U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K140300 - 269 pages
COMPANY:	ROTATION MEDICAL, INC. (ROTAMEDI)
PRODUCT:	MESH, SURGICAL, COLLAGEN, ORTHOPAEDICS, REINFORCEMENT OF TENDON (OWY)
SUMMARY:	Product: COLLAGEN TENDON SHEET-DDI (CTS-DDI)
DATE REQUESTED:	Nov 4, 2015
DATE PRINTED:	Nov 4, 2015
Note:	Printed

MAR 2 6 2014

rotation MEDICAL

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:	March 19, 2014

Name of Device

Device Common Name:	Tendon Protector
Device Trade Name:	Collagen Tendon Sheet-DDI
Device Classification Name:	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement of Tendon 878.3300 Class II OWY
Secondary Classification Code	ORQ

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s):	Collagen Tendon Sheet-D, K122048 Rotation Medical, Inc.

Description of the Device

Collagen Tendon Sheet-DDI is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet-DDI is designed to provide a layer between the tendon and the surrounding tissue during healing. When hydrated, Collagen Tendon Sheet-DDI is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet-DDI is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, and is packaged preloaded in a cartridge, for use with the Rotation Medical Delivery Instrument, in a dual sterile seal tray-in-tray configuration.

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Intended Use

Collagen Tendon Sheet-DDI 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-DDI is exactly the same product as its predicate, Collagen Tendon Sheet-D (K122048) in regard to all aspects of the collagen scaffold. Only the packaging has changed between the current device and the predicate device. Collagen Tendon Sheet-DDI is packaged in a cartridge to facilitate arthroscopic delivery and positioning of the collagen matrix.

Past safety, biocompatibility and mechanical characterization tests of the predicate product are directly applicable to the current product. Additional tests to confirm the performance characteristics of the packaging change were performed. To confirm performance of the device in the new packaging; suture pull-out testing, hydrothermal transition temperature, and endotoxin testing were evaluated. To confirm the performance of the cartridge assembly itself biocompatibility, simulated use and mechanical integrity tests were evaluated.

In summary, the Collagen Tendon Sheet-DDI device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices. Testing was conducted in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.

Conclusion

The purpose of this 510(k) application was to notify the Food and Drug Administration of proposed modifications to the packaging of the previously cleared Collagen Tendon Sheet-D (K122048). Collagen Tendon Sheet-DDI and Collagen Tendon Sheet-D are exactly the same device excepting their respective packaging. The proposed packaging modifications for the new device raise no new questions regarding safety and effectiveness. Therefore, the proposed Collagen Tendon Sheet-DDI is substantially equivalent to the predicate Collagen Tendon Sheet-D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 26, 2014

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

Re: K140300
Trade/Device Name: Collagen Tendon Sheet-DDI
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, ORQ
Dated: February 3, 2014
Received: February 6, 2014

Dear Mr. Sims:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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. 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140300

Device Name
Collagen Tendon Sheet-DDI

Indications for Use *(Describe)*
Collagen Tendon Sheet-DDI is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S
2014.03.25 14:50:46 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 26, 2014

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

Re: K140300
Trade/Device Name: Collagen Tendon Sheet-DDI
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, ORQ
Dated: February 3, 2014
Received: February 6, 2014

Dear Mr. Sims:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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. 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140300

Device Name
Collagen Tendon Sheet-DDI

Indications for Use *(Describe)*
Collagen Tendon Sheet-DDI is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S
2014.03.25 14:50:46 -04'00'

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

Collins, Virginia *

From: Collins, Virginia *
Sent: Thursday, March 27, 2014 4:25 PM
To: 'jsims@rotationmedical.com'
Cc: DCCLetters
Subject: K140300 SE Letter
Attachments: K140300.pdf

Tracking:

Recipient	Delivery
'jsims@rotationmedical.com'	
DCCLetters	Delivered: 3/27/2014 4:25 PM

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K140300

February 3, 2014

FDA CDRH DMC
FEB 06 2014
Received

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-DDI (b) (4) [redacted]

Note: This submission includes an electronic copy of the 510(k) submission per *eCopy Program for Medical Device Submissions.* The eCopy is an exact duplicate of the paper copy.

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-DDI. Rotation Medical has determined that Collagen Tendon Sheet-DDI is substantially equivalent to current legally marketed tendon protector devices and intends to manufacture and market the device.

(b) (4) [redacted]

Trade Name or Proprietary Name:	Collagen Tendon Sheet-DDI
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.: 3009351468

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

Below is the recommended "Design and Use of the Device" 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	

The purpose of this application is to gain clearance for Collagen Tendon Sheet-DDI, an additional model of the predicate device, Rotation Medical's Collagen Tendon Sheet-D (K122048). Collagen Tendon Sheet-DDI is exactly the same device as its predicate except it is

(b) (4) [redacted]

The indication for use for Collagen Tendon Sheet-DDI is the same as the predicate Collagen Tendon Sheet-D:

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

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Arthroscopic tendon repair procedures constitute a growing percentage of all such procedures.

(b) (4)

[redacted]

If you have any questions, please do not hesitate to contact me. Thank you all in advance for your work toward the clearance of this device.

Sincerely,

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs

Enclosures (submitted including an electronic copy)

Premarket Notification
510(k) Application

For

Collagen Tendon Sheet-DDI

(b) (4) [redacted]

February 3, 2014

Rotation Medical, Inc.
15350 25th Avenue North, Suite 100
Plymouth, Minnesota 55447

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

(b) (4) [redacted]

Table of Contents

APPENDICES

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. 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) 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)	2. CONTACT NAME
ROTATION MEDICAL, INC. FKA DENALI MEDICAL, INC. 15350 25th AVENUE N., SUITE 100 PLYMOUTH MN 55447 US	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
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)	

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm 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) 27-Jan-2014

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: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
February 3, 2014	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ 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.	3009351468		
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			
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 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

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

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

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

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

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

- ☐ Response to FDA correspondence:

- ☐ 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

- ☐ 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

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

- ☐ 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	K122048	1	Collagen Tendon Sheet-D	1	Rotation Medical, Plymouth MN
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-DDI (CTS-DDI)	1	TBD
2		2	
3		3	
4		4	
5		5	

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

1	K131632	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 ☐ Class III ☐ Unclassified

Classification Panel

General and Plastic Surgery

Indications *(from labeling)*

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

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	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	
Company / Institution Name (b) (4)		Establishment Registration Number (b) (4)	
Division Name *(if applicable)*		Phone Number *(including area code)* (b) (4)	
Street Address (b) (4)		FAX Number *(including area code)* (b) (4)	
City (b) (4)	State / Province (b)	ZIP Code (b)	Country (b) (4)
Contact Name (b) (4)	Contact Title (b) (4)	Contact E-mail Address (b) (4)	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b) (4)	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name (b) (4)		Establishment Registration Number (b) (4)	
Division Name *(if applicable)*		Phone Number *(including area code)* (b) (4)	
Street Address (b) (4)		FAX Number *(including area code)* (b) (4)	
City (b)(4) Trade	State / Province (b)	ZIP Code (b) (4)	Country (b) (4)
Contact Name (b)(4)	Contact Title (b) (4)	Contact E-mail Address (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 version	05/01/2007
2	10993	ISO	Biological evaluation of medical devices	3rd edition	08/01/2003
3					
4					
5					
6					
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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February 3, 2014

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-DDI (b) (4) [redacted]

Note: This submission includes an electronic copy of the 510(k) submission per *eCopy Program for Medical Device Submissions.* The eCopy is an exact duplicate of the paper copy.

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-DDI. Rotation Medical has determined that Collagen Tendon Sheet-DDI is substantially equivalent to current legally marketed tendon protector devices and intends to manufacture and market the device.

(b) (4) [redacted]

Trade Name or Proprietary Name:	Collagen Tendon Sheet-DDI
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.: 3009351468

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

Below is the recommended "Design and Use of the Device" 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	

The purpose of this application is to gain clearance for Collagen Tendon Sheet-DDI, an additional model of the predicate device, Rotation Medical's Collagen Tendon Sheet-D (K122048). Collagen Tendon Sheet-DDI is exactly the same device as its predicate except it is (b) (4) [redacted]

The indication for use for Collagen Tendon Sheet-DDI is the same as the predicate Collagen Tendon Sheet-D:

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

rotation
MEDICAL

Arthroscopic tendon repair procedures constitute a growing percentage of all such procedures.
(b) (4)
[redacted]

If you have any questions, please do not hesitate to contact me. Thank you all in advance for your work toward the clearance of this device.

Sincerely,

Jeff Sims
Vice President, Clinical Programs and Regulatory Affairs

Enclosures (submitted including an electronic copy)

Indications for Use

510(k) Number (if known): _____

Device Name: Collagen Tendon Sheet-DDI

Indications for Use:

Collagen Tendon Sheet-DDI 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)

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: February 3, 2014

Name of Device

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

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Tendon Sheet-D, K122048
Rotation Medical, Inc.

Description of the Device

Collagen Tendon Sheet-DDI is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet-DDI is designed to provide a layer between the tendon and the surrounding tissue during healing. When hydrated, Collagen Tendon Sheet-DDI is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet-DDI is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, and is packaged preloaded in a cartridge, for use with the Rotation Medical Delivery Instrument, in a dual sterile seal tray-in-tray configuration.

Intended Use

Collagen Tendon Sheet-DDI 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-DDI is exactly the same product as its predicate, Collagen Tendon Sheet-D (K122048) in regard to all aspects of the collagen scaffold. Only the packaging has changed between the current device and the predicate device. Collagen Tendon Sheet-DDI is packaged in a cartridge to facilitate arthroscopic delivery and positioning of the collagen matrix.

No new device performance or characterization data is included in this submission. Past safety, biocompatibility and mechanical characterization tests of the predicate product are directly applicable to the current product. Additional tests to confirm the performance characteristics of the packaging change were performed.

In summary, the Collagen Tendon Sheet-DDI device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices. Testing was conducted in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh.

Conclusion

The purpose of this 510(k) application was to notify the Food and Drug Administration of proposed modifications to the packaging of the previously cleared Collagen Tendon Sheet-D (K122048). Collagen Tendon Sheet-DDI and Collagen Tendon Sheet-D are exactly the same device excepting their respective packaging. The proposed packaging modifications for the new device raise no new questions regarding safety and effectiveness. Therefore, the proposed Collagen Tendon Sheet-DDI is substantially equivalent to the predicate Collagen Tendon Sheet-D.

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.

2/3/14
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 performed in support of this application, no financial certifications or disclosure statements are applicable.

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, 2007*

9.2 Biocompatibility

The biocompatibility of the finished product was tested according to ISO 10993-1: *Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing, 2003*

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 sterilization and biocompatibility standards are included in Appendix F.

10. EXECUTIVE SUMMARY

10.1 Brief Description of Device

Collagen Tendon Sheet-DDI is exactly the same product as its predicate; each are a bioabsorbable implant device that provides a layer of collagen over injured tendons. Collagen Tendon Sheet-DDI is designed to provide a layer of collagen between a flat tendon and the surrounding tissue during tendon healing. After hydration, Collagen Tendon Sheet-DDI is an easy-to-handle, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet-DDI is provided sterile, non-pyrogenic, for single use only, and is packaged in a cartridge, for use with the Rotation Medical Delivery Instrument, in a dual sterile seal tray-in-tray configuration.

10.2 Design Philosophy

(b) (4) [redacted]

In addition to the direct predicate, Rotation Medical's Collagen Tendon Sheet (K112423), and (b) (4) [redacted] protective environment for tissue healing. Other tendon protector products successfully used for the protection of tendon injuries include (b) (4) [redacted]

(b) (4) [redacted]

Arthroscopic tendon repair procedures constitute a growing percentage of all such procedures. Collagen Tendon Sheet-DDI (b) (4) [redacted]

10.3 Device Comparison

Rotation Medical's Collagen Tendon Sheet-DDI is substantially equivalent to Collagen Tendon Sheet-D (K122048). Collagen Tendon Sheet-DDI is exactly the same device as its predicate, Collagen Tendon Sheet-D (K122048), in regard to all aspects of the collagen scaffold. Only the packaging has changed between the current device and the predicate device. Collagen Tendon Sheet-DDI is packaged preloaded in a cartridge to facilitate arthroscopic delivery and positioning of the collagen matrix.

10.4 Summary of Performance Testing

The results of the safety and biocompatibility testing that were previously submitted in support of the predicate device, Collage Tendon Sheet-D, are directly applicable to Collagen Tendon Sheet-DDI because the two devices are identical. In like manner, the results of the material and mechanical characterization of the predicate device are also directly applicable to the current device.

The materials used in the delivery instrument cartridge head assembly have passed additional biocompatibility and simulated-use and integrity safety tests (Section 15 and 20 respectively). The proposed packaging modifications to the predicate device raise no new questions regarding safety and effectiveness. Therefore, the proposed Collagen Tendon Sheet-DDI is substantially equivalent to the predicate Collagen Tendon Sheet-D.

11. DEVICE DESCRIPTION

11.1 Description

Collagen Tendon Sheet-DDI, like its predicate, is a resorbable type I collagen matrix that provides a layer of collagen over injured tendons. Collagen Tendon Sheet-DDI is designed to provide a layer of collagen between a flat tendon and the surrounding tissue during tendon healing. After hydration, Collagen Tendon Sheet-DDI is an easy-to-use, soft, pliable, nonfriable, porous collagen sheet. Collagen Tendon Sheet-DDI is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, and is packaged in a cartridge, for use with the Rotation Medical Delivery Instrument, in a dual sterile seal tray-in-tray configuration.

11.2 Intended Use

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

11.3 Contract Development and Manufacture

(b) (4) [redacted]

11.4 Collagen Materials

All of the materials in Collagen Tendon Sheet-DDI are identical to the predicate Collagen Tendon Sheet-D. As often stated within this current submission, Collagen Tendon Sheet-DDI and the predicate Collagen Tendon Sheet-D are the exact same device excepting their respective packaging. (b) (4) [redacted]

11.5 Performance Specifications/Design Requirements

The design specifications of Collagen Tendon Sheet-DDI are the same as the predicate Collagen Tendon Sheet-D. Only the packaging has changed between the two products. Therefore the associated shelf life of the device has also changed; (b) (4) [redacted]

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

Table 11-1 Summary of Product Specifications

Parameter	Product Specification
Performance	Management and protection of tendon injuries in which there has been no substantial loss of tendon tissue
Chemical and Physical Properties	
(b) (4)	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	ECH: ≤ 9 mg
Biological Properties	
Biocompatibility	Biocompatible (Pass FDA G95-1 and ISO 10993)
Pyrogenicity+	Non-pyrogenic (≤ 0.5 EU/ml)
Stability	
(b) (4)	[redacted]
Packaging	
(b) (4)	(b) (4)
[redacted]	

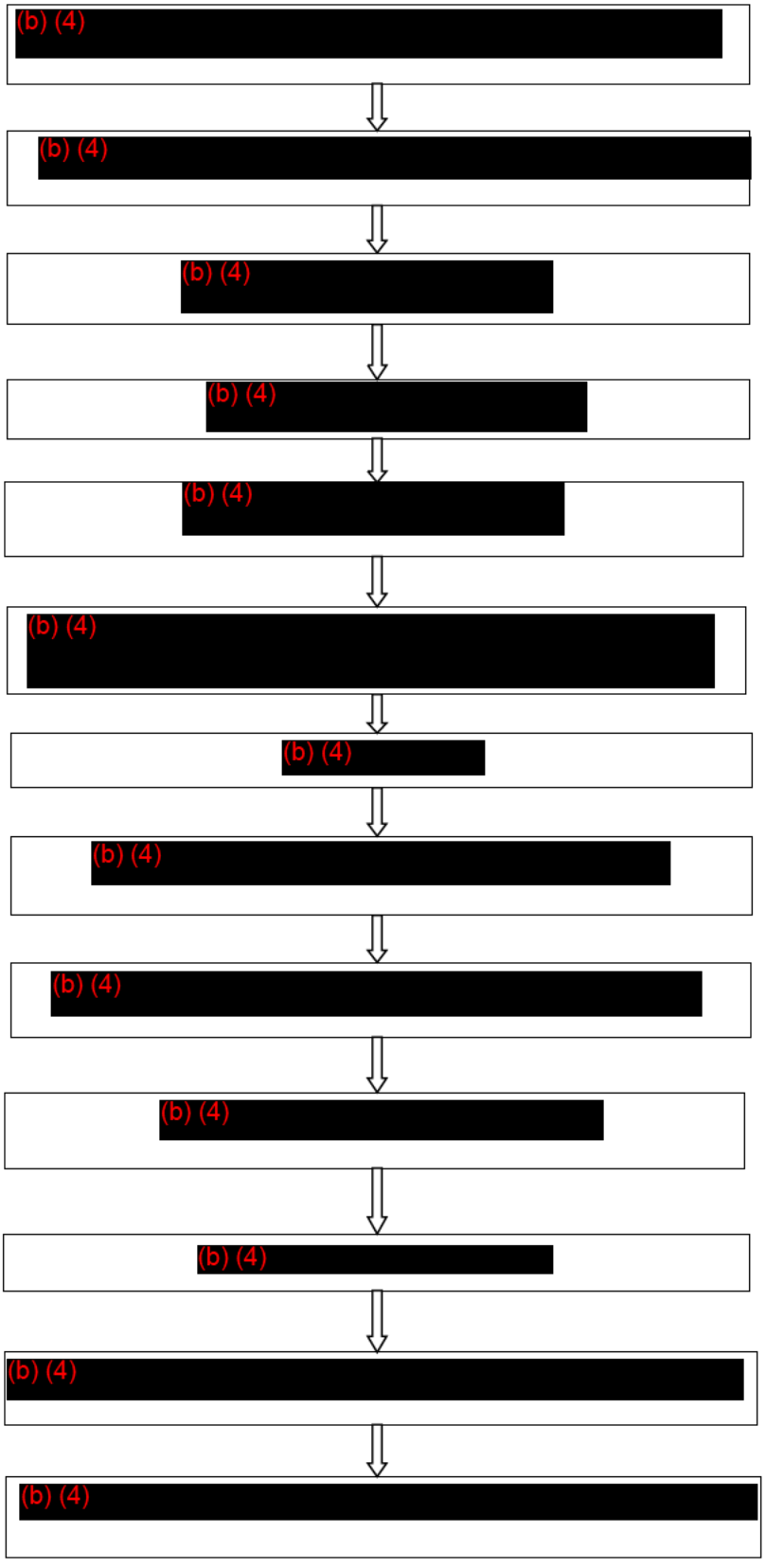
b

11.6 Manufacturing Process

11.6.1 Manufacturing Flowchart

The manufacturing flowchart is shown on the following page. There has been no change in the flowchart as a result of the packaging change between the processing of Collagen Tendon Sheet-DDI and the predicate Collagen Tendon Sheet-D. The packaging change between the two products is described in Section 11.6.2 below.

Manufacturing Flowchart for Collagen Tendon Sheet-DDI



11.6.2 Description of the Manufacturing Process

The only change between the processing of Collagen Tendon Sheet-DDI and the predicate Collagen Tendon Sheet-D is the (b) (4) [redacted] All other aspects of the predicate device manufacturing are applicable to the current device manufacturing and will not be repeated here.

However, since the packaging of the device has changed, this change will be elaborated upon.

(b) (4) [redacted]

Table 11-2 Description of the manufacturing process (b) (4)

(b) (4)

(b) (4)

Note, the actual loading of the collagen scaffold in the cartridge assembly is done in a clean room environment with gloved hands.

(b) (4)

12. SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1 Predicate Devices

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

Collagen Tendon Sheet-D (K122048)
Rotation Medical, Inc. Plymouth, MN

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-DDI are identical and therefore are substantially equivalent to the predicate device referenced above. Indeed they are the same device, only the packaging has changed between the two products as reflected in the last line of Table 12-1.

