, ISO11137
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic
Single Use/ Reuse	Single use only	Single use only	Single use only

7. Performance Data

In vivo and *in vitro* testing of the subject device was conducted to demonstrate substantial equivalence of the subject device to its predicate devices. The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing

Additional biocompatibility data was not required to determine substantial equivalence. There are no changes to the product and the performance data remains the same as that submitted for the original submission (K182074).

Sterilization, Pyrogen, Endotoxin, Packaging and Shelf Life Testing

Sterilization validation, pyrogen testing, packaging validation and shelf life testing were completed under the original submission, K182074, and there have been no changes to the product since the original submission. Each lot of finished devices is tested for bacterial endotoxin for lot release.

Bench Testing

Bench testing was not required to determine substantial equivalence. The technological characteristics remains the same as that submitted for the original submission.

Animal Testing

The performance of the device in a rabbit femoral condyle critical-sized defect model was compared to the performance of the reference device, SIGNAFUSE bioactive bone graft. The results demonstrate performance substantially equivalent to the reference device with regards to the expansion of the indications for use.

Clinical Studies

Clinical performance data was not required to determine substantial equivalence.

8. Conclusions Drawn from Non-clinical Studies

The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to its predicate and reference devices.