FEB 27 2004

K040211

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: January 29, 2004

Device Common Name: Collagen Topical Wound Dressing

Device Trade Name: To be determined

Device Classification Name: Dressing, Wound, Collagen
Unclassified
KGN

Predicate Device(s): Collagen Topical Wound Dressing, K030921
(Original Device)

Description of the Device

Collagen Topical Wound Dressing is a white to off-white, absorbent, porous, sponge-like collagen matrix intended for topical use. The product is supplied sterile and for single use only.

Indications for Use

Collagen Topical Wound Dressing is indicated for the management of moderately to heavily exudating wounds and to control minor bleeding.

Collagen Topical Wound Dressing may be used for the management of exudating wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- Acute wounds, for example trauma and surgical wounds
- Partial-thickness burns

Summary/Comparison of Technical Characteristics

Collagen Topical Wound Dressing has the same fundamental scientific technology and intended use as the predicate device. In particular, the Collagen Topical Wound Dressing and its predicate are the same with respect to intended use, material, source, sterilization, etc.

Safety

Collagen Topical Wound Dressing has been evaluated by a number of tests to assess its 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 Topical Wound Dressing is safe and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

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

Re: K040211
Trade/Device Name: Collagen Topical Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 29, 2004
Received: January 30, 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) 594-4659. 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

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040211

Indications for Use

510(k) Number (if known): K040211

Device Name: Collagen Topical Wound Dressing

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K040211