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510(k) Summary

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Applicant Information

Applicant Name:	Rotation Medical, Inc.
Applicant Address:	15350 25th Avenue North, Suite 100 Plymouth, MN 55447
Telephone:	763-746-7502
Fax:	763-746-7501
Contact Person:	Jeff Sims Vice President, Clinical Programs and Regulatory Affairs
Date Prepared:	January 7, 2013

Name of Device

Device Common Name:	Tendon Protector
Device Trade Name:	Collagen Tendon Sheet-D
Device Classification Name:	Mesh, Surgical 878.3300 Class II FTM

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s):	Collagen Tendon Sheet, K112423 Rotation Medical, Inc.

Description of the Device

Collagen Tendon Sheet-D is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet-D is designed to provide a layer between the tendon and the surrounding tissue. When hydrated, Collagen Tendon Sheet-D is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet-D is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, in double peel packages.

Intended Use

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

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Summary/Comparison of Technical Characteristics

Collagen Tendon Sheet-D is the same product as its predicate Collagen Tendon Sheet (K112423) in all regards excepting the addition of a small amount of FD&C Blue #2 on the perimeter of the upper surface to provide contrast with surrounding tissue during fixation.

Collagen Tendon Sheet-D has been evaluated in a number of *in vitro* and *in vivo* tests to assess its safety/biocompatibility, including: cytotoxicity (agarose overlay, liquid and extract methods), sensitization, intracutaneous reactivity, systemic toxicity, hemolysis, genotoxicity (bacterial and mouse micronucleus), pyrogenicity and muscle implantation tissue response tests. The device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Collagen Tendon Sheet-D and its predicate share the same base material that has been characterized for chemical composition and purity using SDS-PAGE analysis, collagen typing, residual testing and viral inactivation (four appropriate viruses selected for assessment). Mechanical characterization included density, strength, stiffness and tear resistance to demonstrate substantial equivalence. Testing was conducted in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.

Conclusion of Non-clinical Studies

The results of the in vitro product characterization studies, and in vitro and in vivo biocompatibility studies, demonstrate that Collagen Tendon Sheet-D is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Rotation Medical, Incorporated
% Mr. Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
15350 25th Avenue North, Suite 100
Plymouth, Minnesota 55447

January 8, 2013

Re: K122048
Trade/Device Name: Collagen Tendon Sheet-D
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OWY
Dated: December 06, 2012
Received: December 11, 2012

Dear Mr. Sims:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122048

Confidential
Rotation Medical, Inc.

Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Tendon Sheet-D

Indications for Use:

Collagen Tendon Sheet-D 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)

David Krowe for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K122048