rotation MEDICAL

DEC 2 2 2011

510(k) Summary

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/Revised: August 22, 2011/November 14, 2011/December 13, 2011

Name of Device

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

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Tendon Wrap, K0080452
Collagen Matrix, Inc., Oakland, NJ

Description of the Device

Collagen Tendon Sheet is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet is designed to provide a layer between the tendon and the surrounding tissue. When hydrated, Collagen Tendon Sheet is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet 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.

Summary/Comparison of Technical Characteristics

Collagen Tendon Sheet and its predicate device have the same technological characteristics. In particular, Collagen Tendon Sheet and its predicate are the same with respect to intended use, design, materials, and material characterization. The substantial equivalence of the Collagen Tendon Sheet and its predicate was demonstrated primarily based on in vitro characterization studies, biocompatibility studies, an animal efficacy study, and clinical experience of the predicate device. In vitro characterization studies included evaluation of material properties, biological properties, chemical and physical properties.

The Collagen Tendon Sheet and its predicate device are manufactured with similar processing, in the same facilities, by the same manufacturer, using the same raw materials. They vary with respect to size and thickness. In addition, the Collagen Tendon sheet is provided in a flat form.

Collagen Tendon Sheet and its predicate have been characterized for chemical composition, purity, density, and strength to demonstrate substantial equivalence. Testing was conducted in accordance to FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.

Collagen Tendon Sheets have been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

An animal efficacy study was conducted to evaluate the device as compared to its predicate device. No clinical tests were performed on the product; however clinical history of the predicate device was referenced in the submission.

Viral inactivation studies were performed to ensure the viral safety of the product.

Conclusion of Non-clinical Studies

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, as well as the animal efficacy study show that Collagen Tendon Sheet 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 Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 2 2011

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

Re: K112423
Trade/Device Name: Collagen Tendon Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: December 16, 2011
Received: December 16, 2011

Dear Mr. Sim:

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,

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

Enclosure

 K112423

Confidential
Rotation Medical, Inc.

Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Tendon Sheet

Indications for 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.

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 Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112423

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

DEC 2 2 2011

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

Re: K112423
Trade/Device Name: Collagen Tendon Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
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Dated: December 16, 2011
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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.

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Sincerely yours,

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

Enclosure

 K112423

Confidential
Rotation Medical, Inc.

Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Tendon Sheet

Indications for 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.

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 Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112423

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 16, 2011

ROTATION MEDICAL, INC.
15350 25TH AVENUE N
SUITE 100
PLYMOUTH, MINNESOTA 55447
ATTN: JEFF SIMS

510k Number: K112423

Product: COLLAGEN TENDON SHEET

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

DEC 12 2011

Re: K112423
Trade Name: Collagen Tendon Sheet
Dated: November 30, 2011
Received: November 30, 2011

Dear Mr. Sims:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Maegen Colehour at (301) 796-6970 or Maegen.Colehour@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause, Ph.D.
Chief, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES *Public Health Service*

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 30, 2011

ROTATION MEDICAL, INC.
15350 25TH AVENUE N
SUITE 100
PLYMOUTH, MINNESOTA 55447
ATTN: JEFF SIMS

510k Number: K112423

Product: COLLAGEN TENDON SHEET

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We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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Sincerely,

510(k) Staff

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

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

OCT 31 2011

Re: K112423
Trade Name: Collagen Tendon Sheet
Dated: August 22, 2011
Received: August 23, 2011

Dear Mr. Sims:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) Deficiencies

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processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Maegen Colehour at (301) 796-6970 or Maegen.Colehour@fda.hhs.gov. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause, Ph.D.
Chief, Plastic & Reconstructive
Surgery Branch
Division of Surgical, Orthopedic
and Restorative Devices

K112423 – Rotation Medical, Inc.

DSORD/PRSB – M. Colehour
f/t:MTC:tlm:10-31-11:1224p

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DSORD/PRSB	Colehour	10/31/11			
11 4	Krame	10/31/11			

(Please include 510(k) number here: K112423)

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table in footer
8/25/09	Brandi Stuart	Updated Title of Boiler
8/29/09	Brandi Stuart	Updated Websites
12/2/09	Diane Garcia	Removed Least Burdensome Language
1/21/10	Diane Garcia	Updated web address for 510k actions
3/30/11	Edwena Jones	Updated Heparin Boilerplate Language

96

763 746 7501

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 24, 2011

ROTATION MEDICAL, INC.
15350 25TH AVENUE N
SUITE 100
PLYMOUTH, MINNESOTA 55447
ATTN: JEFF SIMS

510k Number: K112423
Received: 8/23/2011
Product: COLLAGEN TENDON SHEET

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

SO / DSORD

K112423

rotation MEDICAL

August 22, 2011

VIA FEDERAL EXPRESS
Document Mail Center (WO66-G609)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

AUG 23 2011

Re: 510(k) Premarket Notification (Traditional)
Collagen Tendon Sheet

K123

Dear Sir or Madam:

Pursuant to 21 CFR Part 807, Subpart E, Premarket Notification Procedures, Section 807.81, Rotation Medical, Inc. is submitting this 510(k) Premarket Notification for its Collagen Tendon Sheet. Rotation Medical has determined that Collagen Tendon Sheet is substantially equivalent to current legally marketed tendon protector devices and intends to manufacture and market the device.

This submission includes an electronic copy of the 510(k) as per the FDA's web instructions. The electronic copy is an exact duplicate of the paper copy.

Trade Name or Proprietary Name:	Collagen Tendon Sheet
Common or Usual Name:	Tendon Protector
Device Classification Name:	Mesh, Surgical
Regulation Number:	878.3300
Product Code:	FTM
Device Class:	Class II
Name and Address of Manufacturer:	Rotation Medical, Inc. 15350 25th Avenue North, Suite 100 Plymouth, MN 55447
Establishment Registration No.:	TBD upon clearance
Name, Address, and Telephone Number of Contact Person:	Jeff Sims Vice President, Clinical Programs and Regulatory Affairs Rotation Medical, Inc. 15350 25th Avenue North, Suite 100 Plymouth, MN 55447 Tel: 763.746.7502 Fax: 763.746.7501 E-mail: jsims@rotationmedical.com

Premarket Notification
510(k) Application

For

Collagen Tendon Sheet

August 22, 2011

Rotation Medical, Inc.
55350 25th Avenue North, Suite 100
Plymouth, Minnesota 55447

Premarket Notification, 510(k) Application
for
Collagen Tendon Sheet

Table of Contents

APPENDICES

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ROTATION MEDICAL, INC. FKA DENALI MEDICAL, INC.
15350 25th AVENUE N., SUITE 100
PLYMOUTH MN 55447
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****6675

2. CONTACT NAME
Jeff Sims

2.1 E-MAIL ADDRESS
jsims@rotationmedical.com

2.2 TELEPHONE NUMBER (include Area code)
763-746-7502

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
763-746-7501

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD110285

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]
15-Aug-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/22/2011	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Rotation Medical, Inc.	TBD upon clearance		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	763.746.7502		
Street Address	FAX Number *(including area code)*		
15350 25th Avenue N., Suite 100	763.746.7501		
City	State / Province	ZIP/Postal Code	Country
Plymouth	MN	55447	USA
Contact Name			
Jeff Sims			
Contact Title	Contact E-mail Address		
Vice President, Clinical Programs and Regulatory Affairs	jsims@rotationmedical.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
same as above			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Graphics (301) 443-1090 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FTM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K0080452	1	Collagen Tendon Wrap	1	Collagen Matrix, Inc., Oakland, NJ
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Surgical Mesh

	Trade or Proprietary or Model Name for This Device		Model Number
1	Collagen Tendon Sheet	1	TBD
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FTM	878.3300	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
General and Plastic		

Indications *(from labeling)*

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

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b)(4)	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b)(4)	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	11135-1	ISO	Sterilization of health care products - Ethylene oxide	1st edition	05/01/2007
	Standards No.	Standards Organization	Standards Title	Version	Date
2	10993	ISO	Biological evaluation of medical devices	3rd edition	08/01/2003
	Standards No.	Standards Organization	Standards Title	Version	Date
3					
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
5					
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

August 22, 2011

VIA FEDERAL EXPRESS
Document Mail Center (WO66-G609)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: 510(k) Premarket Notification (Traditional)
Collagen Tendon Sheet

Dear Sir or Madam:

Pursuant to 21 CFR Part 807, Subpart E, Premarket Notification Procedures, Section 807.81, Rotation Medical, Inc. is submitting this 510(k) Premarket Notification for its Collagen Tendon Sheet. Rotation Medical has determined that Collagen Tendon Sheet is substantially equivalent to current legally marketed tendon protector devices and intends to manufacture and market the device.

This submission includes an electronic copy of the 510(k) as per the FDA's web instructions. The electronic copy is an exact duplicate of the paper copy.

Trade Name or Proprietary Name:	Collagen Tendon Sheet
Common or Usual Name:	Tendon Protector
Device Classification Name:	Mesh, Surgical
Regulation Number:	878.3300
Product Code:	FTM
Device Class:	Class II
Name and Address of Manufacturer:	Rotation Medical, Inc. 15350 25th Avenue North, Suite 100 Plymouth, MN 55447
Establishment Registration No.:	TBD upon clearance
Name, Address, and Telephone Number of Contact Person:	Jeff Sims Vice President, Clinical Programs and Regulatory Affairs Rotation Medical, Inc. 15350 25th Avenue North, Suite 100 Plymouth, MN 55447 Tel: 763.746.7502 Fax: 763.746.7501 E-mail: jsims@rotationmedical.com

rotation
MEDICAL

Below is the recommended "Design and Use of the Design" questions per the *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s.*

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		n/a
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

If you have any questions, please do not hesitate to contact me.

Sincerely,

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs

Enclosures (submitted including an electronic copy)

15350 25th Avenue No • Suite 100 • Plymouth MN 55447 • 763.746.7500

Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Tendon Sheet

Indications for 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.

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)

510(k) Summary

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: August 22, 2011

Name of Device

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

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Tendon Wrap, K0080452
Collagen Matrix, Inc., Oakland, NJ

Description of the Device

Collagen Tendon Sheet is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet is designed to provide a layer between the tendon and the surrounding tissue. When hydrated, Collagen Tendon Sheet is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet 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.

Summary/Comparison of Technical Characteristics

Collagen Tendon Sheet and its predicate device have the same technological characteristics. In particular, Collagen Tendon Sheet and its predicates are the same with respect to intended use, design, materials, and material characterization. The substantial equivalence of the Collagen Tendon Sheet and its predicate was demonstrated primarily based on in vitro characterization studies, biocompatibility studies, an animal efficacy study, and clinical experience of the predicate device. In vitro characterization studies included evaluation of material properties, biological properties, chemical and physical properties.

Collagen Tendon Sheets have been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

An animal efficacy study was conducted to evaluate the device as compared to its predicate device. No clinical tests were performed on the product; however clinical history of the predicate device was referenced in the submission.

Viral inactivation studies were performed to ensure the viral safety of the product.

Conclusion of Non-clinical Studies

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, as well as the animal efficacy study show that Collagen Tendon Sheet is safe and substantially equivalent to the predicate device.

6. TRUTHFUL AND ACCURACY STATEMENT

I certify that, in my capacity as Vice President, Clinical Programs and Regulatory Affairs for Rotation Medical, Inc., I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been omitted.

Jeff Sims,
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical, Inc.

8/22/11
Date

7. Class III Summary and Certification

Class III Summary and Certification is not applicable to this device.

8. Financial Certification or Disclosure Statement

Since clinical studies were not conducted, a financial certification or disclosure statement is not applicable to this submission.

9. Declarations of Conformity and Summary Reports

9.1 Sterilization

Sterilization is conducted in accordance with ISO 11135 *Sterilization of Health Care Products – Ethylene Oxide.*

9.2 Biocompatibility

The biocompatibility of the finished product was tested according to ISO 10993 *Biological Evaluation of Medical Devices*.

9.3 FDA Guidance Documents

FDA Guidance Document entitled, “Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh,” issued on March 2, 1999, was used in the development and testing of the product.

Standards Data Reports (Form FDA 3654) for the above-referenced standards are included in Appendix H.

10. EXECUTIVE SUMMARY

10.1 Brief Description of Device

Collagen Tendon Sheet is a bioabsorbable implant device that provides a layer of collagen over injured tendons. Collagen Tendon Sheet is designed to provide a layer of collagen between a flat tendon and the surrounding tissue. After hydration Collagen Tendon Sheet is an easy-to-handle, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, in double-peel packages.

10.2 Design Philosophy

The design of the Collagen Tendon Sheet is based on the concept that providing a protective environment for a tendon injury or repair site during tendon healing. The collagen membrane acts as an interface between the tendon injury and its surrounding tissue, thereby restoring the integrity of the tendon sheath.

(b)(4) [redacted]

Rotation Medical was interested in developing a flat collagen sheet, similar to the existing Collagen Tendon Wrap product. Rotation Medical's Collagen Tendon Sheet would be provided to the customer as a flat collagen sheet, rather than the coiled configuration of the Collagen Tendon Wrap.

(b)(4) [redacted]

10.3 Device Comparison

Rotation Medical's Collagen Tendon Sheet is substantially equivalent to Collagen Matrix's Collagen Tendon Wrap. The Collagen Tendon Sheet is similar to its predicate device in terms of intended use, product design, material, physical characteristics, chemical composition, and handling properties. The data to support substantial equivalence are provided in this submission.

10.3 Summary of Performance Testing

Bench testing, animal studies, literature review, and (b)(4) [redacted] for Collagen Tendon Sheet, as well as the clinical history of the predicate Collagen Tendon Wrap and relevant products were compiled to support the performance of the Collagen Tendon Sheet.

11. DEVICE DESCRIPTION

11.1 Description

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

11.2 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.

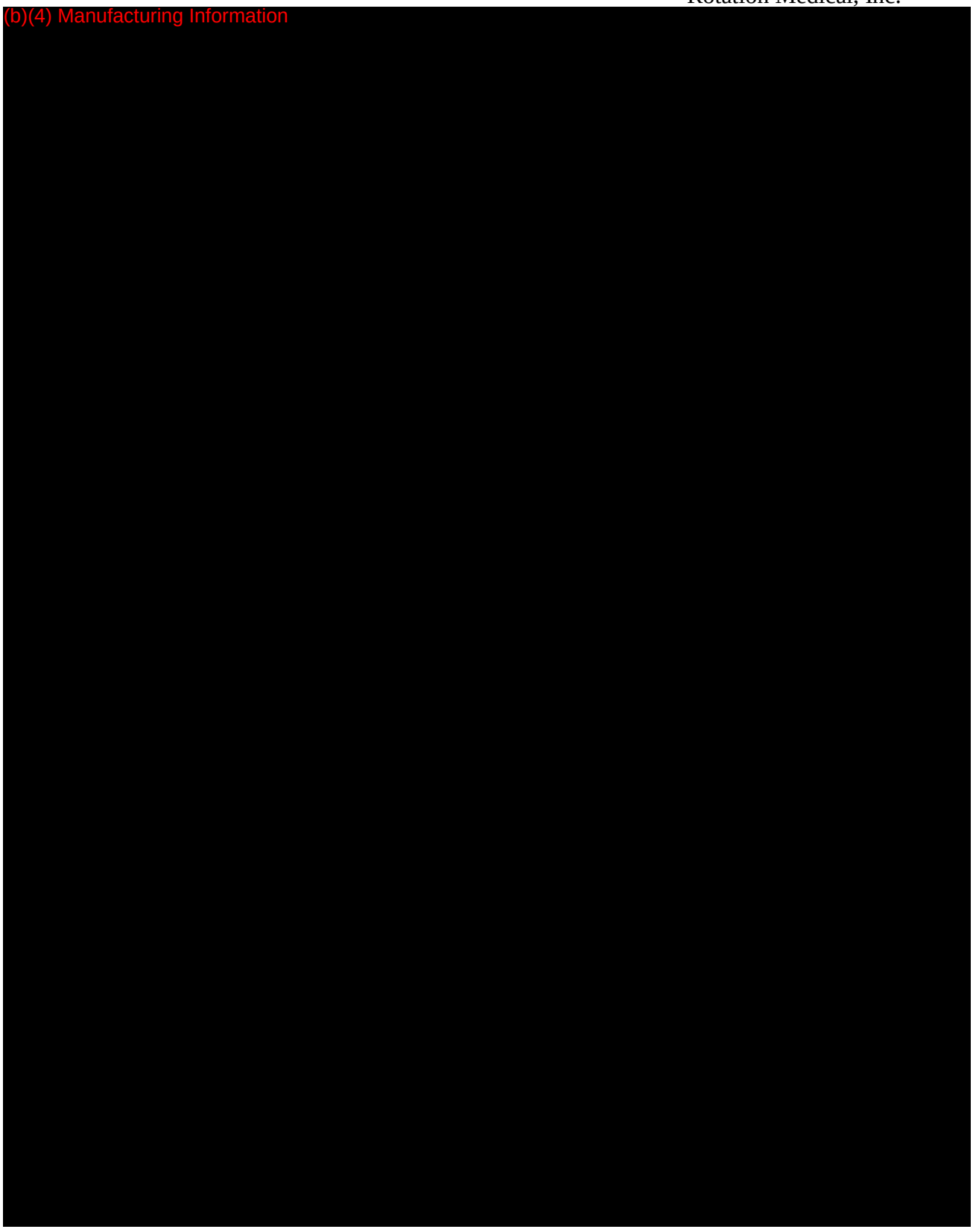
(b)(4) Manufacturing Information

11.4 Materials

Collagen Tendon Sheet consists of crosslinked type I collagen derived from (b)(4) (b)(4). The materials are identical to the materials used in Collagen Matrix's other marketed implantable devices:

- Collagen Tendon Wrap, K080452
- Collagen Nerve Wrap, K060952
- Collagen Bone Healing Protective Sheet, K052041
- Collagen Dura Substitute Membranes, K040888, K061487
- Collagen Nerve Cuff, K012814
- Collagen Periodontal Membrane, K003339
- Collagen Dental Membranes, K011695, K062881, K062846
- Collagen Dental Wound Dressing, K033729
- Collagen Wound Dressing – Oral, K040403

(b)(4) Manufacturing Information



(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

11.5 Performance Specifications/Design Requirements

The design of the Collagen Tendon Sheet was (b)(4) The key design parameters and final product specifications of the Collagen Tendon Sheet are summarized in Table 11-1. The design has been verified and validated through the design control process.

