K060952 (1/2)

510(k) Summary of Safety and Effectiveness

JUL 14 2006

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: April 5, 2006

Device Common Name: Nerve Protector

Device Trade Name: Collagen Nerve Wrap

Device Classification Name: Cuff, Nerve
Regulation Number: 882.5275
Device Class: Class II
Product Code: JXI

Predicate Device(s): Collagen Nerve Cuff, K012814
Collagen Matrix, Inc., Franklin Lakes, NJ

NeuraWrap™ Nerve Protector, K041620
Integra LifeSciences Corporation, Plainsboro, NJ

FASTUBE™ Nerve Regeneration Device, K850785
Research Medical, Inc., Salt Lake City, UT

Description of the Device

Collagen Nerve Wrap is a resorbable collagen matrix that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment. Collagen Nerve Wrap is designed to be an interface between the nerve and the surrounding tissue. When hydrated, Collagen Nerve Wrap is an easy to handle, soft, pliable, nonfriable, porous collagen conduit. The wall of the conduit has a longitudinal slit that allows Collagen Nerve Wrap to be spread open for easy placement over the injured nerve. The resilience of the Collagen Nerve Wrap allows the product to recover and maintain closure once the device is placed around the nerve. Collagen Nerve Wrap is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, and in double peel packages.

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Collagen Matrix, Inc.
510(k) Summary of Safety and Effectiveness
Collagen Nerve Wrap

Intended Use

Collagen Nerve Wrap is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity.

Summary/Comparison of Technical Characteristics

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

Safety

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

Effectiveness

The characteristics of the Collagen Nerve Wrap meet the design requirements for an effective nerve protector.

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2006

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

Re: K060952
Trade/Device Name: Collagen Nerve Wrap
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: II
Product Code: JXI
Dated: June 16, 2006
Received: June 19, 2006

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.

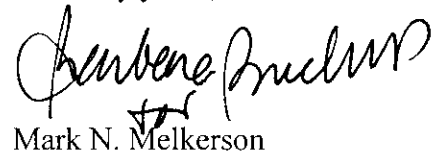
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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 (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

K060952

Indications for Use

510(k) Number (if known): K060952

Device Name: Collagen Nerve Wrap

Indications for Use:

Collagen Nerve Wrap is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity.

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)

Barbara Ruhland for MXM

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

510(k) Number K060952