K092608

510(k) Summary

MAY 2 8 2010

Applicant Name and Address:	Collagen Matrix, Inc. 509 Commerce Street Franklin Lakes, New Jersey 07417
Contact Person:	Peggy Hansen, RAC VP, Clinical, Regulatory, QA, and Marketing Tel: (201) 405-1477 Fax: (201) 405-1355
Date of Summary:	May 27, 2010
Device Common Name:	Bone Grafting Material
Device Trade Name:	Synthetic Mineral - Collagen Bone Graft Matrix
Device Classification Name:	Filler, Bone Void, Calcium Compound
Regulation Number:	888.3045
Product Code:	MQV
Device Class	Class II
Predicate Device(s):	OssiMend™ Bone Graft Material K052812

Description of the Device

Synthetic Mineral – Collagen Bone Graft Matrix is a composite of synthetic calcium phosphate based granules and type I collagen. The calcium phosphate mineral has an apatite structure similar to that of natural bone. The type I collagen is derived from bovine Achilles tendon. The composite material is a resorbable, porous, osteoconductive bone graft matrix. The product is supplied dry in granular (putty) or block/strip form that is hydrated with autogenous bone marrow at the point of use. The product is sterile, non-pyrogenic, and for single use only.

Intended Use

Synthetic Mineral – Collagen Bone Graft Matrix, combined with autogenous bone marrow, is intended for orthopaedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Synthetic Mineral – Collagen Bone Graft Matrix is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e., extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Summary/Comparison of Technological Characteristics

(a) Technological Characteristics

Synthetic Mineral – Collagen Bone Graft Matrix and its predicates have the same key technological characteristics. In particular, the Synthetic Mineral – Collagen Bone Graft Matrix and its predicates are the same with respect to intended use, design, materials, material characterization, and product forms.

Synthetic Mineral – Collagen Bone Graft Matrix and its predicates are designed as 3-dimensional, resorbable, porous, osteoconductive matrices intended to support bone formation in areas of bone deficit. The materials used are a combination of previously cleared and commercially marketed calcium phosphate mineral and type I collagen. The product was characterized by physical and chemical bench tests comparing its characteristics to those of the predicate devices. Such tests included mineral structure analysis, collagen purity, resorption studies,

Synthetic Mineral – Collagen Bone Graft Matrix has 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.

(b) Performance Data

Performance studies supporting the product were a rabbit round femur defect model and a segmental radial defect model. Endpoint measurements included radiographs and histology. These studies demonstrated with respect to predicate device the safety and performance of the Synthetic Mineral and Mineral – Collagen Composite materials in supporting bone ingrowth in orthopaedic applications.

No clinical tests were performed for the premarket submission, however, clinical experience of the predicate devices was presented in support of the candidate device.

(c) Conclusions Drawn from Nonclinical and Clinical Tests

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, animal performance studies, and clinical experience with predicate devices show that the Synthetic Mineral – Collagen Bone Graft Matrix is safe with respect to predicate device and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Collagen Matrix, Inc
% Ms. Peggy Hansen, RAC
VP Clinical, Regulatory, QA, and Marketing
509 Commerce Street
Franklin Lakes, New Jersey 07417

MAY 2 8 2010

Re: K092608
Trade/Device Name: Synthetic Mineral – Collagen Bone Graft Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: May 18, 2010
Received: May 26, 2010

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.

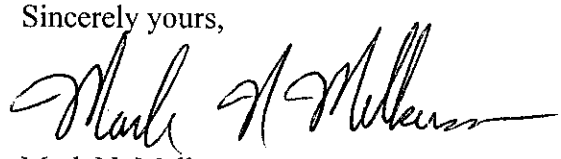
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K092608

Device Name: Synthetic Mineral - Collagen Bone Graft Matrix

Indications for Use:

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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