K033729

MAR 17 2004

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
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Date of Summary: March 11, 2004

Device Common Name: Collagen Dental Sponge Membranes

Device Trade Name: To be determined

Device Classification Name: Bone filling augmentation material
Unclassified
LYC

Predicate Device(s): Collagen Dental Membrane, K011695
Collagen Periodontal Membrane, K003339

Description of the Device
Collagen Dental Sponge Membranes are white to off-white, implantable, resorbable, porous, collagen membrane manufactured from crosslinked type I collagen derived from bovine Achilles tendon. The product is supplied sterile, non-pyrogenic, and for single use only.

Indications for Use
Collagen Dental Sponge Membranes are intended for use in patients with moderate to severe periodontal disease as a resorbable material for placement in periodontal defects to aid in wound healing post periodontal surgery.

Summary/Comparison of Technical Characteristics
Collagen Dental Sponge Membranes and its predicates have similar technological characteristics. In particular, the Collagen Dental Sponge Membranes and their predicates are similar with respect to intended use, material, source, sterilization, etc.

Safety
Collagen Dental Sponge Membranes have been evaluated by a number of tests to assess the safety/biocompatibility. The device passed all applicable ISO 10993-1 testing for the biological evaluation of medical devices.

Conclusion
The results of the *in vitro* product characterization studies and biocompatibility studies show that the Collagen Dental Sponge Membranes are safe and substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

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

Re: K033729
Trade/Device Name: Collagen Dental Sponge Membrane
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LYC
Dated: January 26, 2004
Received: January 27, 2004

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.

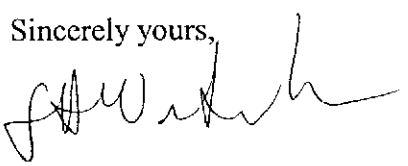
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,



for 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

Indications for Use

510(k) Number (if known): K033729

Device Name: Collagen Dental Sponge Membranes

Indications for Use:

Collagen Dental Sponge Membranes are intended for use in patients with moderate to severe periodontal disease as a resorbable material for placement in periodontal defects to aid in wound healing post periodontal surgery.

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 K033729