

HOLOGIC, Inc.

Premarket Notification

MAR 23 2012

**5. 510(k) SUMMARY****1. Submitter:**

Hologic, Inc.  
250 Campus Dr.  
Marlborough, MA 01752  
Telephone: 508.263.8857

Contact: Sarah Fairfield, Sr. Regulatory Affairs Specialist

**2. Device:**

Trade Name: MyoSure™ Hysteroscopic Tissue Removal System  
Common Name: Hysteroscope and accessories  
Classification Name: Hysteroscope and accessories  
Class: II

**3. Predicate Device:**

MyoSure™ Hysteroscopic Tissue Removal System (K100559)

**4. Device Description:**

The modified Myosure Hysteroscopic Tissue Removal System consists of the following procedural components which are identical to those found in the predicate Myosure System:

- Myosure Control Unit
- Myosure Tissue Removal Device
- Myosure Foot Pedal

The Myosure Control Unit contains an electric motor and software controller that drives the Myosure Tissue Removal Device. The Control Unit motor is activated and deactivated by the Myosure Foot Pedal. The Myosure Tissue Removal Device is a tissue morcellator that is connected to the Control Unit via a flexible drive cable. The morcellator's cutter blade is controlled by a drive system that enables simultaneous rotation and reciprocation of the cutter. The cutter is also connected to a vacuum source which aspirates resected tissue through a side-facing cutting window in the device's outer tube. Distension fluid and resected tissue are transported from the Myosure Tissue Removal Device to a tissue trap and vacuum canister via a tube protruding from the proximal end of the Tissue Removal Device. The Myosure Hysteroscopic Tissue Removal System is compatible with commercially available fluid management systems and may be used with hysteroscopes that have a straight 3 mm working channel.

**5. Intended Use:**

The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

**6. Comparison of Characteristics:**

The modified Myosure Hysteroscopic Tissue Removal System's intended use and indicated use are identical to that of the predicate Myosure Hysteroscopic Tissue Removal System, K100559.

The principles of operation and primary functional specifications of the modified Myosure Hysteroscopic Tissue Removal System are identical to those of the predicate Myosure Hysteroscopic Tissue Removal System.

The modified Myosure Hysteroscopic Tissue Removal System is different from the predicate Myosure Hysteroscopic Tissue Removal System as follows:

- The motor within the control unit now rotates bidirectionally

**7. Performance Testing:**

Performance verification testing of the modified Myosure Hysteroscopic Tissue Removal System was completed using the same methodology as was used in support of the predicate Myosure System 510(k) submission (K100559). Testing evaluated cutting functionality and heat generation over the test interval for the modified Myosure System. Test results for the predicate and modified Myosure Hysteroscopic Tissue Removal Systems were then compared. Results from this testing demonstrated that:

- the modified Myosure System's fibroid cutting performance is equivalent to that of the predicate device
- cutter durability over time is equivalent for the modified and predicate Myosure Systems
- heat generation over time is equivalent for the modified and predicate Myosure Systems

Verification/validation testing of the modified Myosure System was completed and confirmed that the modified Myosure System meets the same functional and performance specifications as the predicate Myosure System.

**8. Conclusion:**

Based on the intended use, descriptive information and performance evaluation provided in this submission, the modified MyoSure Hysteroscopic Tissue Removal System has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate MyoSure Hysteroscopic Tissue Removal System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 23 2012

Ms. Sarah Fairfield  
Senior Regulatory Affairs Specialist  
Hologic, Inc.  
250 Campus Drive  
MARLBOROUGH MA 01752

Re: K120593  
Trade/Device Name: Myosure Hysteroscopic Tissue Removal System  
Regulation Number: 21 CFR§ 884.1690  
Regulation Name: Hysteroscope and accessories  
Regulatory Class: II  
Product Code: HIH  
Dated: February 27, 2012  
Received: February 29, 2012

Dear Ms. Fairfield:

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

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

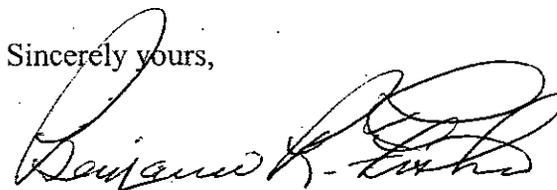
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**4. INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K120593

Device Name: Myosure Hysteroscopic Tissue Removal System

Indications For Use:

The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K120593



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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MARLBOROUGH MA 01752

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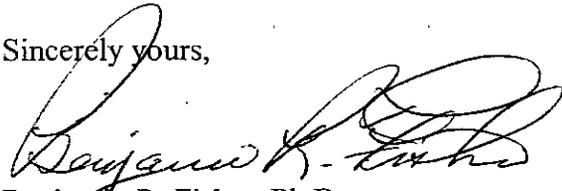
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Sincerely yours,



Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

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(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)

*Norm R. White*

(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K120593



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

March 01, 2012

HOLOGIC, INC.  
250 CAMPUS DRIVE  
MARLBOROUGH, MASSACHUSETTS 01752  
ATTN: SARAH FAIRFIELD

510k Number: K120593

Received: 2/29/2012

Product: MYOSURE CONTROL UNIT

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

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

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

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

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

Sincerely,

510(k) Staff



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

February 28, 2012

**USER FEE HOLD LETTER - HAVE NOT RECEIVED PAYMENT**

HOLOGIC, INC.  
250 CAMPUS DRIVE  
MARLBOROUGH, MASSACHUSETTS 01752  
ATTN: SARAH FAIRFIELD

510k Number: K120593  
Received: 2/28/2012  
User Fee ID Number: 6060436  
Product: MYOSURE CONTROL UNIT

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail  
Food and Drug Administration  
P.O. Box 956733  
St. Louis, MO 63195-6733.

By Private Courier(e.g., Fed Ex, UPS, etc.)  
U.S. Bank  
956733  
1005 Convention Plaza  
St. Louis, MO 63101

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at [www.fda.gov/cdrh/mdufma/fy09userfee.html](http://www.fda.gov/cdrh/mdufma/fy09userfee.html). In addition, the 510k Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-free number (800)638-2041, or contact them at their Internet address

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Edwena Jones at [Edwena.Jones@fda.hhs.gov](mailto:Edwena.Jones@fda.hhs.gov) or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Edwena Jones  
Consumer Safety Technician  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

**Mcdonald, Lisa \***

---

**From:** Microsoft Outlook  
**To:** 'sfairfie@gmail.com'  
**Sent:** Tuesday, February 28, 2012 1:04 PM  
**Subject:** Relayed: K120593 ACK Letter

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

'sfairfie@gmail.com'

**Subject:** K120593 ACK Letter

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Sent by Microsoft Exchange Server 2007

# **HOLOGIC™**

The Women's Health Company

**Special 510(k)  
Myosure Hysteroscopic Tissue Removal System**

**Firmware Update**

**Submitted by:  
Hologic, Inc.  
250 Campus Drive  
Marlborough, MA 01752 USA  
FDA Review Branch: Office of Device Evaluation**

**February 27, 2012**



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Write the Payment Identification number on <b>Process Product</b>
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: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  CYTYC SURGICAL PRODUCTS 250 Campus Drive Marlborough MA 01752 US		2. CONTACT NAME Daniel Phelan 2.1 E-MAIL ADDRESS daniel.phelan@hologic.com 2.2 TELEPHONE NUMBER (include Area code) 508-2638851 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) Trade Secret Process		
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: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> 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? <input checked="" type="checkbox"/> 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.) <input type="checkbox"/> 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 <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> 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). <input type="checkbox"/> YES <input checked="" type="checkbox"/> 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.]		
B. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) Trade Secret		23-Feb-2012

(b)(4) Trade Secret  
Process - Financial

Check Number: (b)(4) Trade

DATE 23-FEB-12

VENDOR NAME: FOOD AND DRUG ADMINISTRATION

VENDOR NO (b)(4)

INVOICE NO.	INV DATE	DESCRIPTION	DISCOUNT	NET AMOUNT
02/23/12	23-FEB-12		.00	(b)(4) Trade S t
			.00	(b)(4)

The Face of This Document Has a Colored Background on White Paper. Paper Includes: Fluorescent Fiber, Bleach Reactive Void, Black Dye Blue Stain and An Artificial Watermark on the Back.