Table 11-1. Summary of Product Specifications

Parameter	Product Specification
Performance	Protection of tendon injuries in which there has been no substantial loss of tendon tissue
Chemical and Physical Properties	
Composition	Type I collagen
Color	White to off white
Form	Sheet
Dimensions	Various sizes to approximate human tendons 1.5 x 2 cm 2 x 2.5 cm 2.5 x 3 cm
Thickness	1.0 – 1.3 mm
Permeability	Semi-permeable (permeable to macromolecules and nutrients); pore size ≤ 10 µm Semi-permeable to carbonic anhydrase (probe molecule)

(b)(4)

Parameter	Product Specification
(b)(4) [redacted]	
Biological Properties	
Biocompatibility	Biocompatible (Pass FDA G95-1 and ISO 10993)
Pyrogenicity+	Non-pyrogenic (≤ 0.5 EU/ml)
Stability	
Shelf-Life	3 years
Packaging	
(b)(4) [redacted]	(b)(4) [redacted]
(b) [redacted]	

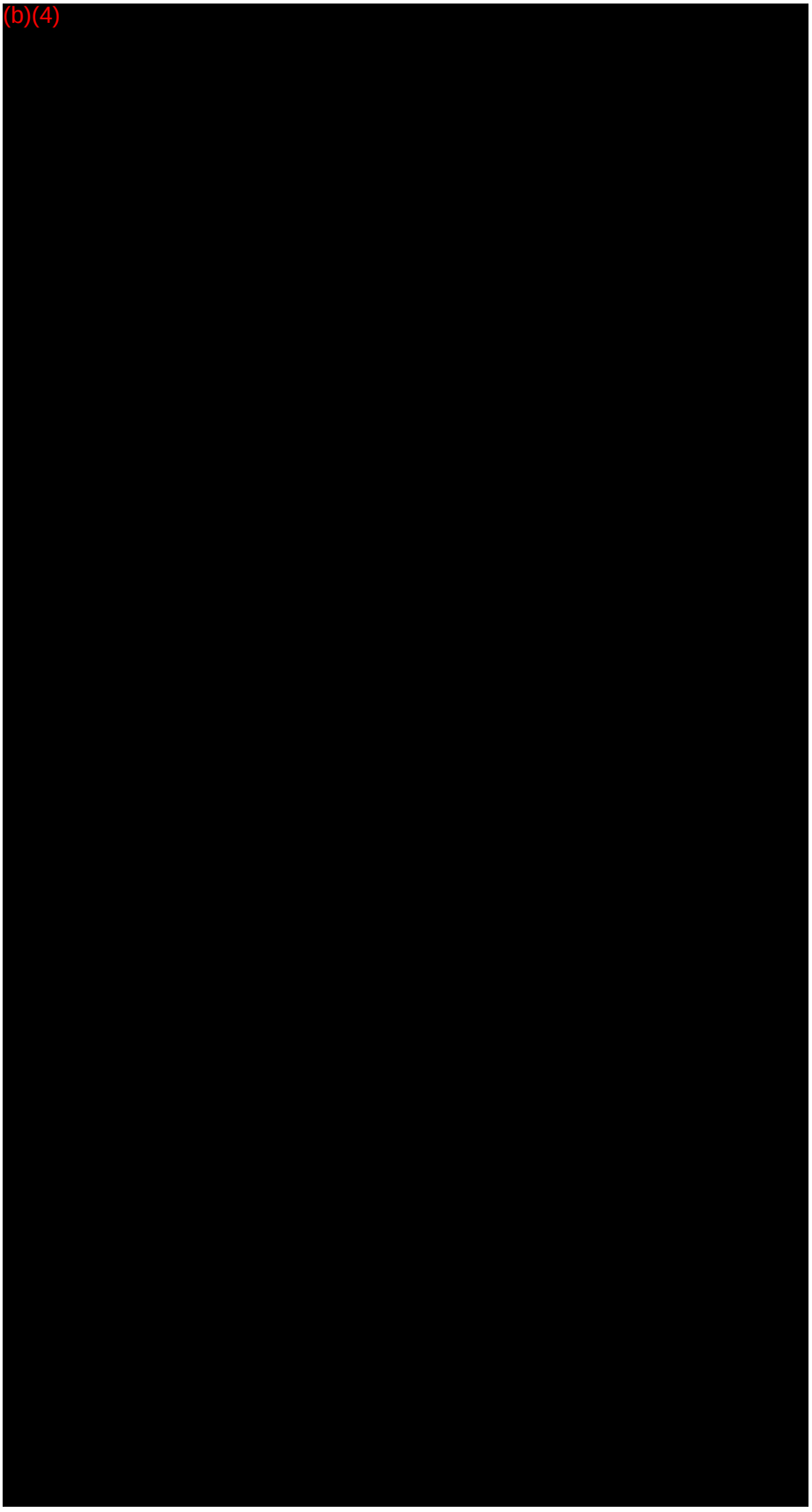
11.6 Manufacturing Process

11.6.1 Manufacturing Flowchart

The manufacturing flowchart is shown below.

Manufacturing Flowchart for Collagen Tendon Sheet

(b)(4)



11.6.2 Description of the Manufacturing Process

(b)(4)

12. SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1 Predicate Devices

The data presented in this 510(k) demonstrate that Collagen Tendon Sheet is substantially equivalent to the following predicate devices:

Collagen Tendon Wrap, K080452
Collagen Matrix, Inc., Oakland, NJ

12.2 Substantial Equivalence Comparison Table

The Substantial Equivalence Comparison Table is presented on the following page (Table 12-1). As the table shows, the technological characteristics of the Collagen Tendon Sheet of this submission are substantially equivalent to the predicate device referenced above.

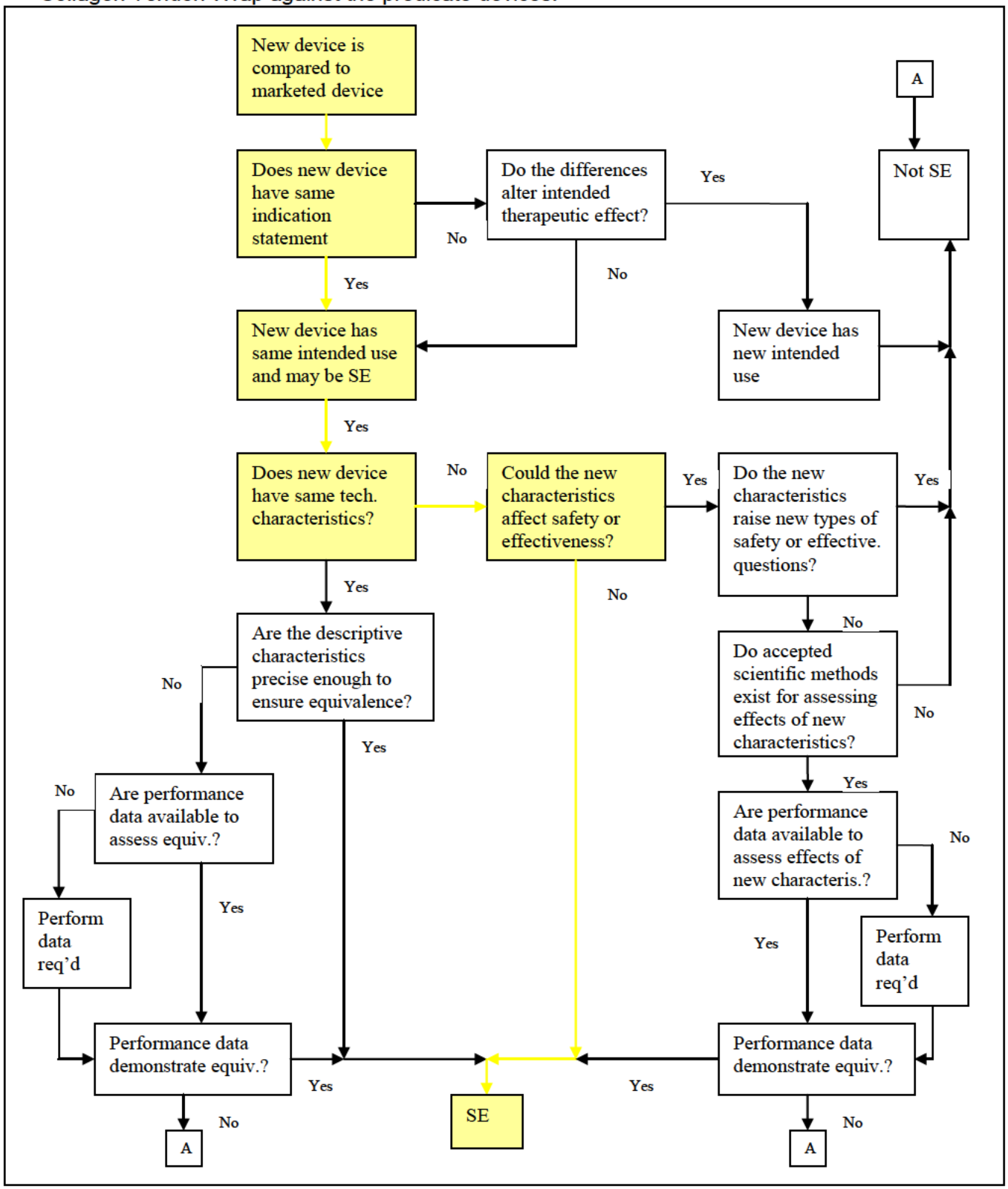
Table 12-1. Substantial Equivalence Comparison Chart with Comparative Data

	Collagen Tendon Sheet (This submission)	Collagen Tendon Wrap K080452
Indications for use	Management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	Management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.
Material	Type I collagen	Type I collagen
Source	(b)(4) [redacted]	(b)(4) [redacted]
Form	Sheet	Sheet (self wrapping)
Color	White to off-white	White to off-white
Dimensions	1.5 x 2 cm 2 x 2.5 cm 2.5 x 3 cm Various sizes to approximate human tendons	4 x 7 cm 5 x 5 cm 10 x 12.5 cm Various sizes to approximate human tendons
Thickness	1 – 1.3 mm	0.4 ± 0.1 mm
Density	0.3 g/cm^3	0.4 g/cm^3
Mechanical Strength	Can be sutured 1.65 ± 0.15 kg	Can be sutured 0.356 ± 0.046 kg
Porosity / Permeability	Semi-permeable Permeable to nutrients and small molecules < 10 µm	Semi-permeable Permeable to nutrients and small molecules < 10 µm
Biocompatibility	Biocompatible	Biocompatible
Thermal Transition Temperature	67 ± 1^{o}C	55 ± 1^{o}C
Resorption / Biodegradation	Gradual resorption Approx. 10 months	Gradual resorption Approx. 6 months
Sterility	Sterile, SAL 10^{-6} ETO sterilization	Sterile, SAL 10^{-6} Gamma irradiation
Pyrogenicity	Non-pyrogenic (≤ 0.5 EU/ml)	Non-pyrogenic (≤ 0.5 EU/ml)
Single use / Reuse	Single use only	Single use only
Packaging	Double peel package	Double peel package

*Based on information from Company brochures, 510(k) Summaries of Safety and Effectiveness, literature, and in-house testing.

12.3 Substantial Equivalence Decision Flowchart

The following Substantial Equivalence Decision-making Flowchart was used to assess Collagen Tendon Wrap against the predicate devices.



12.4 Description of Substantial Equivalence Flowchart Decisions

Does the new device have same indication statement?

Yes. Collagen Tendon Sheet and Collagen Tendon Wrap have the same indication statement, which is management and protection of tendon injuries where there is no substantial loss of tendon tissue.

New device has same intended use and may be substantially equivalent.

Yes. Collagen Tendon Sheet and Collagen Tendon Wrap have the same intended use, which is to provide a protective environment for tissue repair.

Does the new device have same technological characteristics, e.g., design, materials, etc.?

No. There are slight differences in the technological characteristics between the Collagen Tendon Sheet and Collagen Tendon Wrap. The main difference is that the Collagen Tendon Sheet subject device is provided in a flat sheet form, whereas Collagen Tendon Wrap is provided in a curled sheet from. All other technological aspects of the products, such as design, materials, principle of operation, etc. are the same.

Could the new characteristics affect safety and effectiveness?

No. The difference in the flat sheet vs. curled sheet does not affect safety and effectiveness of the product. The Collagen Tendon Wrap curled sheet can be flattened out at the time of implantation to be applied in a flat form. The Collagen Tendon Sheet is the same product offered in a flat form already. The safety of type I collagen is well-established and is not a concern.

Substantial equivalence

The results of the data presented demonstrate that Collagen Tendon Sheet is substantially equivalent to its predicate Collagen Tendon Wrap.

12.5 Detailed Description of Substantial Equivalence

The overall product comparisons were presented in the table above. In this section, a detailed comparison of the key material characterization test results between the candidate product and the predicate products will be discussed:

- Collagen Tendon Sheet – SUBJECT DEVICE
- Collagen Tendon Wrap - PREDICATE DEVICE

12.5.1 Intended Use

The intended use of the Collagen Tendon Sheet and its predicate is identical, which is for management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

12.5.2 Form, Appearance, and Dimensions

Collagen Tendon Sheet and its predicate device are supplied in sheet form and white to off-white in color. The Collagen Tendon Wrap sheet is supplied in a curled form.

Figure 12-1. Collagen Tendon Sheet

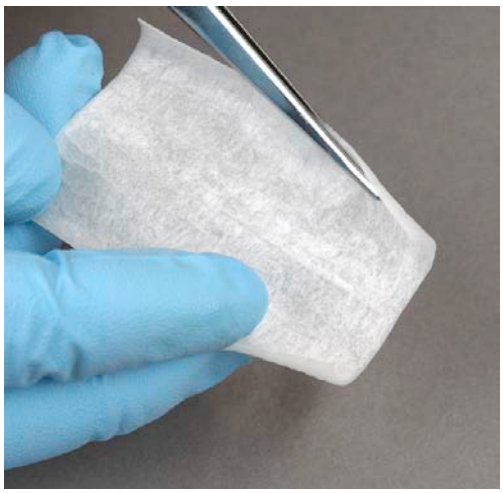


Figure 12-2. Collagen Tendon Wrap

	Collagen Tendon Sheet	Collagen Tendon Wrap
Form	Membrane	Membrane (curled)
Color	White to off-white	White to off-white
Dimensions	1.5 x 2 cm 2 x 2.5 cm 2.5 x 3 cm	4 x 7 cm 5 x 5 cm 10 x 12.5 cm
Thickness	1 – 1.3 mm	0.4 ± 0.1 mm

The Collagen Tendon Sheet is provided in smaller sizes as compared to the Collagen Tendon Wrap, because the Collagen Tendon Sheet subject device is not designed to wrap around an injured tendon. The subject device will be implanted over the surface of an injury or defect of a flat tendon. Therefore, the

larger sizes are not necessary. The thickness of the Collagen Tendon Sheet is greater than that of the Collagen Tendon Wrap. Given that the Collagen Tendon Sheet is not designed to overlap upon itself as compared with the Collagen Tendon Wrap, the thickness of the Collagen Tendon Sheet will not interfere with joint movement. The thinner Collagen Tendon Wrap accommodates overlap with an expectation of double thickness in the overlapped region.

