

K080452 1/2

510(k) Summary of Safety and Effectiveness

MAY 15 2008

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

Contact Person: Peggy Hansen, RAC
Sr. Director, Clinical, Regulatory, and Quality Assurance
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Date of Summary: February 15, 2008

Device Common Name: Tendon Protector

Device Trade Name: Collagen Tendon Wrap

Device Classification Name: Mesh, Surgical
Regulation Number: 878.3300
Device Class: Class II
Product Code: FTM

Predicate Device(s): Tendon Wrap™ Tendon Protector, K053655
Integra LifeSciences Corporation, Plainsboro, NJ

Collagen Nerve Wrap, K060952
Collagen Matrix, Inc., Franklin Lakes, NJ

Description of the Device

Collagen Tendon Wrap is a resorbable type I collagen matrix that provides a non-constricting encasement for injured tendons. Collagen Tendon Wrap is designed to be an interface between the tendon and tendon sheath or the surrounding tissue. When hydrated, Collagen Tendon Wrap is a conformable, nonfriable, porous collagen sheet designed for easy placement under, around or over the injured tendon. Collagen Tendon Wrap is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, in double peel packages.

Intended Use

Collagen Tendon Wrap is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Summary/Comparison of Technical Characteristics

Collagen Tendon Wrap and its predicates have the same technological characteristics. In particular, Collagen Tendon Wrap and their predicates are the same with respect to intended use, design, materials, material characterization, form, and sizes.

Safety

Collagen Tendon Wrap has been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all selected FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Effectiveness and Substantial Equivalence

The characteristics of the Collagen Tendon Wrap meet the design requirements for an effective tendon protector. Animal studies were conducted to demonstrate the effectiveness of the Collagen Tendon Wrap.

Conclusion

The results of the animal studies, *in vitro* product characterization studies, and *in vitro* and *in vivo* biocompatibility studies show that Collagen Tendon Wrap is safe and substantially equivalent to its predicates.



MAY 15 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K080452
Trade/Device Name: Collagen Tendon Wrap
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: May 2, 2008
Received: May 5, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
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): K080452

Device Name: Collagen Tendon Wrap

Indications for Use:

Collagen Tendon Wrap is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

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)

Neil AP Ojahn for mkm
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080452