

JUL 16 2014

## 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:** Peggy Hansen, RAC  
VP, Clinical, Regulatory, QA, and Marketing  
**Date Prepared:** June 16, 2014

**2. Name of the Device**

**Device Trade Name:** Porcine Anorganic Bone Mineral  
**Device Common Name:** Bone Grafting Material  
**Device Classification Name:** Bone Grafting Material, Animal Source  
21 CFR 872.3930  
Product Code NPM  
Device Class II

**3. Legally Marketed Devices to Which Substantial Equivalence is Claimed**

**Predicate Device(s):** OsteoGuide™ Anorganic Bone Mineral  
K043034  
  
Bio-Oss® Granules  
K952617

**4. Description of the Device**

Porcine Anorganic Bone Mineral is a porous bone graft material consisting predominantly of calcium phosphate supplied in granular form for use in dental surgeries. The anorganic bone mineral is produced by removal of the organic components from porcine bone. The composition of Porcine Anorganic Bone Mineral meets the requirements of ASTM F1581 Standard Specification for Composition of Anorganic Bone for Surgical Implants. The anorganic bone mineral matrix is biocompatible, having interconnecting macro- and microscopic porous structure that supports the formation and ingrowth of new bone at the implantation site. The use of Porcine Anorganic Bone Mineral may be considered when autogenous bone is not indicated, or insufficient in quantity to fulfill the needs of the proposed surgical procedure.

The granular product is supplied sterile, non-pyrogenic, and for single use only.

## 5. Intended Use

Porcine Anorganic Bone Mineral 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

## 6. Summary of Technical Characteristics

Porcine Anorganic Bone Mineral has been determined to be substantially equivalent to the predicate devices having similar technological characteristics as follows:

Appearance:	White to off-white granules
Mineral Structure:	Carbonate Apatite
Material Composition:	Calcium Phosphate
Particle Size:	0.25 – 1 mm and 1 – 2 mm
pH:	6 – 9.5
Nitrogen Content:	Meets Specification (ASTM 1581)

The final composition of the anorganic bone mineral for both devices consists of a calcium phosphate mineral in a carbonate apatite that is produced by removal of organic components from the bone tissue structure.

## 7. Discussion of Non-clinical Testing

The substantial equivalence of Porcine Anorganic Bone Mineral and its predicates was demonstrated based on *in vitro* characterization studies, biocompatibility studies, and animal efficacy studies.

Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidelines as follows:

FDA Guidance Document entitled, "Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices," issued on April 28, 2005

ASTM F1581, Standard specifications for composition of anorganic bone for surgical implants.

ISO 22442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management

ISO 22442-2 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling

ISO 22442-3 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents

ISO 10993-3:2009 Biological Evaluation of Medical Devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for *in vitro* cytotoxicity

ISO 10993-6:2009 Biological Evaluation of Medical Devices- Part 6: Test for local effects after implantation

ISO 10993-10:2009 Biological Evaluation of Medical Devices- Part 10 Test for local effects after implantation

ISO 10993-11:2009 Biological Evaluation of Medical devices – Part 11 Tests for systemic toxicity

#### Non-clinical Testing Conducted

Material characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate devices. A series of bench tests were conducted to verify the design characteristics such as material composition, structure, physico-chemical properties and resorption profile as compared to the predicate devices.

A series of *in vitro* and *in vivo* biocompatibility testing was performed to assess safety of the Porcine Anorganic Bone Mineral as an implantable material.

Two separate animal efficacy studies were conducted to evaluate the device as compared to its predicate device; one in a dog dental intrabony defect model and the other in a rabbit femoral condyle defect model.

Viral inactivation studies were performed to ensure the viral safety of the product.

## **8. Conclusion of Non-clinical Studies**

The results of the material characterization and biocompatibility testing, as well as animal efficacy studies show that Porcine Anorganic Bone Mineral is substantially equivalent to the identified predicate devices.



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

July 16, 2014

Collagen Matrix, Incorporated  
Ms. Peggy Hansen, RAC  
Vice President, Clinical, Regulatory, QA and Marketing  
15 Thornton Road  
Oakland, New Jersey 07436

Re: K140714  
Trade/Device Name: Porcine Anorganic Bone Mineral  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: NPM  
Dated: June 16, 2014  
Received: June 17, 2014

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Digitally signed  
by Richard C.  
Chapman -S  
Date: 2014.07.16  
08:15:10 -04'00'

for

Erin I. Keith, M.S.  
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): K140714

Device Name: Porcine Anorganic Bone Mineral

### Indications for Use:

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- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Sheena A. Green -S**  
**2014.07.15 08:21:02 -04'00'**