12.5.3 Material Composition

(b)(4)

[redacted]

12.5.4 Physical Properties

(b)(4)

[redacted]

12.4.4 Physico-chemical Properties

(b)(4)

[redacted]

(b)(4) Manufacturing Information

[redacted]

12.4.5 In Vivo (b)(4) Study

(b)(4)

[redacted]

12.4.6 Sterility

The subject device and its predicates are all terminally sterilized for a sterility assurance level of 10^{-6}.

	Collagen Tendon Sheet	Collagen Tendon Wrap
Sterilization Method	Ethylene oxide	Gamma irradiation

12.5 Conclusions of Comparative Analysis

Based on the comparative analysis, Collagen Tendon Sheet has been shown to be substantially equivalent to its predicate. Additional support is provided throughout this submission with respect to safety and performance/effectiveness of the device.

13. PROPOSED LABELING

The product label and instructions for use of the Collagen Tendon Sheet are provided in Appendix B. Because of the similarities in intended use, materials, and product characteristics, the instructions for use of the predicate device Collagen Tendon Wrap was used as a guide in developing the insert for the Collagen Tendon Sheet. A copy of the insert for the Collagen Tendon Wrap is also included in the same appendix for reference.

14. STERILIZATION AND SHELF LIFE

14.1 Sterilization

The method of sterilization is ethylene oxide sterilization. The sterilization method has been validated in accordance with ISO 11135-1, Sterilizaion of health care products - Ethylene oxide. The sterility assurance level of the device is 10^{-6}.

Pursuant to ISO requirements, the ethylene oxide and ethylene chlorohydrins residual must meet the following acceptance criteria:

Ethylene oxide:	≤ 4 mg
Ethylene chlorohydrin	≤ 9 mg

The packaging used to maintain sterility is a (b)(4) [redacted], typical of sterile medical device packaging.

14.2 Shelf Life

(b)(4) Testing [redacted] testing supports a 3-year shelf life for the Collagen Tendon Sheet. The (b)(4) [redacted] study report is attached in Appendix C.

(b)(4) [redacted]
(b)(4) [redacted] The results of the tests at each time point must meet overall product specifications.

15. BIOCOMPATIBILITY

The biocompatibility testing of the product was performed according to the guideline specified in the FDA Blue Book Memorandum G95-1 and ISO 10993-1 under the category of Implant device, tissue/bone contact, permanent duration (>30 days). The data presented are from the biocompatibility testing of the sterile Collagen Membrane finished product, which is directly applicable since the Collagen Membrane is the exact same composition as the Collagen Tendon Sheet.

All test results showed that the Collagen Tendon Sheet material is biocompatible and safe for human implantation.

(b)(4) biocompatibility testing (b)(4)

The following table summarize the biocompatibility tests. The final reports are provided in Appendix A.

Table 15-1. Summary of Biocompatibility Tests

Test	Test Method/Model	Results
(b)(4)		

Test	Test Method/Model	Results
(b)(4)		

Conclusion

Collagen Tendon Sheet is biocompatible and safe for human implantation.

16. SOFTWARE

The device does not contain software; therefore this section is not applicable to this submission.

17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The device does not include an electronic component; therefore this section is not applicable to this submission.

18. PERFORMANCE TESTING - BENCH

18.1 Design Verification

The design was verified by (b)(4) Table 18.1 shows the Design Verification Matrix for the product. All (b)(4) results were within the specifications originally set for the design input requirements.

Table 18.1. Design Verification Matrix

Parameter	Product Specification / Design Input	Design Output
(b)(4)		

Parameter	Product Specification / Design Input	Design Output
Biological Properties		
Biocompatibility	Biocompatible (Pass FDA G95-1 and ISO 10993)	Passed all biocompatibility tests
Pyrogenicity	Non-pyrogenic (≤ 0.5 EU/ml)	≤ 0.005 EU/ml
Stability		
Shelf-Life	3 years	3 years (b)(4) (Appendix C)
Packaging		
(b)(4)	(b)(4)	(b)(4)

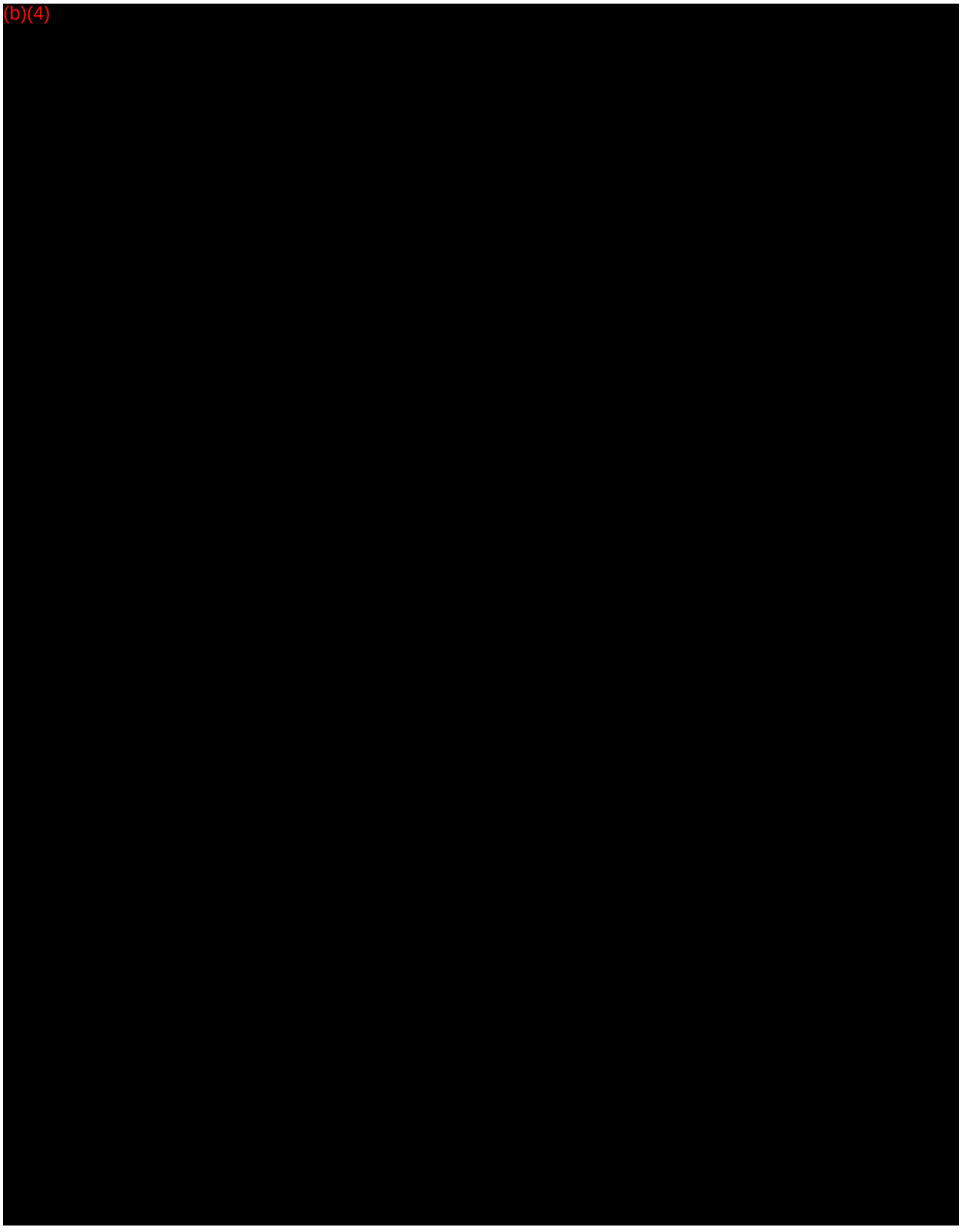
18.2 Design Verification Test Methods and Results

The test methods and results of the design verification testing are included in Appendix E. The tests methods (b)(4)

(b)(4)

19. PERFORMANCE TESTING - ANIMAL

(b)(4)



(b)(4) Testing

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(b)(4) Testing

Table 19-3. Summary of Animal Studies in Literature

(b)(4) Testing

(b)(4) Summary of Animal Testing in Literature

(b)(4) Summary of Animal Testing in Literature

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(b)(4) Summary of Animal Testing in Literature

(b)(4) Summary of Animal Testing in Literature

20. PERFORMANCE TESTING - CLINICAL

20.1 Clinical Experience with Collagen Tendon Wrap (b)(4)

(b)(4)

20.2 Clinical Literature Review

(b)(4)

(b)(4) Clinical Literature Review

20.3 Conclusions from the Clinical Experience and Clinical Literature

(b)(4)

(b)(4) Clinical Literature Review

(b)(4) Clinical Literature Review

(b)(4) Clinical Literature Review

(b)(4) Clinical Literature Review

(b)(4) Clinical Literature Review

21. OTHER

21.1 (b)(4) (b)(4) and Risk Assessment

(b)(4) [redacted]

Compliance with Standards.

(b)(4) (b) complies with available standards and guidances for the handling and control of animal-derived tissues. Such standards and guidances include:

- Medical Devices Containing Materials Derived from Animal Sources, CDRH, FDA, November 6, 1998
- Report of a WHO Consultation on Medicinal and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies," World Health Organization, March 1997
- EN 12442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management
- EN 12442-2 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling
- EN12442-3 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents
- MEDDEV 2.5/5 Guidelines on Assessment of Medical Devices Incorporating Materials of Animal Origin with Respect to Viruses and Transmissible Agents
- Commission Directive 2003/32/EC Detailed Specifications as Regards the Requirements Laid Down in Council Directive 93/42/EEC with Respect to Medical Devices Manufactured Utilising Tissues of Animal Origin

(b)(4) Material Information [redacted]

(b)(4) Manufacturing Information

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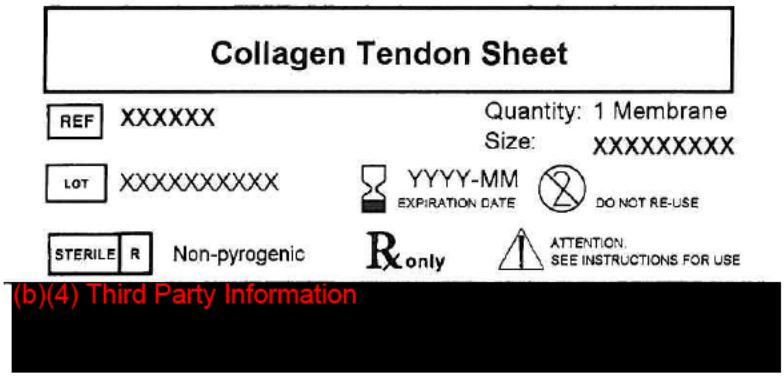

Collagen Tendon Sheet

Description

Collagen Tendon Sheet is a bioabsorbable implant device that provides a layer of collagen over injured tendons. Collagen Tendon Sheet is designed to provide a layer of collagen between a flat tendon and the surrounding tissue. After hydration Collagen Tendon Sheet is an easy-to-handle, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, in double-peel packages.

Indications for 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.

Contraindications

Collagen Tendon Sheet is not designed, sold, or intended for use except as described in the indications for use and is contraindicated in the following situations:

- Collagen Tendon Sheet is not indicated to replace or repair damaged tendon or to reinforce the strength of any tendon repair.
- Collagen Tendon Sheet is not indicated for patients with a known history of hypersensitivity to bovine-derived materials.

Instructions for Use

1. Follow standard procedures for treatment of the injured tendon.
2. Determine the tendon width in millimeters (mm) using a suitable measuring instrument.
3. Select a Collagen Tendon Sheet size that is slightly smaller than the width of the tendon.
4. Pre-hydrate Collagen Tendon Sheet in sterile saline for at least 2 minutes.
5. After hydration place the Collagen Tendon Sheet over the tendon with one end overlapping the tendon insertion.
6. Secure the Collagen Tendon Sheet to the tendon and bone with interrupted sutures. Use the minimum number of sutures to ensure that the Collagen Tendon Sheet is in good contact with the tendon.
7. Thoroughly irrigate the surgical site and close the incision in the standard fashion.
8. Application of the Collagen Tendon Sheet does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

Warnings

- Do not re-sterilize.
- Do not use if the product package is damaged or opened.

Precautions

- Collagen Tendon Sheet should not be applied until bleeding and infection are controlled.

Storage

Store at room temperature. Avoid excessive heat or humidity.

How Supplied

Collagen Tendon Sheet is supplied sterile in single-use, double-peel packages in a variety of sizes. Contents of the package are guaranteed sterile and non-pyrogenic unless the package is opened or damaged. The Collagen Tendon Sheet product and packaging do not contain natural rubber latex.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

Symbols Used on Labeling


See Instructions for Use


Expiration Date


Do not reuse after opening

Lot Number

Method of sterilization – ethylene oxide

Manufactured exclusively for:

Rotation Medical, Inc.
15350 25th Ave. N., Plymouth, MN 55447 USA

By:

(b)(4) Third Party Information

RMICTSIFUUS, Rev 0

(b)(4) Manufacturing Information

(b)(4) Third Party Manufacturing Information

CONFIDENTIAL
Interim Report for
Doc. No. (b)(4) Third Party
Date: 08/21/11

(b)(4) Third Party Manufacturing Information

Summary Report of Collagen Tendon Sheet

(b)(4) Third Party Manufacturing Information

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(b)(4) Third Party Manufacturing Information

(b)(4) Third Party Manufacturing Information

Verification Report – Cover Sheet

Approved by:

Name	Department	Date
(b)(6)	R+D	8/3/11
	CEO	8/3/11
	Clinical Reg.	8/3/11

Verification Report (VER)	Rotation Medical, Inc	Doc Num (b) Rev (
	(b)(4)	

Revision History

Rev	DCR#	Description	Originator	Date
(b)(4)			(b)	7-26-11
			(b)	8-3-11

(b)(4) Manufacturing Information

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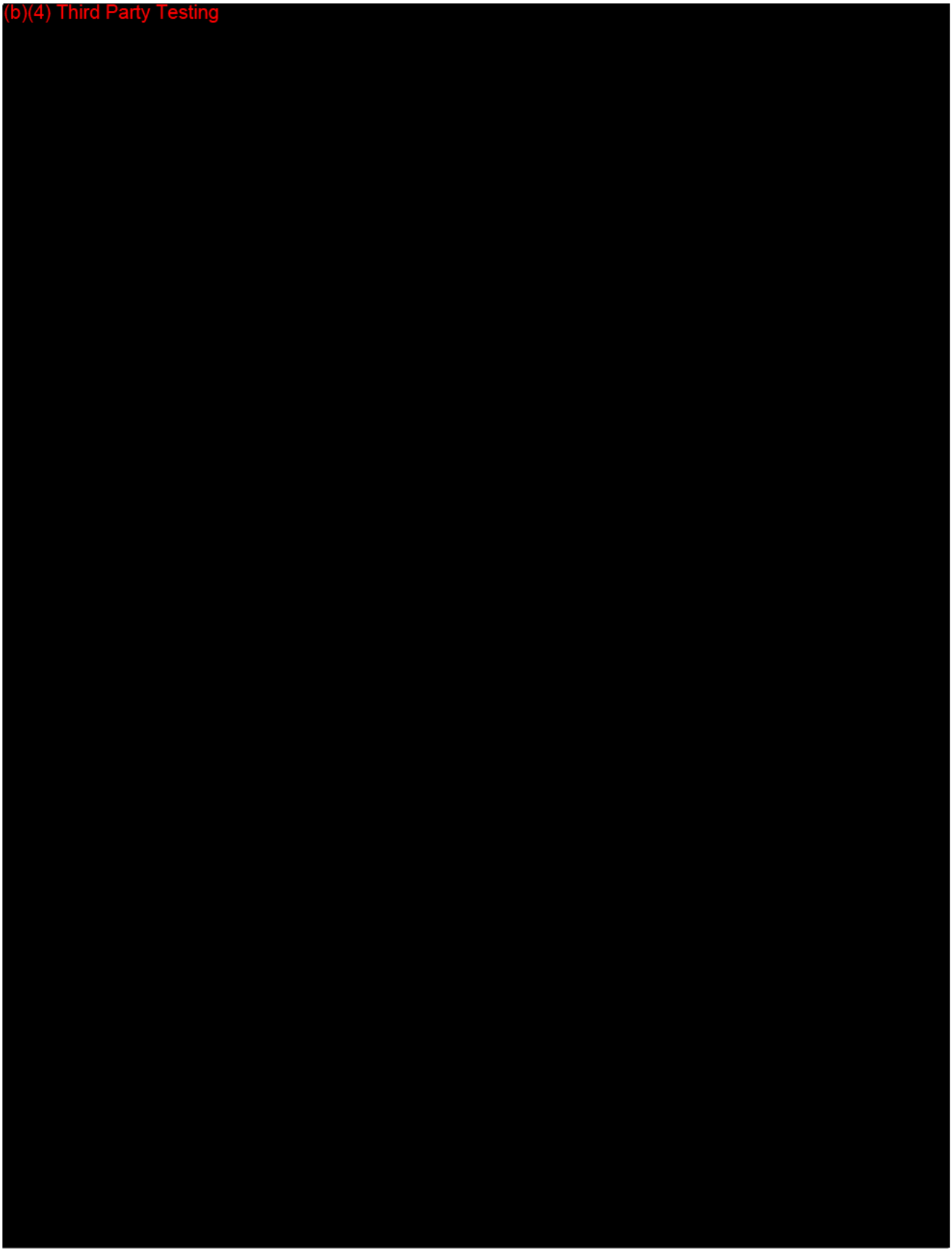
ANIMAL STUDY REPORT

(b)(4) Third Party Testing



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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological evaluation of medical devices - Part 1: Evaluation and testing

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☑	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☑	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☑	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

Biological evaluation of medical devices - Part 1: Evaluation and testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Categorization of medical devices	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4) [redacted]

DESCRIPTION

(b)(4) [redacted]

JUSTIFICATION

The categorization was based on the intended use of the device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Testing	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4) [redacted]

DESCRIPTION

Selected tests were performed per applicable ISO 10993 standards or equivalent methods.