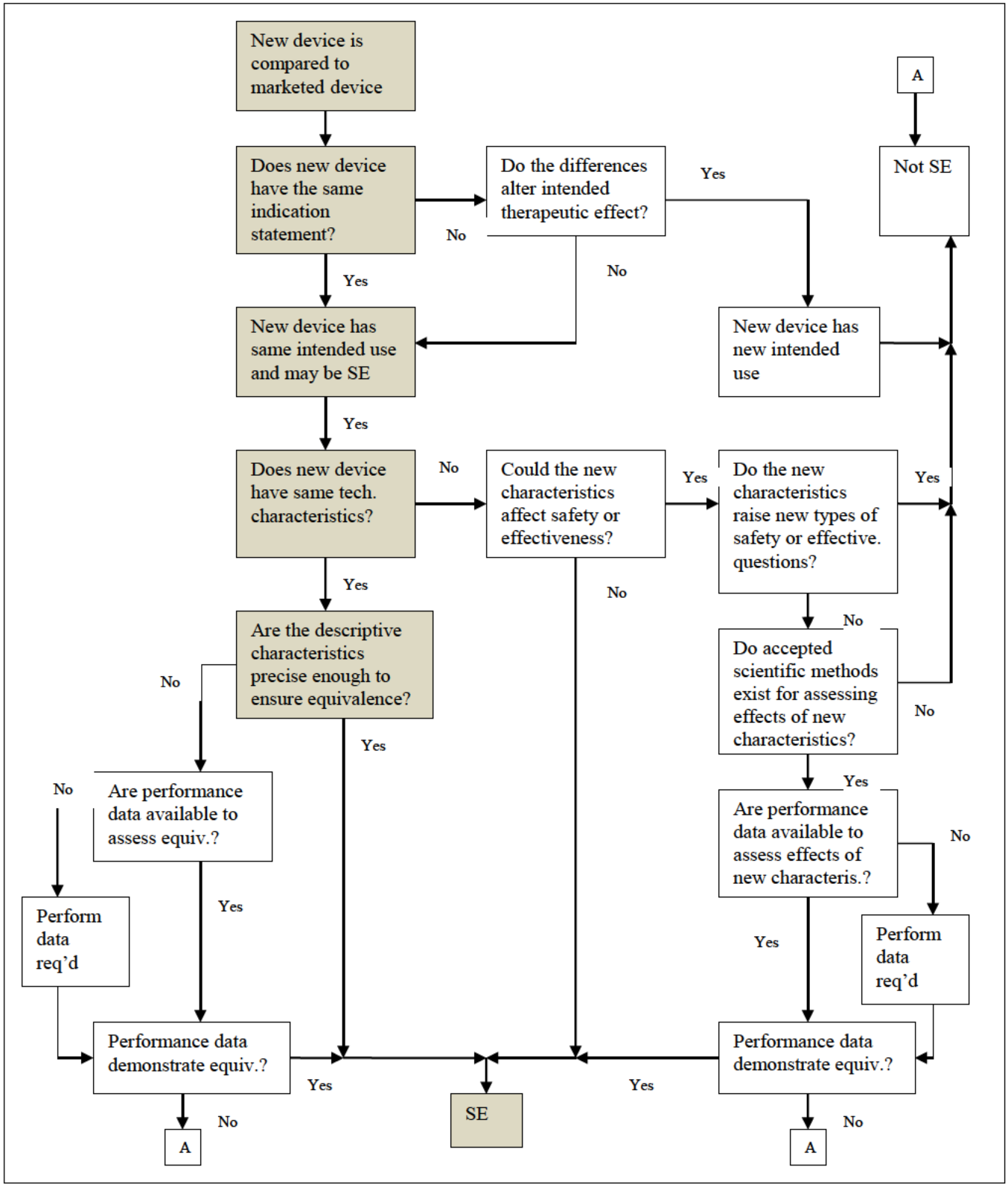
Shelf life assessments of the Collagen Tendon Sheet-DDI device in its new packaging are sufficient to demonstrate that the new device is not impacted by the change in packaging. These assessments and the protocol for future assessments are submitted in Appendix D and Section 14 respectively. Collagen Tendon Sheet-DDI meets its design specifications and is equivalent to its predicate device. Further the ongoing lot acceptance tests are performed on product after packaging and sterilization, these tests too will continually verify the packaging change has no effect on the performance characteristics of the device.

Table 12-1 Substantial Equivalence Comparison Chart with Comparative Data

	Collagen Tendon Sheet-DDI (This submission)	Collagen Tendon Sheet-D K122048
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	(b)(4) Trade Secret Process-Product Specs	
Source		
Form		
Color		
Dimensions		
Thickness		
Density		
Mechanical Strength		
Biocompatibility		
Sterility	Sterile, SAL 10^{-6} ETO sterilization	Sterile, SAL 10^{-6} ETO sterilization
Pyrogenicity	Non-pyrogenic (≤ 0.5 EU/ml)	Non-pyrogenic (≤ 0.5 EU/ml)
Single use / Reuse	(b)(4) Trade Secret Process-Product Specs	
Packaging		

12.3 Substantial Equivalence Decision Flowchart

The following Substantial Equivalence Decision-making Flowchart was used to assess Collagen Tendon Sheet-DDI against the predicate Collagen Tendon Sheet-D.



12.4 Description of Substantial Equivalence Flowchart Decisions

Does the new device have the same indication statement?

Yes. Collagen Tendon Sheet-DDI and Collagen Tendon Sheet-D have the same indication statement, which is: the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

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

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

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

Yes. There is no difference in the technological, material or processing characteristics of the implanted devices. Indeed they are the same device. Only the packaging has changed between the two products. The only difference is that Collagen Tendon Sheet-DDI is (b) (4) [redacted].

Could the new characteristics affect safety and effectiveness?

Yes. Although the packaging change was not likely to affect either the safety or performance of the device, a complete set of shelf life performance tests was undertaken on three lots of Collagen Tendon Sheet-DDI to demonstrate such was indeed the case. See Sections 12.5 below for more information on the packaging change and Section 14 for more information on the associated shelf life testing protocol.

Substantial equivalence

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

12.5 Detailed Description of Substantial Equivalence

The overall product comparisons were presented in Table 12-1 above. In this section, a detailed comparison of the key material characterization test results between the subject device and the predicate device will be discussed:

- Collagen Tendon Sheet-DDI – Subject Device
- Collagen Tendon Sheet-D (K122048) – Predicate Device

12.5.1 Intended Use

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

12.5.2 Form, Appearance, and Dimensions

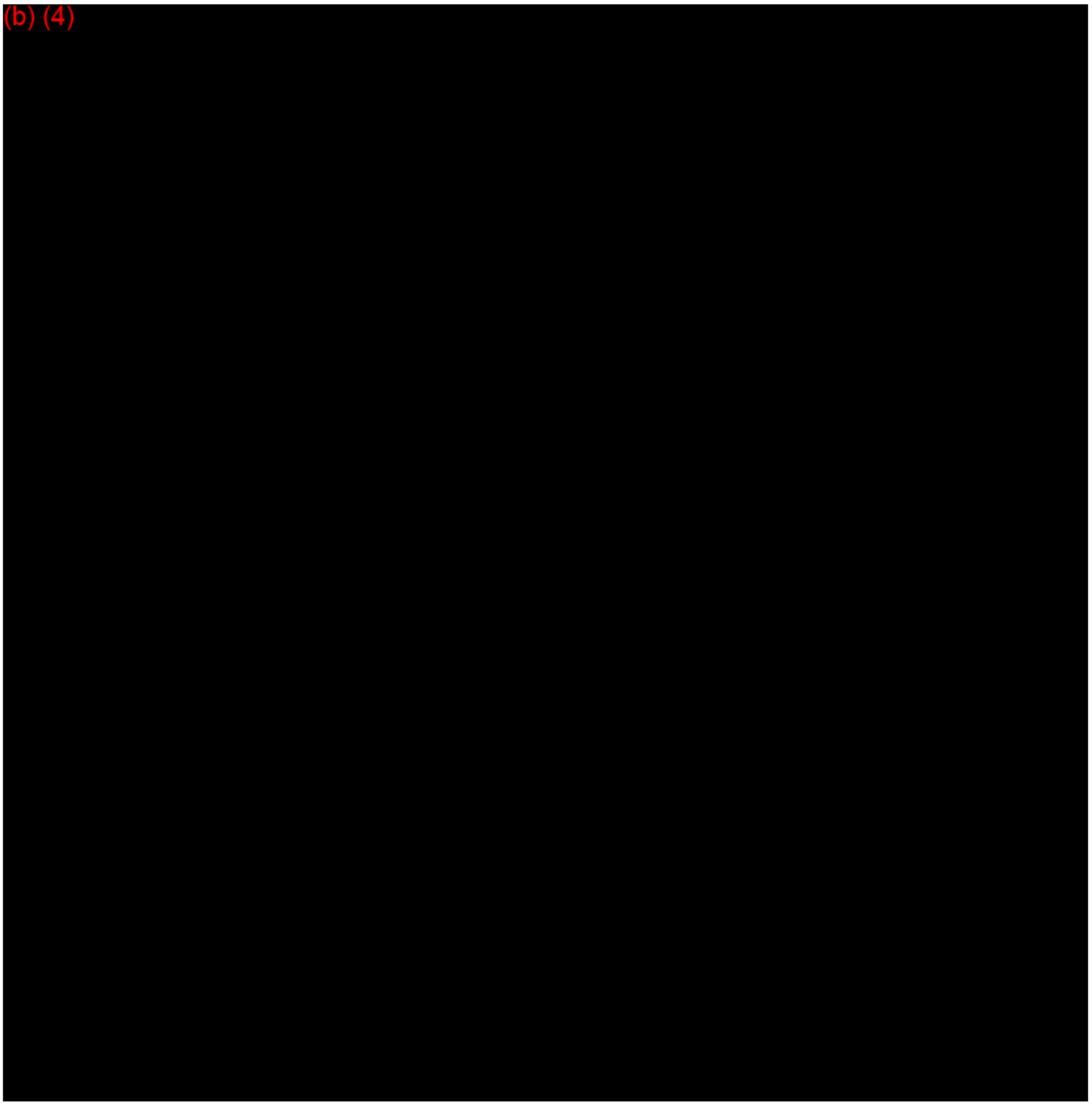
Collagen Tendon Sheet-DDI and its predicate device, Collagen Tendon Sheet-D, are exactly the same device prior to Collagen Tendon Sheet-DDI being loaded into the delivery instrument cartridge for packaging. The manufacturing process for preloading the device in the cartridge is described in Section 11.6.2. (b) (4)

(b) (4)

Figure 12-1 Collagen Tendon Sheet-DDI Figure 12-2 Collagen Tendon Sheet-D

(b) (4)

(b) (4)



The size and dimensions of the current product and its predicate are identical.

	Collagen Tendon Sheet-DDI	Collagen Tendon Sheet-D
Form	(b)(4) Trade Secret Process-Product Specs	
Color		
Dimensions		
Thickness		

The Collagen Tendon Sheet-DDI is provided in the same sizes and thickness as the predicate Collagen Tendon Sheet-D. Dimensions and thickness are verified on all devices in manufacturing prior to final packaging.

12.5.3 Material Composition

The Collagen Tendon Sheet-DDI and its predicate Collagen Tendon Sheet-D are both manufactured from the identical material, (b)(4) Trade Secret Process-Product Specs

(b)(4) Trade Secret Process-Product Specs

	Collagen Tendon Sheet-DDI	Collagen Tendon Sheet-D
(b)(4) Trade Secret Process-Product Specs		

12.5.4 Physical Properties

(b)(4) Trade Secret Process-Product Specs

(b)(4) Trade Secret Process-Product Specs

	(b)(4) Trade Secret Process-	
(b)(4) Trade Secret Process-Product Specs		

(b)(4) Trade Secret Process-Product Specs

12.5.5 Physico-chemical Properties

(b)(4) Trade Secret Process-Product Specs

(b)(4) Trade Secret Process-Product Specs

	Collagen Tendon Sheet-DDI	Collagen Tendon Sheet-D
(b)(4) Trade Secret Process-Product Specs	(b)(4) Trade Secret Process-	(b)(4) Trade Secret

(b)(4) Trade Secret Process-Product Specs

12.5.6 Sterility

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

	Collagen Tendon Sheet-DDI	Collagen Tendon Sheet-D
Sterilization Method	Ethylene oxide	Ethylene oxide

12.5.7 (b)(4) Trade Secret Process-Product Specs

(b)(4) Trade Secret Process-Product Specs

(b)(4) Trade Secret Process-Product Specs

(b)(4) Trade Secret Process-Product Specs

(b)(4) Trade Secret Process-Product Specs

the Collagen Tendon Sheet-D, and therefore Collagen Tendon Sheet-DDI, [redacted]

	Collagen Tendon Sheet-D	Collagen Tendon Sheet
(b)(4) Trade Secret Process-Product Specs	[redacted]	[redacted]

(b)(4) Trade Secret Process-Product Specs

[redacted]

(b)(4) Trade Secret Process-Product Specs

[redacted]

12.6 Conclusions of Comparative Analysis

Based on the comparative analysis, Collagen Tendon Sheet-DDI has been shown to be substantially equivalent to its predicate, Collagen Tendon Sheet-D; indeed they are exactly the same device, only the packaging has changed. Additional support is provided throughout this submission.

13. PROPOSED LABELING

The product label and instructions for use of the Collagen Tendon Sheet-DDI are provided in Appendix C. Because of the similarities in intended use, materials, and product characteristics, the label and instructions for use of the predicate device Collagen Tendon Sheet-D were used as a guide in developing the insert for Collagen Tendon Sheet-DDI.

(b)(4) Trade Secret Process-Product Specs

14. STERILIZATION AND SHELF LIFE

14.1 Sterilization

The method of sterilization is ethylene oxide sterilization for both Collagen Tendon Sheet-DDI and its predicate, Collagen Tendon Sheet-D. The sterilization method has been validated in accordance with ISO 11135-1, Sterilization 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 final packaging used to maintain sterility is a dual Tyvek sterile barrier tray-in-tray design, typical of sterile medical device packaging.

14.2 Shelf Life

Product stability assessments examine the stability of the product over time as packaged and stored under accelerated or real time aging conditions. (b)(4) Trade Secret Process-Product Specs [redacted]. The results of the tests at each time point must meet overall product specifications.

In order to assess shelf life in real time, Rotation Medical (b)(4) Trade Secret Process-Product Specs [redacted] The protocol when (b)(4) Trade Secret Process-Product Specs [redacted]. Table 14-1 summarizes the on-going shelf life test protocol for the device.

(b)(4) Trade Secret Process-Product Specs [redacted]

Table 14-1 Self Life Testing Protocol

(b)(4) Trade Secret Process-Product Specs	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

(b)(4) Trade Secret Process-Product Specs [redacted]

Table 14-2 Package Integrity Protocol Testing

(b)(4) Trade Secret Process-Product Specs [redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

(b)(4) Trade Secret Process-Product Specs [redacted] The test results to date are provided in Appendix D.

15. BIOCOMPATIBILITY

The extensive biocompatibility testing done in support of the predicate product, Collagen Tendon Sheet-D, is directly applicable to Collagen Tendon Sheet-DDI and was not repeated for the current application.

The following table summarizes the additional biocompatibility tests and assessments made for the cartridge head assembly. The associated final reports are provided in Appendix B. The additional biocompatibility tests were performed (b)(4) Trade Secret Process-Product Specs to established protocols in conformance with ISO 10993-1, 2003 for parts that contact the tissue and bone less than 24 hours. (b)(4) Trade Secret Process-Product Specs

Table 15-1. (b)(4) Trade Secret Process-Product Specs

Test	Test Method/Model or Assessment	Results
(b)(4) Trade Secret Process-Product Specs		

Conclusion

Collagen Tendon Sheet-DDI is exactly the same device as its predicate Collagen Tendon Sheet-D, excepting their respective packaging, and like its predicate, the current device is biocompatible and safe for human implantation. The addition of the acute cartridge components have also been shown to be appropriately biocompatible.

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 of Collagen Tendon Sheet-DDI was verified by comparing the Design Input (Product Design Requirements, Section 11.4) and the Design Output. Table 18.1 shows the Design Verification Matrix for the product. All output 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
Performance	Protection of tendon injuries in which there has been no substantial loss of tendon tissue.	(b)(4) Trade Secret Process-Product Specs
Chemical and Physical Properties		
(b)(4) Trade Secret Process-Product Specs		

Parameter	Product Specification / Design Input	Design Output
(b)(4) Trade S t		
Residual EO and ECH	EO: ≤ 4 mg ECH: ≤ 9 mg	(b) (4) T
Biological Properties		
Biocompatibility	Biocompatible (Pass FDA G95-1 and ISO 10993)	(b)(4) Trade Secret Process-P d t S
Pyrogenicity	Non-pyrogenic (≤ 0.5 EU/ml)	(b)(4) Trade S t
Stability		
Shelf Life	(b)(4) Trade Secret Process-Product Specs	
Packaging		
Double peel packages	(b)(4) Trade Secret Process-Product Specs	

18.2 Design Verification Test Methods and Results

Collagen Tendon Sheet-DDI met all of the product specifications and design requirements set out for the product.

The design verification data sheets that support the summary results above for Collagen Tendon Sheet-DDI are included in Appendix E. (b)(4) Trade Secret Process-Product Specs

19. PERFORMANCE TESTING - ANIMAL

There was no additional animal performance testing done in support of Collagen Tendon Sheet-DDI. The animal testing completed in support of the root predicate product, Collagen Tendon Sheet, is applicable to Collagen Tendon Sheet-DDI since the product specifications and design requirements of both products are the same, (b)(4) Trade Secret Process-Product Specs and the new packaging for Collagen Tendon Sheet-DDI.

20. PERFORMANCE TESTING - CLINICAL

20.1 Clinical Experience with Collagen Tendon Sheet

Rotation Medical Inc. has not yet made its Collagen Tendon Sheet products commercially available, (b)(4) Trade Secret Process-Product Specs [redacted]

20.2 Simulated-Use and Clinical Performance Testing

Rotation Medical has completed a series of simulated use and integrity tests demonstrating the (b)(4) Trade Secret Process-Product Specs [redacted] Collagen Tendon Sheet-DDI. (b)(4) Trade Secret Process-Product Specs [redacted].

In the first test (Report Number 2324 following Protocol Number 2304 included in Appendix G) three areas were assessed, namely: (b)(4) Trade Secret Process-Product Specs [redacted]

(b)(4) Trade Secret Process-Product Specs [redacted]

(b)(4) Trade Secret Process-Product Specs [redacted]

(b)(4) Trade Secret Process-Product Specs [redacted]

