August 2, 2023

Collagen Matrix, Inc.
Victoria Augustine
Regulatory Affairs Specialist
15 Thornton Rd.
Oakland, New Jersey 07436

Re: K231942
Trade/Device Name: Mineral Collagen Composite Bioactive Extra Moldable
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: June 30, 2023
Received: June 30, 2023

Dear Victoria Augustine:

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,

Jesse Muir -S

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231942

Device Name

Mineral Collagen Composite Bioactive Extra Moldable

Indications for Use *(Describe)*

Mineral Collagen Composite Bioactive Extra 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 Extra 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.

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

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510(k) Summary

Prepared on: 2023-06-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Collagen Matrix, Inc.
Applicant Address	15 Thornton Rd. Oakland NJ 07436 United States
Applicant Contact Telephone	6462229564
Applicant Contact	Victoria Augustine
Applicant Contact Email	taugustine@regenity.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Mineral Collagen Composite Bioactive Extra Moldable
Common Name	Resorbable calcium salt bone void filler device
Classification Name	Filler, Bone Void, Calcium Compound
Regulation Number	888.3045
Product Code	MQV

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221735	Mineral Collagen Composite Bioactive Moldable	MQV
K182074	Mineral Collagen Composite Bioactive Moldable	MQV

Device Description Summary

21 CFR 807.92(a)(4)

Mineral Collagen Composite Bioactive Extra 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 osteroconductive, 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 the composition of anorganic bone for surgical implants. The bioactive glass component of the device is made of 45S5 Bioactive Glass and meeting ASTM F1538 standard specifications for glass and glass ceramic 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Mineral Collagen Composite Bioactive Extra 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.

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Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has the same indications for use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same basic design characteristics and technological characteristics (i.e., design, material, chemical composition, principle of operation) as the primary predicate device, with the same specification ranges. A minor modification improves the moldability of the device compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance Data
In vivo and in vitro testing of the subject device was conducted to demonstrate substantial equivalence of the subject device and remains the same as that submitted for the primary predicate device (K221735) and the secondary predicate device (K182074).

Sterilization
There are no changes to the validated sterilization method and the sterility assurance level (SAL 1x^10-6) remains the same as documented in the primary predicate device submission (K221375) and the predicate device submission (K182074).

Pyrogenicity
The subject device is non-pyrogenic. There are no changes to the product and the biocompatibility data remains the same as that submitted for the primary predicate device (K221735) and the secondary predicate device (K182074).

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 primary predicate device submission (K221735).

Animal Testing
Additional animal testing was not required to determine substantial equivalence. The animal testing conducted in the primary predicate device (K221735) and predicate device (K182074) is applicable for the subject device.

Clinical Studies
Clinical performance data was not required to determine substantial equivalence.

Conclusions Drawn from Non-Clinical Sites
The conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to its predicate devices.