K052041

OCT 25 2005

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## 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:** October 25, 2005

**Device Common Name:** Collagen Bone Healing Protective Sheet

**Device Trade Name:** To be determined

**Device Classification Name:**

| Plate, Fixation, Bone | Mesh, Surgical | Cement Obturator |
|---|---|---|
| Class II | Class II | Class II |
| 888.3030 | 878.3300 | 878.3300 |
| HRS | FTM | LZN |

**Predicate Device(s):** Collagen Dental Membrane, K011695
BioGide®, K960724
EBI LactoSorb® Graft Containment System, K033918
MacroPoreOS Protective Sheet, K994158

### Description of the Device

The Collagen Bone Healing Protective Sheet is a white, nonfriable, conformable, resorbable, membrane matrix engineered from highly purified type I collagen derived from bovine Achilles tendon. The Collagen Bone Healing Protective Sheet can be cut with scissors to the desired shape and size. The Collagen Bone Healing Protective Sheet is fully conformable when hydrated and can conform three dimensionally to most any anatomical orientation. The Collagen Bone Healing Protective Sheet can be rolled into a tube or used as a flat sheet. The Collagen Bone Healing Protective Sheet can be used either alone or in conjunction with internal bone fixation devices such as plates and screws, which also can serve to further stabilize the anatomical region.

The Collagen Bone Healing Protective Sheet is provided in sheets of 20 x 20 mm to 120 x 120 mm and will be provided in other sizes as needed for particular surgical procedures. The thickness of the Collagen Bone Healing Protective Sheet ranges from 0.5 mm to 2.0 mm according to the orthopedic region to be treated. The Collagen Bone Healing Protective Sheet consists of micropores <0.008 µm and is provided with or without the addition of macropores in the range of 500 µm to 2,500 µm. Collagen Bone

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Healing Protective Sheet is supplied sterile, non-pyrogenic, in various sizes, and for single use only.

**Intended Use**

The Collagen Bone Healing Protective Sheet is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The Collagen Bone Healing Protective Sheet is also indicated for cement restriction in total joint arthroplasty procedures.

Only when used in conjunction with traditional rigid fixation, the Collagen Bone Healing Protective Sheet is intended to maintain the relative position of weak bony tissue in trauma and reconstructive orthopedic procedures involving:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), the Collagen Bone Healing Protective Sheet is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving:

- Tumor resections where bone strength has not been compromised
- Iliac crest harvests

This device is not intended for use in the spine. The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

**Summary/Comparison of Technical Characteristics**

The indication for use of the Collagen Bone Healing Protective Sheet is the same as that of its predicate devices. The technical characteristics of the Collagen Bone Healing Protective Sheet are comparable to the predicate devices in key aspects of the device such as material, form, sizes, thickness, physical integrity, mechanical strength, porosity and *in vivo* stability. The animal and clinical literature reviews provide compelling support for the use of the Collagen Bone Healing Protective Sheet in containing bone graft material and bony fragments in bone defects.

**Safety**

The safety/biocompatibility of the Collagen Bone Healing Protective Sheet is supported by the biocompatibility testing performed in accordance with FDA's Blue Book Memorandum G95-1 and ISO 10993-1 Biological Evaluation of Medical Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2005

Peggy Hansen, RAC
Director, Clinical, Regulatory & Quality Assurance
Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K052041
Trade/Device Name: Collagen Bone Healing Protective Sheet
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, FTM, LZN
Dated: July 27, 2005
Received: July 29, 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- 0120. 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 Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K052041

Device Name: Collagen Bone Healing Protective Sheet

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K052041