(b)(4) Trade Secret Process- Testing

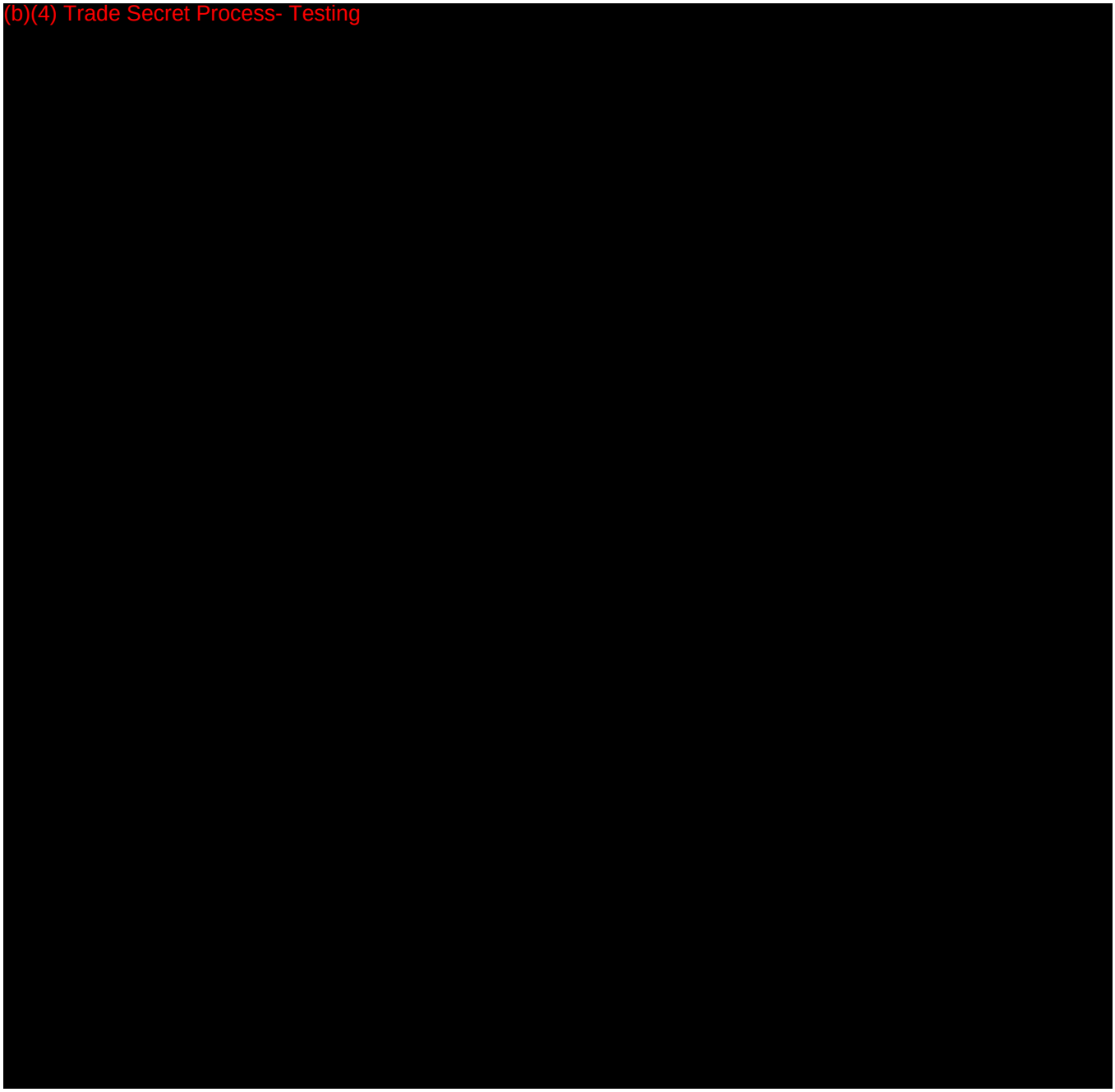
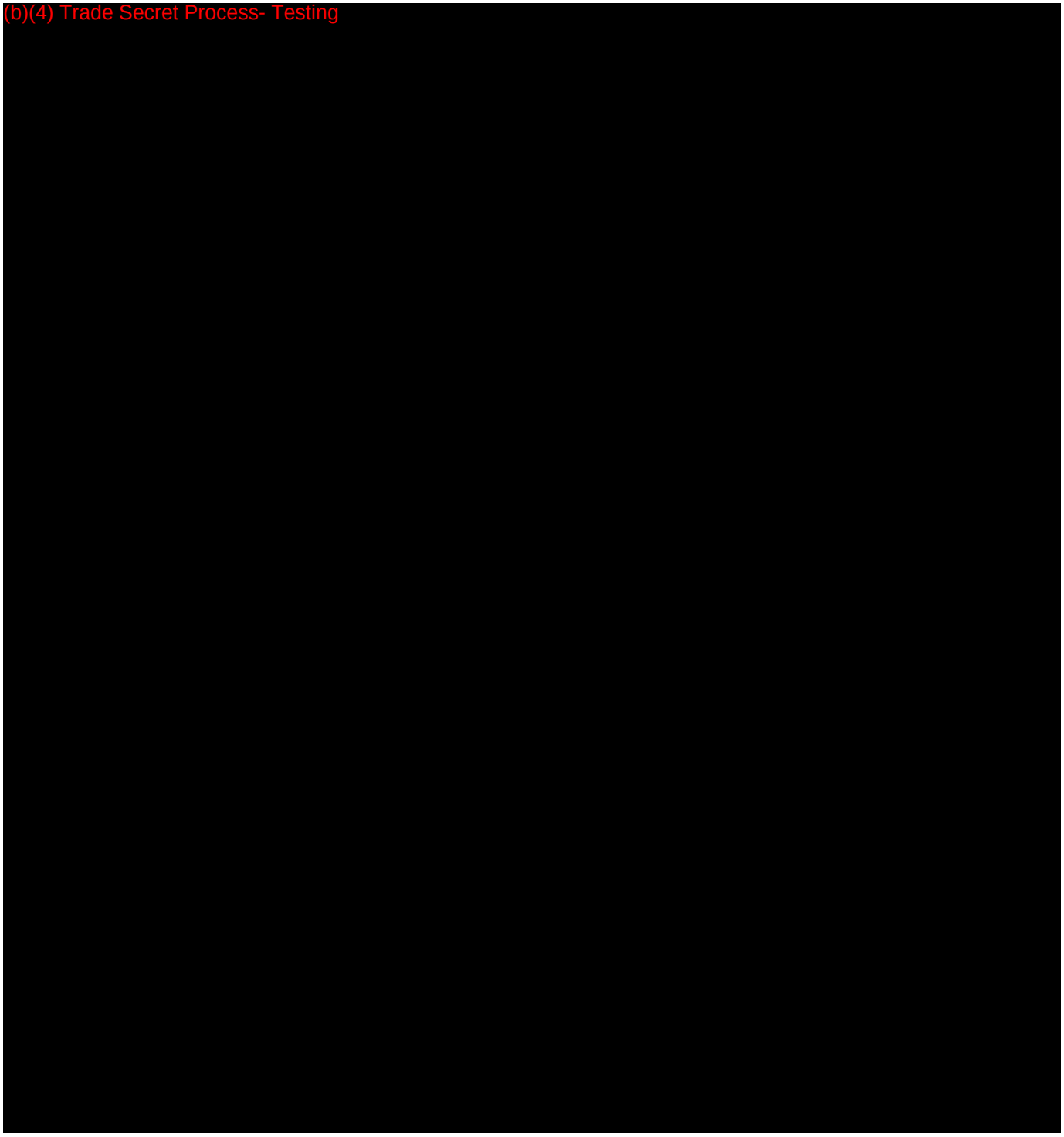


Figure 20-1

(b)(4) Trade Secret Process- Testing

(b)(4) Trade Secret Process- Testing



(b)(4) Trade Secret Process- Testing

Table 20-2

(b)(4) Trade Secret Process- Testing

20.3 Conclusions from the Simulated-Use and Clinical Performance Testing

Rotation Medical (b)(4) Trade Secret Process- Testing

Additionally, the functional integrity and safety of the cartridge (b)(4) Trade Secret Process- Testing

Appendix A – (b)(4) Trade Secret Process- Testing

(b)(4) Trade Secret Process- Testing

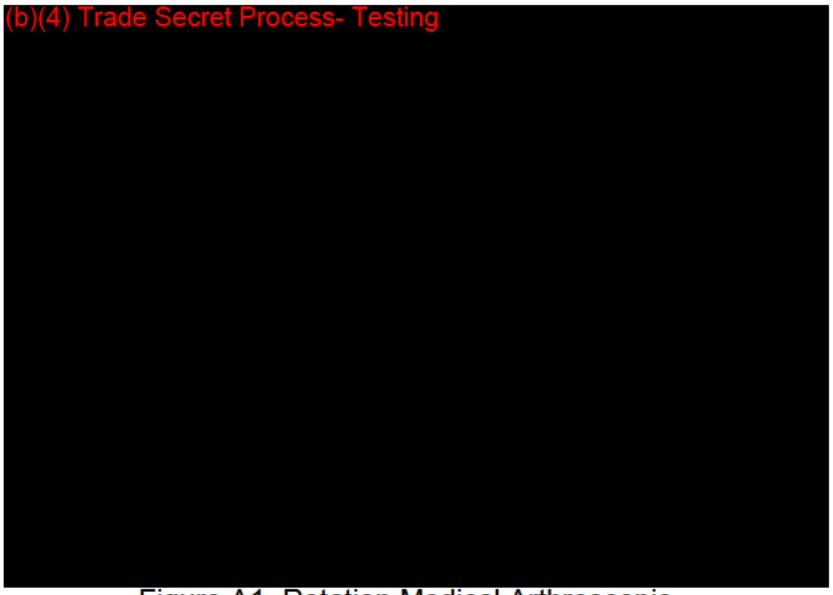
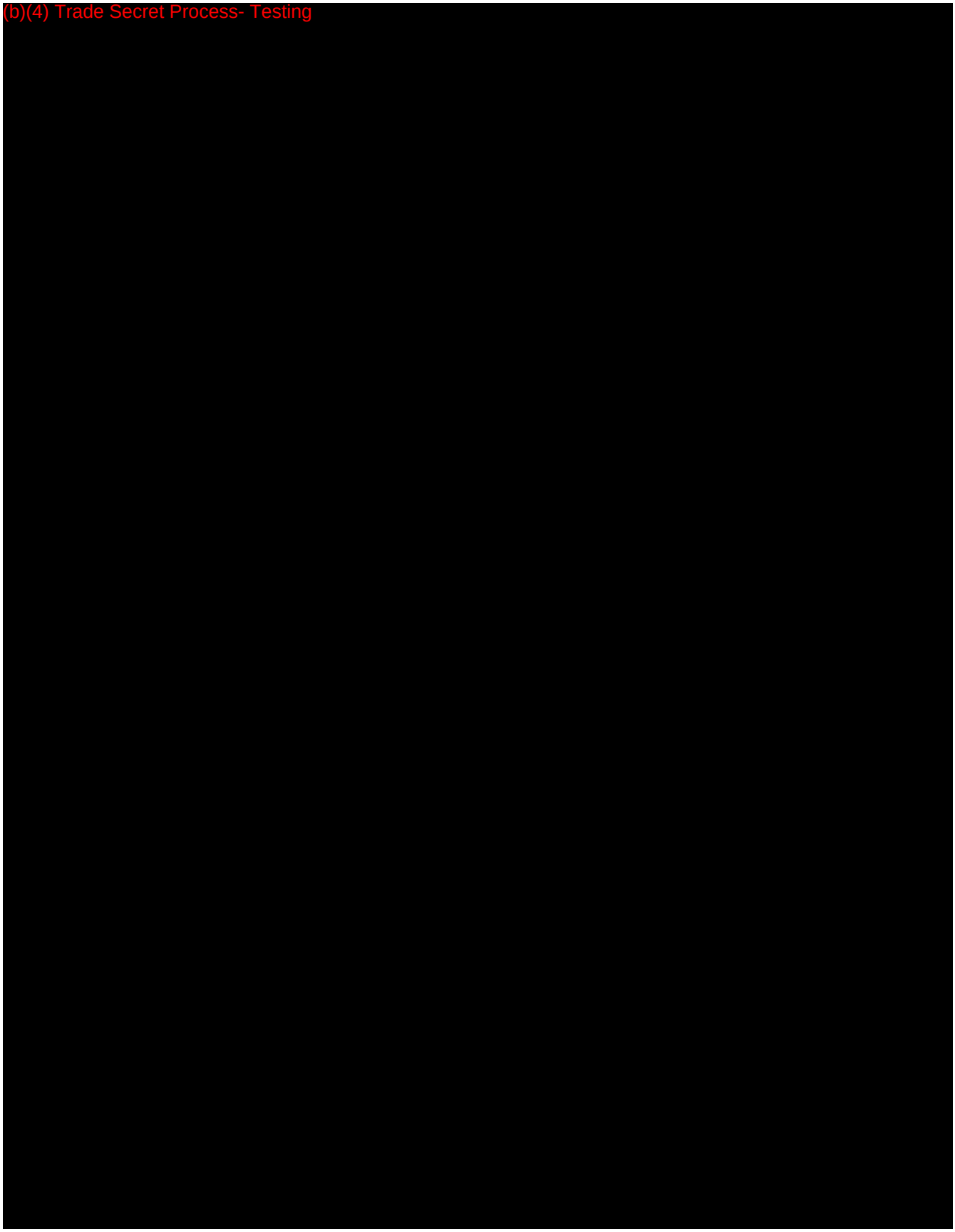


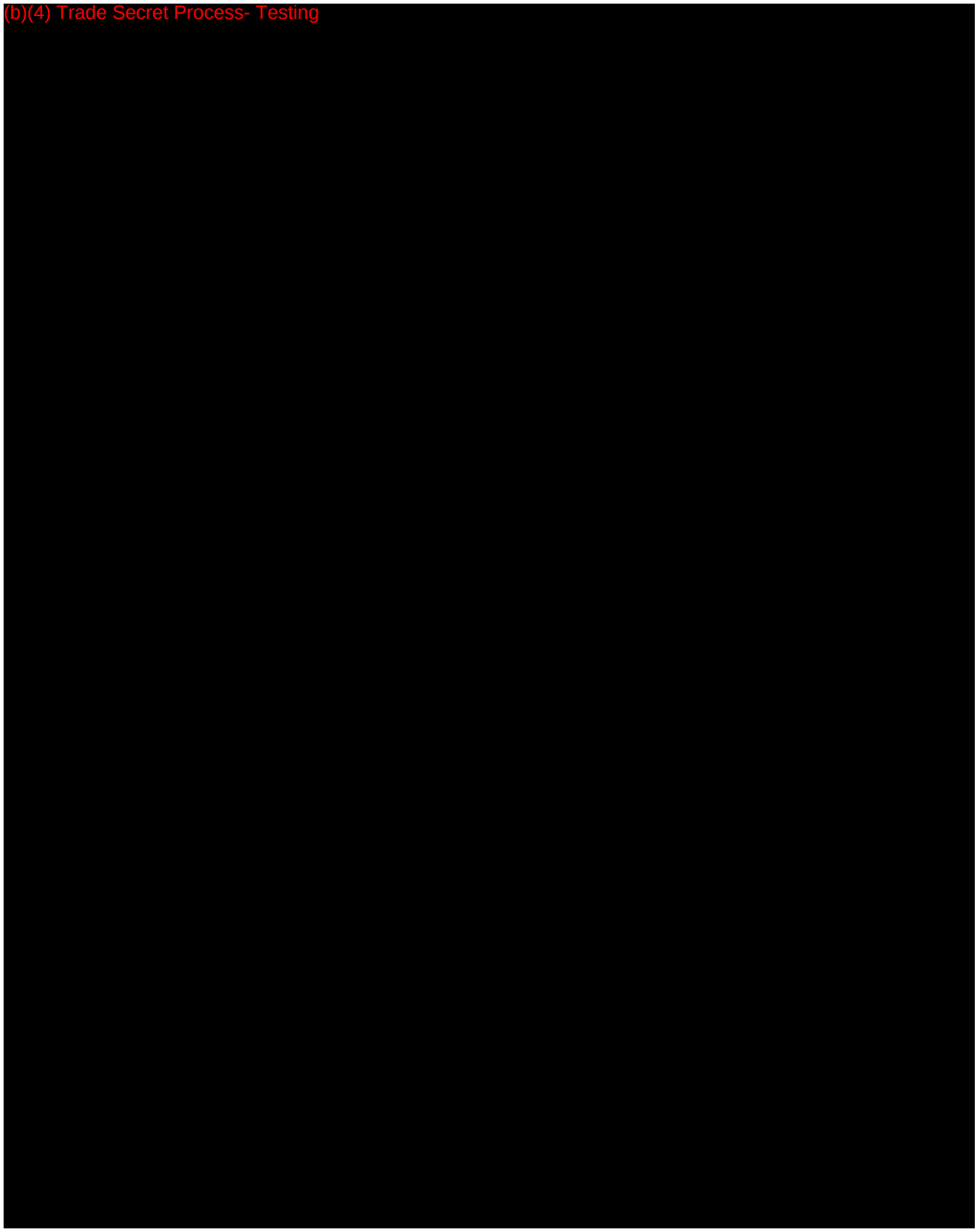
Figure A1. Rotation Medical Arthroscopic
Delivery Instrumentation for Collagen Tendon Sheet-DDI