**HOLOGIC™** CYTYC CORPORATION  
250 Campus Drive  
Marlborough, MA 01752

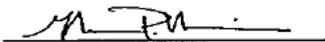
JPMorgan Chase Bank, N.A. 50-937/213  
Syracuse, NY 0347-09

(b)(4) Trade  
Secret Process -

CHECK DATE	CHECK NUMBER	CHECK AMOUNT
23-FEB-12	(b)(4) Trade	(b)(4) Trade S t P

PAY: (b)(4) Trade Secret Process - Financial Specification

TO THE ORDER OF: FOOD AND DRUG ADMINISTRATION  
PO BOX 956733  
SAINT LOUIS, MO 63195-6733  
United States

  
AUTHORIZED SIGNATURE  
VOID AFTER 180 DAYS

(b)(4) Trade Secret Process - Financial Specification

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Form Approval  
OMB No. 0910-0120  
Expiration Date: December 31, 2013  
See OMB Statement on page 5.

Date of Submission  
02/27/2012

User Fee Payment ID Number  
**(b)(4) Trade Secret**

FDA Submission Document Number (if known)

**SECTION A**

**TYPE OF SUBMISSION**

<p><b>PMA</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p><b>PMA &amp; HDE Supplement</b></p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p><b>PDP</b></p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p><b>510(k)</b></p> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p><b>Meeting</b></p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p><b>IDE</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p><b>Humanitarian Device Exemption (HDE)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p><b>Class II Exemption Petition</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Evaluation of Automatic Class III Designation (De Novo)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Other Submission</b></p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Hologic, Inc		Establishment Registration Number (if known) 1222780	
Division Name (if applicable)		Phone Number (including area code) 5082638857	
Street Address 250 Campus Drive		FAX Number (including area code) 5082632403	
City Marlborough	State / Province MA	ZIP/Postal Code 01752	Country USA
Contact Name Sarah Fairfield			
Contact Title Senior Regulatory Affairs Specialist		Contact E-mail Address sfairfie@gmail.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**

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (*specify*):

**SECTION D2**

**REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (*specify*):

**SECTION D3**

**REASON FOR SUBMISSION - 510(k)**

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason ( <i>specify</i> ): Update to the Control Unit Firmware		

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information	
1	HIH	2		3		4		<input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	
5		6		7		8			

Information on devices to which substantial equivalence is claimed (if known)			
	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K073690		
2	K091100		
3	K100559		
4			
5			
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name  
 Myosure Hysteroscopic Tissue Removal System

	Trade or Proprietary or Model Name for This Device	Model Number
1	Myosure Control Unit	1 10-500
2		2
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	K073690	2	K091100	3	K100559
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 HIH	C.F.R. Section (if applicable) 21 CFR 884.1690	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Obstetrics/gynecology		

Indications (from labeling)  
 The MyoSure™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

**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**

<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3006330030	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Hologic, Inc		Establishment Registration Number		
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>		
Street Address 445 Simarano Dr		FAX Number <i>(including area code)</i>		
City Marlborough		State / Province MA	ZIP Code 01752	Country USA
Contact Name Reynol Sanchez		Contact Title QA Manager		Contact E-mail Address reynol.sanchez@hologic.com

<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3007502300	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Hologic Costa Rica SA.		Establishment Registration Number		
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>		
Street Address 562 Parkway Ave 0		FAX Number <i>(including area code)</i>		
City Coyol Free Zone, El Coyol		State / Province Alajuela	ZIP Code	Country Costa Rica
Contact Name Reynol Sanchez		Contact Title QA Manager		Contact E-mail Address reynol.sanchez@hologic.com

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>		
Street Address		FAX Number <i>(including area code)</i>		
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					
2					
3					
4					
5					
6					
7					

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

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

Department of Health and Human Services  
 Food and Drug Administration  
 Office of 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.*



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with  
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER  Hologic, Inc	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES  Feb 27, 2012
3. ADDRESS (Number, Street, State, and ZIP Code)  250 Campus Drive Marlborough, MA 01752	4. TELEPHONE AND FAX NUMBERS (Include Area Code)  (Tel.) 5082638857  (Fax) 5082632403

**PRODUCT INFORMATION**

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)

Myosure Hysteroscopic Tissue Removal System

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**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND     NDA     ANDA     BLA     PMA     HDE     510(k)     PDP     Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301, of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)  	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11  (Name) Sarah Fairfield  (Title) Senior Regulatory Affairs Specialist	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)  250 Campus Drive Marlborough, MA 01752	14. TELEPHONE AND FAX NUMBERS (Include Area Code)  (Tel.) 5082638857  (Fax) 5082632403	15. DATE OF CERTIFICATION  Feb 27, 2012

## Instructions for Completion of Form FDA 3674

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**  
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.  
**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.  
**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.  
**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

### Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. 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 the Chief Information Officer (HFA-250)  
5600 Fishers Lane  
Rockville, MD 20857

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

K120593

February 27, 2012

Food and Drug Administration  
Center for Devices and Radiological Health - Office of Device Evaluation  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

FDA CDRH DMC

FEB 28 2012

Attention: Document Control Clerk

Received

K30

**RE: 510(k) NOTIFICATION Myosure Hysteroscopic Tissue Removal System**

Dear Sir or Madam,

This pre-market notification submission is being made to notify FDA of Hologic, Inc.'s intent to modify (b)(4) Trade the Myosure Control Unit.  
S TP

**Type of Submission:** Special 510(k)

**Device Type:** Common Name: Hysteroscope and accessories

**510(k) Submitter:**  
Hologic, Inc.  
250 Campus Drive  
Marlborough, MA 01752 USA

Establishment Registration No.: 1222780

**Authorized Contact:**  
Sarah Fairfield, Sr. Regulatory Affairs Specialist  
[sarah.fairfield@hologic.com](mailto:sarah.fairfield@hologic.com)

**Confidentiality:** In accordance with 21 CFR 807.95, Hologic Inc. requests that the review status of this submission remain confidential.

**Recommended Classification Regulation:** 21 CFR 884.1690

**HOLOGIC**

Hologic, Inc.  
250 Campus Drive, Marlborough, MA 01752 USA  
Main: +1.508.263.2900 Fax: +1.508.229.2795

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**Device Classification:** Class II

**Panel:** Obstetrics/gynecology

**Product Code:** HHH

**Prior Correspondence:** Not applicable.

**Basis for Submission:** This special 510(k) submission is being made to update (b)(4) Trade (b)(4) control unit to allow for (b)(4) Trade rotation of the motor that drives the cutting blade. This update is being made (b)(4) Trade Secret Process - Product Specification ultimately ease the manufacturing process for the system.

**Design and Use of the Device:**

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
Does the device contain components derived from a tissue or other biologic source?		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?		X
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

**Conclusion:** Hologic, Inc. believes that the information provided in this submission demonstrates the substantial equivalence of form, fit and function of the proposed Myosure Hysteroscopic Tissue Removal System to its predicate, the commercially available Myosure Hysteroscopic Tissue Removal System (K100559).

Please feel free to contact me directly at (508) 263.8857 if questions arise concerning this submission.

