DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

Collagen Matrix, Inc.
Peggy Hansen
Senior Vice President, Quality And Regulatory Affairs
15 Thornton Road
Oakland, New Jersey 07436

Re: K162158
Trade/Device Name: Porcine Anorganic Bone Mineral In Delivery Applicator
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: January 13, 2017
Received: January 17, 2017

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. 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 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 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,

Michael J. Ryan -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

Indications for Use

510(k) Number (if known): K162158

Device Name: Porcine Anorganic Bone Mineral in Delivery Applicator

Indications for Use:

Porcine Anorganic Bone Mineral 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.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801.109)

K162158

510(k) SUMMARY

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
cc:	Danielle Lindner Senior Regulatory Affairs Associate II 201-405-1477 dlindner@collagenmatrix.com
Date Prepared:	February 8, 2017

Name of Device

Trade Name:	Porcine Anorganic Bone Mineral 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)	Porcine Anorganic Bone Mineral K140714

Description of the Device

Porcine Anorganic Bone Mineral in Delivery Applicator is a porous bone mineral matrix consisting predominantly of calcium phosphate, pre-loaded into a delivery applicator. Porcine Anorganic Bone Mineral in Delivery Applicator is produced by removal of the organic components from porcine bone. Porcine Anorganic Bone Mineral in Delivery Applicator is sterilized by gamma irradiation. The product is non-pyrogenic and for single use only.

Indications for Use

Porcine Anorganic Bone Mineral 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 porcine anorganic bone mineral granules to the intended treatment area that may be more difficult to reach. The only 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	**Porcine Anorganic Bone Mineral In Delivery Applicator (this submission)**	**Porcine Anorganic Bone Mineral (K140714)**
Indications for Use	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.	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.
Material Source	Porcine Bone	Porcine Bone
Material Composition	Calcium phosphate	Calcium phosphate
Mineral Structure	Carbonate apatite	Carbonate apatite
Form	Granules	Granules
Color	White to off-white	White to off-white
Physical Appearance	Porous, irregular-shaped particles	Porous, irregular-shaped particles
Product Sizes	0.25 and 0.5 cc	0.25 cc, 0.5 cc, 1.0 cc, 2.0 cc, and 4.0 cc
Particle Size Range	0.25 - 1 mm	0.25 – 1 mm and 1 - 2 mm
pH	7.3 ± 0.1	7.3 ± 0.1
Resorption Profile	Gradual resorption	Gradual resorption
Unit package	Pre-loaded into plastic delivery applicator	Plastic jar

Feature	**Porcine Anorganic Bone Mineral In Delivery Applicator (this submission)**	**Porcine Anorganic Bone Mineral (K140714)**
Sterility	Sterile, SAL 10^{-6} Gamma irradiation ISO 11137	Sterile, SAL 10^{-6} Gamma irradiation ISO 11137
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Single Use/ Reuse	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>
- Biocompatibility of Anorganic Porcine Bone Mineral (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 Porcine Bone Mineral in an intraoral defect in a canine model (previously submitted in the company's own predicate device premarket notification and applicable to the subject device).

Conclusion

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