AUG 4 - 2005

K043034

510(k) Summary of Safety and Effectiveness

Applicant Name and Address: Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Contact Person: Peggy Hansen, RAC
Director, Clinical, Regulatory, and Quality Assurance
Tel: (201) 405-1477
Fax: (201) 405-1355

Date of Summary: February 17, 2005

Device Common Name: Bone Grafting Material

Device Trade Name: OsteoGuide™ Anorganic Bone Mineral
OsteoGuide Collagen™ Anorganic Bone Mineral with Collagen
OsteoGuide Blocks™ Anorganic Bone Mineral with Collagen Blocks

Device Classification Name: Bone Grafting Material
Unclassified
NPM

Predicate Device(s): Bio-Oss®, Bio-Oss® Blocks, Bio-Oss® Collagen, K033815
Bio-Oss® Granules, K952617
Bio-Oss® Blocks, K970569
Bio-Oss® Collagen, K974399

Description of the Device

"OsteoGuide™ Anorganic Bone Mineral," "OsteoGuide Collagen™ Anorganic Bone Mineral with Collagen,"and "OsteoGuide Blocks™ Anorganic Bone Mineral with Collagen Blocks" are natural, porous bone mineral matrices with and without collagen. The anorganic bone mineral is produced by removal of all organic components from bovine bone. Due to its natural structure, the anorganic bone mineral component of the OsteoGuide products is physically and chemically comparable to the mineralized matrix of human bone. The composition of OsteoGuide Anorganic Bone Mineral meets the requirements of ASTM F1581-99 *Standard Specification for Composition of Anorganic bone for Surgical Implants.* OsteoGuide Collagen and OsteoGuide Blocks are product extensions that include highly purified fibrillar type I collagen mixed in with the anorganic bone mineral. The product is supplied in granules or blocks, and it is sterile, non-pyrogenic, and for single use only.

Intended Use

OsteoGuide Anorganic Bone Mineral Products are 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 periodontal defects
- Filling of defects after root resection, apicocectomy, 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

OsteoGuide Anorganic Bone Mineral Products and their predicates have the same technological characteristics. In particular, the OsteoGuide Anorganic Bone Mineral Products and their predicates are the same with respect to intended use, material, material characterization, form, and sizes.

Safety

OsteoGuide Anorganic Bone Mineral Products have been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all selected FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Effectiveness

The characteristics of the OsteoGuide Anorganic Bone Mineral Products meet the design requirements for an effective bone grafting material.

Conclusion

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, show that the OsteoGuide Anorganic Bone Mineral Products are safe and substantially equivalent to Bio-Oss Granules, Bio-Oss Collagen, and Bio-Oss Blocks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 - 2005

Ms. Peggy Hansen
Director, RAC
Collagen Matrix, Incorporated
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K043034
Trade/Device Name: Osteoguide Anorganic Bone Mineral Products
Regulation Number: 21 CFR 872.3930
Regulation Name: Tricalcium phosphate granules for dental bone repair
Regulatory Class: II
Product Code: NPM
Dated: July 21, 2005
Received: July 22, 2005

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043034

Indications for Use

510(k) Number (if known): _____

Device Name: OsteoGuide™ Anorganic Bone Mineral
OsteoGuide Collagen™ Anorganic Bone Mineral with Collagen
OsteoGuide Blocks™ Anorganic Bone Mineral with Collagen - Blocks

Indications for Use:

Natural Mineral Bone Graft Substitutes are 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 periodontal defects
- Filling of defects after root resection, apicocectomy, 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

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043034