March 12, 2024

Collagen Matrix, Inc.
Daniel Fernandez
Regulatory Affairs, Specialist
15 Thornton Road
Oakland, New Jersey 07436

Re: K240424
Trade/Device Name: Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: February 12, 2024
Received: February 13, 2024

Dear Daniel Fernandez:

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)*
K240424

Device Name
Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix

Indications for Use *(Describe)*
Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix 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, intervertebral disc space, 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.

In the posterolateral spine and intervertebral disc space, Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix is combined with either autogenous bone marrow or autograft with saline and can also be used with autograft as a bone graft extender. When used in intervertebral body fusion procedures, Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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.

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: Daniel Fernandez
Regulatory Affairs, Specialist
dfernandez@regenity.com

Date Prepared: March 6, 2024

2. Name of the Device

Device Trade Name: Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix

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

Predicate Device: Catalyst Bone Void Filler
OssDsign Av
K232315

Secondary Predicate Device: Mineral Collagen Composite Bioactive Extra Moldable
Collagen Matrix, Inc
K231942

Reference Device: Mineral Collagen Composite Bioactive Moldable
Collagen Matrix, Inc
K182074

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 / Indications for Use

Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix 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, intervertebral disc space, 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.

In the posterolateral spine and intervertebral disc space, Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix is combined with either autogenous bone marrow or autograft with saline and can also be used with autograft as a bone graft extender. When used in intervertebral body fusion procedures, Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

6. Technological Comparison

The subject device has equivalent indications, design principles, and performance characteristics as the predicate device, OssDsign Catalyst Bone Void Filler (510(k) K232315) and secondary predicate Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix (K231942).

The subject device has the same basic design characteristics and technological characteristics (i.e design, material, chemical composition, principle of operation) as the secondary predicate device, K231942 and reference device K182074, with the same specification range.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues or concerns of safety or efficacy.

7. Non-Clinical and/or Clinical Test Summary and Conclusions

The purpose of this submission is to expand the indications for use of the Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix to include use in the intervertebral disc space in conjunction with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Performance testing of the subject device remains unchanged as that submitted for the secondary predicate (K231942) and reference device (K182074). There is no change to the device characteristics and specifications, manufacturing processes or composition resulted from the expanded indications, and the subject device remains identical to the cleared secondary predicate and reference devices K231942 and K182074.

There are no changes to the validated sterilization method and sterility assurance level (SAL $1x10^{-6}$) remains the same as documented in the secondary predicated device (K231942) and reference device (K182074).

The subject device is non-pyrogenic. There are no changes to the product and the biocompatibility data remains the same as that submitted in the secondary predicate device (K231942) and reference device (K182074).

Biocompatibility testing of the subject device was not required, as there are no changes to the product and the performance data as submitted for the secondary predicate device (K231942) and the reference device (K182074).

Additional animal testing was not required to determine substantial equivalence. The animal testing conducted and submitted in secondary predicate K231942 and reference device K182074 is applicable for the subject device.

Clinical performance data was not required to determine substantial equivalence.

8. Conclusion

The subject device and the predicate devices have the same intended use, similar technological characteristics, and are made of similar materials. The subject device and predicate devices share similar packaging and sterilization methods. The data included and referenced in this submission demonstrates substantial equivalence of the subject device to the predicate devices. Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix is as safe, effective, and performs as well as the predicate devices.