(b)(4) Trade Secret Process- Testing

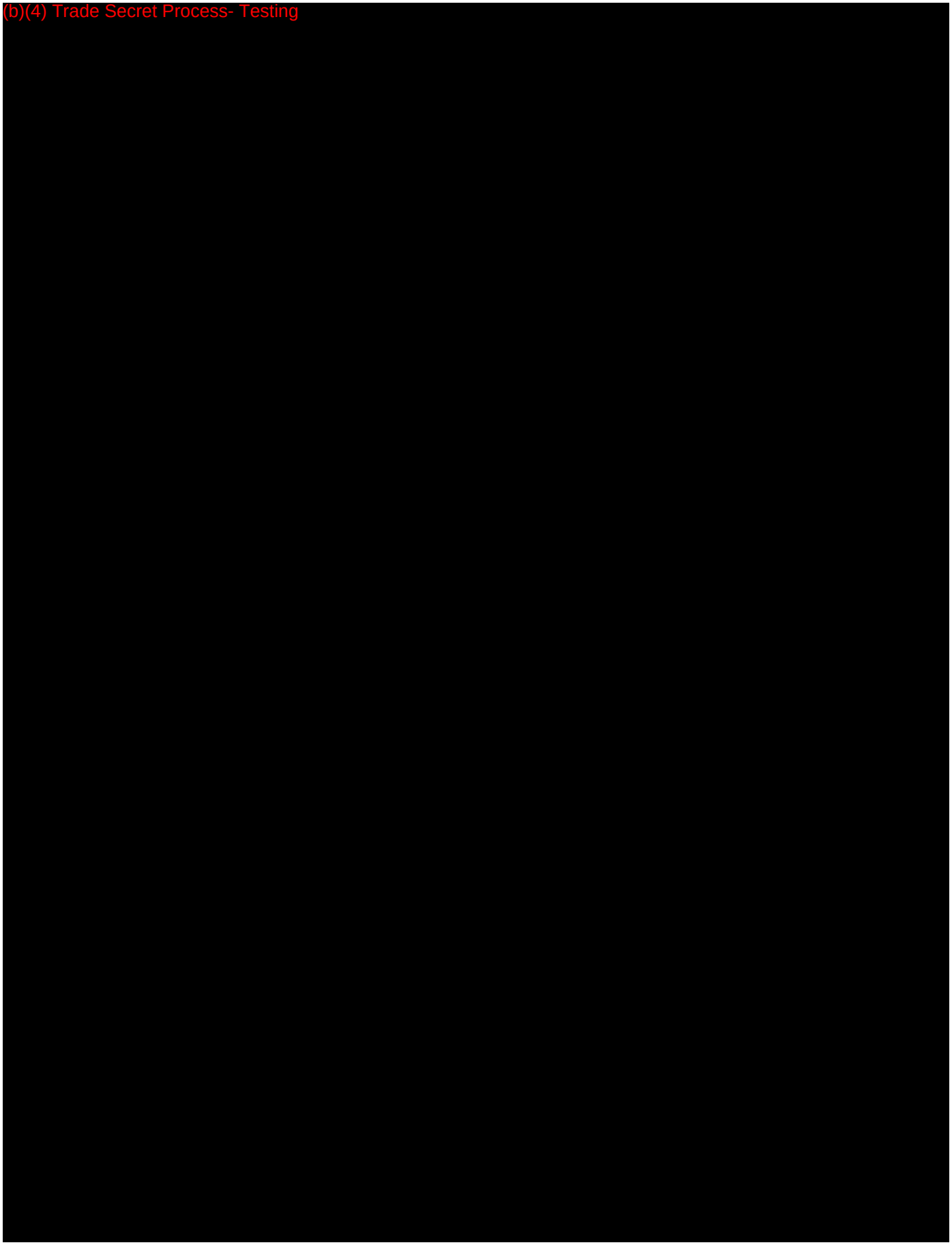
(b)(4) Trade Secret Process- Testing



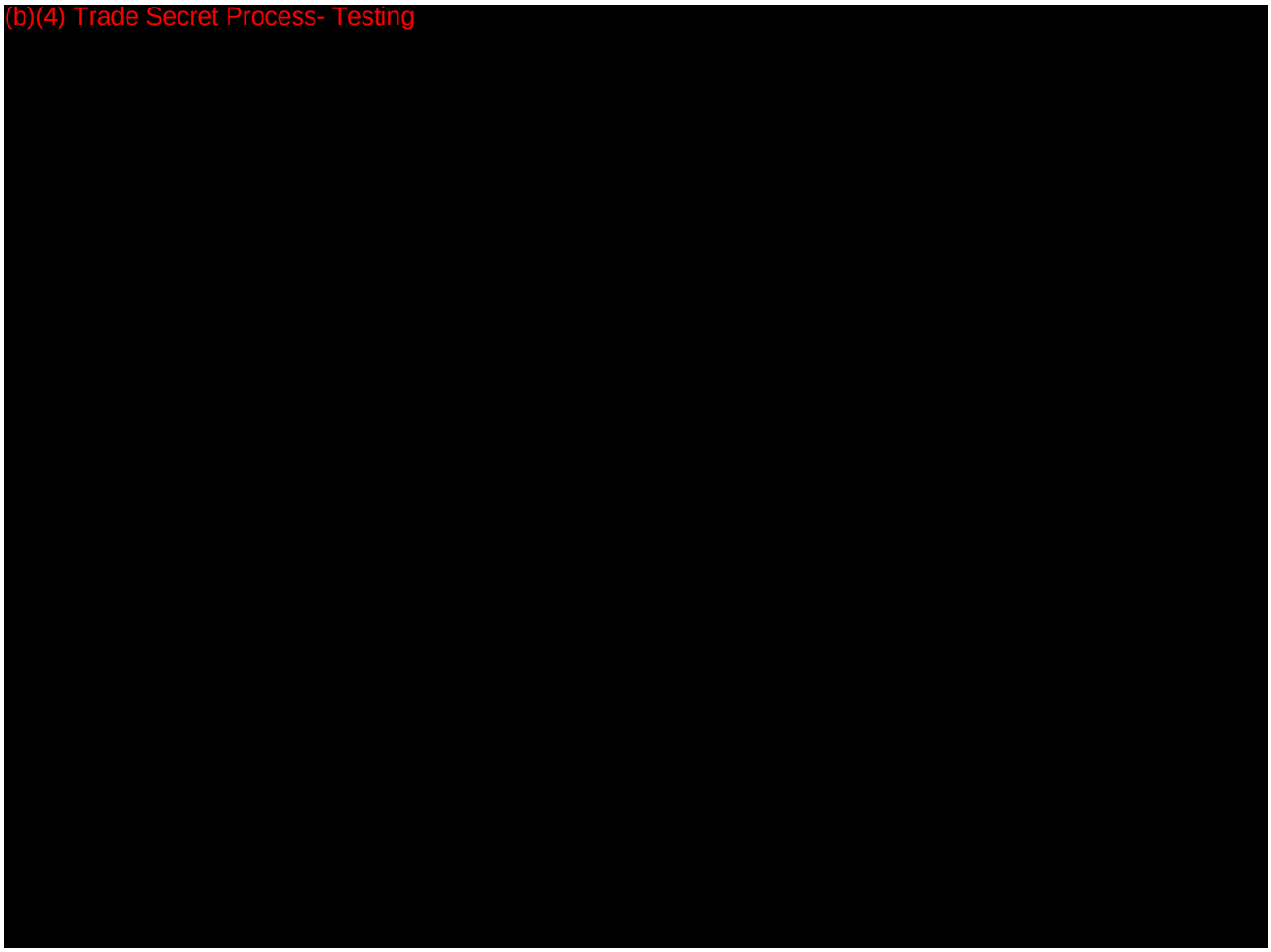
(b)(4) Trade Secret Process- Testing



(b)(4) Trade Secret Process- Testing



(b)(4) Trade Secret Process- Testing



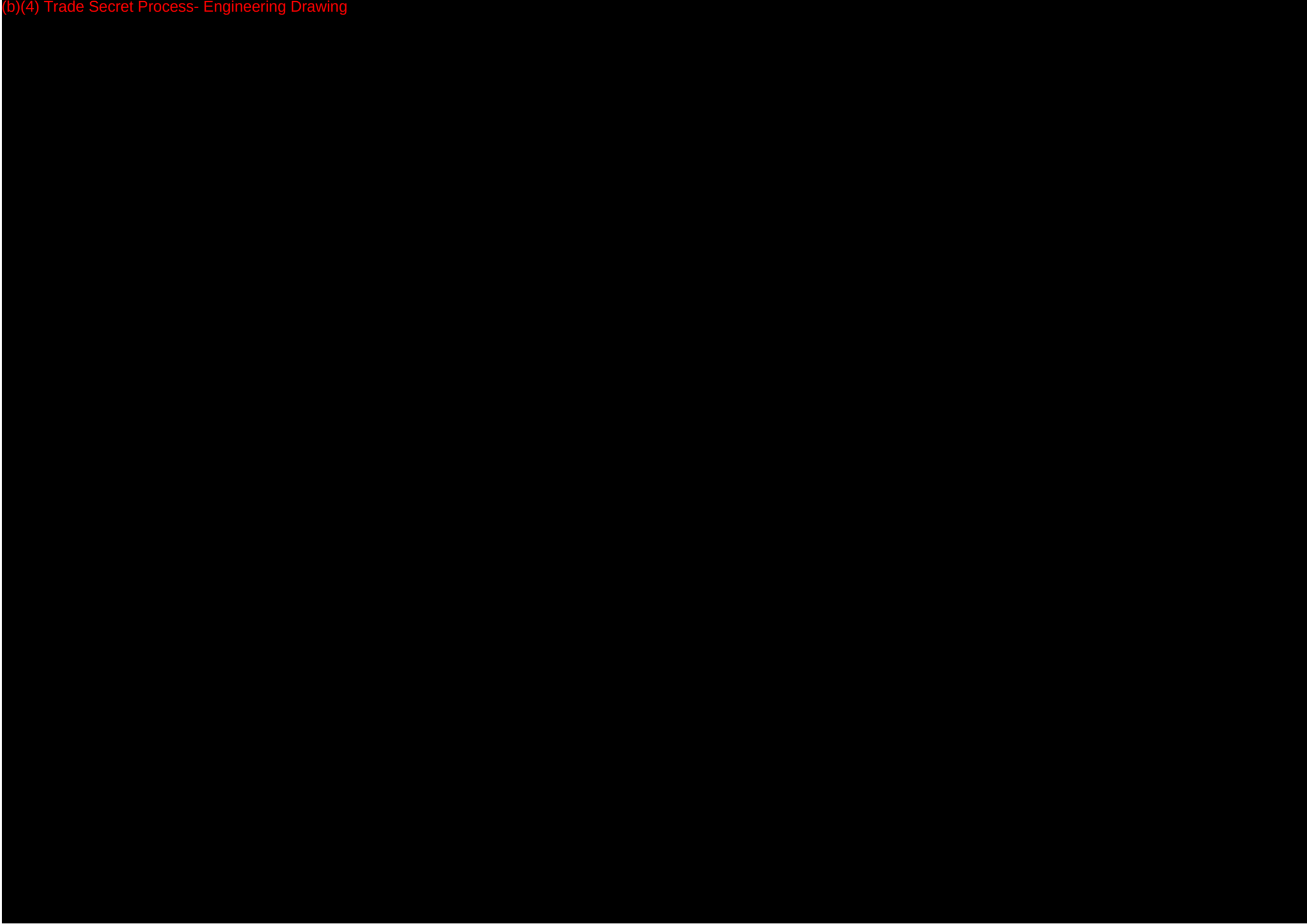
(b)(4) Trade Secret Process- Testing

Instrument	Nominal Length	Nominal Width
(b)(4) Trade Secret Process- Testing		

Table 1 Dimensions of Acute Surgical Instrumentation

(b)(4) Trade Secret Process- Testing

(b)(4) Trade Secret Process- Engineering Drawing


(b)(4) Trade Secret Process- Engineering Drawing

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(b)(4) Trade Secret Process- Testing Report

Collagen Tendon Sheet-DDI

REF XXXXXX

Quantity: 1 Membrane

Size: XXXXXXXXX

LOT XXXXXXXXXX

YYYY-MM
EXPIRATION DATE

DO NOT RE-USE

STERILE EO Non-pyrogenic

℞ only

ATTENTION,
SEE INSTRUCTIONS FOR USE

(b)(4) Trade Secret Process - Product

Rotation Medical, Inc., 15350 25th Avenue North, Suite 100, Plymouth, MN 55447 USA

(b)(4) Trade Secret Process- Product Specs

CTS-DDI label draft

Collagen Tendon Sheet-DDI (CTS-DDI)

Description

Collagen Tendon Sheet-DDI (CTS-DDI) is a bioabsorbable implant device that provides a layer of collagen over injured tendons. CTS-DDI is designed to provide a layer of collagen between a flat tendon and the surrounding tissue. After hydration, CTS-DDI is an easy-to-handle, soft, pliable, nonfriable, porous collagen sheet. CTS-DDI is provided sterile, non-pyrogenic, for single use only, in a variety of sizes, and is packaged pre-loaded in a cartridge, for use with the Rotation Medical Delivery Instrument, in a dual sterile seal tray-in-tray configuration.

Indications for Use

Collagen Tendon Sheet-DDI 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-DDI 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-DDI is not indicated to replace damaged tendon or to reinforce the strength of any tendon repair.
- Collagen Tendon Sheet-DDI 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 CTS-DDI size that is slightly smaller than the width of the tendon.
4. Pre-hydrate CTS-DDI, in the cartridge, in sterile saline for at least 2 minutes.
5. After hydration, use the Rotation Medical Delivery Instrument and accessories to assist in positioning the scaffold over the tendon with one end overlapping the tendon insertion. Reference Delivery Instrument IFU.
6. Secure the CTS-DDI to the tendon and bone. Ensure that CTS-DDI 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-DDI does not modify the postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice.

Warnings

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

Precautions

- Collagen Tendon Sheet-DDI 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-DDI is supplied sterile for single-use, and is packaged pre-loaded in a cartridge, for use with the Rotation Medical Delivery Instrument, in a dual sterile seal tray-in-tray configuration. Contents of the package are guaranteed sterile and non-pyrogenic unless the package is opened or damaged. The CTS-DDI 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

(b)(4) Trade Secret Process-
Rotation Medical, Inc.
15350 25th Ave. N., Plymouth, MN 55447 USA
(b)
(4)
Tr

Rotation Medical Delivery Instrument

Description

The Rotation Medical Delivery Instrument consists of the delivery instrument and a "clamshell" which is used to facilitate attachment of the cartridge containing the Rotation Medical Scaffold onto the end of the delivery instrument. The Rotation Medical Delivery Instrument is provided sterile, non-pyrogenic, for single-use only in a dual sterile seal tray-in-tray configuration.

Indications for Use

The Scaffold Delivery Instrument is indicated for arthroscopic delivery of the Rotation Medical Scaffold into the subacromial space.

Contraindications

The Scaffold Delivery Instrument is not designed, sold, or intended for use except as described in the indications for use and is contraindicated in the following situation:

- The Scaffold Delivery Instrument is not indicated for use with scaffolds manufactured by any company other than Rotation Medical.

Instructions for Use

1. Place the cartridge containing the Rotation Medical Scaffold into the clamshell with the slot in the introducer tube engaging with the nub on the blue side of the clamshell and snap the clamshell closed.
2. Submerse the clamshell containing the cartridge in sterile saline for at least 2 minutes to hydrate the scaffold.
3. After hydration, snap the clamshell onto the end of the delivery instrument with the blue side of the clamshell facing down.
4. Pinch the wings of the clamshell and pull the clamshell, including the introducer tube, off of the delivery instrument.
5. Insert the guidewire into the small hole in the shaft of the delivery instrument and advance the cartridge down the guidewire until the cartridge has passed through the arthroscopic portal into the subacromial space. The cartridge is fully advanced to the desired location when the red button on the back of the delivery instrument is pushed out.
6. Press the trigger release button on the side of the delivery instrument and squeeze the trigger to retract the sheath, which allows the scaffold to flatten out over the tendon.
7. While holding the handle of the delivery instrument, align the scaffold with the direction of the tendon and maintain that position and alignment while the scaffold is attached to the tendon.
8. After the scaffold has been securely attached to the tendon, pull back on the delivery instrument to remove it from the arthroscopic portal. The Nitinol fingers will easily bend to allow removal.

Warnings

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

Precautions

- The cartridge should not be delivered into the subacromial space unless it is securely snapped onto the end of the delivery instrument.

Storage

Store at room temperature.

How Supplied

The Scaffold Delivery Instrument is supplied sterile for single-use in a dual sterile seal tray-in-tray configuration. Contents of the package are guaranteed sterile and non-pyrogenic unless the package is opened or damaged. The Scaffold Delivery Instrument 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 by:

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

(b)(4) Trade Secret Process- Testing

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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]

ISO 11135-1, Sterilization of health care products - Ethylene oxide - Part 1, 2007

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-331	
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
ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B	Conservative determination of lethal rate of the sterilization process, Overkill	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Annex B is the option selected.

DESCRIPTION
PCDs and biological indicators were used in fractional cycle analyses; sterilization for the device was then subjected to a full cycle at least double the half cycle.

JUSTIFICATION
The methods of sterilization assurance are recognized by the standard and implemented by the contract sterilizer, (b)(4) Trade Secret using established procedures in their facilit(b)(4) Trade S t certified as a Contract Sterilization Service using ISO 11135-1.

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

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 10993-1:2003, Biologic Evaluation of medical devices - Part 1

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: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation..."

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1:2003, Biologic Evaluation of medical devices - Part 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10993-5:2009	(b) (4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Tests performed by (b) (4) in accordance with the standard and established professional business practices.

DESCRIPTION
(b) (4)

JUSTIFICATION
(b)(4) Trade Secret Process- Product Specs

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10993-10:2010	(b) (4)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Tests performed (b) (4) in accordance with the standard and established professional business practices.

DESCRIPTION
(b)(4) Trade Secret Process- Product Specs

JUSTIFICATION
(b)(4) Trade Secret Process- Product Specs

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

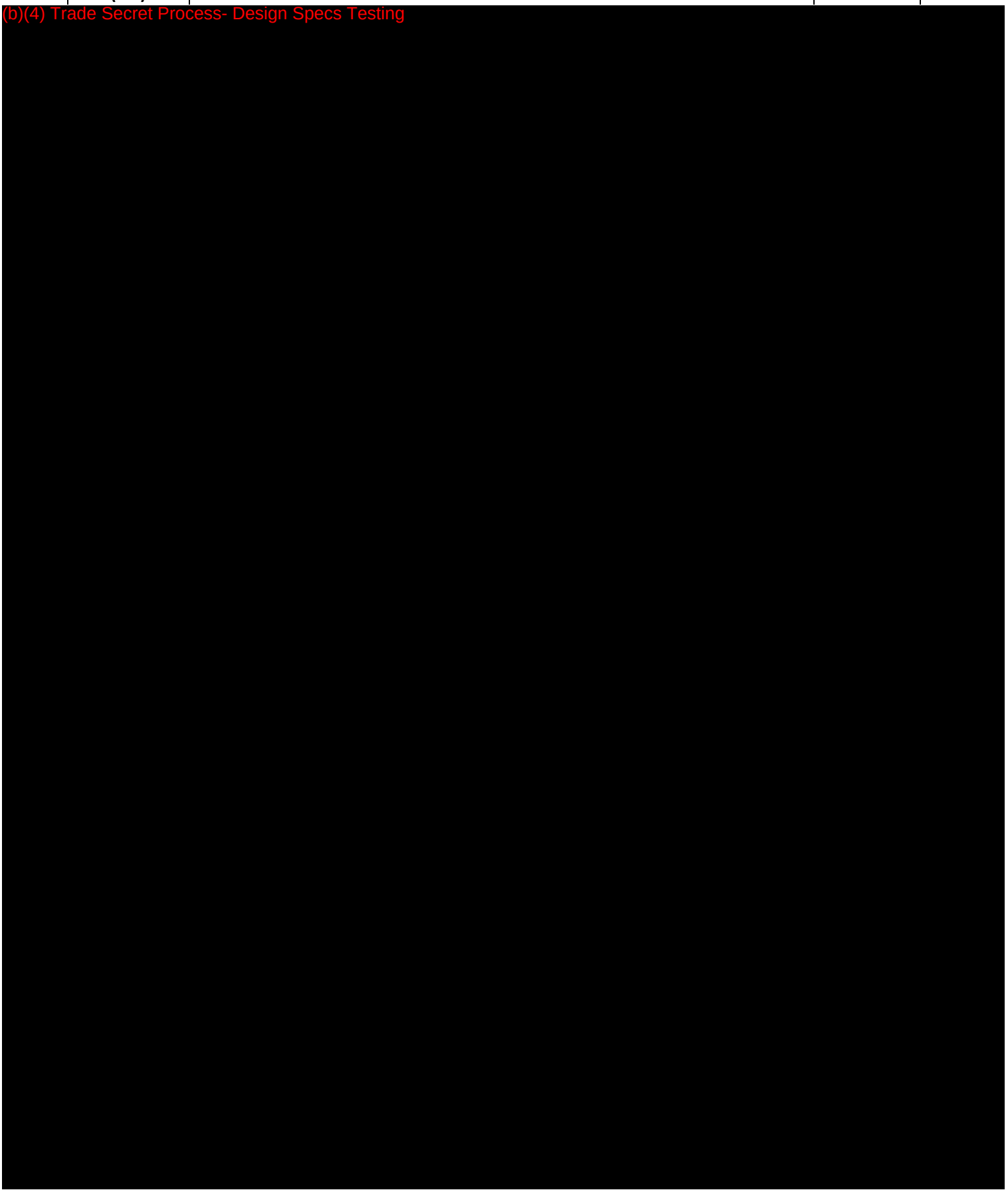
DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

(b)(4) Trade Secret Process- Design Specs Testing



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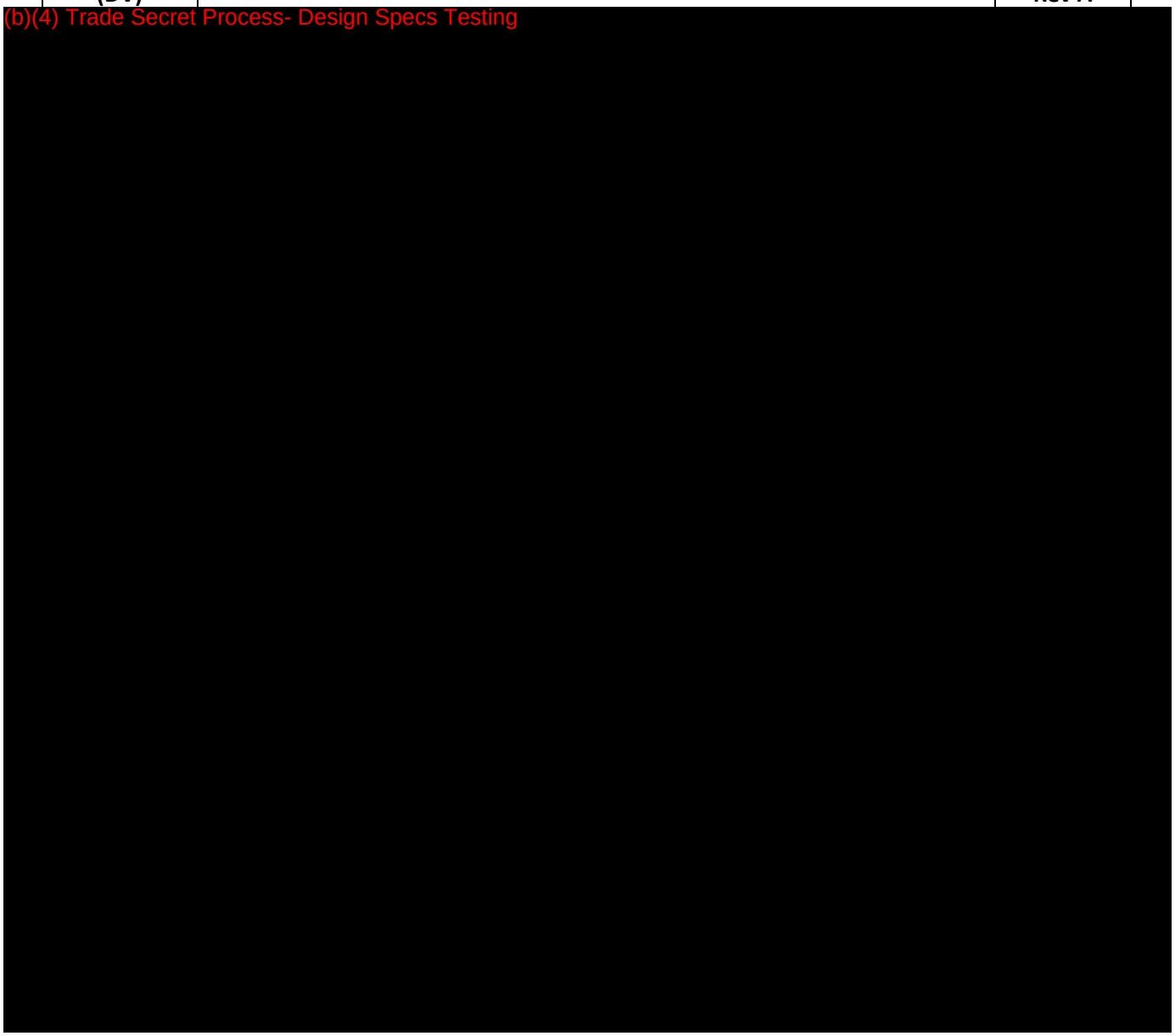

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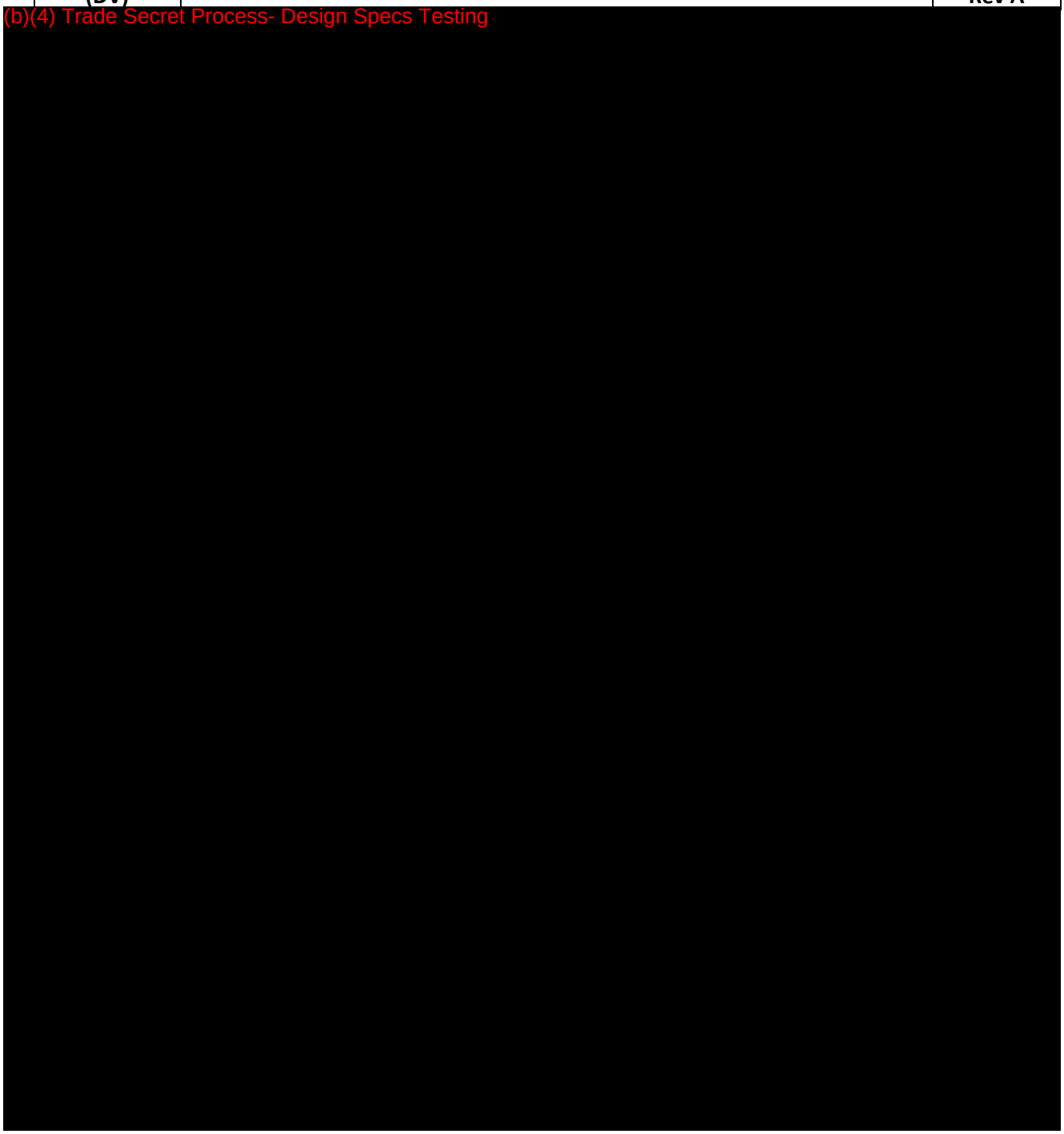

