DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 5,2014

Collagen Matrix, Inc.
Peggy Hansen
Vice President, Clinical, Regulatory, Quality Assurance and Marketing
15 Thornton Road
Oakland, New Jersey 07436

Re: K141909
Trade/Device Name: Collagen Dental Membrane – Conformable PP
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: Class II
Product Code: NPL
Dated: October 6, 2014
Received: October 9, 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 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" (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 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 yours,

Susan Runner DDS, MA

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): K141909

Device Name: Collagen Dental Membrane - Conformable PP

Indications for Use:

Collagen Dental Membrane - Conformable PP is intended for use in oral surgical procedures as a resorbable membrane material for use in:

- Simultaneous use of GBR-membrane and implants
- Augmentation around implants placed in immediate extraction sockets
- Augmentation around implants in delayed extraction sockets
- Localized ridge augmentation for later implantation
- Alveolar ridge reconstruction for prosthetic treatment
- Filling of bone defects after root resection, cystectomy or removal of retained teeth
- 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)

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: October 6, 2014

2. Name of the Device

Device Common Name: Resorbable Collagen Membrane
Device Trade Name: Collagen Dental Membrane – Conformable PP
Device Classification Name: Barrier, animal source, intraoral
872.3930
NPL
Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): BIO-GIDE®
K042197

Collagen Dental Membrane V
K100156

4. Description of the Device

Collagen Dental Membrane – Conformable PP is a white, nonfriable, resorbable, single layered, conformable collagen membrane matrix manufactured from purified porcine peritoneum. Collagen Dental Membrane – Conformable PP is sterilized by gamma irradiation and is supplied sterile, non-pyrogenic and for single use only.

The collagen dental membrane has a thickness of approximately 0.1 to 0.8 mm and is available in the following sizes 12 x 25 mm, 15 x 20 mm, 25 x 25 mm, 20 x 30 mm, and 30 x 40 mm.

5. Intended Use

Collagen Dental Membrane - Conformable PP is intended for use in oral surgical procedures as a resorbable membrane material for use in:

- Simultaneous use of GBR-membrane and implants
- Augmentation around implants placed in immediate extraction sockets
- Augmentation around implants in delayed extraction sockets
- Localized ridge augmentation for later implantation

- Alveolar ridge reconstruction for prosthetic treatment
- Filling of bone defects after root resection, cystectomy or removal of retained teeth
- Guided bone regeneration in dehiscence defects and
- Guided tissue regeneration procedures in periodontal defects.

6. Summary/Comparison of Technical Characteristics

Collagen Dental Membrane-Conformable PP and its predicate devices have similar technological characteristics. In particular, the Collagen Dental Membrane-Conformable PP and its predicates are similar with respect to intended use, material (porcine peritoneum), form, sizes, thickness, physical integrity, permeability and conformability.

Nonclinical Tests Submitted

The substantial equivalence of Collagen Dental Membrane-Conformable PP and its predicates was demonstrated based on *in vitro* characterization studies, biocompatibility studies, in vivo animal studies, and clinical history of the predicate devices.

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate devices. A series of bench tests were conducted which included an evaluation of physical properties such as membrane thickness, conformability, suture strength, and an evaluation of physicochemical properties such as product permeability and hydrothermal transition temperature.

A series of *in vitro* and *in vivo* biocompatibility testing was performed to assess safety of the Collagen Dental Membrane-Conformable PP as an implantable material. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Test	Test Method/Model	Results
Cytotoxicity	Agarose Overlay, ISO 10993-5	Non-cytotoxic; No evidence of causing any cell lysis or toxicity.
Sensitization	Guinea Pig Maximization, ISO 10993-10	No evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig test.
Intracutaneous Reactivity	Intracutaneous Study in Rabbits, ISO 10993-10	Under the conditions of the study, there was no erythema or edema from the extract injected intracutaneously into rabbits. The test article extract met the requirements of the test since the difference between the mean score of the test extract and the corresponding control was passing.
Acute Systemic Toxicity	Acute Systemic Toxicity in Mice, ISO 10993-11	No mortality or evidence of systemic toxicity.
Genotoxicity	Bacterial Reverse Mutation Study, ISO 10993-3	Non-mutagenic to *Salmonella typhimurium* and to *Escherichia coli* strain WP2uvra.

Test	Test Method/Model	Results
	Mouse Lymphoma Assay, ISO 10993-3:2003	None of the test article treatments induced substantial increases in the number of revertant colonies. Based on the criteria and conditions of the study protocol, the test article is considered non-mutagenic.
Pyrogenicity	Rabbit Pyrogen study-USP <151>	Non-pyrogenic
Muscle Implantation	Muscle Implantation Study in Rabbits, 2 Weeks, ISO 10993-6	The macroscopic reaction was not significant compared with the sponsor provided control article (bovine tendon collagen membrane) and not significant as compared to the negative control article (HDPE). Microscopically, the test article was classified as a nonirritant as compared to the sponsor provided control article and as a moderate irritant as compared to the negative control article.
Subchronic Toxicity	Subcutaneous implantation study in rat.	Minimum tissue reaction up to 24 weeks of implantation and no adverse tissue reaction to the host.

In addition to the in vitro characterization tests, animal studies using a rabbit intra-oral model, as well as a rat subcutaneous model were conducted to evaluate the in vivo stability and local tissue response to the subject device as compared to its predicate device (BioGide®).

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

Clinical Test Submitted

Given the similarities between Collagen Dental Membrane - Conformable PP and the predicate devices, it was determined that a clinical study would not be necessary to demonstrate substantial equivalence.

7. Conclusion of Non-clinical Studies

The results of the in vitro product characterization and biocompatibility testing, as well as the animal study show that Collagen Dental Membrane-Conformable PP is safe and substantially equivalent to the identified predicate devices.