JUSTIFICATION

Choice of test procedures took into account the factors listed in the standard.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of biological evaluation tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Evaluation included both a study of relevant experiences and actual testing.

DESCRIPTION

Selected tests were performed per applicable ISO 10993 standards or equivalent methods.

JUSTIFICATION

Selected tests were adequate to confirm safety of the final product for its intended use.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-117	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☑	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☑	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Genotoxicity tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4) [redacted]

DESCRIPTION

(b)(4) [redacted]

JUSTIFICATION

(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Carcinogenicity tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4) [redacted]

DESCRIPTION

(b)(4) [redacted]

JUSTIFICATION

(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Reproductive and developmental toxicity tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4) [redacted]

DESCRIPTION

(b)(4) [redacted]

JUSTIFICATION

(b)(4) [redacted]

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-120	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
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Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☑	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☑	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Test methods, general aspects	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Test model selected was (b)(4) per ISO standard.

DESCRIPTION

(b)(4)

JUSTIFICATION

To determine the potential for a local irritant or toxic response to material implanted in direct contact with muscle tissue.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☑	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☑	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
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Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Acute systemic toxicity (Study design)	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

Type of (b)(4) [redacted]

DESCRIPTION

Test conditions performed were in accordance with the standard. (b)(4) [redacted]

JUSTIFICATION

(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Repeated exposure systemic toxicity (subacute, subchronic, chronic)	☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

(b)(4) [redacted]

DESCRIPTION

JUSTIFICATION

(b)(4) [redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☑	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☑	☐
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed hypersensitivity tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
(b)(4)

DESCRIPTION
(b)(4)

JUSTIFICATION
(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☑ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 2-64	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☑
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Sample preparation	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Test was performed or (b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Test procedures	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.5	Determination of cytotoxicity	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

Qualitative evaluation was performed according to the standard.

JUSTIFICATION

Appropriate method of determination based on test procedure selected.

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Maegen Colehour, M.S.

Subject: 510(k) Number K112423/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?		✓	
All Pediatric Patients age<=21			✓

Rev. 5/12/11

Neonate/Newborn (Birth to 28 days)			~
Infant (29 days -< 2 years old)			~
Child (2 years -< 12 years old)			~
Adolescent (12 years -< 18 years old)			~
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			~
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			~
Nanotechnology			~
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		~

Regulation Number **Class*** **Product Code**

878.3300 II FTM

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Krause (Branch Chief) PRSB (Branch Code) Dec 22, 2011 (Date)

Final Review: (Division Director) 12/22/11 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review

Traditional

K112423/S002

Date: December 20, 2011
To: The Record
From: Maegen Colehour, M.S. (ODE/DSORD/PRSB)

Device Name: Collagen Tendon Sheet
510(k) Holder: Rotation Medical, Inc.
Address: 15350 25th Avenue N, Suite 100
Plymouth, MN 55447

Establishment Registration Number:

Contact: Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Phone: (763) 746-7502
Fax: (763) 746-7501
Email: jsims@rotationmedical.com

TABLE OF CONTENTS

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I. Purpose of Submission

The 510(k) holder would like to introduce the following device into interstate commerce:
Device name: Collagen Tendon Sheet

II. Document History

K112423/S002 (dated 12/16/11 and received 12/16/11) was assigned to me on 12/16/11 with a final date of 12/28/11. Dr. Peter Hudson (PRSB) provided a biocompatibility consult (attached).

K112423/S001 (dated 11/30/11 and received 11/30/11) was assigned to me on 12/1/11, and an AI letter was sent on 12/9/11. A biocompatibility consult by Dr. Peter Hudson (PRSB) was requested on 11/30/11 and received on 12/7/11.

K112423 (dated 8/22/11 and received 8/23/11) was assigned to me on 8/25/11, and an AI letter was sent on 10/31/11. A biocompatibility consult by Dr. Peter Hudson (PRSB) was requested on 10/18/11 and received on 10/28/11.

III. Recommendation

Substantially Equivalent

Regulation Number:	21 CFR §878.3300
Regulation Name:	Surgical Mesh
Regulatory Class:	II
Product Code:	FTM

IV. Document Summary

The subject device is a resorbable, crosslinked, type I collagen matrix derived from (b)(4) (b)(4) and is designed to act as an interface between the tendon and tendon sheath or the surrounding tissue. Specifically, the device is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue, and these indications are identical to those of the predicate device (K080452 – Collagen Tendon Wrap). The sponsor notes that the subject device (Collagen Tendon Sheet) and predicate device (Collagen Tendon Wrap) are(b)(4) are (b)(4) The subject device appears to differ from the predicate only in physical dimensions/configuration (i.e., the subject device is thicker than the predicate and is manufactured in flat sheet form as opposed to the coiled form of the predicate device) and sterilization method (the subject device is sterilized via EtO instead of Gamma Irradiation in order to (b)(4) (b)(4)

The sponsor is heavily relying on(b)(4) (b)(4) (b)(4) (b)(4) (b) to those that have been considered adequate for clearance of the predicate submissions. The sponsor has also identified product specifications that appear to be substantially equivalent to those of the predicate device. (b)(4) (the testing performed to support clearance of the predicate device were provided. (b)(4) (b)(4) (b)(4) Data from an animal studies performed on both the predicate and

subject devices were also provided. Finally, [redacted] viral inactivation testing [redacted] appears to have been performed on the subject device.

During my original review, I consulted with Dr. Peter Hudson (PRSB) regarding the adequacy of the data (i.e. biocompatibility, viral inactivation, animal data) [redacted]. Dr. Hudson reviewed the [redacted] and identified a number of deficiencies related to [redacted]. Dr. Hudson also noted concern related to [redacted]. We consulted with Mr. Ron Brown (OSEL/OSEL/DB) regarding the [redacted], Mr. Brown noted (see attached review) that [redacted]. With regards to the [redacted] Dr. Hudson notes [redacted] however, I discussed the issue with both Dr. Hudson and Dr. Krause, who agreed that we [redacted]. However, Dr. Krause noted that we [redacted]. Thus, I recommend that the subject device be found substantially equivalent to the predicate device. Please see the Response to FDA Request for Additional Information and Deficiencies sections below and Dr. Hudson's consult review memos for more details.

V. Administrative Requirements

	YES	NO	N/A	MISC
Indications for Use page (Indicate if: Prescription or OTC)	X			
Truthful and Accurate Statement	X			
510(k) Summary or 510(k) Statement	X			
Standards Form	X			

VI. Device Description

	YES	NO	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The Collagen Tendon Sheet is described as a resorbable, crosslinked, type I collagen matrix derived from [redacted]. The device is intended to provide a layer of collagen over

injured tendons. The design of the Collagen Tendon Sheet is based on the concept of providing a protective environment for a tendon injury or repair site during tendon healing with the collagen membrane acting as an interface between the tendon injury and its surrounding tissue, thereby restoring the integrity of the tendon sheath. When hydrated, Collagen Tendon Sheet is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. It is provided sterile, non-pyrogenic, for single-use only, in a variety of sizes, in double peel packages.

The sponsor notes that Rotation Medical was interested in developing a collagen sheet similar (b)(4) existing Collagen Tendon Wrap product (K080452), but which would be supplied as a flat collagen sheet, rather than the coiled configuration of the Collagen Tendon Wrap. (b)(4) The sponsor notes that the materials of the Collagen Tendon Sheet are (b)(4)

The sponsor identified the following product specifications/design requirements on page 30:

Parameter	Specification
Dimensions	Various sizes to approximate human tendons • 1.5 x 2 cm • 2 x 2.5 cm • 2.5 x 3 cm
Thickness	1.0 – 1.3 mm
Permeability/Pore Size	Semi-permeable (permeable to macromolecules and nutrients); pore size ≤ 10 µm Semi-permeable to carbonic anhydrase (probe molecule)
Suture Pullout Strength	≥ 0.065 kg
Tensile Strength	≥ 50 kg/cm^2
In vivo Stability	6 to 12 months (as assessed by (b)(4) (b)
Hydration	M(b)(4)
Residual crosslinking agent	≤ 0.065%
Sterility	SAL 10^{-6} Residual (b)(4) Residual
Pyrogenicity	≤ 0.5 EU/ml

Sourcing of Collagen Material

The sponsor notes that the (b)(4) material is obtained from an (that is (b)(4)

(b)(4) [redacted]. The Collagen Sourcing information is summarized in the following table:

(b)(4) Manufacturing Information [redacted]

In addition, the sponsor notes compliance with the following standards and guidelines for handling and control of animal-derived tissues:

- Medical Devices Containing Materials Derived from Animal Sources, CDRH, FDA, November 6, 1998
- Report of a WHO Consultation on Medicinal and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies," World Health Organization, March 1997
- EN 12442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management
- EN 12442-2 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling

- EN12442-3 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents
- MEDDEV 2.5/5 Guidelines on Assessment of Medical Devices Incorporating Materials of Animal Origin with Respect to Viruses and Transmissible Agents
- Commission Directive 2003/32/EC Detailed Specifications as Regards the Requirements Laid Down in Council Directive 93/42/EEC with Respect to Medical Devices Manufactured Utilizing Tissues of Animal Origin

(b)(4) Manufacturing Information

Reviewer Comment:

As noted by Dr. Hudson in his original consult review (b)(4) Manufacturing Information (b)(4) Manufacturing (b)(4) Manufacturing (b)(4) Manufacturing Information No additional information regarding these issues is necessary.

Device Manufacture

(b)(4) Manufacturing Information

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VII. Indications for 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.

Reviewer Comment:
The Indications for Use are identical to those of the predicate.

VIII. Predicate Device Comparison

K080452: Collagen Tendon Wrap (Collagen Matrix, Inc.)

Indications for Use:
Management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Device Description:
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, non-friable, 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.

Additional Predicates:

The sponsor cited the following additional predicates, which they note are tendon protector products successfully used for the protection of tendon injuries: TenoGlide™ Tendon Protector Sheet (K053655, Integra Lifescience), GraftJacket® Regenerative Tissue Matrix (Wright Medical Technology) and ProPatch® Soft Tissue Repair Matrix (K061892 & K101587, CryoLife, Inc.). Finally, the sponsor cited (p. 28) the following cleared devices that are manufactured by [redacted] (b)(4) Manuf

- Collagen Tendon Wrap, K080452
- Collagen Nerve Wrap, K060952
- Collagen Bone Healing Protective Sheet, K052041
- Collagen Dura Substitute Membranes, K040888, K061487
- Collagen Nerve Cuff, K012814
- Collagen Periodontal Membrane, K003339
- Collagen Dental Membranes, K011695, K062881, K062846
- Collagen Dental Wound Dressing, K033729
- Collagen Wound Dressing – Oral, K040403

Reviewer Comment:
[redacted] (b)(4) [redacted] As outlined on page 36 of the submission, the two devices have the following differences:

Parameter	Collagen Tendon Sheet (K112423)	Collagen Tendon Wrap (K080452)
Dimensions	1.5 x 2 cm 2 x 2.5 cm 2.5 x 3 cm Various sizes to approximate human	4 x 7 cm 5 x 5 cm 10 x 12.5 cm Various sizes to approximate human

	tendons	Tendons
Thickness	1 – 1.3 mm	0.4 ± 0.1 mm
Density	0.3 g/cm^3	0.4 g/cm^3
(b)(4) [redacted]		
Resorption	Gradual resorption ~10 months	Gradual resorption ~6 months
Sterility	EtO	Gamma Irradiation

The sponsor notes that the subject device is provided in smaller sizes as compared to the Collagen Tendon Wrap because the Collagen Tendon Sheet subject device is not designed to wrap around an injured tendon. Instead, the subject device will be implanted over the surface of an injury or defect of a flat tendon. The sponsor also notes that the subject device is thicker than the predicate since the predicate wrap accommodates overlap with an expectation of double thickness in the overlapped region. (b)(4) Manufacturing Information [redacted]. The increased thickness is similar to the available thicknesses of CryoLife, Inc.'s bovine pericardial tissue derived device ProPatch (K061892, K101587), which ranges from 0.5 – 2.5mm in thickness (per K061892 review memo) and includes indications for use during tendon repair, and of Wright Medical Technology's GraftJacket® Regenerative Tissue Matrix, which appears to range from 0.5 – 1.4mm in thickness and is indicated for tendon and tendon sheath repair and reinforcement of the hand and foot (per a Substantial Equivalence Comparison table provided in K080452). Finally, the sponsor notes in the animal study summary that the switch from gamma irradiation to EtO sterilization was intended to (b)(4) Manufacturing Information [redacted] (b)(4) [redacted] (see Performance Testing section below for more details).

IX. Labeling

Proposed labeling is included in Appendix 11 of Supplement 1. The Instructions for Use include the following safety information:

Contraindications:
- Collagen Tendon Sheet is not indicated to replace or repair damaged tendon or to reinforce the strength of any tendon repair
- Collagen Tendon Sheet is not indicated for patients with known history of hypersensitivity to bovine-derived materials

Warnings:
- Do not re-sterilize
- Do not use if the product or package is damaged or opened

Precautions:
- Collagen Tendon Sheet should not be applied until bleeding and infection are controlled

Adverse Reactions:
- Infection may occur if device sterility is compromised
- An allergic reaction to Collagen Tendon Sheet may be experienced in patients with a hypersensitivity to bovine-derived materials

Reviewer Comment:
The labeling is essentially identical to the predicate device labeling, apart from necessary changes related to the physical differences between the devices. No warning statements have been changed or removed. The proposed labeling is consistent with the predicate labeling and can be considered adequate for the subject device.

X. Sterilization/Reuse

Review Template for Sterile Devices

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	EtO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	EO: ≤ 4 mg (not detectable) ECH: ≤ 9 mg (not detectable)	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ISO 11135	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	10^{-6}	
4. Is it labeled "Pyrogen Free"?	X	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	LAL (≤ 0.5 EU/ml) – *Lot release specification*	
5. A description of the packaging (not including package integrity test data):	(b)(4) [redacted]	

XI. Shelf Life/Stability Testing

The sponsor proposes to label the subject device with a 3-year shelf life based on a (b)(4) [redacted] is provided in Appendix C. The report notes that (b)(4) [redacted]

(b)(4) [redacted]

Reviewer Comment:

(b)(4) [redacted]. Therefore, based

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(b)(4) (b)(4)

XII. Biocompatibility

The sponsor provided the following summary of biocompatibility testing performed in accordance with ISO 10993-1 by (b)(4) . Complete test reports are provided in Appendix A.

Test	Test Method/Model	Results
(b)(4)		

(b)(4) Third Party Manufacturing Information

Viral Inactivation

(b)(4) Third Party Manufacturing Information

(b)(4) Third Party Manufacturing Information

[redacted]

Based on the information provided in Supplement 1, Dr. Hudson noted that FDA can reasonably deduce that there is enough (b)(4) Third Party M f t i l f ti the material safe for human use.

XIII. Software

Not applicable.

XIV. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XV. Performance Testing – Bench

The sponsor provided the following Design Verification Matrix table to summarize the product specification/design input versus the design output observed. Test methods and results are included in Appendix E, and the sponsor notes that (b)(4) Third Party Manufacturing Information.

