K053655

510(K) SUMMARY

Tendon Wrap™ Tendon Protector

FEB 3 2006

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Diana Bordon
Manager, Regulatory Affairs
Telephone: (609) 275-0500
Fax: (609) 275-9445

Date Summary was prepared:

December 29, 2005

Name of the device:

Proprietary Name: Tendon Wrap™
Common Name: Tendon Protector
Classification Name: Unclassified

Substantial Equivalence:

Tendon Wrap™ Tendon Protector is substantially equivalent in function and intended use to the following products which have been cleared to market under Premarket Notifications 510(k): NeuraWrap® K041620 Nerve Protector and Medist International Tendon Spacer 510 K 000019.

Device Description:

Tendon Wrap is an absorbable implant (device) that provides a non-constricting, protective encasement for injured tendons, it is comprised of a porous matrix of cross-linked bovine Type I collagen and glycosaminoglycan (GAG). Tendon Wrap is designed to serve as an interface between the tendon and tendon sheath or the surrounding tissues. Tendon Wrap is an easy to handle, conformable, porous collagen-GAG sheet designed for easy placement under, around or over the injured tendon. Tendon Wrap is supplied sterile, non-pyrogenic, for single use, in double peel packages in a variety of sizes.

Intended Use:

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

Testing and Test Results:

Biocompatibility studies have demonstrated Tendon Wrap Tendon Protector to be non-cytotoxic, non-pyrogenic, non-irritating, non-sensitizing, non-toxic, non- genotoxic and non-hemolytic. Results of physical testing, animal studies and clinical experience have demonstrated the Tendon Wrap collagen-glycosaminoglycan matrix provides a protective interface that improves mobility of repaired tendons.

Conclusion

Tendon Wrap Tendon Protector is safe and effective under the proposed conditions of use, and substantially equivalent to its predicate devices. Safety and efficacy are supported through physician experience with the collagen-glycosaminoglycan matrix, animal testing, biocompatibility, and physical property testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Diana M. Bordon
Manager, Regulatory Affairs
Integra LifeSciences Corp.
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K053655
Trade/Device Name: Tendon Wrap™ Tendon Protector
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: December 29, 2005
Received: January 3, 2006

Dear Ms. Bordon:

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.

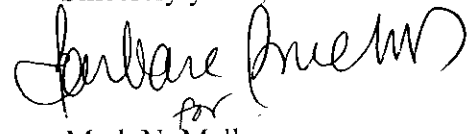
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K053655

Indications for Use

510(k) Number (if known):

Device Name: Tendon Wrap™ Tendon Protector

Indications For Use:

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

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)

Barbara Buchwald for MKM

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

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