Sincerely,



Sarah Fairfield  
Senior Regulatory Affairs Specialist  
GYN-Surgical Products  
Hologic, Inc  
250 Campus Drive  
Marlborough, MA 01752 USA  
(508) 263-8857 (p)

cc: Office of Compliance

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**HOLOGIC**

Hologic, Inc.  
250 Campus Drive, Marlborough, MA 01752 USA  
Main: +1.508.263.2900 Fax: +1.508.229.2795

[www.hologic.com](http://www.hologic.com)

#### 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Myosure Hysteroscopic Tissue Removal System

Indications For Use:

The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**5. 510(k) SUMMARY**

**1. Submitter:**

Hologic, Inc.  
250 Campus Dr.  
Marlborough, MA 01752  
Telephone: 508.263.8857

Contact: Sarah Fairfield, Sr. Regulatory Affairs Specialist

**2. Device:**

Trade Name: MyoSure™ Hysteroscopic Tissue Removal System  
Common Name: Hysteroscope and accessories  
Classification Name: Hysteroscope and accessories  
Class: II

**3. Predicate Device:**

MyoSure™ Hysteroscopic Tissue Removal System (K100559)

**4. Device Description:**

The modified Myosure Hysteroscopic Tissue Removal System consists of the following procedural components which are identical to those found in the predicate Myosure System:

- Myosure Control Unit
- Myosure Tissue Removal Device
- Myosure Foot Pedal

The Myosure Control Unit contains an electric motor and software controller that drives the Myosure Tissue Removal Device. The Control Unit motor is activated and deactivated by the Myosure Foot Pedal. The Myosure Tissue Removal Device is a tissue morcellator that is connected to the Control Unit via a flexible drive cable. The morcellator's cutter blade is controlled by a drive system that enables simultaneous rotation and reciprocation of the cutter. The cutter is also connected to a vacuum source which aspirates resected tissue through a side-facing cutting window in the device's outer tube. Distension fluid and resected tissue are transported from the Myosure Tissue Removal Device to a tissue trap and vacuum canister via a tube protruding from the proximal end of the Tissue Removal Device. The Myosure Hysteroscopic Tissue Removal System is compatible with commercially available fluid management systems and may be used with hysteroscopes that have a straight 3 mm working channel.

**5. Intended Use:**

The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

**6. Comparison of Characteristics:**

The modified Myosure Hysteroscopic Tissue Removal System's intended use and indicated use are identical to that of the predicate Myosure Hysteroscopic Tissue Removal System, K100559.

The principles of operation and primary functional specifications of the modified Myosure Hysteroscopic Tissue Removal System are identical to those of the predicate Myosure Hysteroscopic Tissue Removal System.

The modified Myosure Hysteroscopic Tissue Removal System is different from the predicate Myosure Hysteroscopic Tissue Removal System as follows:

- The motor within the control unit now rotates bidirectionally

**7. Performance Testing:**

Performance verification testing of the modified Myosure Hysteroscopic Tissue Removal System was completed using the same methodology as was used in support of the predicate Myosure System 510(k) submission (K100559). Testing evaluated cutting functionality and heat generation over the test interval for the modified Myosure System. Test results for the predicate and modified Myosure Hysteroscopic Tissue Removal Systems were then compared. Results from this testing demonstrated that:

- the modified Myosure System's fibroid cutting performance is equivalent to that of the predicate device
- cutter durability over time is equivalent for the modified and predicate Myosure Systems
- heat generation over time is equivalent for the modified and predicate Myosure Systems

Verification/validation testing of the modified Myosure System was completed and confirmed that the modified Myosure System meets the same functional and performance specifications as the predicate Myosure System.

**8. Conclusion:**

Based on the intended use, descriptive information and performance evaluation provided in this submission, the modified MyoSure Hysteroscopic Tissue Removal System has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate MyoSure Hysteroscopic Tissue Removal System.



**7. PREMARKET NOTIFICATION CLASS III CERTIFICATION  
AND SUMMARY (As Required by 21 CFR 807.94)**

**Not applicable to this submission.**

**8. FINANCIAL INTERESTS AND ARRANGEMENTS OF  
CLINICAL INVESTIGATORS & STEPS TAKEN TO MINIMIZE  
BIAS OF CLINICAL STUDY RESULTS**

**Not applicable to this submission**



## 10. EXECUTIVE SUMMARY

### Intended Use

The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

### Description of Device

The procedural components of the modified Myosure Hysteroscopic Tissue Removal System are the same as those of the predicate Myosure device, i.e.: the Myosure Control Unit, Myosure Tissue Removal Device and Myosure Foot Pedal. The Myosure Hysteroscopic Tissue Removal System remains unchanged with respect to its operating principles, functional performance, intended use and indicated use since the most recent clearance of the predicate Myosure device (K100559), despite the following minor changes to the device's firmware:

- (i) To ease manufacturing processes (b)(4) Trade Secret Process - Product within the handpiece, (b)(4) Trade Secret Process - Product (b)(4) Trade Secret Process - Product Specification

**Device Comparison:** The modified MyoSure Hysteroscopic Tissue Removal System is compared to the predicate MyoSure Hysteroscopic Tissue Removal System (K100559) below.

**Table 10-1 – Device Comparison**

Attribute	Predicate MyoSure Hysteroscopic Tissue Removal System (K100559)	Modified MyoSure Hysteroscopic Tissue Removal System	Status
Method of Use	Hysteroscopic surgical removal of intrauterine tissue including submucous myomas and endometrial polyps using an electro-mechanical device.	Hysteroscopic surgical removal of intrauterine tissue including submucous myomas and endometrial polyps using an electro-mechanical device.	Identical to predicate device
Indicated Use	The MyoSure™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.	The MyoSure™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.	Identical to predicate device
Device Description	Electro-mechanical surgical device consisting of a reusable Control Unit & Foot Pedal and a Single Use Morcellator Device	Electro-mechanical surgical device consisting of a reusable Control Unit & Foot Pedal and a Single Use Morcellator Device	Identical to predicate device
Drive System	Hand-piece is connected via flexible cable to a single motor in the Control Unit; the motor is controlled by a Maxon EPOS 2 24/5 motor controller w/ firmware	Hand-piece is connected via flexible cable to a single motor in the Control Unit; the motor is controlled by a Maxon EPOS 2 24/5 motor controller w/ firmware	Identical to predicate device
Cutting Tip Configuration	Smooth, external beveled circular edge	Smooth, external beveled circular edge	Identical to predicate device
Mechanism of Action	The morcellator consists of a stationary outer sheath with a side-facing cutting window and a rotating and reciprocating inner cutter.	The morcellator consists of a stationary outer sheath with a side-facing cutting window and a rotating and reciprocating inner cutter.	Identical to predicate device

Hologic, Inc. Premarket Notification

Attribute	Predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100)	Modified MyoSure™ Hysteroscopic Tissue Removal System	Status
<b>Mode of Operation</b>	Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	Identical to predicate device
<b>Aspiration vacuum pressure</b>	200-650 mmHg	200-650 mmHg	Identical to predicate device
(b)(4) Trade Secret Process Product Specification			
<b>Tissue Volume Spec.</b>	Resects > 14 cc fibroid tissue / 10 minute (14 cc = 3 cm spherical fibroid)	Resects > 14 cc fibroid tissue / 10 minute (14 cc = 3 cm spherical fibroid)	Identical to predicate device
<b>Access to Targeted Tissue</b>	The morcellator is inserted transcervically through a sheath or hysteroscope operating channel and it is visually guided to the target tissue.	The morcellator is inserted transcervically through a sheath or hysteroscope operating channel and it is visually guided to the target tissue.	Identical to predicate device
<b>Visualization Techniques</b>	Hysteroscope	Hysteroscope	Identical to predicate device
<b>IFU &amp; Operating Manual</b> Device Description Indications for Use Contraindications Warnings Precautions Instructions for Use	As in K100559	Updated to remove references to single directional motor	Similar to predicate device

**Equivalency Summary**

The intended use and indicated use of the modified Myosure Hysteroscopic Tissue Removal System are identical to those of the predicate Myosure System (K100559).

