Collagen Matrix, Inc.
Danielle Lindner
Senior Regulatory Affairs Associate II
15 Thornton Road
Oakland, New Jersey 07436

October 30, 2017

Re: K171008
Trade/Device Name: Anorganic Bone Mineral with Collagen in Delivery Applicator
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: September 26, 2017
Received: September 28, 2017

Dear Danielle Lindner:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Anorganic Bone Mineral with Collagen in Delivery Applicator

Indications for Use *(Describe)*

Anorganic Bone Mineral with Collagen in Delivery Applicator is intended for use in dental surgery. The products may be used in surgical procedures such as:

- Augmentation or reconstructive treatment of alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration.

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) SUMMARY

K171008

Applicant Information

Applicant Name:	Collagen Matrix, Inc.
Owner Operator No.:	9043463
Address:	15 Thornton Road Oakland, New Jersey 07436
Telephone:	(201) 405-1477
Fax:	(201) 405-1355
Contact Person:	Peggy Hansen Senior VP, Quality and Regulatory Affairs (201) 405 -1477 phansen@collagenmatrix.com
Date Prepared:	September 25, 2017

Name of Device

Trade Name:	Anorganic Bone Mineral with Collagen in Delivery Applicator
Common Name:	Bone Grafting Material
Classification Name:	Bone Grafting Material, Animal Source 21 CFR 872.3930 NPM Class II Dental

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s)	Anorganic Bone Mineral Anorganic Bone Mineral with Collagen Anorganic Bone Mineral with Collagen Blocks K043034

Reference Predicates:	Porcine Anorganic Bone Mineral in Delivery Applicator K162158 21 CFR 872.3930 Bone Grafting Material Class II NPM
	Geistlich Bio-Oss Pen® K120601 21 CFR 872.3930 Bone Grafting Material Class II NPM

Description of the Device

Anorganic Bone Mineral with Collagen in Delivery Applicator are porous bone mineral matrices consisting of calcium phosphate derived from bovine bone with the addition of bovine type I collagen, pre-loaded into a delivery applicator for ease of placement in the defect site. The anorganic bone mineral component is produced by removal of the organic components from bovine bone. The type I collagen component is derived from bovine Achilles tendon. Anorganic Bone Mineral with Collagen in Delivery Applicator is sterilized by gamma irradiation. The products are non-pyrogenic and for single use only.

Indications for Use

Anorganic Bone Mineral with Collagen in Delivery Applicator is intended for use in dental surgery. The products may be used in surgical procedures such as:

- Augmentation or reconstructive treatment of alveolar ridge
- Filling of infrabony periodontal defects
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration.

Summary/Comparison of Technical Characteristics

The delivery applicator has been designed to deliver the anorganic bone mineral products to the intended treatment area that may be more difficult to reach. The significant modifications that were made are (i) additional sizes offered to the user in a pre-loaded applicator and (ii) new packaging configuration. The key device characteristics, environment for use, performance specifications, principals of operation, mechanism of action and technological characteristics remain unchanged.

The addition of the delivery applicator does not affect the product performance of the bone grafting material, and therefore does not affect substantial equivalence when comparing the subject device to its predicate device. The table below summarizes the comparison of technical characteristics.

Feature	Anorganic Bone Mineral with Collagen in Delivery Applicator (Subject Device)	Anorganic Bone Mineral with Collagen (K043034)
Indications for Use	- Augmentation or reconstructive treatment of alveolar ridge - Filling of infrabony periodontal defects - Filling of defects after root resection, apicoectomy, and cystectomy - Filling of extraction sockets - Elevation of maxillary sinus floor - Filling of periodontal and peri-implant defects in conjunction with products intended for GTR and GBR	- Augmentation or reconstructive treatment of alveolar ridge - Filling of infrabony periodontal defects - Filling of defects after root resection, apicoectomy, and cystectomy - Filling of extraction sockets - Elevation of maxillary sinus floor - Filling of periodontal and peri-implant defects in conjunction with products intended for GTR and GBR
Material	Anorganic Bone Mineral with Purified Type I Collagen	Anorganic Bone Mineral with Purified Type I Collagen
Source	Bovine bone (anorganic bone mineral) with bovine tendon (collagen)	Bovine bone (anorganic bone mineral) with bovine tendon (collagen)
Form:	Preformed Plug & Moldable Plug	Block
Sizes	0.25 cc, 0.5 cc, 1.0 cc	0.25 g, 0.5 g, 1.0 g, 2.0 g
Biocompatibility	Biocompatible for the cleared indications for use	Biocompatible for the cleared indications for use
Packaging	Plastic delivery applicator in a single blister tray with Tyvek lid	Glass vial with plastic screw cap in a single blister with Tyvek lid
Plunger Force	4.5 N ± 1.3 N (preformed plug) 4.1 N ± 1.1 N (moldable plug)	Not applicable
Sterility	Gamma irradiation, SAL 10^{-6}	Gamma irradiation, SAL 10^{-6}
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Single Use	Single Use Only	Single Use Only

Non-Clinical Performance Testing

To demonstrate substantial equivalence, the following non-clinical performance testing on the subject device was performed:

- Biocompatibility of Sterile Finished Device: cytotoxicity, irritation, and sensitization
- Biocompatibility of Delivery Applicator: cytotoxicity, physicochemical attributes of a polymeric material, containers – plastics, physicochemical tests USP <661>, physicochemical (material/chemical) characterization testing of non-aged and 36 month real time aged delivery applicators with extraction conditions and methods in accordance with ISO 10993-12 and ISO 10993-18.
- Biocompatibility of Anorganic Bone Mineral and Purified Type I Collagen (previously submitted in the company's own predicate device premarket notification and applicable to the subject device): cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, pyrogenicity, implantation, subacute/subchronic toxicity
- Sterilization validation was performed in accordance with ISO 11137-1 Sterilization of health care products - Radiation
- Bench testing of delivery applicator functionality and customer assessment.
- Animal performance testing of the Anorganic Bone Mineral derived from porcine bone tissue (K140714) in an intraoral defect in a canine model and the Anorganic Bone Mineral with and without Collagen (K043034) in a rabbit femoral condyle defect model.
- Animal performance testing of the Purified Type I Collagen derived from bovine Achilles tendon in a rat subcutaneous implantation study.

Conclusion

The results of the *in vitro* product characterization studies, functionality testing, animal performance testing, and biocompatibility studies show that the Anorganic Bone Mineral with Collagen in Delivery Applicator is substantially equivalent to its predicate device.