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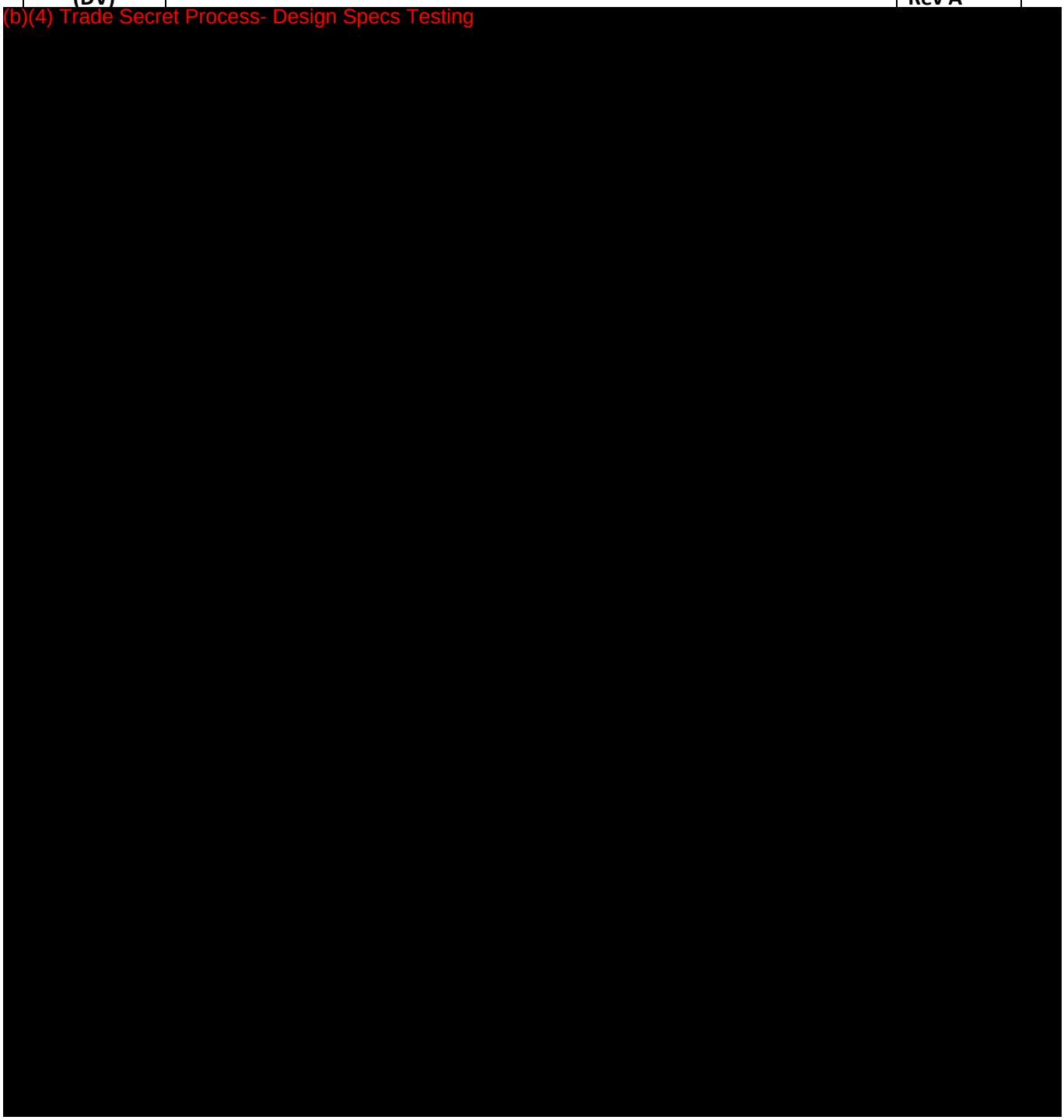

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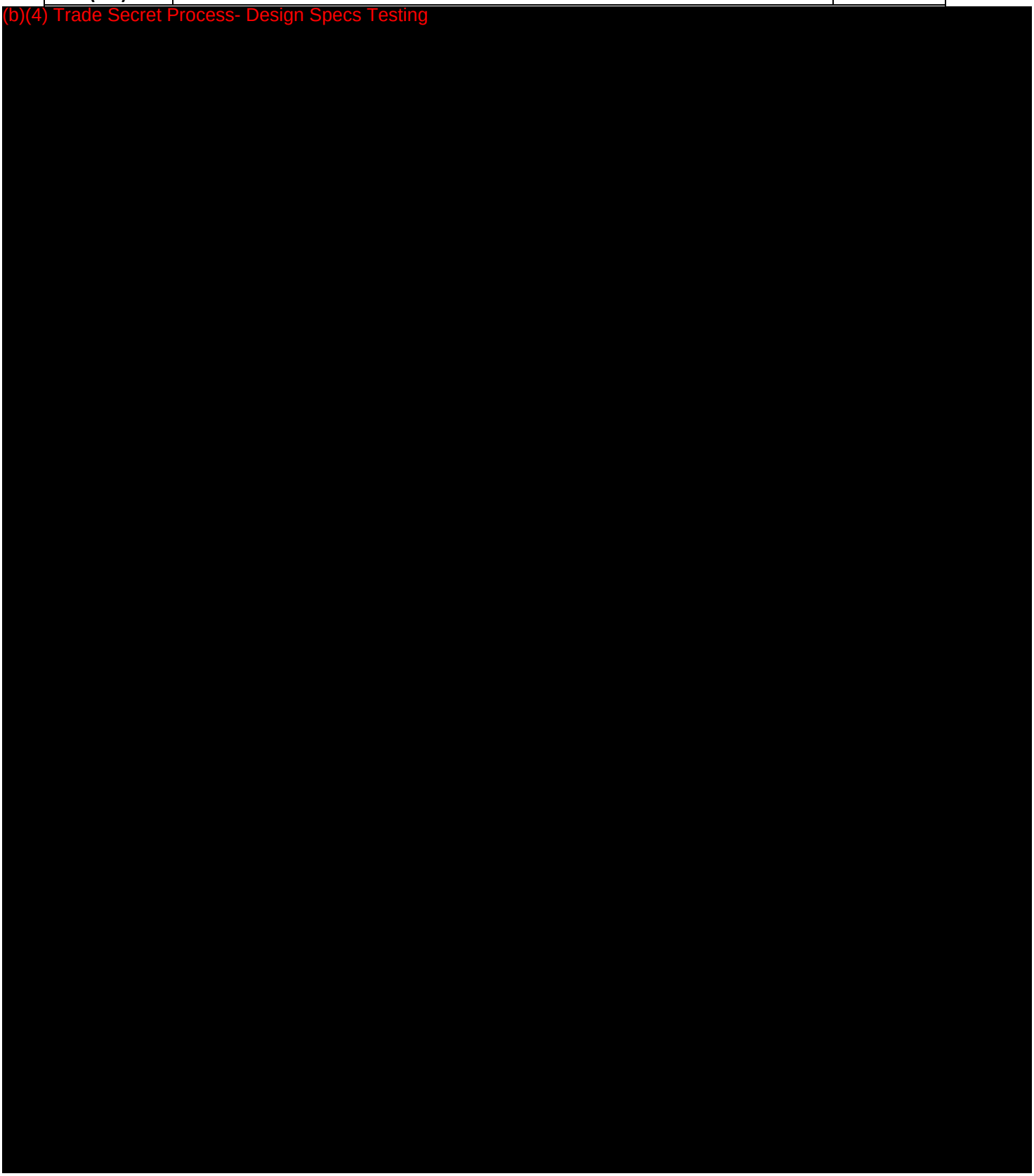

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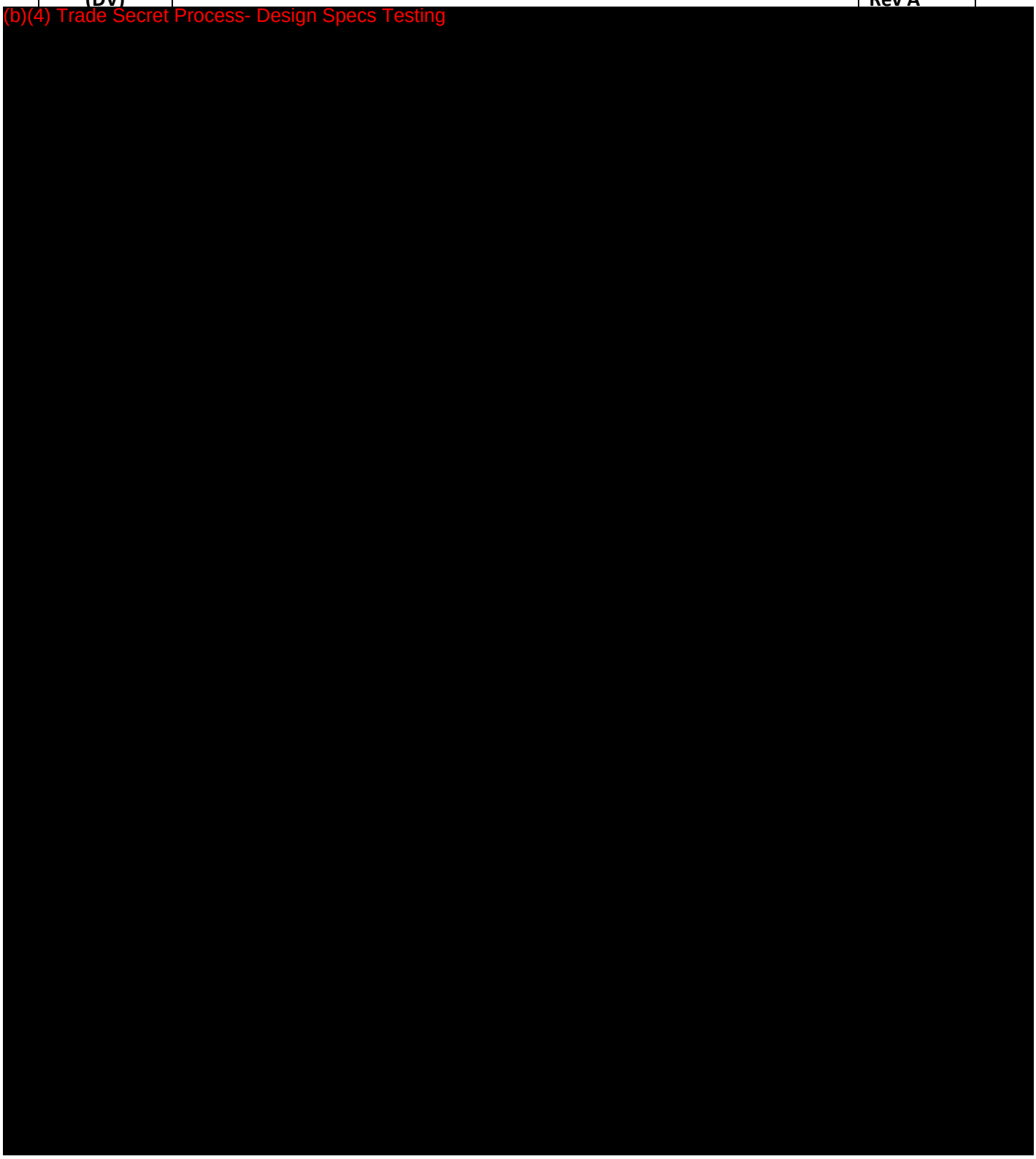

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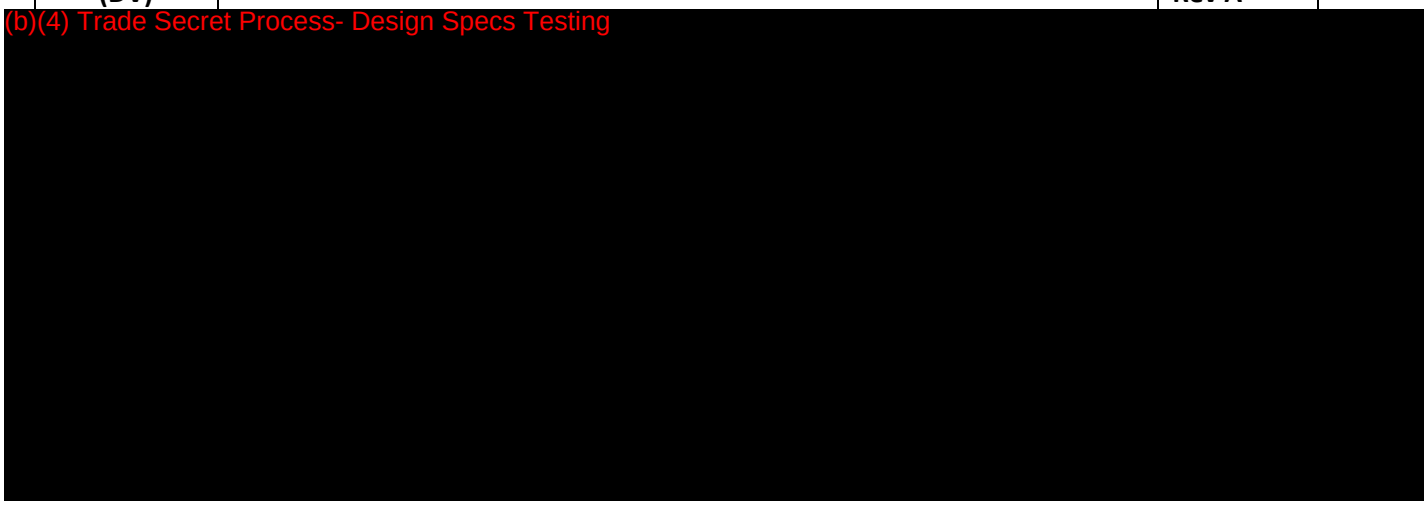

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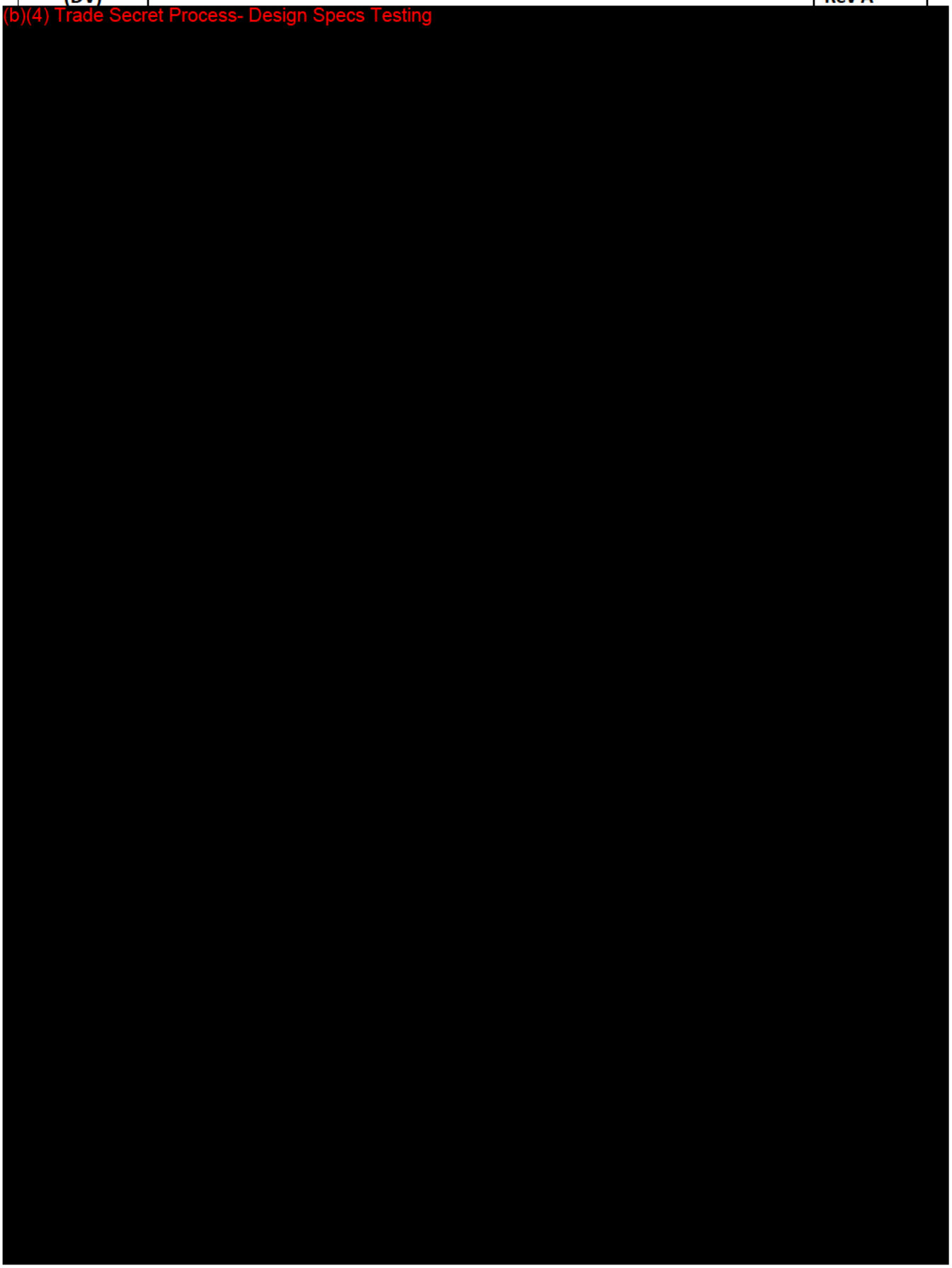

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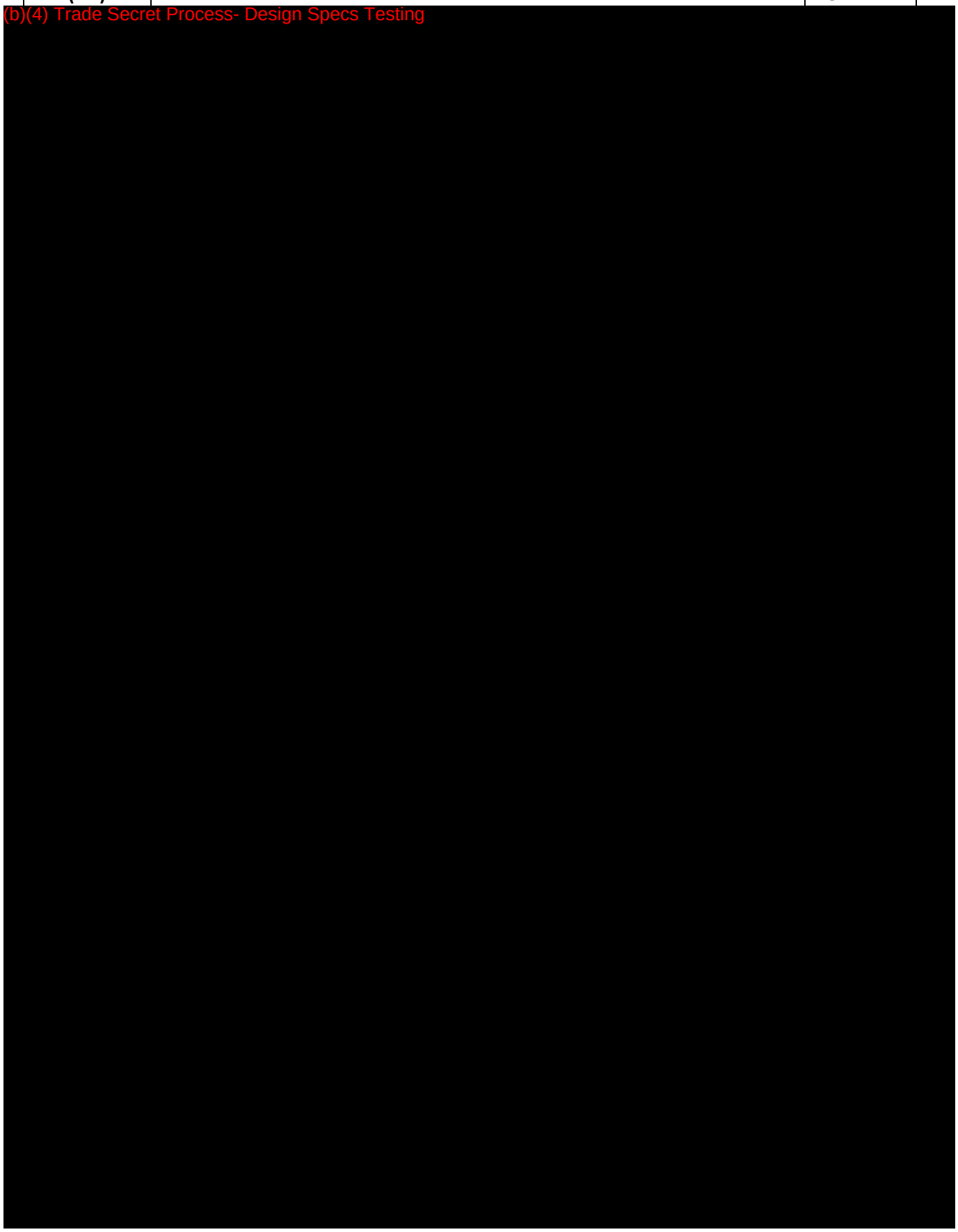