The method of use, mechanism of action, mode of operation and functional performance of the modified Myosure Hysteroscopic Tissue Removal System are identical to that of the predicate Myosure System (K100559).

The form, fit, ergonomic design and hardware design of the modified Myosure System is identical to those of the predicate Myosure System (K100559). The modified Myosure System's control unit is identical in design and materials of construction to the predicate Myosure device.

Product labeling for the modified Myosure System is identical in terms of contraindications, precautions, potential complications and warnings to those present in labeling for the predicate Myosure System.

**Biocompatibility Testing**

No biocompatibility testing of the Myosure Hysteroscopic Tissue Removal System is required to support the device modifications described in this submission.

**Performance Testing**

Performance testing applicable to the modified Myosure Hysteroscopic Tissue Removal System was determined based on an analysis of risks and hazards posed by the proposed modifications to the device. The following documents were reviewed:

(b)(4) Trade Secret Process - Testing

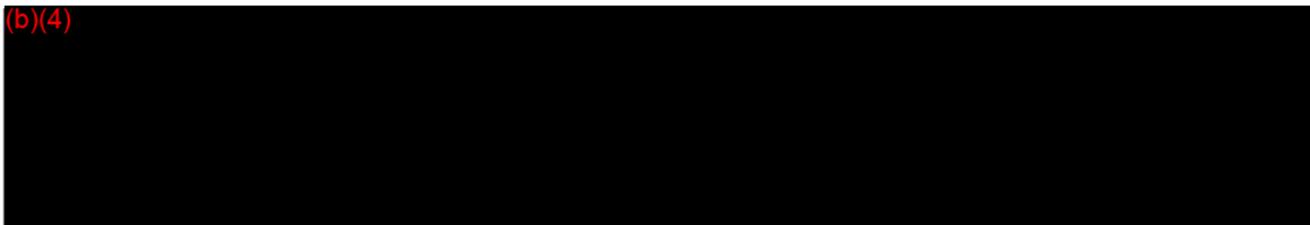


Based on the above review, no new hazards or risks were identified that relate to the proposed Myosure Hysteroscopic Tissue Removal System modifications. Accordingly, the following testing was performed to confirm functional equivalence of the modified and predicate Myosure Systems:

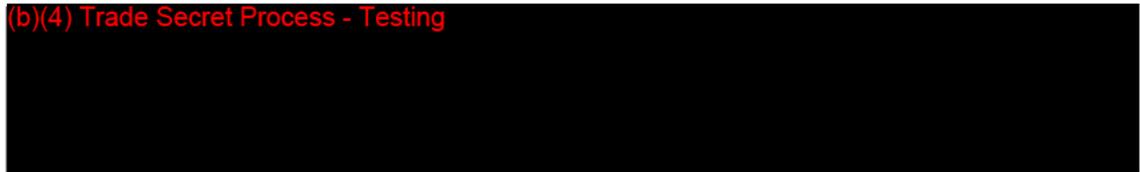
**Bench Testing**

Summarized bench test results are presented in **Section 18** of this submission.

(b)(4)



(b)(4) Trade Secret Process - Testing

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**Pre-Clinical Testing**

(b)(4) Trade Secret Process - Testing

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**Clinical Use**

(b)(4) Trade Secret Process - Testing

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### 11. DEVICE DESCRIPTION

#### Background

Hologic, Inc., acquired Interlace Medical on January 6, 2011. The Myosure Hysteroscopic Tissue Removal System was a part of that acquisition. The Myosure Hysteroscopic Tissue Removal System is currently available in the United States based on a series of clearances that have been summarized in Table 1.

**Table 1.** Summary of previous clearances

510(k) Number	Overview of Submission
(b)(4) Trade Secret Process - Product K091100	(b) (4)
K100559	

#### Intended Use

The Myosure Tissue Removal Device is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

#### System Overview

The MyoSure Tissue Removal System is designed to meet the requirements of intrauterine resection procedures. It is intended for use in gynecological procedures to resect and remove tissue for the following indications: intrauterine tissue including submucous myomas and endometrial polyps.

The MyoSure Tissue Removal Device is a single-use device that is intended for the morcellation and removal of tissue under hysteroscopic visualization. The MyoSure Tissue Removal System is used with a hysteroscope and fluid management systems.

The MyoSure Tissue Removal System is comprised of the main components as listed below.

- MyoSure Control Unit
- MyoSure Tissue Removal Device
- Foot pedal

The MyoSure Tissue Removal System is designed for resection of intrauterine tissue.

[Redacted text block with (b)(4) markings]

(b)(4) Trade Secret Process - Product Specifications  
[Redacted text block]

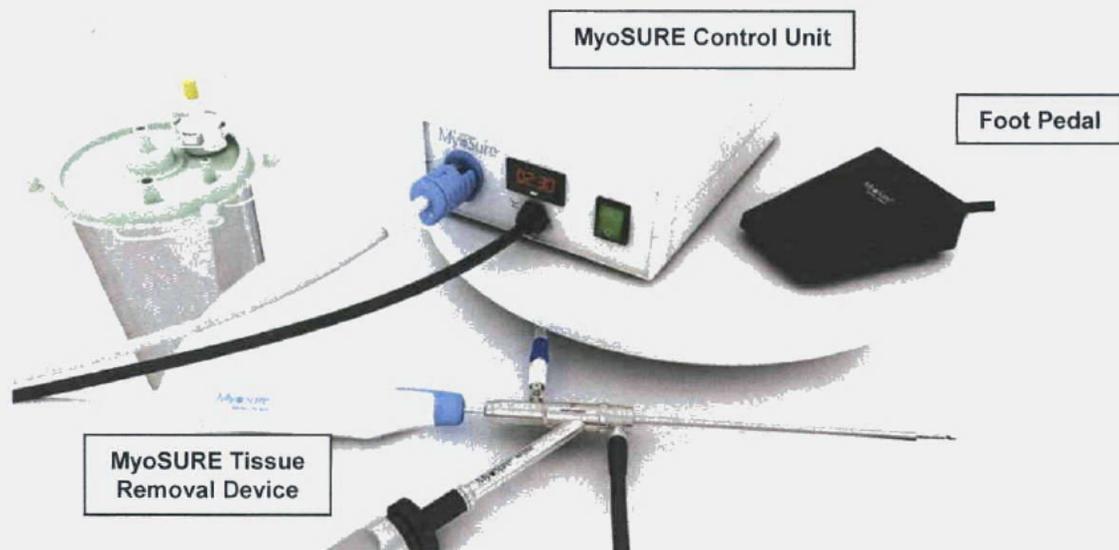


Figure 1. Myosure System

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

It has single pedal and is pneumatically operated. (b)(4) Trade Secret Process - Product Specifications

Tubing is connected to a stainless steel barbed connector on the proximal end of the handpiece. (b)(4) Trade Secret Process - Product Specifications



Figure 2: Photograph of the Handpiece

The morcellator consists of two concentric tubes. (b)(4) Trade Secret Process - Product Specifications

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

### Control Unit Overview

The control unit front panel includes Morcellation Timer Display, Footswitch and Handpiece Connectors (Figure 1). The Footswitch and Handpiece connectors are located on the front panel. (b)(4) Trade Secret Process - Product Specifications