Table 18.1. Design Verification Matrix

Parameter	Product Specification / Design Input	Design Output
(b)(4)		

(b)(4) Design Verification Matrix

[redacted]

(b)(4) Testing

[redacted]

XVI. Performance Testing – Animal

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

[redacted]

XVII. Performance Testing – Clinical

(b)(4) Testing

[redacted]

XVIII. Response to FDA Request for Additional Information

The following deficiencies (in plain text) were issued to the sponsor on 12/9/11. The sponsor's responses are summarized in *italics*, and reviewer comments are in **bold**.

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

XIX. *Substantial Equivalence Discussion*

Note: Use the 510(k) Decision Tree to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

	YES	NO	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	X		If NO = **Request Data**
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics: *The subject device is provided in flat sheet form, rather than as a curled sheet, and has some other slightly different physical properties (thickness, density, dimensions).*

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4. Explain how new characteristics could or could not affect safety or effectiveness: *The device materials and principles of operation are the same, and whether the sheet is provided flat or curled should not affect the safety or effectiveness of the product. The sponsor notes that the curled sheet can be flattened at the time of implantation.*
5. Explain how descriptive characteristics are not precise enough: (b)(4) [redacted]
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *Data indicate that the subject device is substantially equivalent to the predicate devices in terms of material composition, intended use, and mechanical properties.*

XX. Deficiencies

No deficiencies remain. However, the following Advisory, drafted by Dr. Hudson, was issued to the sponsor via email on 12/21/11:

(b)(4) [redacted]

XXI. Contact History

Date	Type - Topic
12/21/2011	Email - Issued an Advisory to the sponsor regarding (b)(4) [redacted]
12/15/2011	Email - Provided feedback regarding (b)(4) [redacted]
12/14/2011	Email - Informed sponsor that I would provide feedback to them by 12/15/11
12/13/2011	Email - Sponsor requested feedback on (b)(4) [redacted]

Maegen Colehour, M.S. — Date 12/21/11

I concur w SE

David Krause, Ph.D. — Date 12/22/2011
Branch Chief, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

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Colehour, Maegen

From: Jeff Sims [JSims@RotationMedical.com]
Sent: Wednesday, December 21, 2011 10:29 AM
To: Colehour, Maegen
Subject: RE: K112423 - Advisory Regarding Collagen Purity

Maegen,

Thank you for the update on our submission, we will look forward to the final documentation on your recommendation. I also thank you for the information regarding the direction the FDA is headed (b)(4) (b)(4) . We will look forward to the updated guidance that you mention.

It is good to be back on American soil in time for this blessed holiday season. I hope you have a great holiday.
Jeff

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical
Direct Line: 763.746.7502
Cell: 952.594.2795
jsims@rotationmedical.com

rotation MEDICAL
15350 28th Ave N
Suite 100
Plymouth, MN 55447-2092
763-746-7500

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Wednesday, December 21, 2011 9:09 AM
To: Jeff Sims
Cc: Gail Schroeder
Subject: K112423 - Advisory Regarding Collagen Purity

Dear Mr. Sims,

We are in the process of completing our review of your 510(k) submission (K112423) for your Collagen Tendon

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Sheet device. Although I am recommending a Substantially Equivalent determination, please make note of the following (b)(4) in your device:

(b)(4)

Thank you,

Maegen Colehour, MS
Biomedical Engineer
Plastic and Reconstructive Surgery Branch
Division of Surgical, Orthopedic, and Restorative Devices
FDA/CDRH/ODE

U.S. Food and Drug Administration
Center for Devices and Radiological Health
White Oak #66, Room G423
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301.796.6970
Maegen.Colehour@fda.hhs.gov

Colehour, Maegen

From: Gail Schroeder [gschroeder@RotationMedical.com]
Sent: Thursday, December 15, 2011 10:22 AM
To: Colehour, Maegen
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Maegen –
Thank you for the Summary review – glad to see we hit the mark this time. I still anticipate having the complete response ready late this afternoon, and will definitely send you a copy via e-mail as soon as it's complete (followed by a hard-copy via FedEx).

Thank you again, and have a pleasant morning.
-Gail

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Thursday, December 15, 2011 9:08 AM
To: Gail Schroeder
Cc: Jeff Sims
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Ms. Schroeder,

I reviewed the updated (b)(4) [redacted], and the revisions appear adequate. I would appreciate an email containing the completed response to the AI letter as soon as it's available.

Thank you!

-Maegen

From: Gail Schroeder [mailto:gschroeder@RotationMedical.com]
Sent: Wednesday, December 14, 2011 12:39 PM
To: Colehour, Maegen
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Maegen –
I appreciate the update. Technology sure is great when it works...and equally frustrating when it doesn't.

I am currently planning to have the full response sent on Thurs. afternoon (tomorrow) for delivery to you Fri. morning. I will definitely send you a full electronic copy as well. I really do appreciate your open communication on this. I want to make sure we get this right.

Thanks again,
Gail

Gail Schroeder
Director of Quality Assurance and Operations
Rotation Medical
Phone: 763-746-7521
Cell: 651-285-9701

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rotation MEDICAL

15350 25th Ave N
Suite 100
Plymouth, MN 55447-2082
763-746-7500

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Wednesday, December 14, 2011 11:30 AM
To: Gail Schroeder
Cc: Jeff Sims
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Ms. Schroeder,

I am working off-site today, and my computer is acting up and not allowing me to download files from my email. I will plan to review your (b)(4) first thing tomorrow morning when I am back in the office and will get back to you with any feedback that I have. Do you have an estimated submission date for your response to the AI letter? Also, I would again appreciate if you can provide me with an electronic copy of your Supplement at the time of submission.

Thank you,

Maegen Colehour, MS
Biomedical Engineer
Plastic and Reconstructive Surgery Branch
Division of Surgical, Orthopedic, and Restorative Devices
FDA/CDRH/ODE

U.S. Food and Drug Administration
Center for Devices and Radiological Health
White Oak #66, Room G423
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301.796.6970
Maegen.Colehour@fda.hhs.gov

From: Gail Schroeder [mailto:gschroeder@RotationMedical.com]
Sent: Tuesday, December 13, 2011 6:27 PM

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To: Colehour, Maegen
Cc: Jeff Sims
Subject: K112423 - Collagen Tendon Sheet

Maegen -
Good afternoon. Thank you for your timely review of our response to your questions regarding our submission K112423 – Collagen Tendon Sheet. We received the follow-up questions yesterday, and are finalizing the complete response to send to you shortly.

I noted that this second letter also contains feedback regarding the content of our (b)(4) in the letter – attached for ease of reference). In an effort to ensure we understand your feedback, I have attached the additionally (b)(4) for your review. Please note the changes in the (b)(4) (b(b)(4) section. We are committed to providing an appropriate (b)(4), and I believe this further revision addresses your comments. Your feedback is very much appreciated. Thank you.

Best Regards,
Gail

Gail Schroeder
Director of Quality Assurance and Operations
Rotation Medical
Phone: 763-746-7521
Cell: 651-285-9701

EmailFooter_052510att

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Colehour, Maegen

From: Hudson, Peter
Sent: Wednesday, December 21, 2011 8:58 AM
To: Colehour, Maegen
Cc: Krause, David
Subject: K112423 S2 Collagen Tendon Sheet - suggested Advisory wording

In review of the sponsor's (b)(4) [redacted], the following deficiency was posed to the sponsor:

Deficiency

(b)(4) [redacted]

Colehour, Maegen

From: Brown, Ronald P.
Sent: Monday, December 12, 2011 4:57 PM
To: Colehour, Maegen; Hudson, Peter
Cc: Krause, David
Subject: RE: Consult
Attachments: K112324 S001 (b)(4).doc

Maegen and Peter,

(b)(4)

Hope this helps and gets to you in time to be useful.

Ron

December 12, 2011

To: Maegan Colehour, Biomedical Engineer, ODE/DSORD
From: Ronald Brown, Toxicologist, OSEL/DB
Re: Toxicology consult for K112423.S001, (b)(4)

A toxicology consult was requested to review a risk assessment submitted by Collagen Matrix, Inc. (b)(4)

(b)(4)

[redacted]

(b)(4) Manufacturing Information

[redacted]

Grayson, Giovanna *

From: Microsoft Exchange
To: 'jsims@rotationmedical.com'
Sent: Friday, December 16, 2011 12:26 PM
ubject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'jsims@rotationmedical.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

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Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Friday, December 16, 2011 12:26 PM
To: 'jsims@rotationmedical.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 16, 2011

SIMS
JEFF
ROTATION MEDICAL, INC.
15350 25TH AVENUE N
SUITE 100
PLYMOUTH, MINNESOTA 55447
ATTN: JEFF SIMS

510k Number: K112423

Product: COLLAGEN TENDON SHEET

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510 (k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : DEC. 12. 2011 12:23PM FILE MODE	OPTION	ADDRESS	RESULT	PAGE
1629 MEMORY TX		7637467501	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

DEC 12 2011

Re: K112423
Trade Name: Collagen Tendon Sheet
Dated: November 30, 2011
Received: November 30, 2011

Dear Mr. Sims:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) Deficiencies

[redacted]

43

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Maegen Colehour

Subject: 510(k) Number K112423/S1

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

44

Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

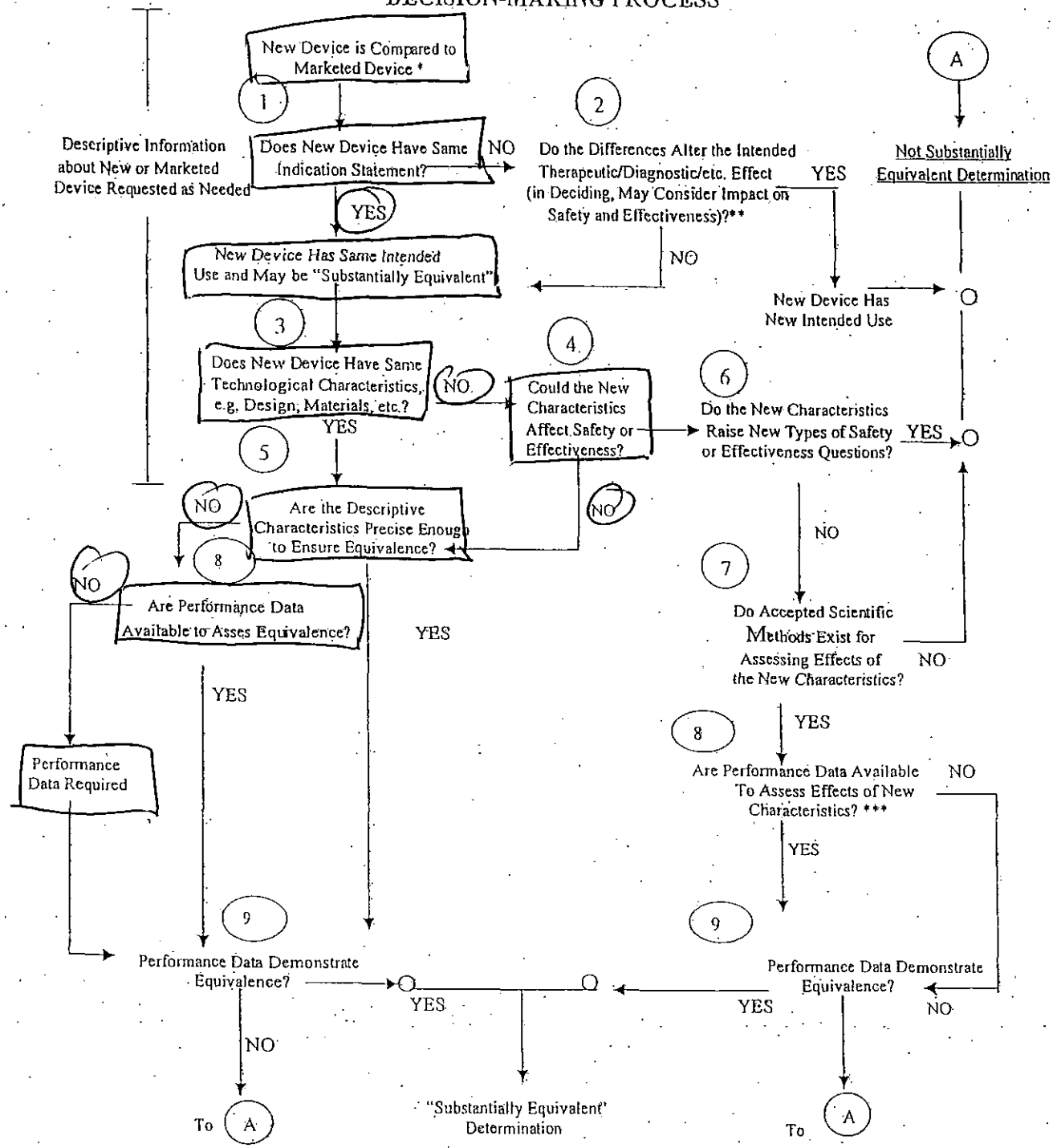
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Krause (Branch Chief) PRSB (Branch Code) 12/9/2011 (Date)

Final Review: David Krause (Division Director) 12/9/2011 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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XX. Deficiencies

(b)(4)

[redacted]

XXI. Contact History

Date	Type - Topic
11/29/2011	Email - Sponsor acknowledged my email and thanked me for my response
11/29/2011	Email - Sponsor provided electronic copy of S001, excluding one response that was not yet completed
11/29/2011	Email - Thanked the sponsor for the e-copy & noted that the hard copy should contain complete responses
11/18/2011	Email - Reminded the sponsor to send an electronic copy of S001
11/17/2011	Email - Sponsor thanked me for the clarifications and provided an estimated response date
11/17/2011	Email - Provided clarification in response to the sponsor's request on 11/10/11
11/16/2011	Email - Acknowledged email & noted that I'd address the questions asap as I had been out of the office
11/10/2011	Email - Sponsor requested clarification regarding two deficiencies
11/09/2011	Email - Requested that the sponsor provide me with an e-copy upon submission of S001

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Date	Type - Topic
11/09/2011	Email - Thanked sponsor for prompt response and reminded them to feel free to contact me with questions
11/09/2011	Email - Sponsor acknowledged request and agreed to provide electronic copy of S001

Maegen Colehour, M.S. 12/9/11
Date

I concur
CAL

David Krause 12/9/2011
David Krause, Ph.D. Date
Branch Chief, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

Colehour, Maegen

From: Jeff Sims [JSims@RotationMedical.com]
Sent: Tuesday, November 29, 2011 12:15 PM
To: Colehour, Maegen
Cc: (b)(6) (b)(4); Gail Schroeder
Subject: RE: K112423 - Collagen Tendon Sheet

Wow Maegen,
Thank you for your quick response, we do expect the final document to be completed today and included in the final package.
Thanks again, it is a pleasure working with you.
Jeff

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Tuesday, November 29, 2011 11:12 AM
To: Jeff Sims
Cc: (b)(6) (b)(4); Gail Schroeder
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Jeff,

Thank you very much for the electronic copy, and I'm glad that I was able to provide you with useful information during our earlier correspondence. Please be sure that you do include Appendix 5 in your hard copy response as the submission may be rejected as an incomplete response if it is not included. I will also look for the attachment you mentioned will be sent via email.

Thanks again,

-Maegen

From: Jeff Sims [mailto:JSims@RotationMedical.com]
Sent: Tuesday, November 29, 2011 12:07 PM
To: Colehour, Maegen
Cc: (b)(6) (b)(4); Gail Schroeder
Subject: FW: K112423 - Collagen Tendon Sheet

Maegen,

I just want to thank you again for the resources you pointed us toward that enabled us to provide you a more complete response. It has been a fun challenge putting this together across the (b)(4) (b)(4), the holidays, and across many time zones as I continue to work in Australia until almost Christmas time.

Because I am out of the states, my colleague, Gail Schroeder our director of Quality Assurance and Operations, has provided the original signatures, as required, on the response that will be sent today through the formal channels via FedEx. Included here is the response on email per your request. We are still waiting on the completion of one document in answer to question 5, which will be sent as Appendix 5 via email from Gail when it is finished; we will also include it in the final formal response we send out today as well.

Thank you again for your assistance.
Sincerely,
Jeff

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical
Direct Line: 763.746.7502
Cell: 952.594.2795
jsims@rotationmedical.com

rotation MEDICAL
15350 25th Ave N
Suite 100
Plymouth, MN 55447-2092
763-746-7500

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Friday, November 18, 2011 6:51 AM
To: Jeff Sims
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Jeff,

I'm happy that I could help. Again, if you could send me an electronic copy of your response via email at the earliest possible time after you complete it, *I would really* appreciate it.

Thank you,

Maegen Colehour, MS
Biomedical Engineer
Plastic and Reconstructive Surgery Branch
Division of Surgical, Orthopedic, and Restorative Devices
FDA/CDRH/ODE

U.S. Food and Drug Administration
Center for Devices and Radiological Health
White Oak #66, Room G423
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

75

301.796.6970
Maegen.Colehour@fda.hhs.gov

From: Jeff Sims [mailto:JSims@RotationMedical.com]
Sent: Thursday, November 17, 2011 8:39 PM
To: Colehour, Maegen
Cc: (b)(6) (b)(4)
Subject: RE: K112423 - Collagen Tendon Sheet

Maegen,

Thank you for your thorough response. We have already put your information to good use in our response. We do plan to have that response to you by the end of the month.

