March 21, 2019

Collagen Matrix, Inc.
Gloria Zuclich
Director, Regulatory Affairs
15 Thornton Road
Oakland, New Jersey 07436

Re: K182074
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: February 18, 2019
Received: February 19, 2019

Dear Ms. Zuclich:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  

Indications for Use

510(k) Number (if known)
K182074

Device Name

Mineral Collagen Composite Bioactive Moldable

Indications for Use (Describe)

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.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASestff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) SUMMARY

1. Applicant Information

<table>
<thead>
<tr>
<th>Applicant Name:</th>
<th>Collagen Matrix, Inc.</th>
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</thead>
<tbody>
<tr>
<td>Address:</td>
<td>15 Thornton Road</td>
</tr>
<tr>
<td></td>
<td>Oakland, New Jersey 07436</td>
</tr>
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<td>Telephone:</td>
<td>(201) 405-1477</td>
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<td>Fax:</td>
<td>(201) 405-1355</td>
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<tr>
<td>Contact Person:</td>
<td>Gloria Zuclich</td>
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<tr>
<td></td>
<td>Director of Regulatory Affairs</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:gzuclich@collagenmatrix.com">gzuclich@collagenmatrix.com</a></td>
</tr>
<tr>
<td>Date Prepared:</td>
<td>March 19, 2019</td>
</tr>
</tbody>
</table>

2. Name of the Device

<table>
<thead>
<tr>
<th>Device Trade Name:</th>
<th>Mineral Collagen Composite Bioactive Moldable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Common Name(s):</td>
<td>Bone Void Filler</td>
</tr>
<tr>
<td></td>
<td>Bone Graft Matrix</td>
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<tr>
<td></td>
<td>Bone Graft Substitute</td>
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<tr>
<td>Device Classification Name:</td>
<td>Filler, Bone Void, Calcium Compound</td>
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<td></td>
<td>888.3045</td>
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<td>MQV</td>
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<td>Class II</td>
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3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

| Primary Predicate Device: | Vitoss® Bioactive Foam Bone Graft Substitute |
|                          | Orthovita, Inc. |
|                          | K083033 |

| Predicate Device: | MASTERGRAFT® Strip/Putty |
|                  | Medtronic Sofamor Danek USA, Inc. |
|                  | K140375 |

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 deep flexor 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 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.

6. Summary/Comparison of Technical Characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>Mineral Collagen Composite Bioactive Moldable Bone Graft Matrix (This submission)</th>
<th>VITOSS Bioactive Foam Bone Graft Substitute* K083033</th>
<th>MASTERGRAFT Strip/Putty K140375</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>Vitoss Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.</td>
<td>MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Putty resorbs and is replaced with bone during the healing process.</td>
</tr>
<tr>
<td>Physical Form</td>
<td>Strip or Cylindrical matrix (moldable upon hydration)</td>
<td>Foam Pack (moldable upon hydration)</td>
<td>Strip or Putty Matrix (Putty is moldable upon)</td>
</tr>
</tbody>
</table>

*VITOSS Bioactive Foam Bone Graft Substitute* is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Vitoss Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e. the extremities, pelvis, and spine, which includes posterolateral fusion procedures), and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.
Nonclinical Tests Submitted

*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 performance of the device in posterolateral spine fusion rabbit model was compared to the performance of the predicate device, Vitoss BA and to the performance of the Autograft control. The results of the animal study demonstrate performance substantially equivalent to the predicate device Vitoss BA and performance substantially equivalent to autograft when used as an autograft extender.

The materials are safe and biocompatible as demonstrated through ISO 10993 Biological Evaluation of medical Devices. The device is considered bioactive based on *in vitro* testing, that show apatite layer formation on the surface of the bioactive glass particles following immersion in simulated body fluid (SBF). In vitro characterization studies included evaluation of physical properties such as density, mineral content, absorbency and an evaluation of physicochemical properties such as pH. The characterization test results of the subject device were equivalent to those of the predicate devices. Viral inactivation studies were performed to ensure the viral safety of the product.

Material-mediated pyrogenicity testing was performed on the final finished device in accordance with USP<151>. Bacterial endotoxin testing performed using the limulus amebocyte lysate (LAL) method showed that the device meets the endotoxin limits in accordance with ANSI/AAMI ST72:2011.

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