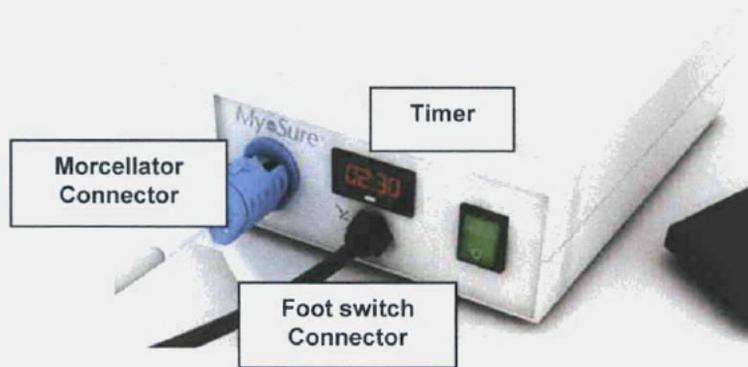


Figure 3: Photograph of the Control Unit

The control unit has a 3-pronged electrical connector (b)(4) Trade Secret Process - Product Specifications

The control unit power supply automatically detects the local power standard (b)(4) Trade Secret Process - Product Specifications

**12. SUBSTANTIAL EQUIVALENCE DISCUSSION**

**Predicate Device**

Hologic, Inc. claims substantial equivalence to the following previously cleared devices:

**Tradename:** MyoSure™ Hysteroscopic Tissue Removal System

**Model #'s:** Control Unit 10-500

**Submitter / 510(k) Holder:** Hologic, Inc.

**510(k) #'s:** K100559

**Predicate Device Comparison**

**Intended and Indicated Use**

The intended use and indicated use of the modified Myosure Hysteroscopic Tissue Removal System are identical to those of the predicate **Myosure Hysteroscopic Tissue Removal System (K100559)** in that both systems are used to resect and remove gynecologic tissue.

**Table 12-1 – Device Comparison - Intended and Indicated Use**

Attribute	Predicate Myosure Hysteroscopic Tissue Removal System (K100559)	Modified Myosure Hysteroscopic Tissue Removal System
Intended Use	Resection and removal of gynecologic tissue	Resection and removal of gynecologic tissue
Indicated Use	The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.	The Myosure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

**Method of Operation**

The method of use, mechanism of action and mode of operation of the predicate and modified Myosure Hysteroscopic Tissue Removal Systems are identical in that both systems utilize an electro-mechanical instrument to hysteroscopically remove intrauterine tissue including submucous myomas and endometrial polyps. In both devices, the morcellator consists of a stationary outer sheath with a side-facing cutting window and a rotating and reciprocating inner cutter. Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.

**Table 12-2 – Device Comparison – Method of Operation**

Attribute	Predicate Myosure Hysteroscopic Tissue Removal System (K100559)	Modified Myosure Hysteroscopic Tissue Removal System	Status
<b>Method of Use</b>	Hysteroscopic surgical removal of intrauterine tissue including submucous myomas and endometrial polyps using an electro-mechanical device.	No change	Identical to predicate
<b>Mechanism of Action</b>	The morcellator consists of a stationary outer sheath with a side-facing cutting window and a rotating and reciprocating inner cutter.	No change	Identical to predicate
<b>Mode of Operation</b>	Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	No change	Identical to predicate

**Technology**

The underlying technology of the predicate and modified Myosure Hysteroscopic Tissue Removal Systems is identical in that both systems (b)(4) Trade Secret Process - Product Specifications

The modified Myosure System includes one minor technology difference compared to the predicate Myosure System as follows:

**Myosure Control Unit:** (b)(4) Trade Secret Process - Product Specifications

This proposed modification (b)(4) Trade Secret Process - Product Specifications ease the manufacturing process of the handpiece. (b)(4) Trade Secret Process - Product Specifications

**Table 12-3 – Device Comparison - Technology**

Attribute	Predicate MyoSure Hysteroscopic Tissue Removal System (K100559)	Modified MyoSure Hysteroscopic Tissue Removal System	Status
Device Description	Electro-mechanical surgical device consisting of a reusable Control Unit & Foot Pedal and a Single Use Morcellator Device	No change	Identical to predicate
(b)(4) Trade Secret Process - Product Specifications		No change	Identical to predicate
		No change	Identical to predicate
		No change	Identical to predicate
		No change	Identical to predicate
		No change	Identical to predicate
Aspiration vacuum pressure	200-650 mmHg	No change	Identical to predicate
(b)(4) Trade Secret Process - Product Specifications			Similar to predicate
			Identical to predicate

**Labeling**

The labeling (Instructions for Use and Operator’s Manual) for the modified Myosure Hysteroscopic Tissue Removal System subject to this submission and the predicate Myosure System (K100559) are identical with respect to the Precautions, Potential Complications, Warning and Procedure sections except that any references to ‘single direction rotation’ have been removed. These updates are included in **Section 13, Labeling.**

Based on the preceding analysis, the modified Myosure Hysteroscopic Tissue Removal System is substantially equivalent to the previously cleared predicate Myosure Hysteroscopic Tissue Removal System (K100559).

### 13. LABELING

The product labeling for the Myosure Hysteroscopic Tissue Removal System will remain the same for the entire system, with the exception of two instances within the Myosure Hysteroscopic Tissue Removal System Operating Manual and the Myosure Hysteroscopic Tissue Removal System Instructions for Use. This update is necessary to remove references to the device only operating in one direction and speed. The following table describes the updates to these manuals, and a redlined copy of the manuals has also been included in this section.

<b>Manual</b>	<b>Location</b>	<b>Current Language</b>	<b>Updated Language</b>
Myosure Hysteroscopic Tissue Removal System Operating Manual	Page 6	Since the tissue removal device operates only in one direction and speed; the foot pedal merely turns the motor ON and OFF.	The foot pedal turns the motor ON and OFF.
Myosure Hysteroscopic Tissue Removal System Instructions for Use	Page 4	Since the tissue removal device operates only in one direction and speed; the foot pedal merely turns the motor ON and OFF.	The foot pedal turns the motor ON and OFF.

# MyoSure® Hysteroscopic Tissue Removal System

## Operating Manual



**Preface**

This manual provides the information you need to operate and maintain the Hologic MyoSure® Hysteroscopic Tissue Removal System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

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**Symbols Used On Labeling**

Authorized Representative in the European Community	
Batch code Lot number	
Catalogue number Part number or reorder number	
Caution: see instructions for use	
Contents	
Earth ground	
Equipotential terminal	
Equipment classification Type BF equipment	
European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC	
Foot pedal Foot pedal control	
Fuse	
Manufacturer	
Non-sterile	
OFF Main electrical power off.	
ON Main electrical power on.	
Patient contact parts do not contain phthalates	
Radio-frequency (RF) energy (non-ionizing radiation)	
Serial number	
Sterilized using irradiation	
U.S. federal law restricts this device to sale by or on the order of a physician	
Use by	
Watertight Equipment per IEC 529	<b>IPX1</b>
<b>Symbols used only on Tissue Removal Device</b>	
Do not reuse	
Do not use if package is damaged	
Sterilized using ethylene oxide	

**Introductions, Indications for Use, Contraindications**

**Introduction**

Read these instructions completely prior to using the MyoSure® Hysteroscopic Tissue Removal System.

The MyoSure® Hysteroscopic Tissue Removal System is designed to meet the requirements of intrauterine tissue removal. The system consists of the following procedural components:

- Control Unit
- Tissue Removal Device (Single Use)
- Foot Pedal

A sterile, disposable, hand-held tissue removal device is used for tissue removal. It is connected via a flexible drive shaft to a motorized control unit. A foot pedal allows the user to control the tissue removal device by turning the motor in the control unit off and on.

The MyoSure® Hysteroscopic Tissue Removal System features many performance and ease-of-use advantages, including:

- A simple user interface with only a power switch and
- A display that shows the time spent cutting and removing tissue.

**Indications for Use**

The MyoSure® Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue including submucous myomas and endometrial polyps.