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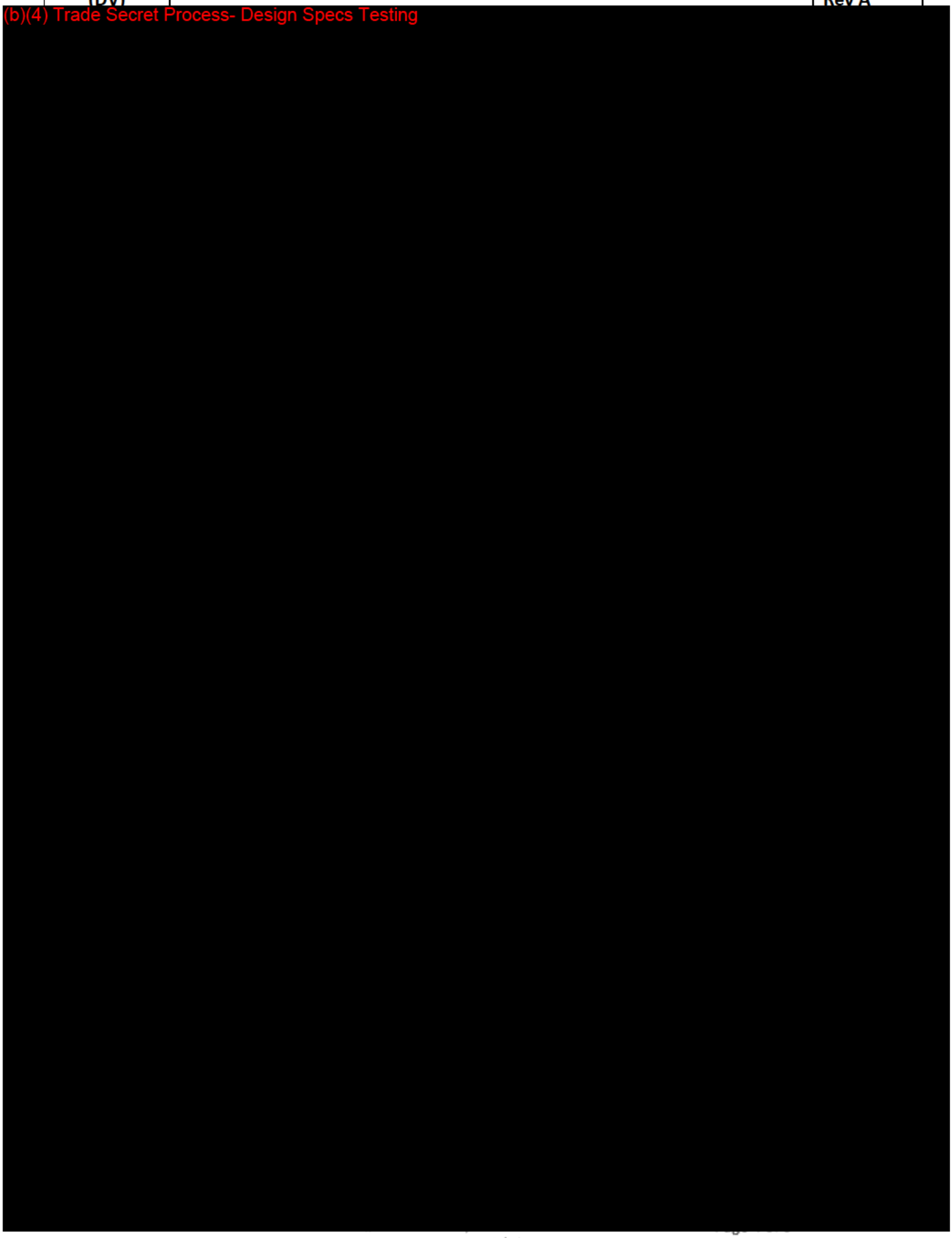

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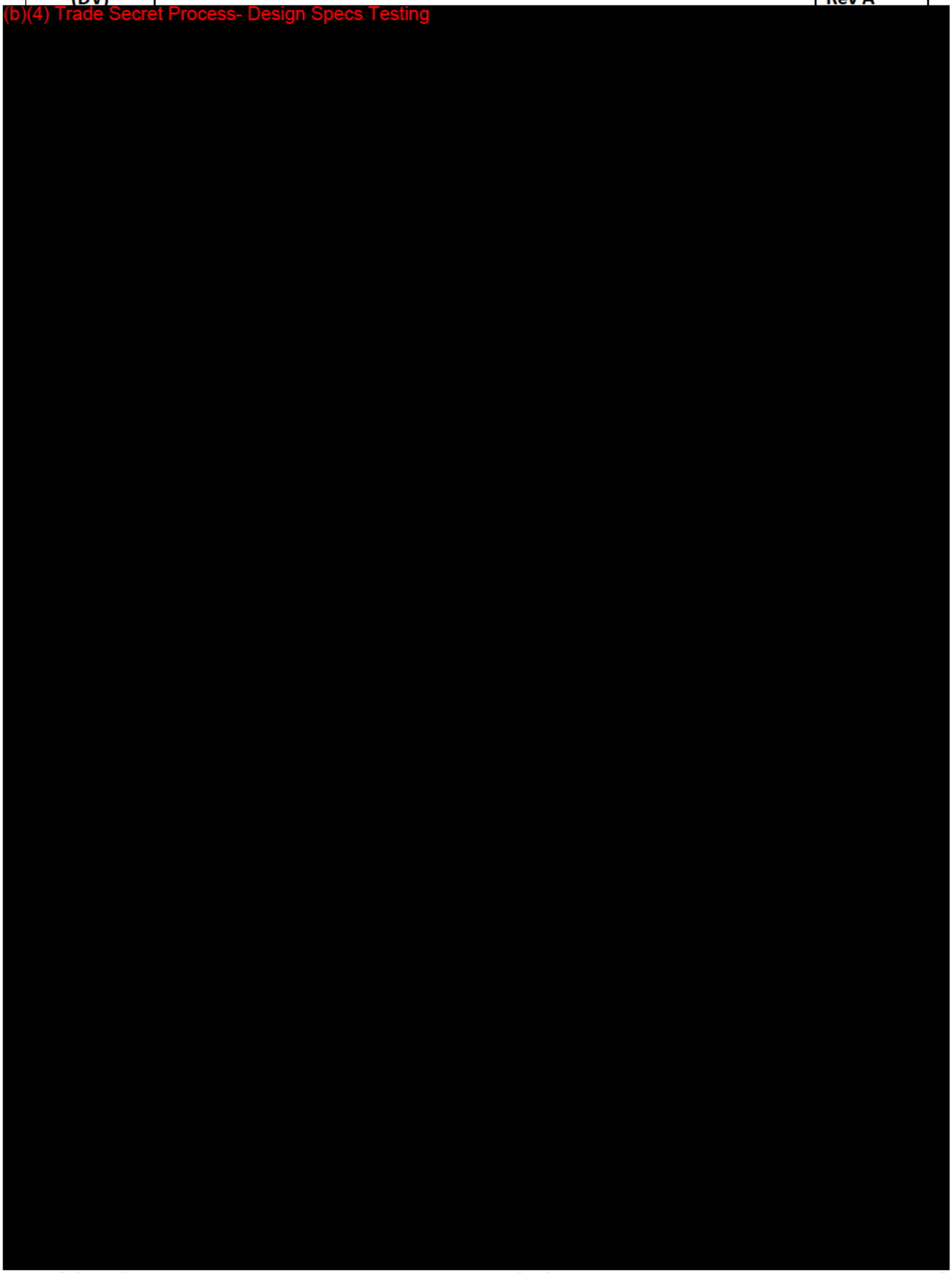

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Design Verification (DV)	Rotation Medical, Inc	Doc Num 2304 Rev A

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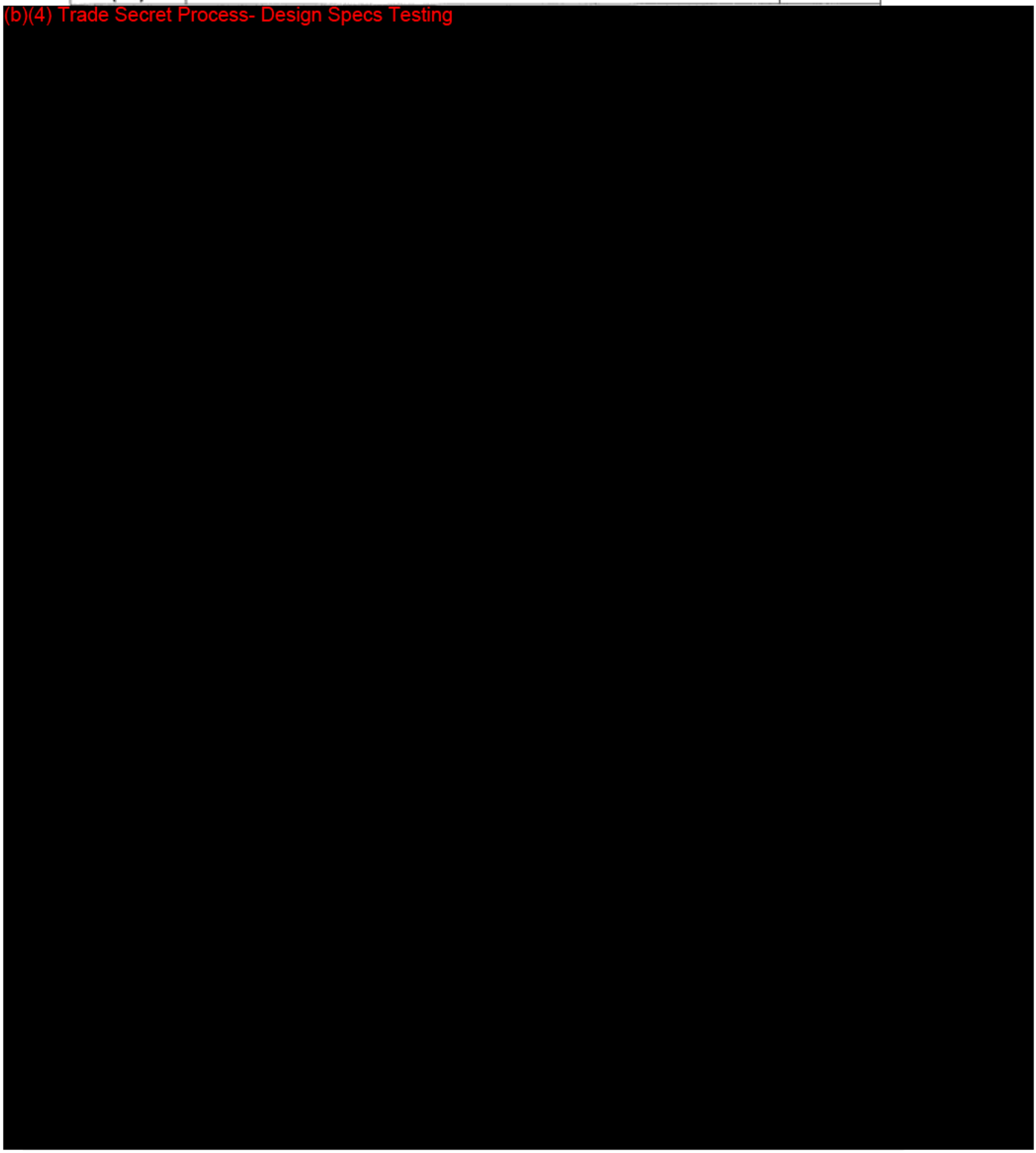

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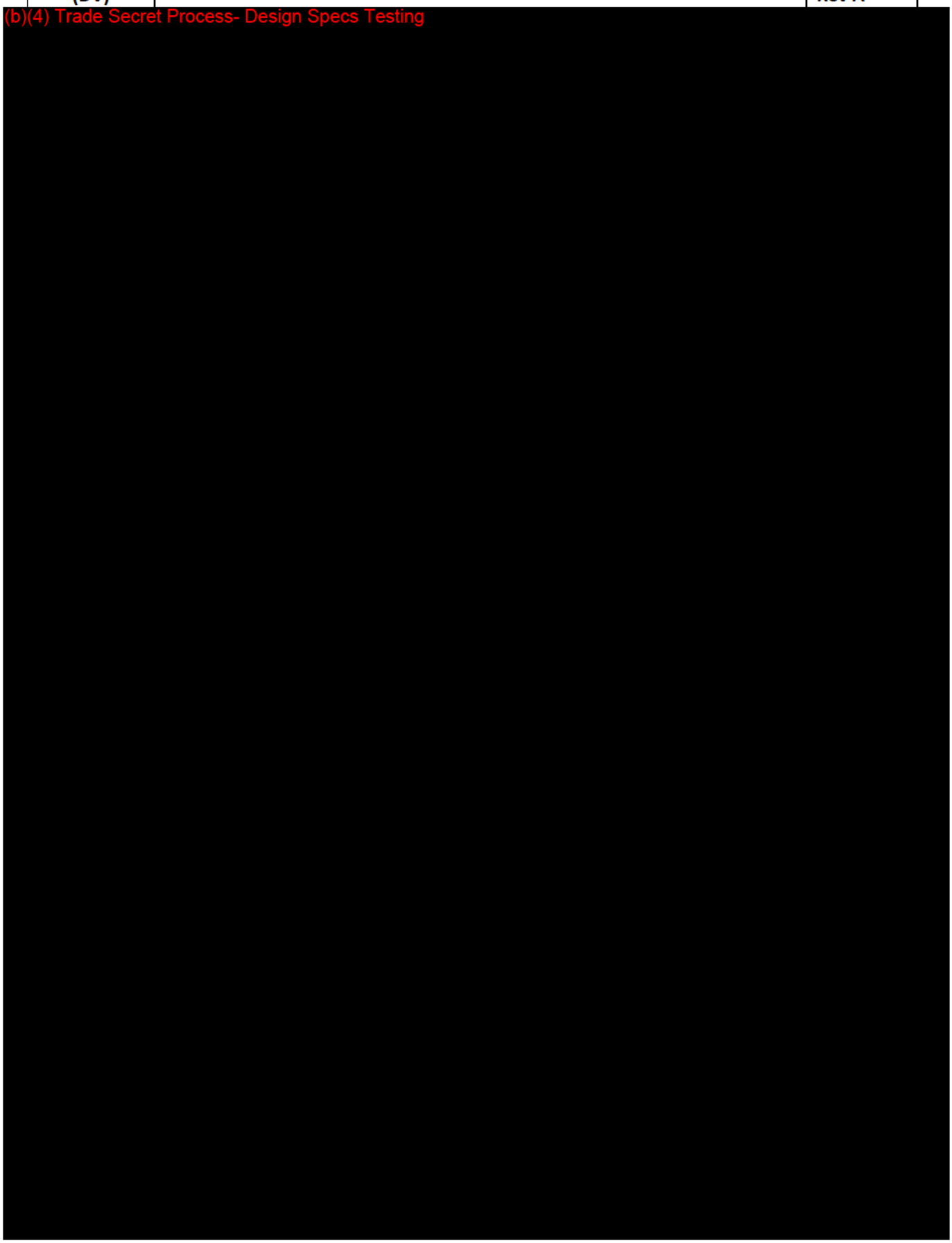

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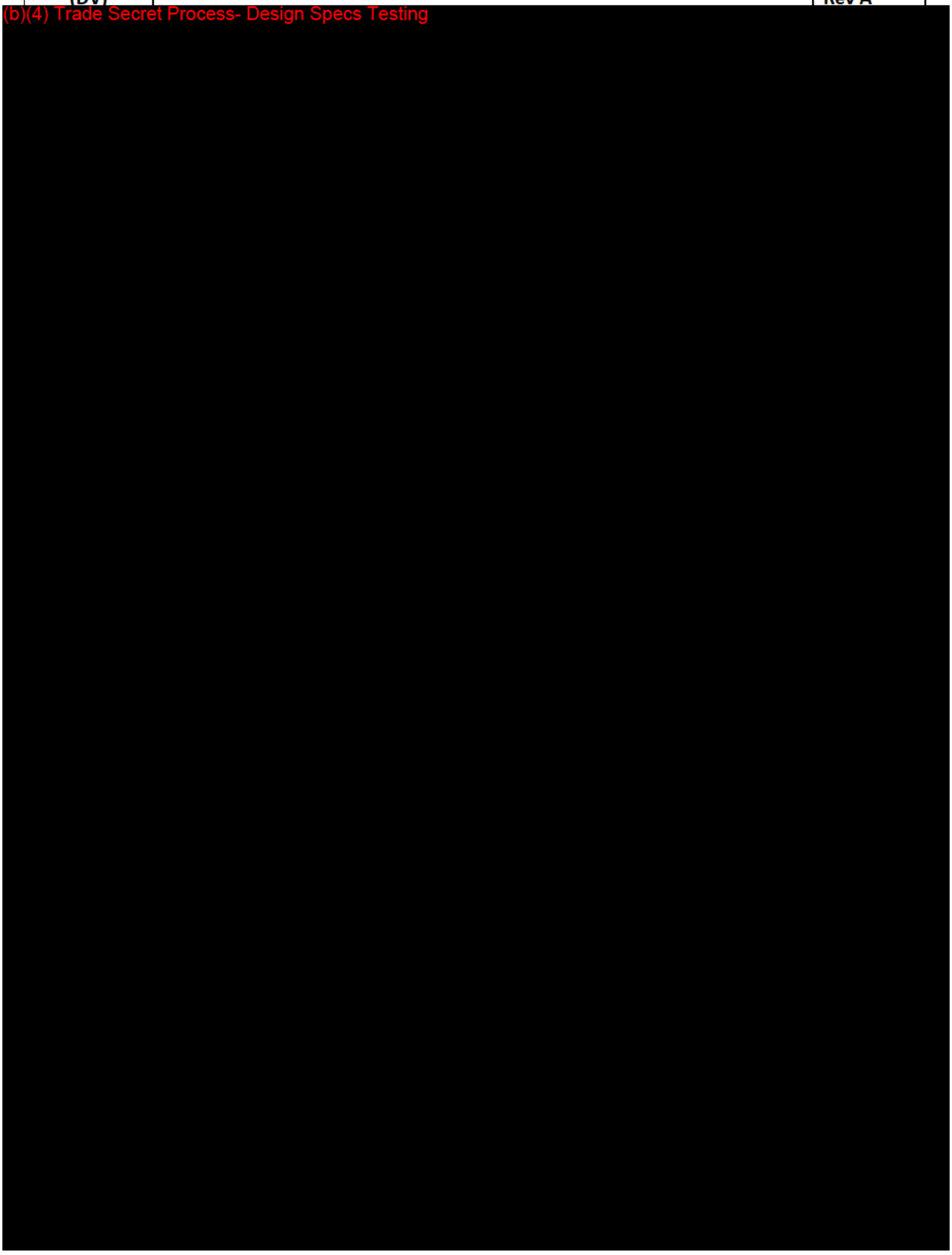