Thanks again, have a good weekend.
Jeff

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical
Direct Line: 763.746.7502
Cell: 952.594.2795
jsims@rotationmedical.com

rotation MEDICAL
15350 25th Ave N
Suite 100
Plymouth, MN 55447-2082
763-746-7590

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Thursday, November 17, 2011 7:46 AM

To: Jeff Sims
Cc: (b)(6) (b)(4)
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Jeff,

In response to your question regarding (b)(4)

(b)(4)

With regards to your question regarding (b)(4) (b)(4)

I hope this helps, and please let me know if you have any additional questions.

Thank you,

Maegen Colehour, MS
Biomedical Engineer
Plastic and Reconstructive Surgery Branch
Division of Surgical, Orthopedic, and Restorative Devices
FDA/CDRH/ODE

U.S. Food and Drug Administration
Center for Devices and Radiological Health
White Oak #66, Room G423
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301.796.6970
Maegen.Colehour@fda.hhs.gov

From: Colehour, Maegen
Sent: Wednesday, November 16, 2011 6:57 AM
To: 'Jeff Sims'
Cc: (b)(6) (b)(4)
Subject: RE: K112423 - Collagen Tendon Sheet

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Dear Jeff,

I just wanted to confirm receipt of your email and to let you know that I have been out of the office and hope to get back to you shortly regarding your questions below.

Thank you,

-Maegen

From: Jeff Sims [mailto:JSims@RotationMedical.com]
Sent: Thursday, November 10, 2011 5:50 PM
To: Colehour, Maegen
Cc: (b)(4)
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Maegen,

After our internal meetings to begin to address your AI letter , we do have two questions we believe you can assist us with. (b)(4)

[redacted]

Maegen, I thank you again for this pathway of exchange. And thank you for your work on our behalf to receive a timely approval.
Best Regards,
Jeff

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical
Direct Line: 763.746.7502
Cell: 952.594.2795
jsims@rotationmedical.com

rotation MEDICAL
15350 25th Ave N
Suite 100
Plymouth, MN 55447-2082
763-746-7500

received this message by mistake, please immediately notify us by replying to the message and delete the original message immediately thereafter. Thank you.

Colehour, Maegen

From: Jeff Sims [JSims@RotationMedical.com]
Sent: Wednesday, November 09, 2011 10:34 PM
To: Colehour, Maegen
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Maegen,

Thank you again for the communication. It is our belief that we should be able to get you answers that address your questions in the statutory timeframe and continue your timely review. But I do appreciate knowing about the option of an extension.
Thanks again,
Jeff

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical
Direct Line: 763.746.7502
Cell: 952.594.2795
jsims@rotationmedical.com

rotation MEDICAL
15350 25th Ave N
Suite 100
Plymouth, MN 55447-2082
763-746-7500

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Wednesday, November 09, 2011 1:36 PM
To: Jeff Sims
Cc: (b)(6) (b)(4)
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Jeff,

Thank you for your prompt response and for agreeing to provide an electronic copy. I also just wanted to note that you can feel free to request an extension (up to 180 days) if you are feeling pressed for time - many sponsors are unaware of this. Again, feel free to contact me with questions, and I look forward to receiving your responses.

Thanks!

80

-Maegen

From: Jeff Sims [mailto:JSims@RotationMedical.com]
Sent: Wednesday, November 09, 2011 2:20 PM
To: Colehour, Maegen
Cc: (b)(6) (b)(4)
Subject: RE: K112423 - Collagen Tendon Sheet

Dear Maegen,

I so appreciate your personal contact. I had already flown to Australia on business when your request for additional information arrived. Per your first question, we are working closely with (b)(4) (b)(4) (b)(4) (b)(4) AI letter, but given (b)(6) travel schedule and me being in Australia, coordinating a time to work with them on the responses has been difficult given the limited hours of overlap in the work day. We do have some time set aside tomorrow to begin the process of addressing your questions. We will certainly provide you with an electronic copy of the responses and thank you for the offer to contact you directly with any further questions.

Thank you too for your work on our behalf.

Best Regards,
Jeff

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical
Direct Line: 763.746.7502
Cell: 952.594.2795
jsims@rotationmedical.com

rotation MEDICAL
15350 25th Ave N
Suite 100
Plymouth, MN 55447-2092
763-746-7500

From: Colehour, Maegen [mailto:Maegen.Colehour@fda.hhs.gov]
Sent: Wednesday, November 09, 2011 1:05 PM
To: Jeff Sims

Subject: K112423 - Collagen Tendon Sheet

Dear Mr. Sims,

I am the lead reviewer for your 510(k) Submission (K112423) for your Collagen Tendon Sheet device. I'm not sure if you've yet received FDA's request for additional information or how long you anticipate it will take to complete your responses, but I just wanted to request that you email me an electronic copy of your responses at the time you send the hard copy so that I can begin review and assign appropriate consults at the earliest possible time. Please also feel free to contact me with any clarifying questions you may have regarding the AI letter.

Regards,

Maegen Colehour, MS
Biomedical Engineer
Plastic and Reconstructive Surgery Branch
Division of Surgical, Orthopedic, and Restorative Devices
FDA/CDRH/ODE

U.S. Food and Drug Administration
Center for Devices and Radiological Health
White Oak #66, Room G423
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301.796.6970
Maegen.Colehour@fda.hhs.gov

This email message is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

82

MEMO TO THE RECORD

K112423/S1 consult

DATE: 12/7/11
OFFICE: HFZ-410
DIVISION: DSORD/PRSB
FROM: Biologist
RE: Review of responses to deficiencies previously posed
APPLICANT: Rotation Medical
CONSULT TO: Ms. Maegen Colehour

Recommendation: The information provided in response to the deficiency concerning (b)(4) has prompted the need for additional information – a deficiency is identified at the end of the review.

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : NOV. 30. 2011 1:39PM

FILE MODE	OPTION	ADDRESS	RESULT	PAGE
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REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 30, 2011

ROTATION MEDICAL, INC.
15350 25TH AVENUE N
SUITE 100
PLYMOUTH, MINNESOTA 55447
ATTN: JEFF SIMS

510k Number: K112423

Product: COLLAGEN TENDON SHEET

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a *letter from* FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

89

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : NOV. 1. 2011 11:02AM FILE MODE	OPTION	ADDRESS	RESULT	PAGE
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REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

OCT 3 1 2011

Re: K112423
Trade Name: Collagen Tendon Sheet
Dated: August 22, 2011
Received: August 23, 2011

Dear Mr. Sims:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) Deficiencies

[redacted]

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Maegen Colehour, MS

Subject: 510(k) Number K112423

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			

Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

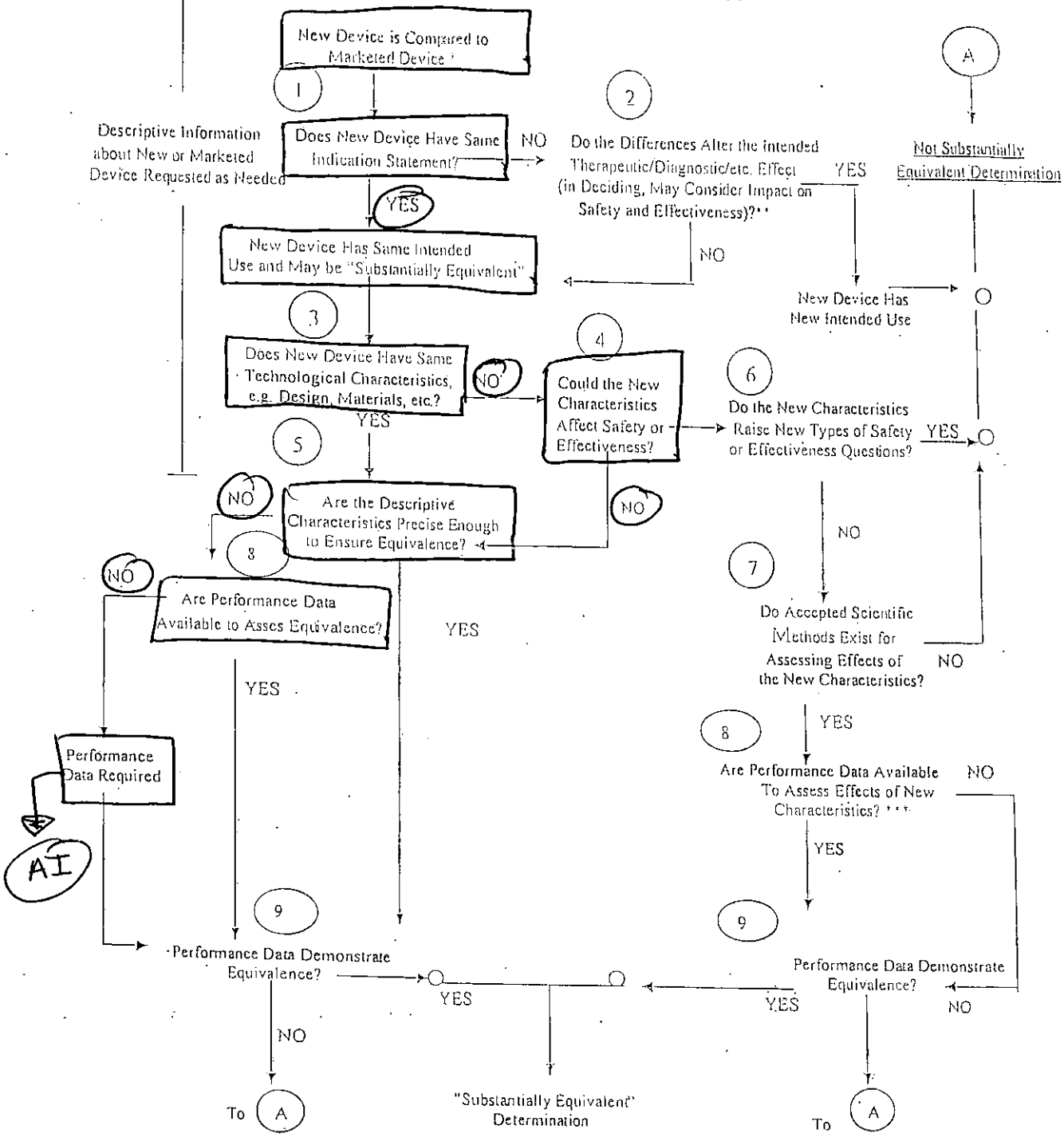
Additional Product Code(s):

Review: David Krause PRSB Oct. 31, 2011
(Branch Chief) (Branch Code) (Date)

Final Review: David Krause 10/31/2011
(Division Director) (Date)

98

510(K) SUBSTANTIAL EQUIVALENCE DECISION-MAKING PROCESS



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** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review

Traditional

K112423

Date: October 31, 2011
To: The Record
From: Maegen Colehour, M.S. (ODE/DSORD/PRSB)

Device Name: Collagen Tendon Sheet
510(k) Holder: Rotation Medical, Inc.
Address: 15350 25th Avenue N, Suite 100
Plymouth, MN 55447

Establishment Registration Number:

Contact: Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Phone: (763) 746-7502
Fax: (763) 746-7501
Email: jsims@rotationmedical.com

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I. Purpose of Submission

The 510(k) holder would like to introduce the following device into interstate commerce:

Device name: Collagen Tendon Sheet

II. Document History

K112423 (dated 8/22/11 and received 8/23/11) was assigned to me on 8/25/11 with a branch due date of 10/7/11.

III. Recommendation

Hold for Additional Information

Regulation Number:	21 CFR §878.3300
Regulation Name:	Surgical Mesh
Regulatory Class:	II
Product Code:	FTM

IV. Document Summary

The subject device is a resorbable, crosslinked, type I collagen matrix derived from (b)(4) and is designed to act as an interface between the tendon and tendon sheath or the surrounding tissue. Specifically, the device is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue, and these indications are identical to those of the predicate device (K080452 – Collagen Tendon Wrap). The sponsor states that the subject device (Collagen Tendon Sheet) and predicate device (Collagen Tendon Wrap) are (b)(4) [redacted]. The subject device appears to differ from the predicate only in physical dimensions/configuration (e.g., the subject device is thicker than the predicate and is manufactured in flat sheet form, rather than the coiled form of the predicate device) and sterilization method (the subject device is sterilized via EtO instead of Gamma Irradiation in (b)(4) [redacted]).

The sponsor has identified product specifications that appear to be substantially equivalent to those of the predicate device. (b)(4) [redacted] I consulted with Dr. Peter Hudson (PRSB) regarding the adequacy of the data (i.e. biocompatibility, viral inactivation, animal data, etc.) in light of the change in sterilization method and with respect to (b)(4) [redacted] Dr. Hudson reviewed the (b)(4) [redacted] (see Dr. Hudson's review memo - attached).

The sponsor is (b)(4) [redacted]

(b)(4) [redacted] Please see the Deficiencies section below and Dr. Hudson's review memo (attached) for more details.

V. Administrative Requirements

	YES	NO	N/A	MISC
Indications for Use page (Indicate if: Prescription or OTC)	X			
Truthful and Accurate Statement	X			
510(k) Summary or 510(k) Statement	X			
Standards Form	X			

DEFICIENCY – (b)(4) [redacted]

VI. Device Description

	YES	NO	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The Collagen Tendon Sheet is described as a resorbable, crosslinked, type I collagen matrix derived from (b)(4) [redacted]. The device is intended to provide a layer of collagen over injured tendons. The design of the Collagen Tendon Sheet is based on the concept of providing a protective environment for a tendon injury or repair site during tendon healing with the collagen membrane acting as an interface between the tendon injury and its surrounding tissue, thereby restoring the integrity of the tendon sheath. When hydrated, Collagen Tendon Sheet is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. It is provided sterile, non-pyrogenic, for single-use only, in a variety of sizes, in double peel packages.

The sponsor notes that Rotation Medical was interested in developing a collagen sheet similar to Collagen Matrix, Inc's existing Collagen Tendon Wrap product (K080452), but which would be supplied as a flat collagen sheet, rather than the coiled configuration of the Collagen Tendon Wrap. (b)(4) [redacted]

(b)(4) [redacted]

DEFICIENCY – (b)(4) [redacted]

The sponsor identified the following product specifications/design requirements on page 30:

Parameter	Specification
Dimensions	Various sizes to approximate human tendons • 1.5 x 2 cm • 2 x 2.5 cm • 2.5 x 3 cm
Thickness	1.0 – 1.3 mm
Permeability/Pore Size	Semi-permeable (permeable to macromolecules and nutrients); pore size ≤ 10 µm Semi-permeable to carbonic anhydrase (probe molecule)
(b)(4) [redacted]	
Sterility	SAL 10^{-6}
	(b)(4) [redacted]
Pyrogenicity*	≤ 0.5 EU/ml

*Finished product release tests

Sourcing of Collagen Material

(b)(4) [redacted]

(b)(4) Collagen Material

[redacted]

In addition, the sponsor notes compliance with the following standards and guidelines for handling and control of animal-derived tissues:

- Medical Devices Containing Materials Derived from Animal Sources, CDRH, FDA, November 6, 1998
- Report of a WHO Consultation on Medicinal and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies," World Health Organization, March 1997
- EN 12442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management
- EN 12442-2 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling
- EN12442-3 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents
- MEDDEV 2.5/5 Guidelines on Assessment of Medical Devices Incorporating Materials of Animal Origin with Respect to Viruses and Transmissible Agents

- Commission Directive 2003/32/EC Detailed Specifications as Regards the Requirements Laid Down in Council Directive 93/42/EEC with Respect to Medical Devices Manufactured Utilizing Tissues of Animal Origin

Finally, the sponsor notes that a (b)(4) Collagen Material [redacted].

Reviewer Comment:
As noted by Dr. Hudson in his review ([redacted]). No additional information regarding these issues is necessary.

(b)

Device Manufacture

(b)(4) [redacted]

department.

Reviewer Comment:
(b)(4) [redacted] (DEFICIENCY)

VII. Indications for 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.

Reviewer Comment:
The Indications for Use are identical to those of the predicate.

VIII. Predicate Device Comparison

K080452: Collagen Tendon Wrap (Collagen Matrix, Inc.)
Indications for Use:
Management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Device Description:
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, non-friable, 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.