**Contraindications**

The MyoSure® Hysteroscopic Tissue Removal System should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

**Warnings and Precautions**

The brief operating instructions in this guide will make the system easier to use, while the recommended maintenance procedures will ensure optimal performance over years of reliable use. Of course, as with any surgical instrument, there are important health and safety considerations. These are listed below and highlighted within the text.

**Warnings**

- Before using the MyoSure® Tissue Removal System for the first time, please review all available product information.
- Before using the MyoSure® System, you should be experienced in hysteroscopic surgery with powered instruments. Healthy uterine tissue can be injured by improper use of the tissue removal device. Use every available means to avoid such injury.
- Use only the MyoSure® Control Unit to connect to the MyoSure® Tissue Removal Device. Use of any other drive mechanism may result in failure of the device to operate or lead to patient or physician injury.
- If visualization is lost at any point during the procedure, stop cutting immediately.
- Periodic irrigation of the tissue removal device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.
- Ensure that vacuum pressure >200 mm Hg is available before commencing surgery.

- **DANGER:** Risk of explosion if used in the presence of flammable anesthetics.
- **WARNING - Exercise extreme caution when resecting tissue in patients who have implants that extend into the uterine cavity.** Do not use the MyoSure® Tissue Removal Device to resect tissue that is adjacent to an implant. When resecting tissue in patients that have implants, assure that:
  - the MyoSure Tissue Removal Device's cutting window is facing away (i.e., 180° opposite) the implant;
  - the visual field is clear;
  - the MyoSure Tissue Removal Device's cutting window is engaged in tissue and is moved away from the implant as tissue resection proceeds.

In the event an implant becomes entangled with a MyoSure cutter, the following steps are recommended:

- cease cutting immediately;
- kink the MyoSure Tissue Removal Device's outflow tube to prevent a loss of uterine distension;
- disconnect the MyoSure Tissue Removal Device's drive cable from the control box;
- grasp the end of the MyoSure Tissue Removal Device drive cable with a hemostat or other clamping device;
- hold the drive cable hub and tissue removal device to prevent twisting;
- open the tissue removal device's cutting window by manually twisting the hemostat counterclockwise;
- gently pull the MyoSure Tissue Removal Device into the hysteroscope to detach the MyoSure device from the implant.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment in the patient vicinity not complying with the equivalent medical safety requirements of this equipment may lead to a reduced level of safety of the resulting system. The use of accessory equipment outside the patient vicinity not complying with medical or otherwise appropriate safety requirements may lead to a reduced level of safety of the resulting system.
- The use of an accessory, transducer, or cable, other than those specified by Hologic may result in increased emissions or decreased immunity of the MyoSure® Hysteroscopic Tissue Removal System.

### Precautions

- R** U.S. Federal law restricts this device to sale by or on the order of a physician.
- The MyoSure® Tissue Removal Device should be stored at room temperature, away from moisture and direct heat.
  - Do not use after expiration date.
  - Do not use the device if the sterile package is open or appears compromised. Do not use the device if damage is observed.
  - To assure optimal performance, replace the tissue removal device after 2 hours of cutting time.
  - The tissue removal device is intended for single use only. Do not re-sterilize. Do not lubricate tissue removal device. Discard tissue removal device assembly after use.

- Use of a reprocessed, single-use tissue removal device may permanently damage, impede performance, or cause failure of the MyoSure® Hysteroscopic Tissue Removal System. Use of such products may render any warranties null and void.
- DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or kinked drive cable may cause the MyoSure® Control Unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the MyoSure® Control Unit and the MyoSure® Tissue Removal Device to allow the drive cable to hang in a large arc with no bends, loops, or kinks.
- DO NOT rotate the tissue removal device >180° if the tissue removal device is not running. The cutting window may open up which will lead to inability to maintain distension. If such situation occurs, just tap the foot pedal once or twice to run the tissue removal device; the cutting window will then close automatically.
- If it appears that the MyoSure® Tissue Removal Device's cutter blade has stopped rotating during a procedure, check to ensure that all connections to the MyoSure® Tissue Removal Device and the MyoSure® Control Unit (both mechanical and electrical) are secure and that the drive cable has not wrapped up into a loop.
- Exercise care when inserting or removing the device. Insertion and removal of the device should be performed under direct visualization at all times.
- To avoid perforation, keep the device tip under direct visualization and exercise care at all times when maneuvering it or cutting tissue close to uterine wall. Never use the device tip as a probe or dissecting tool.
- Exercise care when inserting or removing the device. Excessive bending of the device distal tip can cause the tissue removal device's cutter to come out of the cutting window. If such damage occurs, replace the device immediately.
- Do not allow the rotating portion of the tissue removal device to touch any metallic object such as a hysteroscope or sheath. Damage to both instruments is likely. Damage to the tissue removal device can range from a slight distortion or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a tissue removal device is damaged, replace it immediately.
- Do not operate the tissue removal device in the open air for an extended period, as the lack of irrigation may cause the tissue removal device to overheat and seize.
- Excessive leverage on the tissue removal device does not improve cutting performance and, in extreme cases, may result in wear, degradation, and seizing of the inner assembly.
- Do not sterilize or immerse the MyoSure® Control Unit in disinfectant.
- Do not cool the tissue removal device by immersing it in cold water.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment, it should

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be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

### Electromagnetic Safety

- The MyoSure® Hysteroscopic Tissue Removal System needs special precautions regarding electromagnetic safety and needs to be installed and put into service according to the electromagnetic safety information provided in this manual.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- All equipment performance is considered safety-related performance. That is, the failure or degradation of the performance specified in this manual will pose a safety risk to the patient or operator of this equipment.
- **Note: If the MyoSure® Hysteroscopic Tissue Removal System is put into service in accordance to the safety instruction in this manual, the product should remain safe and provide the performance listed above. If the product fails to provide this level of performance, the procedure should be aborted and the biomedical staff alerted to the observed problem. The problem needs to be corrected before continuing or starting a new procedure.**
- Portable and mobile RF communications equipment, including cellular telephones and other wireless devices can affect medical electrical equipment. To insure safe operation of the MyoSure® Hysteroscopic Tissue Removal System, do not operate communications equipment or cellular telephones at a distance closer than specified in Table 4 of this manual.
- The MyoSure® Hysteroscopic Tissue Removal System is not designed to work with or in the vicinity of electrical surgical equipment. If electrical surgical equipment must be used in the same area as the MyoSure® Hysteroscopic Tissue Removal System, the MyoSure® Hysteroscopic Tissue Removal System should be observed for proper operation before performing a procedure. This includes operating the electrical surgical equipment in its active mode at a power level suitable for the procedure.
- For more information regarding the electromagnetic safety of this product, please see Tables 1–4 in the back of this manual.

## System Components

### MyoSure® Control Unit (REF 10-500)

#### Control Unit—Front Panel

The MyoSure® Control Unit front panel includes power switch, tissue removal system timer display, foot pedal, and tissue removal device connectors (Figure 1).

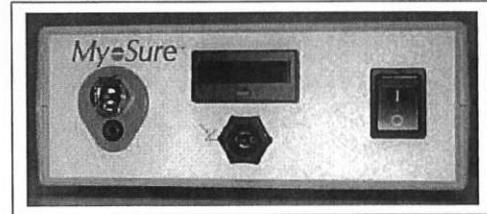


FIGURE 1. MYOSURE® CONTROL UNIT—FRONT PANEL

#### Power Switch

The power switch is the power ON / OFF switch for the entire system and must be activated prior to use.

**NOTE: If system is turned off for any reason, wait at least 15 seconds before turning power back on.**

#### Timer Display Window

The MyoSure® Control Unit displays the elapsed operating time for the tissue removal device in MIN:SEC format.

#### MyoSure® Foot Pedal and Tissue Removal Device Connectors

The foot pedal and tissue removal device connectors are located on the front panel.