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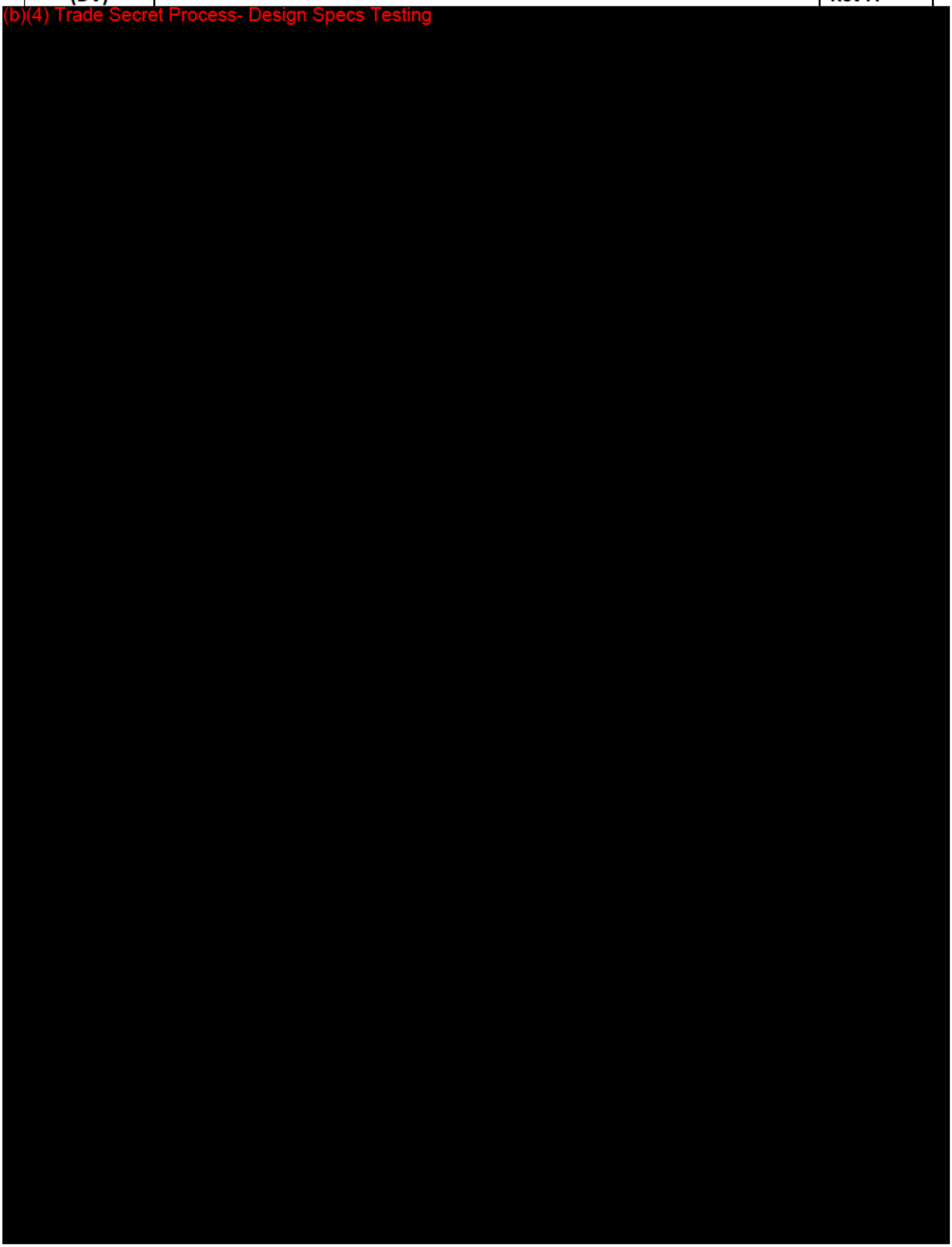

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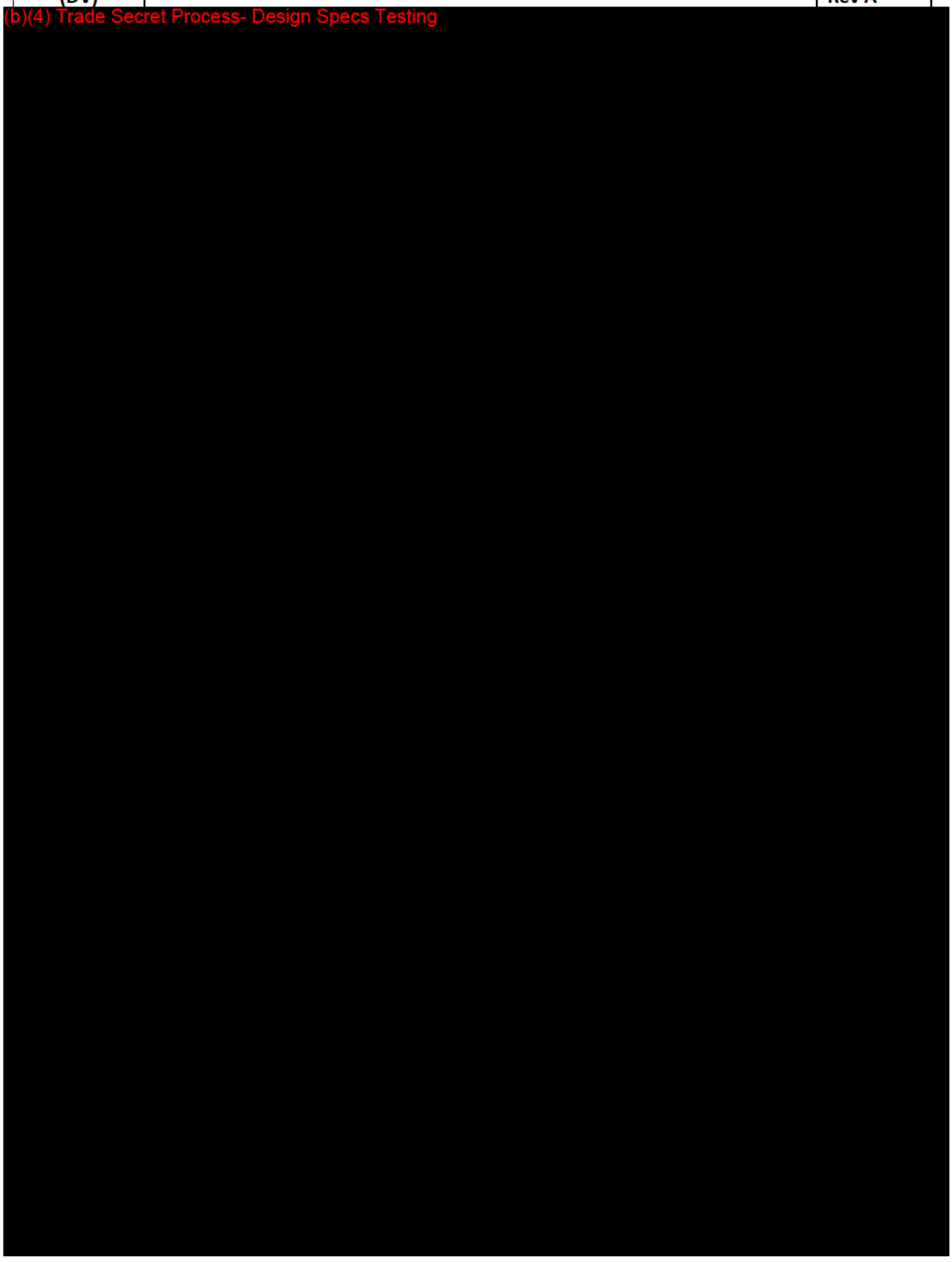

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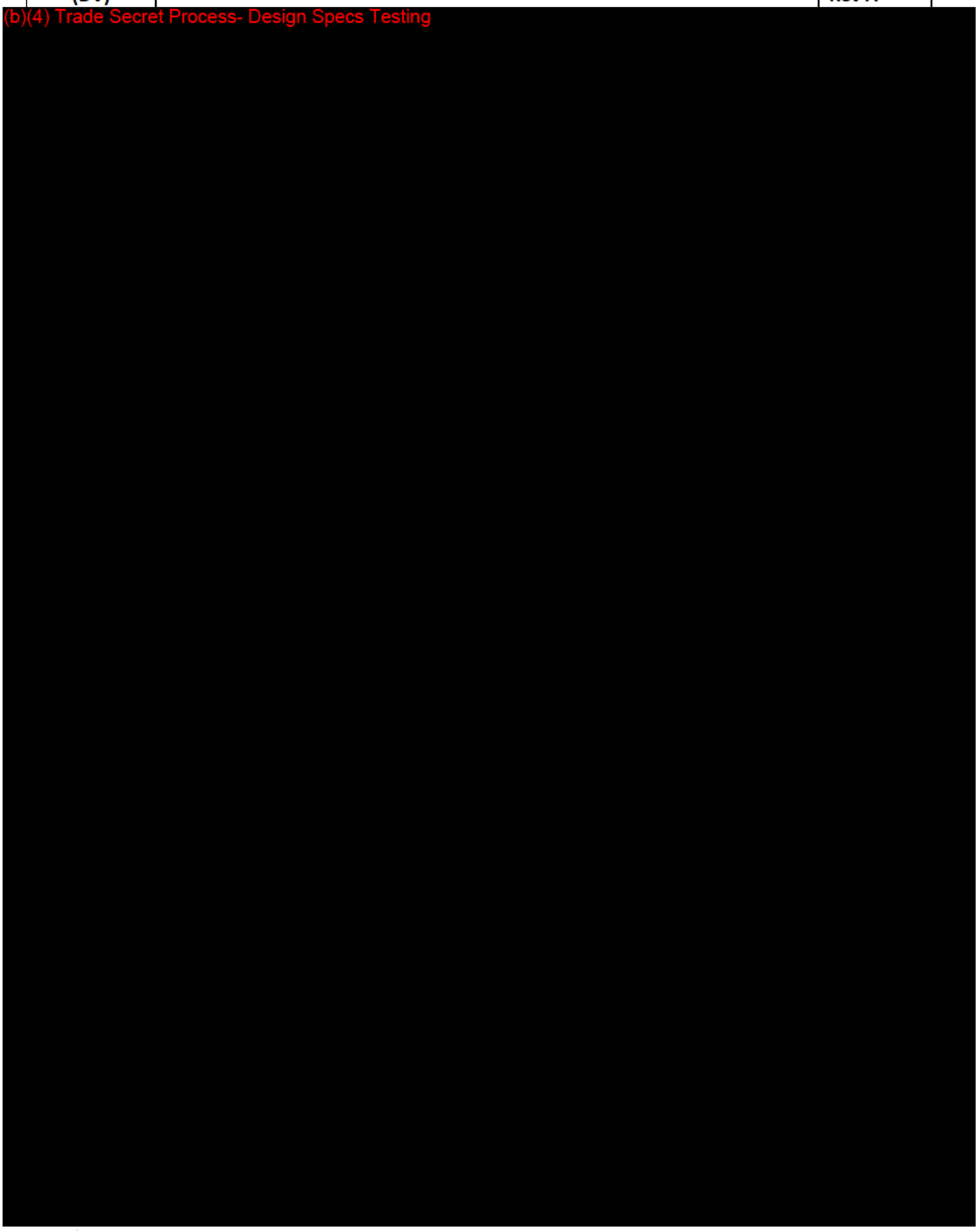

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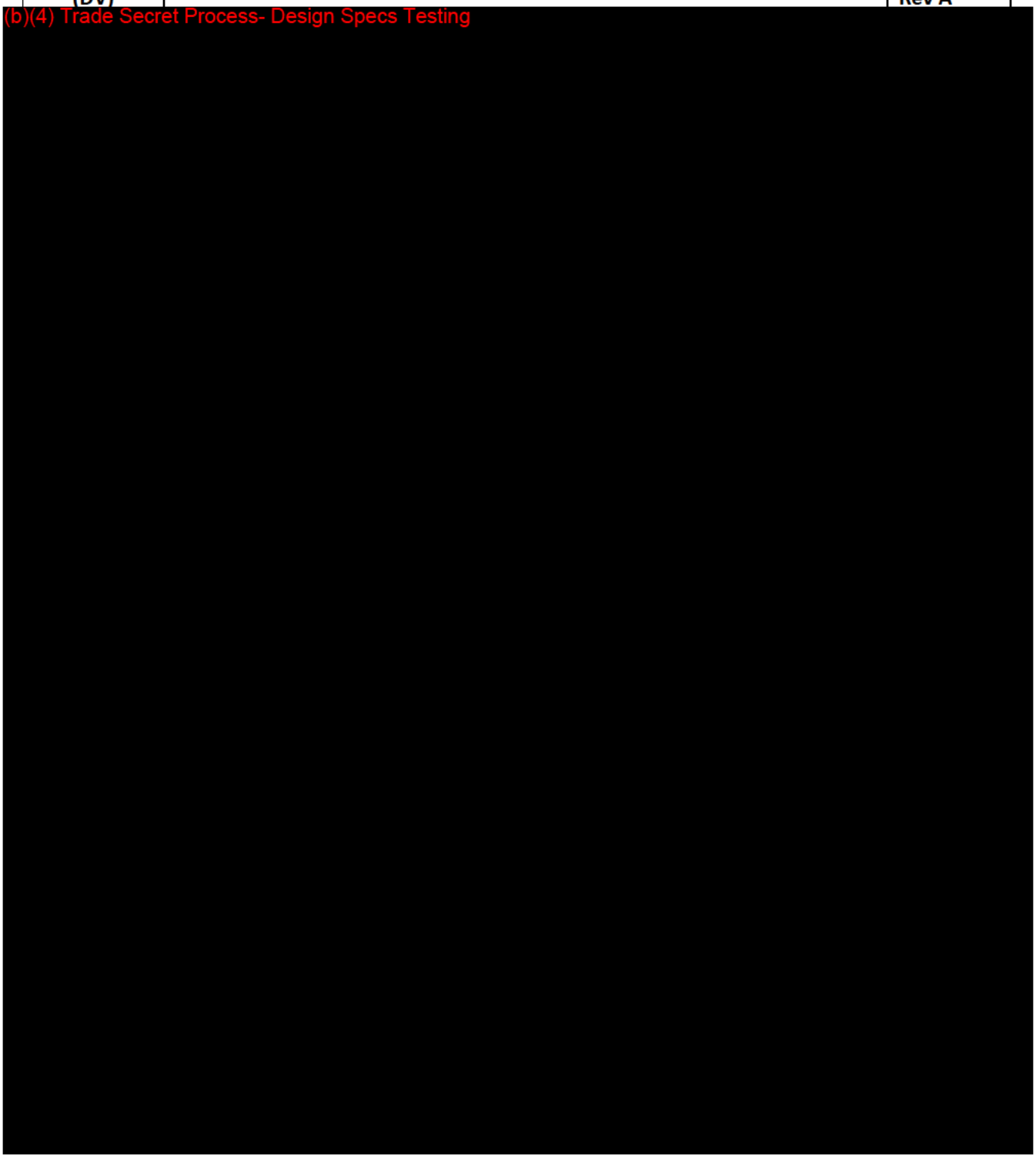

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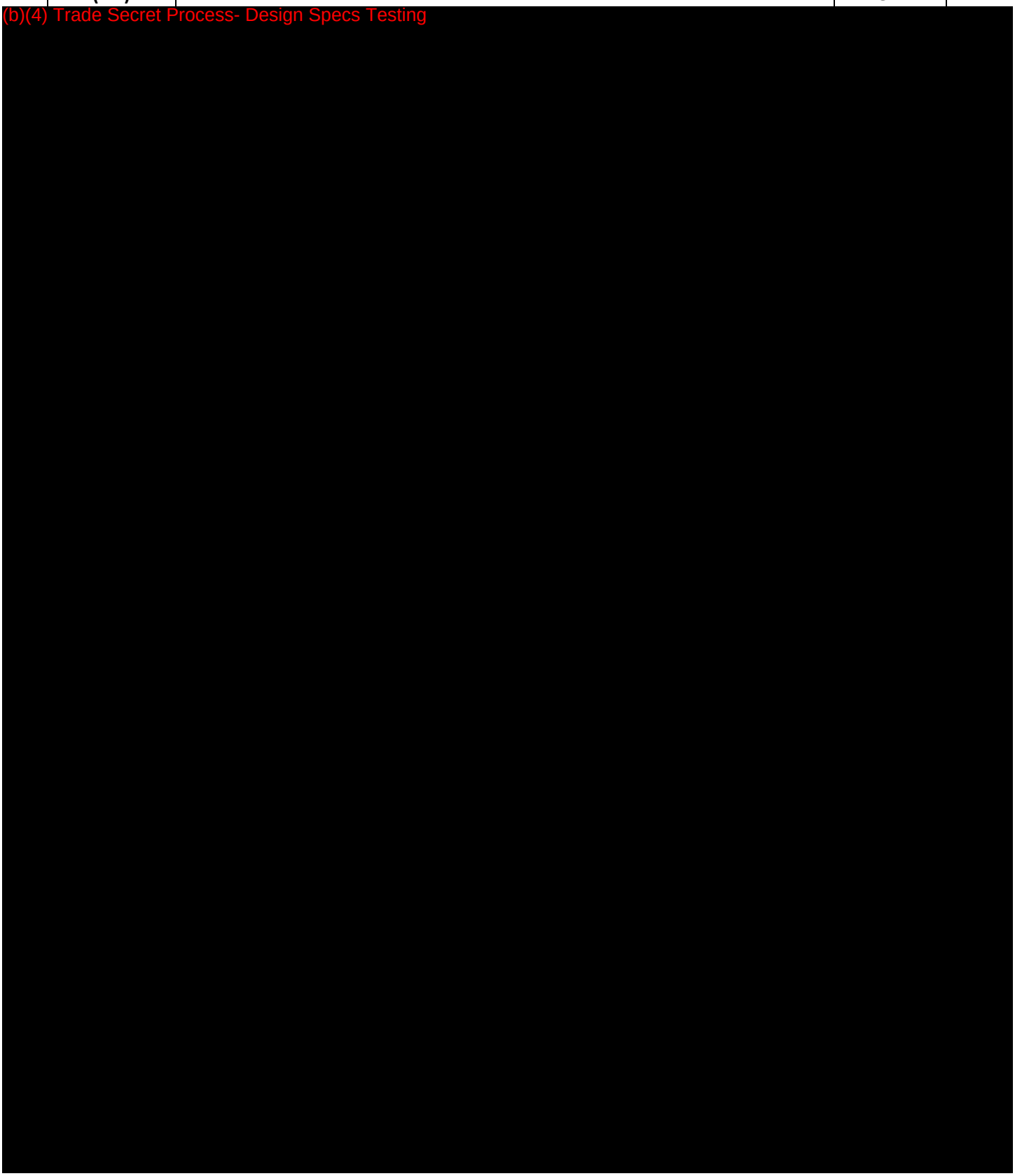

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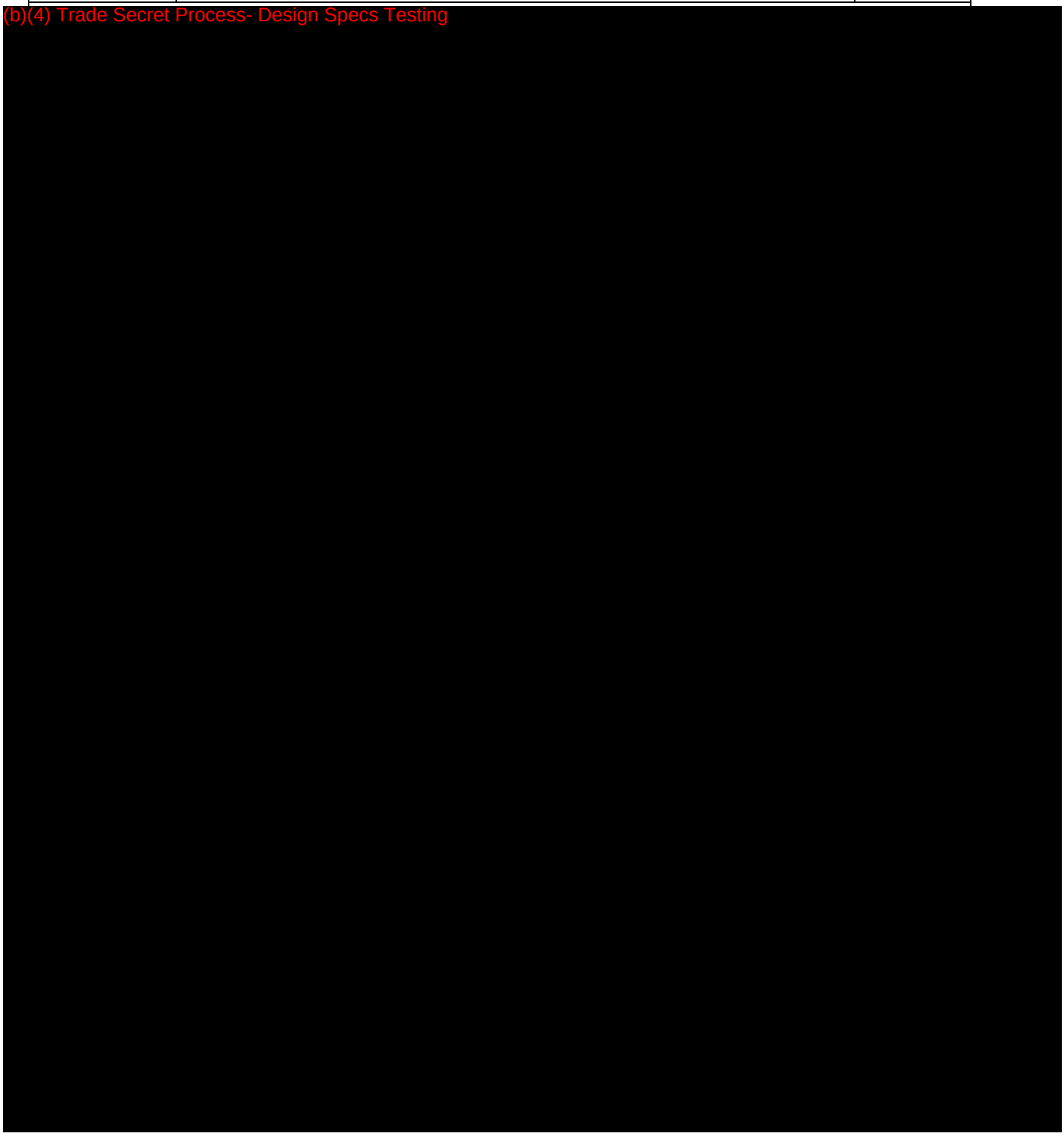

