

K100156

1082

510(k) Summary of Safety and Effectiveness

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

AUG 11 2010

Contact Person: Peggy Hansen, RAC
Vice President, Clinical, Regulatory, QA, and Marketing
Tel: (201) 405-1477
Fax: (201) 405-1355

Date of Summary: January 14, 2010

Device Common Name: Resorbable Collagen Membrane

Device Trade Name: Collagen Dental Membrane V

Device Classification Name: Barrier, animal source, intraoral
872.3930
NPL
Class II

Predicate Device(s): Collagen Dental Membrane IV
K090216

Bio-Gide™ Resorbable Bilayer Membrane for Guided
Tissue and Bone Regeneration
K050446

Description of the Device

Collagen Dental Membrane V is a white, nonfriable, conformable, resorbable, membrane matrix consisting of highly purified type I and III collagen derived from porcine dermis. It is flexible and conforms to the contours of the defect site. Collagen Dental Membrane V is supplied sterile, non-pyrogenic, in various sizes, and for single use only.

Intended Use

Collagen Dental Membrane V is intended for use in oral surgical procedures as a resorbable material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

Summary/Comparison of Technical Characteristics

Collagen Dental Membrane V and its predicates have similar technological characteristics. In particular, the Collagen Dental Membrane V and its predicate are

similar with respect to intended use, form, animal source, sizes, thickness, physical integrity, permeability and conformability.

Safety

Collagen Dental Membrane V has been evaluated in a number of *in vitro* and *in vivo* tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Conclusion

The results of the *in vitro* product characterization studies and *in vivo* animal studies show that Collagen Dental Membrane V is safe and substantially equivalent to the predicate devices.



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

Ms. Peggy Hansen
Vice President, Clinical, Regulatory,
Quality Assurance and Marketing
Collagen Matrix, Incorporated
509 Commerce Street
Franklin Lakes, New Jersey 07417

AUG 11 2010

Re: K100156

Trade/Device Name: Collagen Dental Membrane V

Regulation Number: 21 CFR 872.3930

Regulation Name: Bone Grafting Material

Regulatory Class: II

Product Code: NPL

Dated: July 22, 2010

Received: July 23, 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

Page 2- Ms. Hansen

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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 100156

1071

Indications for Use

510(k) Number (if known): _____

AUG 11 2010

Device Name: Collagen Dental Membrane V

Indications for Use:

Collagen Dental Membrane V is intended for use in oral surgical procedures as a resorbable membrane material for use in augmentation around implants placed in immediate extraction sockets, delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

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)

Kevin Mulvey for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100156 Page 1 of 1