#### MyoSure® Control Unit—Rear Panel

There is one connector and equipotential compensator terminal on the rear panel (Figure 2).



FIGURE 2. MYOSURE® CONTROL UNIT—REAR PANEL  
(\*=EQUIPOTENTIAL COMPENSATOR TERMINAL)

The 3-pronged electrical connector allows any 100–120/200–240 VAC, 50/60 Hz, ISO VA source using the power cord supplied with the system. The MyoSure® Control Unit power supply automatically detects the local power standard and adapts the tissue removal device to that standard. The equipotential compensator terminal permits connection of the MyoSure® Control Unit to an external earthing system (not shown).

#### Tissue Removal Device (REF 10-401)

The MyoSure® Tissue Removal Device is shown in Figure 3. It is a hand-held unit which is connected to the MyoSure® Control Unit via a 6-foot (1.8-meter) flexible drive cable and to a collection canister via a 10-foot (3-meter) vacuum tube. Cutting action is activated by a

foot pedal. The MyoSure® Tissue Removal Device is a single-use device designed to hysteroscopically remove intrauterine tissue.

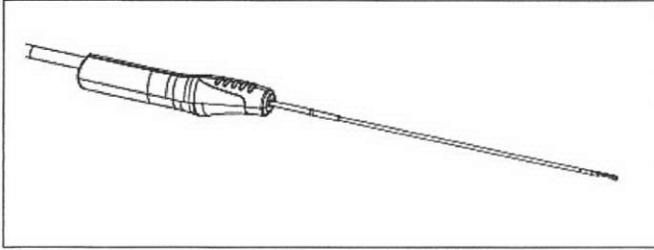


FIGURE 3. MYOSURE® TISSUE REMOVAL DEVICE

The flexible drive cable is inserted into the drive cable connection on the front panel of the MyoSure® Control Unit.

The proximal end of the vacuum tubing is connected to a collection canister. The vacuum pressure draws fluid and resected tissue through the tissue removal device's cutting window.

**MyoSure® Foot Pedal (REF 10-903)**

The tissue removal system foot pedal (Figure 4) controls tissue removal device operation. The foot pedal plugs into the connector on the front of the MyoSure® Control Unit panel. It has a single pedal and is pneumatically operated.

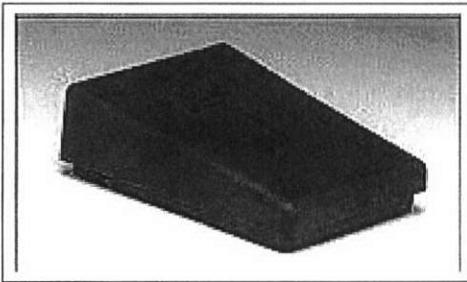


FIGURE 4. FOOT PEDAL

**Set-up**

Setting up the Hologic MyoSure® Hysteroscopic Tissue Removal System

**WARNING:** Before using the MyoSure® Tissue Removal System for the first time, you should review all available product information. You should be experienced in hysteroscopic surgery with powered instruments. Healthy uterine tissue can be injured by improper use of the tissue removal device. Use every available means to avoid such injury.

The MyoSure® Tissue Removal Device is EtO sterilized. Verify that the tissue removal device is sterile prior to use. Do not use if package is opened or damaged. Discard all opened, unused devices. Do not use after expiration date.

**CAUTION:** The MyoSure® Tissue Removal Device is intended for single use only. DO NOT RE-STERILIZE. DO NOT REUSE. Do not lubricate MyoSure® Tissue Removal Device. Discard MyoSure® Tissue Removal Device after use. Dispose of the MyoSure® Tissue Removal Device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.

**WARNING-DANGER:** Risk of explosion if used in the presence of flammable anesthetics

1. Review the system configuration diagram in Figure 5 for set-up outline.

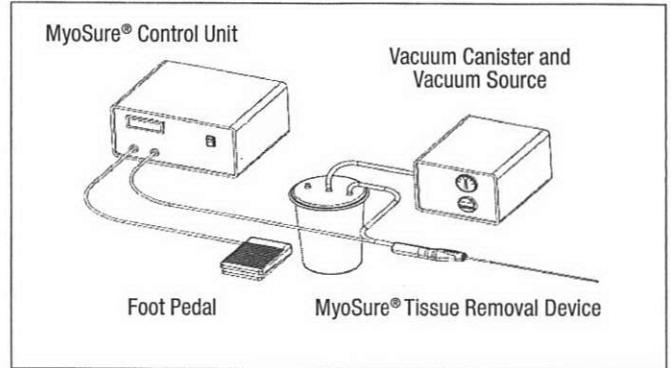


FIGURE 5. SYSTEM CONFIGURATION

2. Place the MyoSure® Control Unit on top of a cart or other stable work surface. Plug the MyoSure® Control Unit power cord into the rear panel connector and a grounded AC power source.
3. Connect the foot pedal tube to the connector on the front of the MyoSure® Control Unit panel.

**Connecting Tissue Removal Device to the MyoSure® Control Unit**

1. Remove the tissue removal device (REF 10-401) from the sterile package.
2. Sterile person hands the flexible drive cable and vacuum tubing to the non-sterile person.
3. Non-sterile person inserts the flexible cable into the corresponding connection on the MyoSure® Control Unit as shown in Figure 6.
4. The tissue removal device flexible drive cable has a keyed feature that serves to align the handpiece cable to the MyoSure® Control Unit connector. The metal tab on the connector is pushed down, the flexible cable inserted and then the tab is released.

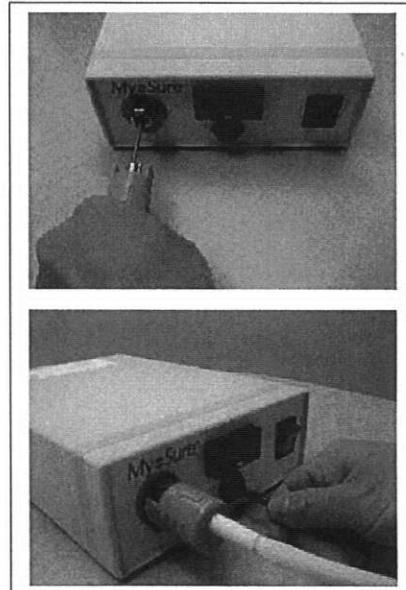


FIGURE 6. INSERT DRIVE CABLE AND FOOT PEDAL INTO MYOSURE® CONTROL UNIT

**CAUTION:** DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply

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bent or kinked drive cable may cause the MyoSure® Control Unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the MyoSure® Control Unit and the MyoSure® Tissue Removal Device to allow the drive cable to hang in a large arc with no bends, loops, or kinks.

5. Non-sterile person attaches the tissue removal device vacuum tubing to the corresponding connection on the tissue trap of the collection canister as shown in Figure 7.

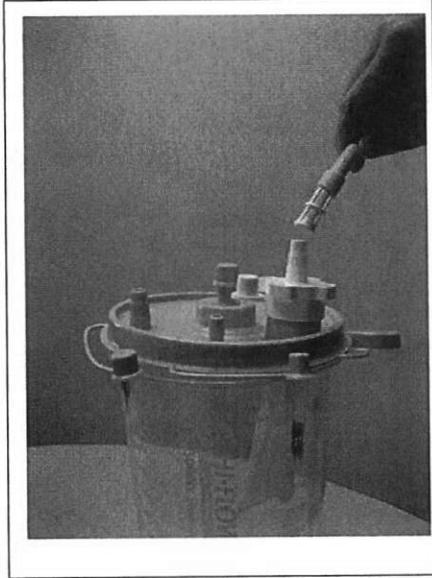


FIGURE 7. ATTACH VACUUM TUBE TO COLLECTION CANISTER

## Operation

1. Push the power switch to the ON (|) position.
2. The foot pedal activates tissue removal device operation. ~~Since the tissue removal device operates in only one direction and speed, the foot pedal merely turns the motor ON and OFF. Once the foot pedal is depressed, the tissue removal device accelerates and rotates to the set speed and continues until the foot pedal is released.~~
3. Press the foot pedal and observe the tissue removal device action to verify that the motor runs and that the cutting window is closed as shown in Figure 8.