Additional Predicates:
The sponsor cited the following additional predicates, which they note are tendon protector products successfully used for the protection of tendon injuries: TenoGlide™ Tendon Protector Sheet (K053655, Integra Lifescience), GraftJacket® Regenerative Tissue Matrix (Wright Medical Technology) and ProPatch® Soft Tissue Repair Matrix (K061892 & K101587, CryoLife, Inc.). Finally, the sponsor cited (p. 28) the following cleared devices that are manufactured by Collagen Matrix, Inc. and are composed of identical material to the subject device:

- Collagen Tendon Wrap, K080452
- Collagen Nerve Wrap, K060952
- Collagen Bone Healing Protective Sheet, K052041
- Collagen Dura Substitute Membranes, K040888, K061487
- Collagen Nerve Cuff, K012814
- Collagen Periodontal Membrane, K003339
- Collagen Dental Membranes, K011695, K062881, K062846
- Collagen Dental Wound Dressing, K033729
- Collagen Wound Dressing – Oral, K040403

Reviewer Comment:
On page 40, the sponsor states that ***the Collagen Tendon Sheet and Collagen Tendon Wrap*** (b)(4) [redacted] As outlined on page 36 of the submission, the two devices have the following differences:

Parameter	Collagen Tendon Sheet (K112423)	Collagen Tendon Wrap (K080452)
Dimensions	1.5 x 2 cm 2 x 2.5 cm 2.5 x 3 cm Various sizes to approximate human tendons	4 x 7 cm 5 x 5 cm 10 x 12.5 cm Various sizes to approximate human Tendons
Thickness	1 – 1.3 mm	0.4 ± 0.1 mm
Density	0.3 g/cm^3	0.4 g/cm^3
(b)(4) [redacted]		
Resorption	Gradual resorption ~10 months	Gradual resorption ~6 months
Sterility	EtO	Gamma Irradiation

The sponsor notes that the subject device is provided in smaller sizes as compared to the Collagen Tendon Wrap because the Collagen Tendon Sheet subject device is not designed to

wrap around an injured tendon. Instead, the subject device will be implanted over the surface of an injury or defect of a flat tendon. The sponsor also notes that the subject device is thicker than the predicate since the predicate wrap accommodates overlap with an expectation of double thickness in the overlapped region. The thicker nature of the subject device also translates to higher mechanical strength properties as compared to the predicate. The increased thickness is similar to the available thicknesses of CryoLife, Inc.'s bovine pericardial tissue derived device ProPatch (K061892, K101587), which ranges from 0.5 – 2.5mm in thickness (per K061892 review memo) and includes indications for use during tendon repair, and of Wright Medical Technology's GraftJacket® Regenerative Tissue Matrix, which appears to range from 0.5 – 1.4mm in thickness and is indicated for tendon and tendon sheath repair and reinforcement of the hand and foot (per a Substantial Equivalence Comparison table provided in K080452). Finally, the sponsor notes in the animal study summary that the switch from gamma irradiation to EtO sterilization was intended f(b)(4) [redacted] section below for more details).

IX. Labeling

The labeling is essentially identical to the predicate device labeling, apart from necessary changes related to the physical differences between the devices. No warning statements have been changed or removed. The following safety information is included:

Contraindications:
- Collagen Tendon Sheet is not indicated to replace or repair damaged tendon or to reinforce the strength of any tendon repair
- Collagen Tendon Sheet is not indicated for patients with known history of hypersensitivity to bovine-derived materials

Warnings:
- Do not re-sterilize
- Do not use if the product or package is damaged or opened

Precautions:
- Collagen Tendon Sheet should not be applied until bleeding and infection are controlled

Reviewer Comment:
The labeling is in-line with the predicate labeling; however, the sponsor([redacted] b)(b)(4) [redacted] (**DEFICIENCY**).

X. Sterilization/Reuse

Review Template for Sterile Devices

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	EtO	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide	(b)(4) [redacted]	

sterilization residuals," does not include measurement of ethylene glycol residuals);		
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ISO 11135	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	$\cdot 10^{-6}$	
4. Is it labeled "Pyrogen Free"?	X	
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	LAL (≤ 0.5 EU/ml) – *Lot release specification*	
5. A description of the packaging (not including package integrity test data):	(b)(4)	

XI. (b)(4) Testing

(b)(4)

XII. Biocompatibility

The sponsor provided the following summary of biocompatibility testing performed in accordance with ISO 10993-1 ((b)(4) b (in accordance with ISO 10993-1. Complete test reports are provided in Appendix A.) b

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Test	Test Method/Model	Results
(b)(4) Testing		

(b)(4) Testing

[redacted]

Viral Inactivation

(b)(4) Testing

[redacted]

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing [redacted]

DEFICIENCY – (b)(4) [redacted]

XIII. Software

Not applicable.

XIV. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XV. Performance Testing – Bench

(b)(4) [redacted]

Table 18.1. Design Verification Matrix

Parameter	Product Specification / Design Input	Design Output
(b)(4)		
Biological Properties		
Biocompatibility	*Biocompatible* (Pass FDA G95-1 and ISO 10993)	Passed all biocompatibility tests
Pyrogenicity	Non-pyrogenic (≤ 0.5 EU/ml)	≤ 0.005 EU/ml
(b)(4)		

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(b)(4) Testing

[redacted]

XVI. Performance Testing – Animal

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

[redacted]

XVII. Performance Testing – Clinical

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

XVIII. Substantial Equivalence Discussion

Note: Use the 510(k) Decision Tree to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

	YES	NO	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		X	If NO = **Request Data**
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:

   The subject device is provided in flat sheet form, rather than as a curled sheet, and has some other slightly different physical properties (thickness, density, dimensions).

4. Explain how new characteristics could or could not affect safety or effectiveness:

   The device materials and principles of operation are the same, and whether the sheet is provided flat or curled should not affect the safety or effectiveness of the product. The sponsor notes that the curled sheet can be flattened at the time of implantation.

5. Explain how descriptive characteristics are not precise enough:

   (b)(4) [redacted].

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

   (b)(4) [redacted]. *See Deficiencies below.*

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(b)(4) Deficiencies

[redacted]

XIX. Deficiencies

(b)(4) Deficiencies

[redacted]

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(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

XX. Contact History

None.

Maegen Colehour, M.S. — Date 10/31/11

David Krause, Ph.D. — Date 10/31/2011
Branch Chief, Plastic & Reconstructive Surgery Branch
Division of Surgical, Orthopedic and Restorative Devices

MEMO TO THE RECORD
K112423 Consult

DATE: 10/28/11
OFFICE: HFZ-410
DIVISION: DSORD/PRSB
FROM: Biologist
RE: (b)(4)
CONSULT TO: Ms. Megan Colehour

Recommendation: Additional information is necessary – deficiencies are identified at the end of the review. (b)(4)

(b)(4)

Review:
Ms. Colehour has requested a consult review of the sponsor's surgical mesh product, the Collagen Tendon Sheet device. This sponsor, Rotation Medical, (b)(4)

(b)(4)

Ms. Colehour has requested that I review this manufacturer's information regarding (b)(4).

Indications for use
The [device] is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Device description
The sponsor describes the Collagen Tendon Sheet as a resorbable Type I collagen matrix that will be used as a layer over injured tendons; ostensibly the sheet provides an interface between the injured tendons and the surrounding/overlying tissues. The material is described as pliable and porous.

The collagen is derived from (b)(4) (b)(4) (b)(4) The sponsor states that it is identical to the materials used in Collagen Matrix's other legally marketed, 510(k)-cleared medical devices:

11.4 Materials

Collagen Tendon Sheet consists of crosslinked type I collagen derived from (b)(4) (b)(4). The materials are identical to the materials used in Collagen Matrix's other marketed implantable devices:

- Collagen Tendon Wrap, K080452
- Collagen Nerve Wrap, K060952
- Collagen Bone Healing Protective Sheet, K052041
- Collagen Dura Substitute Membranes, K040888, K061487
- Collagen Nerve Cuff, K012814
- Collagen Periodontal Membrane, K003339
- Collagen Dental Membranes, K011695, K062881, K062846
- Collagen Dental Wound Dressing, K033729
- Collagen Wound Dressing – Oral, K040403

Material/tissue sourcing

The sponsor has provided the following information regarding (b)(4)

(b)(4)

[redacted]

(b)(4) Materials

[redacted]

Manufacturing process/product specifications

(b)(4)

[redacted]

Deficiencies

(b)(4)

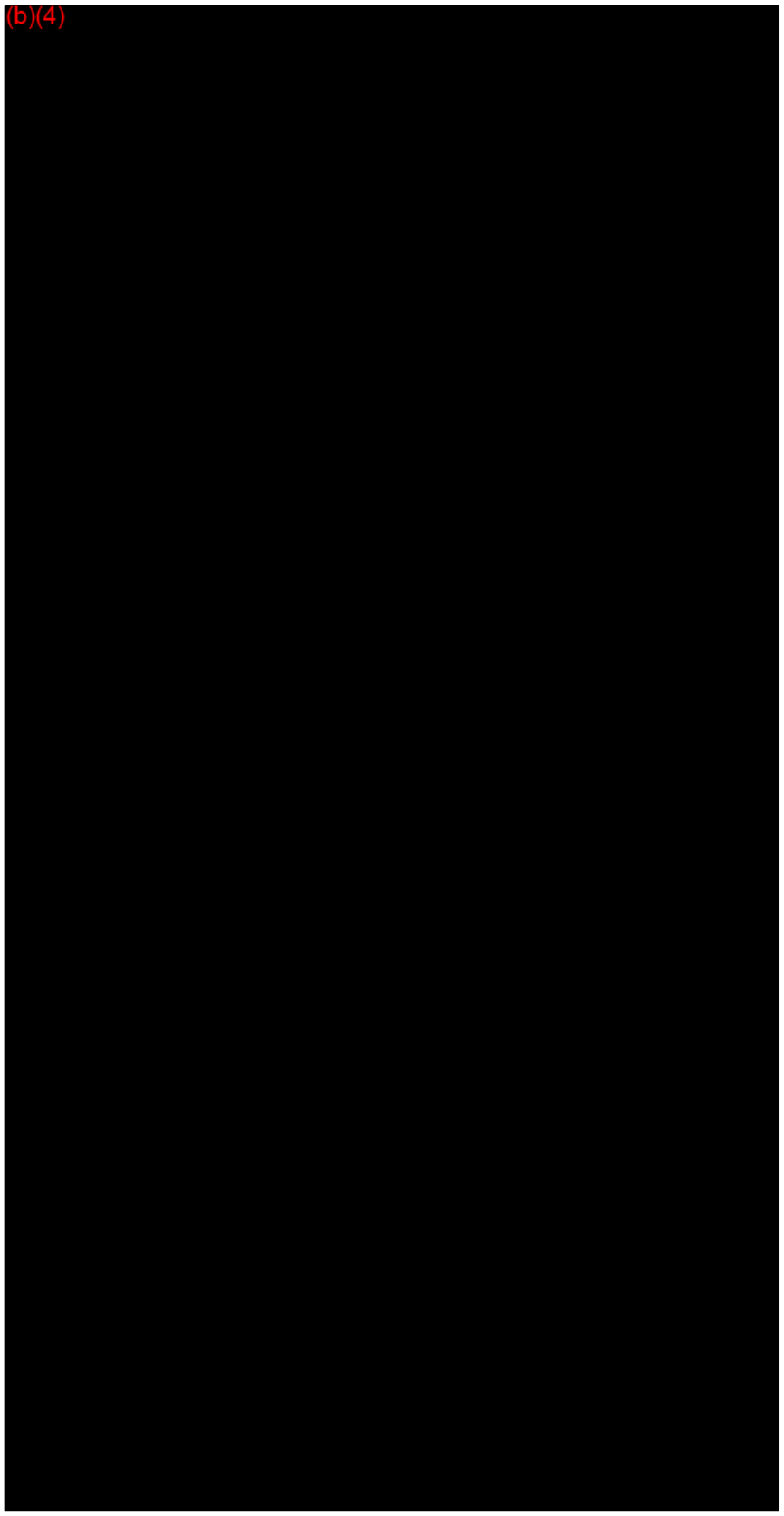
[redacted]

(b)(4) Deficiencies

[redacted]

Manufacturing Flowchart for Collagen Tendon Sheet

(b)(4)



The sponsor describes the manufacturing process within section 11.6.2 as consisting of (b)(4)

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Testing

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information (the study included (

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

[redacted]

(b)(4) [redacted] (Deficiency).

Deficiency

(b)(4)

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

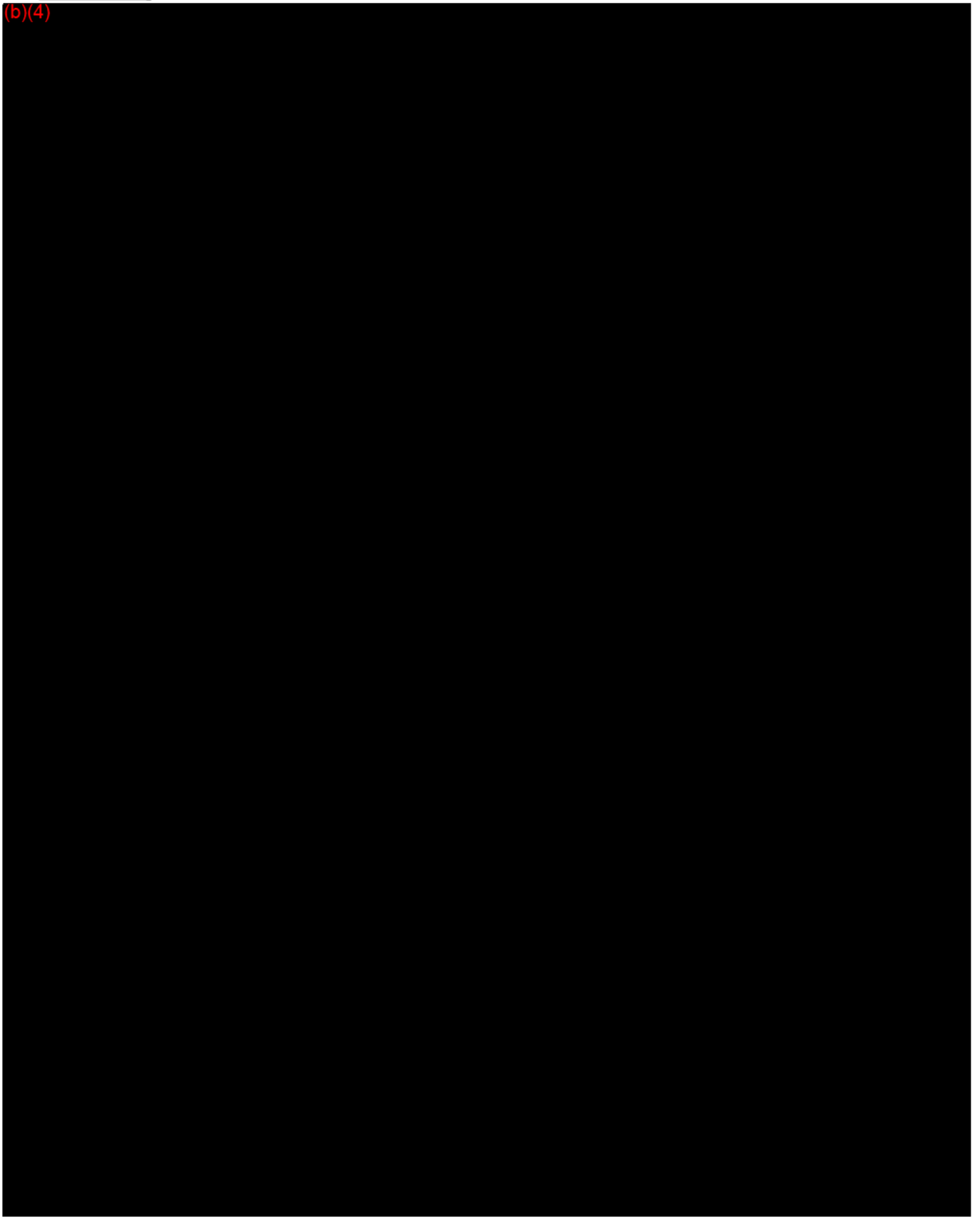
(b)(4) [redacted] ***Study***

(b)(4)

[redacted]

Deficiencies

(b)(4)



(b)(4)

[redacted]

Peter L. Hudson, Ph.D./Reviewer (Date)
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

Benjamin, Mark D*

'om:	Microsoft Exchange
J:	'jsims@rotationmedical.com'
Sent:	Wednesday, August 24, 2011 11:48 AM
Subject:	Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'jsims@rotationmedical.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

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Benjamin, Mark D*

From: Benjamin, Mark D*
Sent: Wednesday, August 24, 2011 11:48 AM
To: 'jsims@rotationmedical.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 24, 2011
SIMS
JEFF
ROTATION MEDICAL, INC.
15350 25TH AVENUE N
SUITE 100
PLYMOUTH, MINNESOTA 55447
ATTN: JEFF SIMS

510k Number: K112423
Received: 8/23/2011
Product: COLLAGEN TENDON SHEET

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301) 796-5640.