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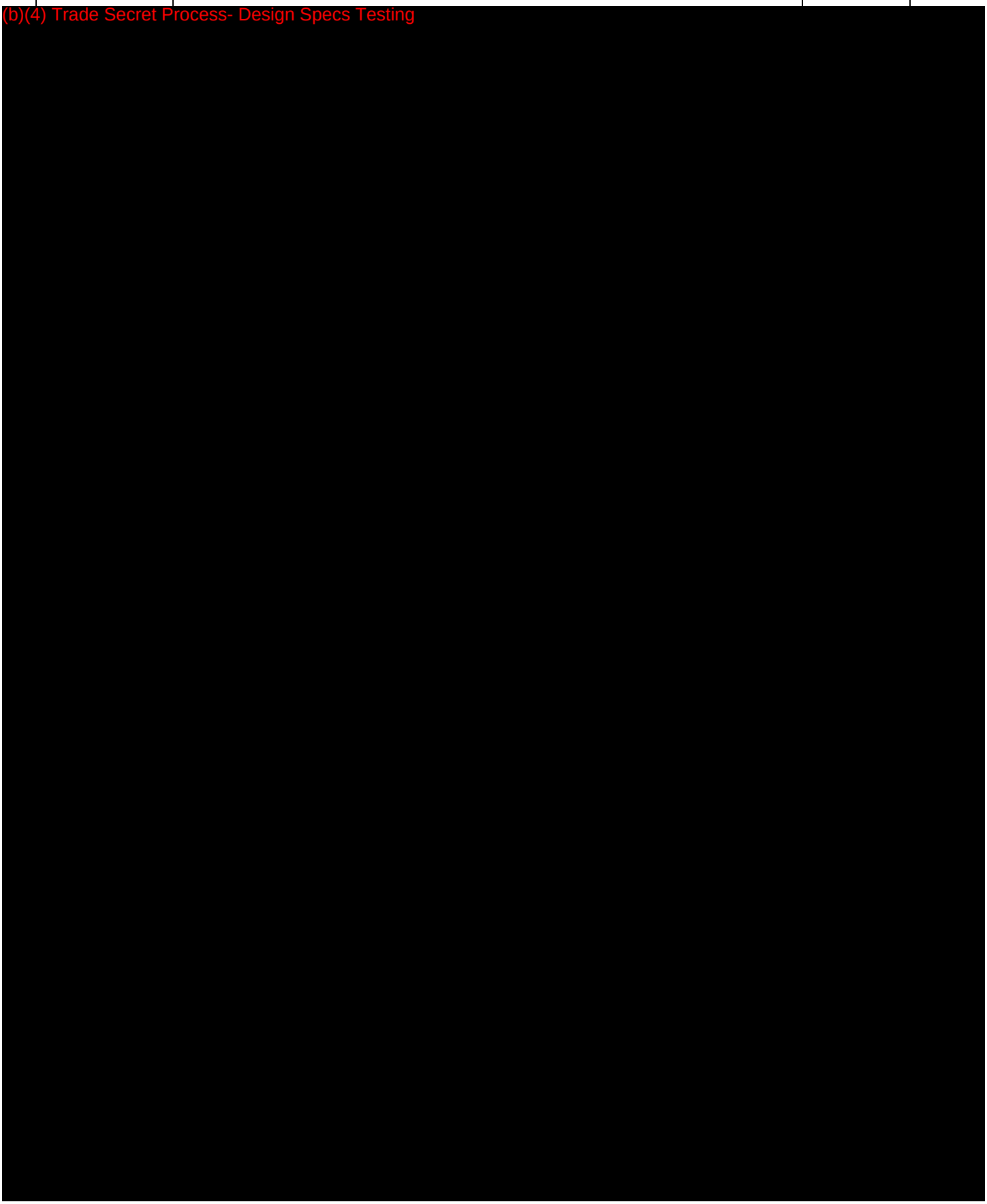

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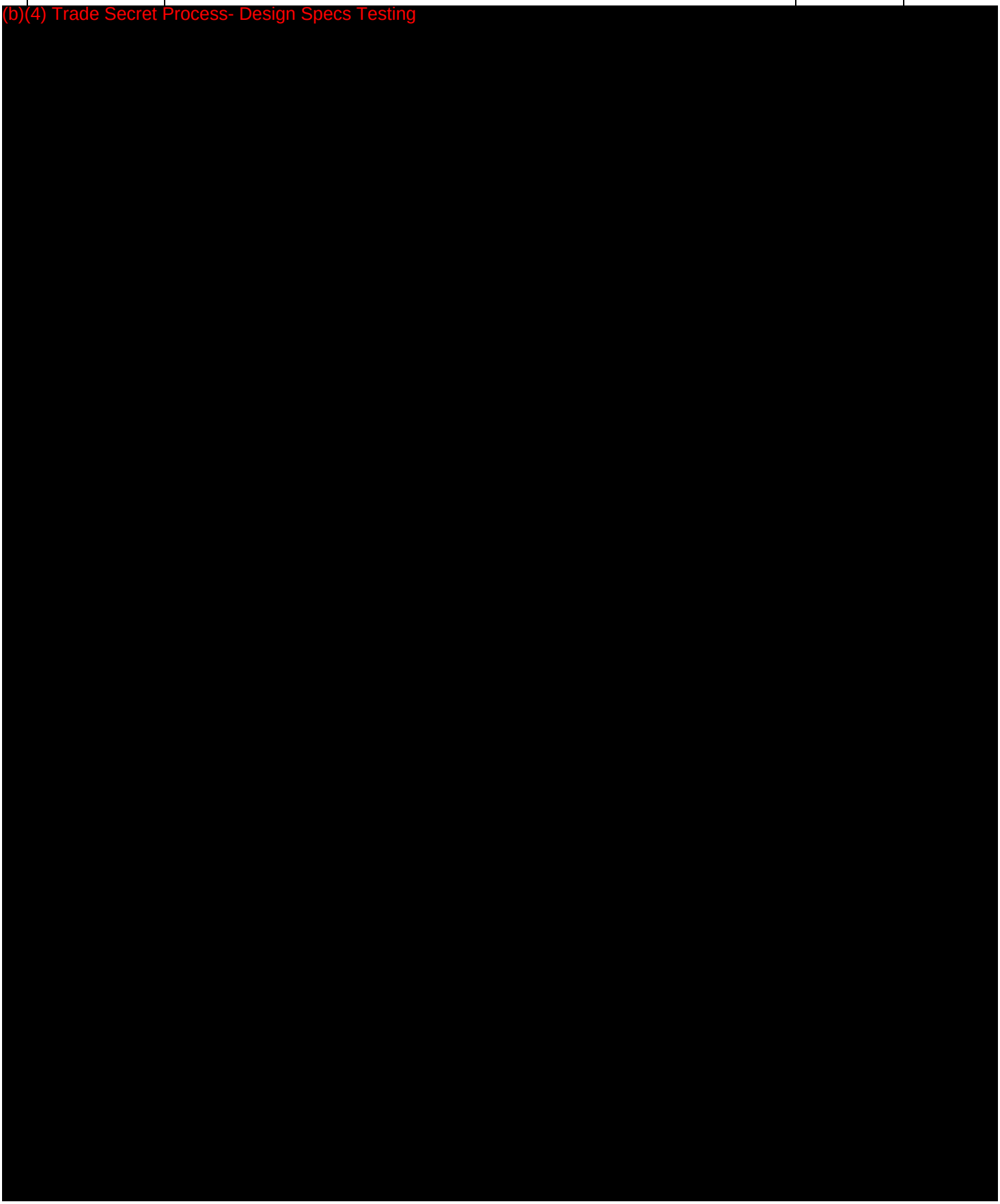

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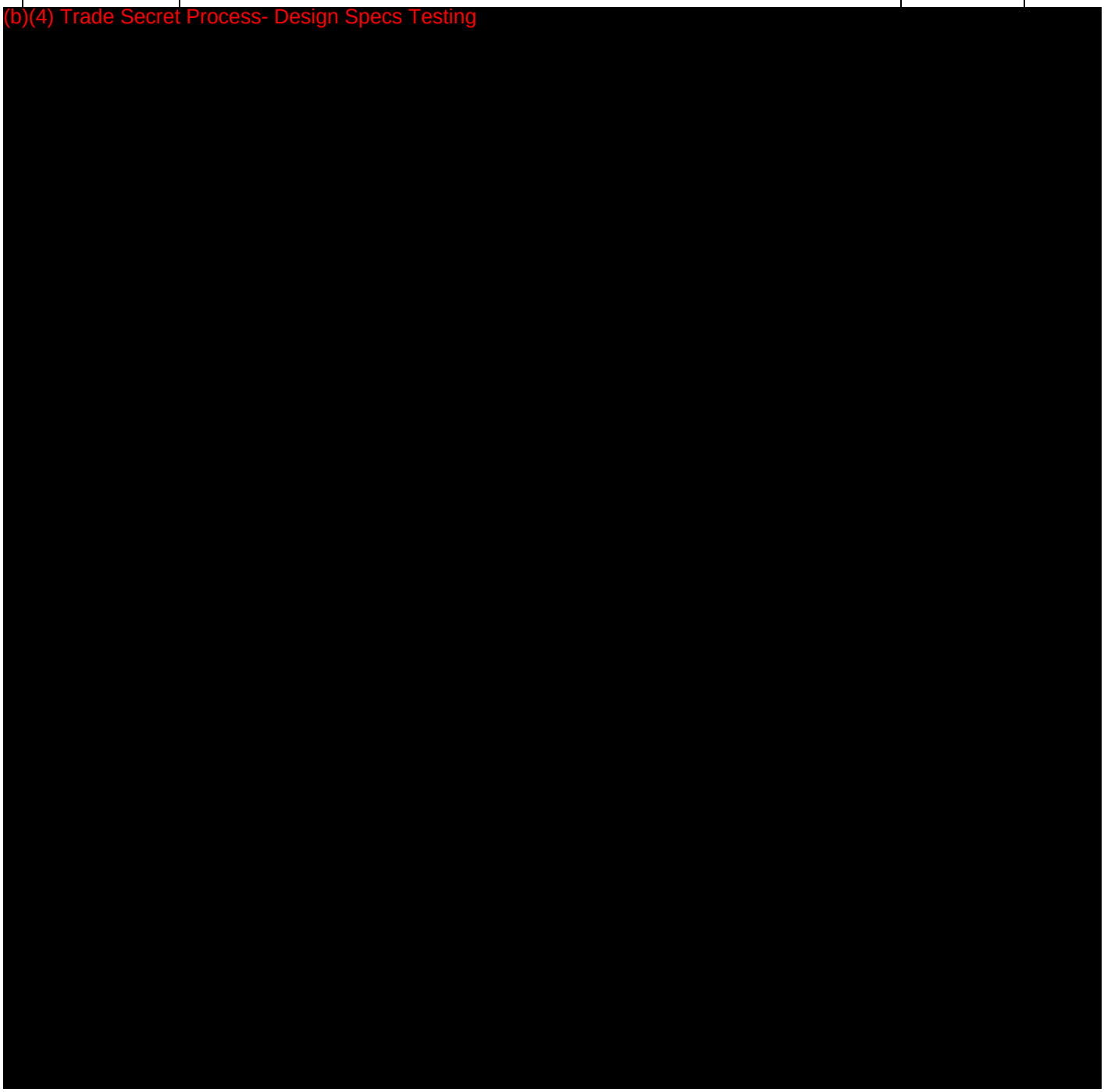

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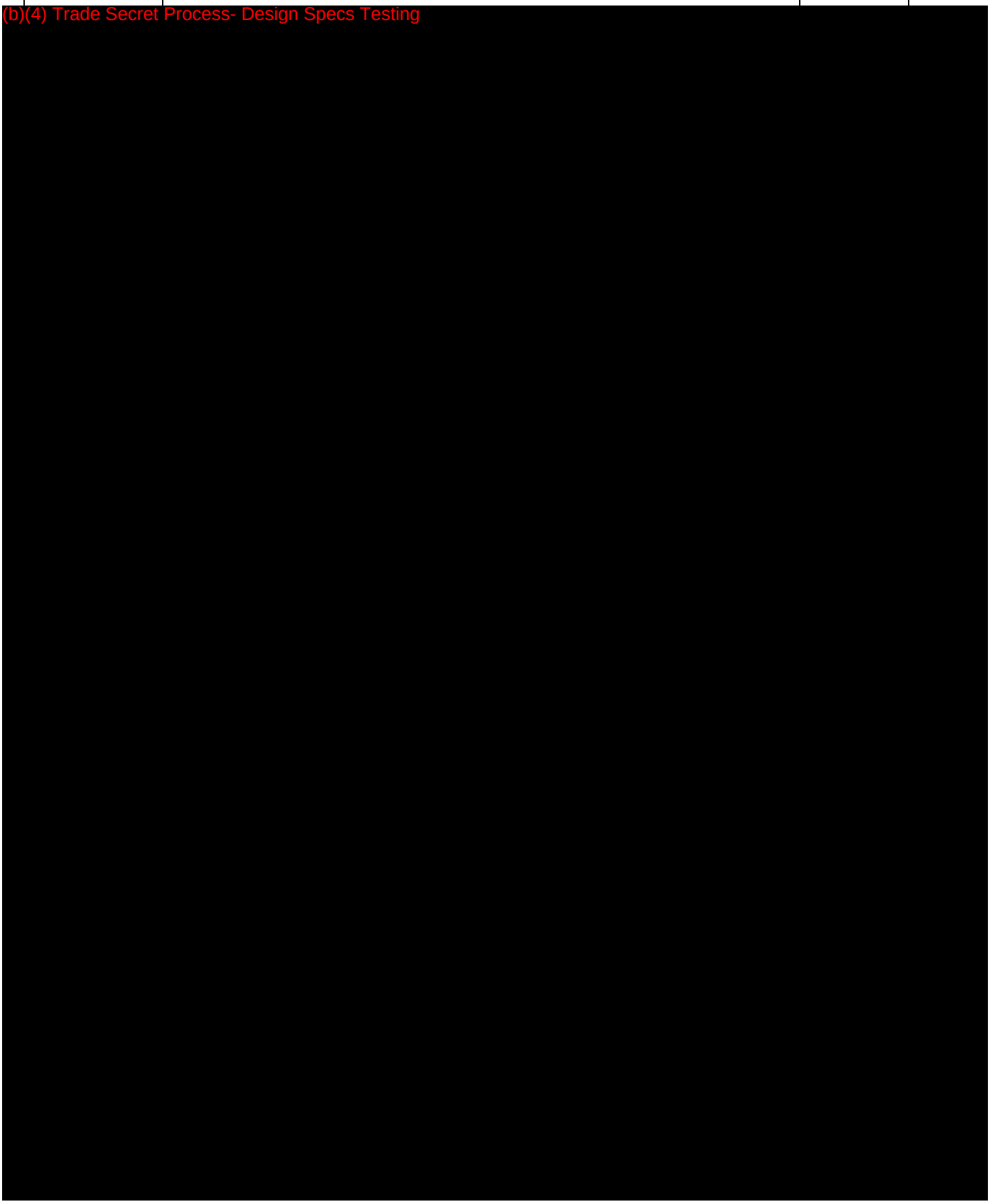

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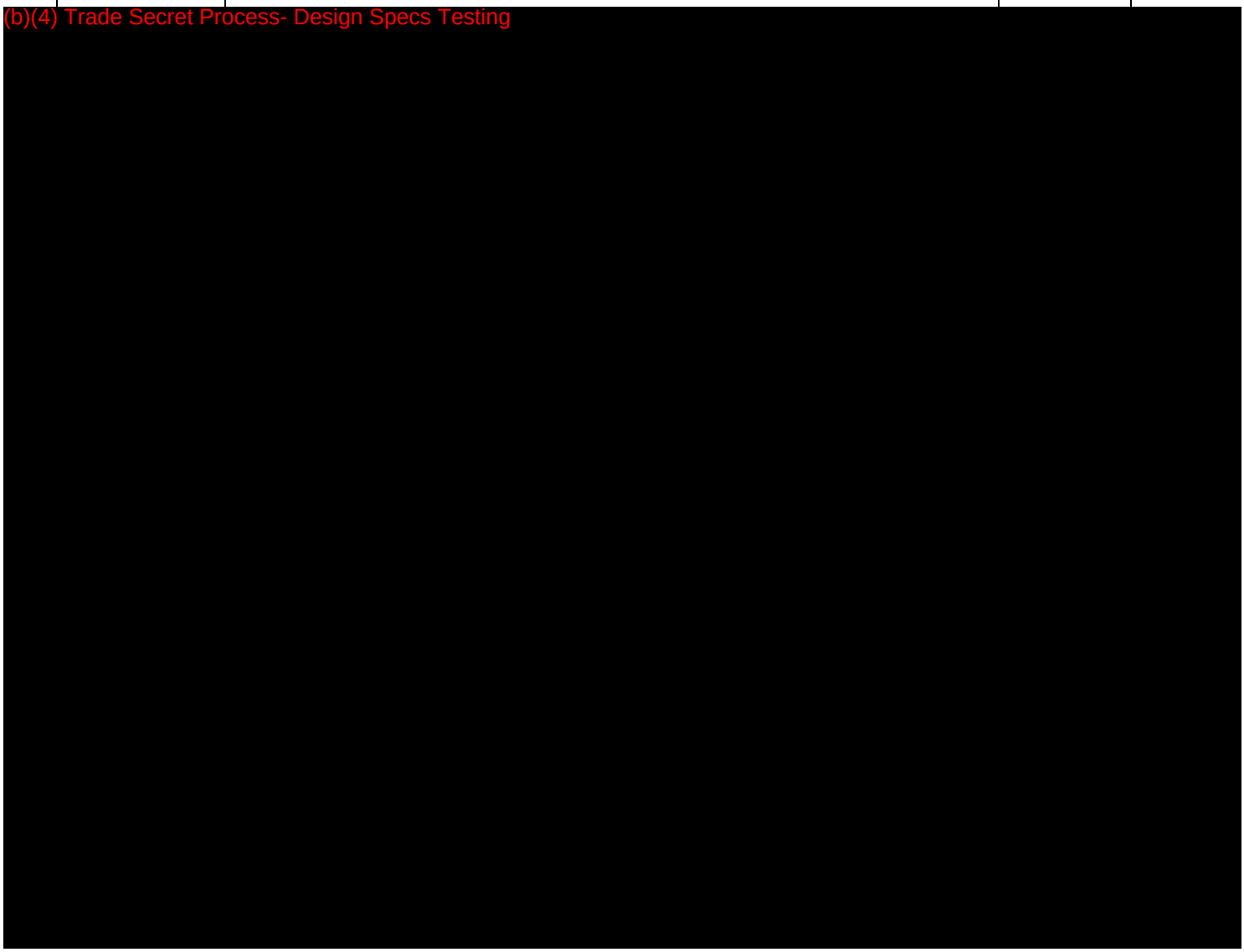

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COVER SHEET MEMORANDUM

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

NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name Maegen Colehour, MS

510(k) Number K140300

Please list CTS decision code: SE - Substantially Equivalent

☐ Hold (Additional Information or Telephone Hold) Hold Date

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

☐ Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

☐ Add to File
(review staff should follow the instructions and complete the memo/routing sheet at: http://eroom.fda.gov/eRoom/CDRH3/CDRHPremarketNotification510kProgram/0_3bba7. DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

Class:	II
Regulation Number:	878.3300
Product Code:	OWY
Additional Product Codes:	ORQ

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Is this a combination product?		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
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 was incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X

DCC
3.27

Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Peter L. Hudson -S 2014.03.25 14:45:18 -04'00'
Division Sign-Off	David Krause -S 2014.03.26 16:17:32 -04'00'