Sincerely,

510(k) Staff

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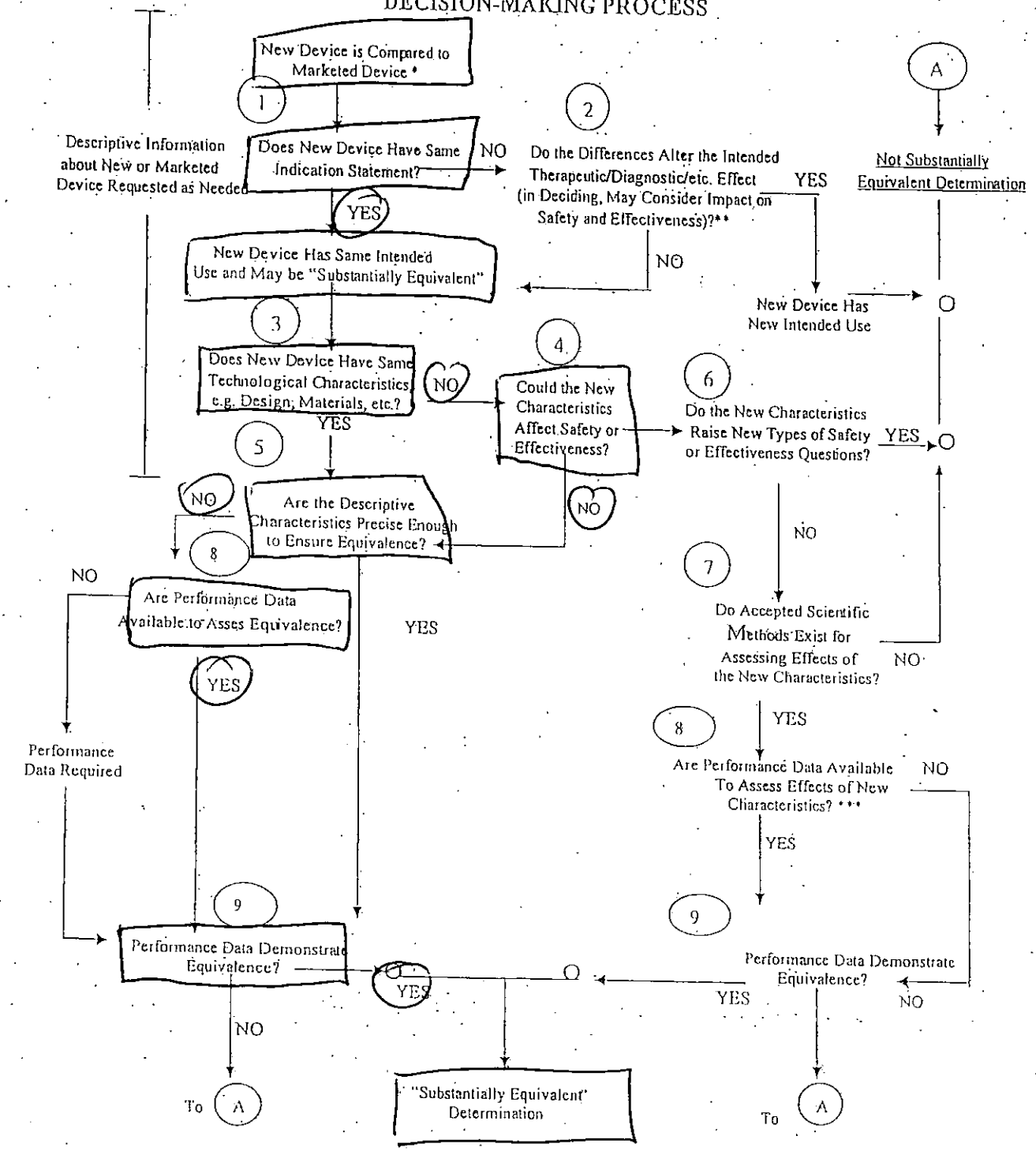
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

K112423/S1

rotation MEDICAL

NOV 30 2012

K35

U.S. Food and Drug Administration
C/O Maegen Colehour; Re: K112423
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Siver Spring, MD 20993-0002

Dear Maegen,

Thank you so much for your availability during our work to answer the questions posed in your request for additional information, received November 1st, regarding our 510(k) for Collagen Tendon Sheet (K112423). We have addressed each of your requests sequentially with your requests restated in italics for easy reference. Our responses follow, non-italic, providing a reference to an attached document in a numbered appendix that completes the answer to each question. Thank you too for your efforts to review and clear this product for market.

(b)(4) Deficiencies

[redacted]

15350 25th Avenue No • Suite 100 • Plymouth MN 55447 • 763.746.7500

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

rotation
MEDICAL

All of us at Rotation Medical, Inc. and our colleagues at Collagen Matrix, Inc. trust you will find our answers to your additional information requests satisfactory.

Once again, we all wish to thank you Maegen, and your colleagues, for your work on our behalf to achieve a timely review and clearance.

Best Regards,

Gail Schroeder
Director of Operations and Quality
Rotation Medical, Inc.

For

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical, Inc.

15350 25th Avenue No • Suite 100 • Plymouth MN 55447 • 763.746.7500

rotation MEDICAL

U.S. Food and Drug Administration
C/0 Maegen Colehour; Re: K112423
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Siver Spring, MD 20993-0002

Dear Maegen,

Thank you so much for your availability during our work to answer the questions posed in your request for additional information, received November 1st, regarding our 510(k) for Collagen Tendon Sheet (K112423). We have addressed each of your requests sequentially with your requests restated in italics for easy reference. Our responses follow, non-italic, providing a reference to an attached document in a numbered appendix that completes the answer to each question. Thank you too for your efforts to review and clear this product for market.

(b)(4) Deficiencies

15350 25th Avenue No • Suite 100 • Plymouth MN 55447 • 763.746.7500

(b)(4) Deficiencies

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(b)(4) Deficiencies

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(b)(4) Deficiencies

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All of us at Rotation Medical, Inc. and our colleagues at Collagen Matrix, Inc. trust you will find our answers to your additional information requests satisfactory.

Once again, we all wish to thank you Maegen, and your colleagues, for your work on our behalf to achieve a timely review and clearance.

Best Regards,

Gail Schroeder
Director of Operations and Quality
Rotation Medical, Inc.

For

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical, Inc.

15350 25th Avenue No • Suite 100 • Plymouth MN 55447 • 763.746.7500

(b)(4) Third Party Information

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U.S. Food and Drug Administration
C/0 Maegen Colehour
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Siver Spring, MD 20993-0002

Re: K112423, Collagen Tendon Sheet

Dear Maegen,

Rotation Medical, Inc. does not intend and will not promote the subject device (Collagen Tendon Sheet, K112423) as an adhesion barrier with device claims related to prevention or minimization of tissue attachment.

Sincerely,

Gail Schroeder

Gail Schroeder
Director of Operations and Quality
Rotation Medical, Inc.

For:

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical, Inc.

15350 25th Avenue No • Suite 100 • Plymouth MN 55447 • 763.746.7500

Additional Data Regarding (b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

[redacted]

(b)(4) Manufacturing Information

[redacted]

BIOLOGICAL RISK ASSESSMENT
Collagen Tendon Sheet

(b)(4) Risk Assessment

[redacted]

(b)(4) Risk Assessment

(b)(4) Risk Assessment

(b)(4) Risk Assessment

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(b)(4) Risk Assessment

(b)(4) Risk Assessment

(b)(4) Risk Assessment

(b)(4) **FDA Question # 5**

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

SUMMARY REPORT
(b)(4) Testing Test Results

(b)(4) Testing

(b)(4) Testing

MASTER COPY

COLLAGEN MATRIX, INC.

CONFIDENTIAL
Attachment 1 for
Doc. No. (b)(4) Manufacturi
Page: 6 of 8
Issue/Rev. No. (b)(4) Manu
Date Effective: 3/27/02

(b)(4) Manufacturing Information Data Form

Lot No.: (b)(4) Manufacturing Information

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(b)(4) Third Party Testing

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STUDY PROTOCOL
(b)(4) Testing Test

(b)(4) Testing

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(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Manufacturing Information

Additional Data Regarding Product Specifications

Table 11-1 on page 30 of the submission shows the Product Specifications for the device. The Product Specifications are the product requirements for the design of the device. At the Design Verification stage, (b)(4) Manufacturing Information [redacted]

Table 11-1a. Summary of Product Specifications and Rationale

Parameter	Product Specification	Rationale
Performance	Protection of tendon injuries in which there has been no substantial loss of tendon tissue	Routine test not applicable for assessment of performance.
Chemical and Physical Properties		(b)(4) Manufacturing Information [redacted]
Composition	Type I collagen	
Color	White to off white	
Form	Sheet	
Dimensions	Various sizes to approximate human tendons 1.5 x 2 cm 2 x 2.5 cm 2.5 x 3 cm	
Thickness	1.0 – 1.3 mm	
(b)(4) Manufacturing Information [redacted]		
Hydration	Membrane weight is ≥ 75% of dry weight after hydrating for ≤ 5 minutes	

Parameter	Product Specification	Rationale
		(b)(4) Manufacturing Information
Residual crosslinking agent+	≤ 0.065%	
Residual EO and ECH	(b)(4) M	(b)(4)
Biological Properties		
Biocompatibility	Biocompatible (Pass FDA G95-1 and ISO 10993)	
Pyrogenicity+	Non-pyrogenic (≤ 0.5 EU/ml)	
Stability		
Shelf-Life	3 years	
Packaging		
(b)(4) Manufacturing Information		
b		

Collagen Tendon Sheet

Description

Collagen Tendon Sheet is a bioabsorbable implant device that provides a layer of collagen over injured tendons. Collagen Tendon Sheet is designed to provide a layer of collagen between a flat tendon and the surrounding tissue. After hydration Collagen Tendon Sheet is an easy-to-handle, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, in double-peel packages.

Indications for 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.

Contraindications

Collagen Tendon Sheet is not designed, sold, or intended for use except as described in the indications for use and is contraindicated in the following situations:

- Collagen Tendon Sheet is not indicated to replace or repair damaged tendon or to reinforce the strength of any tendon repair.
- Collagen Tendon Sheet is not indicated for patients with a known history of hypersensitivity to bovine-derived materials.

Warnings

- Do not re-sterilize.
- Do not use if the product package is damaged or opened.

Precautions

- Collagen Tendon Sheet should not be applied until bleeding and infection are controlled.

Adverse Reactions

Infection may occur if device sterility is compromised.

An allergic reaction to Collagen Tendon Sheet may be experienced in patients with a hypersensitivity to bovine-derived materials.

Instructions for Use

1. Follow standard procedures for treatment of the injured tendon.
2. Determine the tendon width in millimeters (mm) using a suitable measuring instrument.
3. Select a Collagen Tendon Sheet size that is slightly smaller than the width of the tendon.
4. Pre-hydrate Collagen Tendon Sheet in sterile saline for at least 2 minutes.
5. After hydration place the Collagen Tendon Sheet over the tendon with one end overlapping the tendon insertion.
6. Secure the Collagen Tendon Sheet to the tendon and bone with interrupted sutures. Use the minimum number of sutures to ensure that the Collagen Tendon Sheet is in good contact with the tendon.
7. Thoroughly irrigate the surgical site and close the incision in the standard fashion.
8. Application of the Collagen Tendon Sheet does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

Storage

Store at room temperature. Avoid excessive heat or humidity.

How Supplied

Collagen Tendon Sheet is supplied sterile in single-use, double-peel packages in a variety of sizes. Contents of the package are guaranteed sterile and non-pyrogenic unless the package is opened or damaged. The Collagen Tendon Sheet product and packaging do not contain natural rubber latex.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

Symbols Used on Labeling


See Instructions for Use


Expiration Date


Do not reuse after opening

Lot Number

Method of sterilization – ethylene oxide

Manufactured exclusively for:

Rotation Medical, Inc.
15350 25th Ave. N., Plymouth, MN 55447 USA
(b)(4)

510(k) Summary

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/Revised: August 22, 2011/November 14, 2011

Name of Device

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

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Tendon Wrap, K0080452
Collagen Matrix, Inc., Oakland, NJ

Description of the Device

Collagen Tendon Sheet is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet is designed to provide a layer between the tendon and the surrounding tissue. When hydrated, Collagen Tendon Sheet is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet 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.

Summary/Comparison of Technical Characteristics

Collagen Tendon Sheet and its predicate device have the same technological characteristics. In particular, Collagen Tendon Sheet and its predicate are the same with respect to intended use, design, materials, and material characterization. The substantial equivalence of the Collagen Tendon Sheet and its predicate was demonstrated primarily based on in vitro characterization studies, biocompatibility studies, an animal efficacy study, and clinical experience of the predicate device. In vitro characterization studies included evaluation of material properties, biological properties, chemical and physical properties.

The Collagen Tendon Sheet and its predicate device are manufactured with similar processing, in the same facilities, by the same manufacturer, using the same raw materials.

Collagen Tendon Sheet and its predicate have been characterized for chemical composition, purity, density, and strength to demonstrate substantial equivalence.

Collagen Tendon Sheets have been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

An animal efficacy study was conducted to evaluate the device as compared to its predicate device. No clinical tests were performed on the product; however clinical history of the predicate device was referenced in the submission.

Viral inactivation studies were performed to ensure the viral safety of the product.

Conclusion of Non-clinical Studies

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, as well as the animal efficacy study show that Collagen Tendon Sheet is safe and substantially equivalent to the predicate device.

K112423/S2
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U.S. Food and Drug Administration
C/O Maegen Colehour; Re: K112423
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Siver Spring, MD 20993-0002

FDA/CDRH/DCC
DEC 16 2011
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Dear Maegen,

Following is the additional information and revised 510(k) Summary in response to your AI letter received on December 12, 2011. We have restated your requests in italics for easy reference, followed by a reference to a detailed document provided in the attached appendix that completes the answer to each question. Thank you for your continued efforts to review and clear this product for market.

(b)(4)

[redacted]

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(b)(4) Deficiencies

[redacted]

15350 25th Avenue No • Suite 100 • Plymouth MN 55447 • 763.746.7500

rotation
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All of us at Rotation Medical, Inc. and our colleagues at Collagen Matrix, Inc. are committed to providing complete and timely responses to your feedback and trust you will find our answers to your additional information requests in the follow-up AI letter satisfactory.

Thank you for your continued work, and that of your colleagues, to achieve a timely review and clearance.

Best Regards,

Gail Schroeder
Director of Operations and Quality
Rotation Medical, Inc

For

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical, Inc.

rotation MEDICAL

U.S. Food and Drug Administration
C/0 Maegen Colehour; Re: K112423
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Siver Spring, MD 20993-0002

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(b)(4) Deficiencies

[redacted]

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(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

510(k) Summary

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/Revised:	August 22, 2011/November 14, 2011/December 13, 2011

Name of Device

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

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s):	Collagen Tendon Wrap, K0080452 Collagen Matrix, Inc., Oakland, NJ

Description of the Device

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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.

Summary/Comparison of Technical Characteristics

Collagen Tendon Sheet and its predicate device have the same technological characteristics. In particular, Collagen Tendon Sheet and its predicate are the same with respect to intended use, design, materials, and material characterization. The substantial equivalence of the Collagen Tendon Sheet and its predicate was demonstrated primarily based on in vitro characterization studies, biocompatibility studies, an animal efficacy study, and clinical experience of the predicate device. In vitro characterization studies included evaluation of material properties, biological properties, chemical and physical properties.

The Collagen Tendon Sheet and its predicate device are manufactured with similar processing, in the same facilities, by the same manufacturer, using the same raw materials. They vary with respect to size and thickness. In addition, the Collagen Tendon sheet is provided in a flat form.

Collagen Tendon Sheet and its predicate have been characterized for chemical composition, purity, density, and strength to demonstrate substantial equivalence. Testing was conducted in accordance to FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.

Collagen Tendon Sheets have been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

An animal efficacy study was conducted to evaluate the device as compared to its predicate device. No clinical tests were performed on the product; however clinical history of the predicate device was referenced in the submission.

Viral inactivation studies were performed to ensure the viral safety of the product.

Conclusion of Non-clinical Studies

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, as well as the animal efficacy study show that Collagen Tendon Sheet is substantially equivalent to the predicate device.

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All of us at Rotation Medical, Inc. and our colleagues at Collagen Matrix, Inc. are committed to providing complete and timely responses to your feedback and trust you will find our answers to your additional information requests in the follow-up AI letter satisfactory.

Thank you for your continued work, and that of your colleagues, to achieve a timely review and clearance.

Best Regards,

Gail Schroeder
Director of Operations and Quality
Rotation Medical, Inc

For

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs
Rotation Medical, Inc.