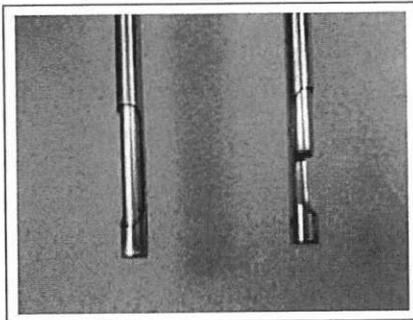


FIGURE 8. CLOSED TISSUE REMOVAL DEVICE CUTTING WINDOW ON LEFT

**WARNING:** Periodic irrigation of the tissue removal device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.

4. Introduce the tissue removal device transvaginally through the straight 3 mm working channel of a previously placed hysteroscope or introducer sheath.
5. Under direct hysteroscopic visualization, position the tissue removal device's side facing cutting window against target pathology.

**CAUTION:** Excessive leverage on the tissue removal device does not improve cutting performance and, in extreme cases, may result in wear, degradation, and seizing of the cutter assembly.

6. Press the foot pedal to activate the tissue removal device's cutting blade.
7. The tissue removal device's reciprocating action alternately opens and closes the device's cutting window to the vacuum flow thereby drawing tissue into the cutting window.
8. Cutting takes place when the tissue removal device cutting edge rotates and translates across the tissue removal device's cutting window.

**CAUTION:** If it appears that the blade has stopped rotating during a procedure, check to ensure that all connections to the MyoSure® Tissue Removal Device and the MyoSure® Control Unit (both mechanical and electrical) are secure and that the drive cable has not wrapped up into a loop.

**NOTE:** If system is turned off for any reason, wait at least 15 seconds before turning power back on.

**CAUTION:** Do not operate the tissue removal device in open air for an extended period, as the lack of irrigation may cause the tissue removal device to overheat and seize.

## Cleaning

### MyoSure® Control Unit and Foot Pedal Cleaning

Follow this procedure after each operation to clean the MyoSure® Control Unit and the foot pedal:

1. Disconnect the tissue removal device from the MyoSure® Control Unit and dispose.
2. Disconnect the MyoSure® Control Unit from the electrical source.
3. Wipe the MyoSure® Control Unit with a clean damp cloth and mild germicide or isopropyl alcohol.

**CAUTION:** Do not sterilize or immerse the MyoSure® Control Unit in disinfectant.

4. Wipe the foot pedal and the foot pedal connecting tube with a clean damp cloth.

The foot pedal (REF 10-903) has no electrical connections and is watertight per IPX8.

## Maintenance and Service

### Maintenance

#### Electrical Interference

**CAUTION:** This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

**Environmental Protection**

**CAUTION:** The control unit and tissue removal device contain electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

**CAUTION:** Tissue removal device (single-use, disposable) may represent biohazard. Treat and dispose of only in accordance with any applicable national or institutional related policy.

**Preventive Maintenance**

**Recommended Annual Performance Checks**

Hologic recommends that Dielectric Strength, Earth Leakage Current, and Protective Earth Testing be performed annually to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications UL 2601-1/IEC 60601-1.

**CAUTION:** Electrical safety testing should be performed by a biomedical engineer or other qualified person.

**Service**

The following are replacement parts for the Hologic MyoSure® Hysteroscopic Tissue Removal System:

REF	Description
10-903	MyoSure® Foot Pedal

**Service Philosophy**

There are no user serviceable components inside the MyoSure® Hysteroscopic Tissue Removal System Control Unit. Repairs and adjustments are to be performed only by Hologic authorized service centers.

If service becomes necessary, refer to the Technical Support Product Return Information in these instructions for use.

**MyoSure® Control Unit Fuses**

The MyoSure® Control Unit is protected by two 1.5 amp/250 V fuses mounted on the rear panel below the three-pronged electrical connector.

If the MyoSure® Control Unit fails to power up when properly connected to a 100–120/200–240 VAC, 50/60Hz, 150 VA, AC power source, check the fuses in the rear panel.

To change the rear panel fuse:

1. Disconnect the unit from the power source.
2. Locate the fuse tray just above the power cord socket and just below the fuse label (refer to Figure 2 rear panel view).
3. Use a slotted screwdriver to press the tabs on either side of the fuse holder in, toward the center of the tray.
4. Slide the fuse tray out.
5. Replace the fuse with 1.5 amp/250 V Slow Acting fuses.
6. Insert the tray into the holder until the tabs click into place.
7. Reapply power to the unit.

**NOTE:** Blown fuses usually indicate a short circuit or a failed component. Make sure components are properly interconnected. If the problem persists, contact Hologic Technical Support for troubleshooting assistance.

**CAUTION:** Electrical safety testing should be performed by a biomedical engineer or other qualified person.

**Troubleshooting**

1. The MyoSure® Hysteroscopic Tissue Removal System is very simple to operate. The control unit is switched ON using the front panel power switch. If the unit does not operate, check the following:
2. Unit is plugged into wall outlet.
3. Wall outlet has power.
4. Power cord is attached to back of MyoSure® Control Unit.
5. Foot Pedal has been connected to front panel.
6. Vacuum pressure is available.
7. Vacuum tubing is connected.

If excess force or bend is applied to the MyoSure® Tissue Removal Device, the control unit will shut off the timer display to protect the system. In this event, switch the main power switch located in the front panel of the control unit to OFF, wait for 15 seconds and then switch the main power switch to ON to resume operation of the MyoSure® Tissue Removal System.

**NOTE:** If the system is turned off for any reason, wait at least 15 seconds before turning the power back on.

**Technical Specifications**

**MyoSure® Control Unit (REF 10-500)**

**Dimensions** 7.5" W x 11" L x 3" H  
19 cm W x 28 cm L x 7.6 cm H

**Weight** 5.4 lbs / 2460 g

**Power** 100–240 VAC, 50/60 Hz, 1.5 A

**Equipment Classification**

Protection against electrical shock class 1 with BF type applied part. Protection against harmful ingress of water, IPX1. Not suitable for use in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide. (Not suitable)

**Mode of Operation** Continuous operation

**Environmental Conditions**

Transportation and Storage  
 Temperature Range: -15°C to 40°C (5° F to 104° F)  
 Relative Humidity: 10 to 93% RH  
 Air Pressure: 500 to 1060 hPa(15 to 31 in Hg)

**Operation**

Temperature Range: 10°C to 40°C (50° F to 104° F)  
 Relative Humidity: 30 to 75% RH  
 Air Pressure: 700 to 1060 hPa (21 to 31 in Hg)

**Front Panel**

**Power ON/OFF** Push button switch

**Time Display Window**

6-character by one-line numeric display which indicates elapsed time  
 Min:Sec

**Connectors**

Flexible drive cable connector for tissue removal device.  
 Foot Pedal cable connector for foot control.

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### Rear Panel

**Cooling** None required

### AC Power

Detachable power cord with a three-pin hospital-grade connector. Power input circuit automatically detects AC power standard.

**Ground Terminal** Equipotential Compensator Terminal

**Fuses** Two 1.5 amp/250 V Slow Acting fuses

### MyoSure® Tissue Removal Device Handpiece (REF 10-401)

Length: 25.25" / 64.14 cm

OD: 3 mm

Weight: 17 oz. / 482 g

### MyoSure® Foot Pedal (REF 10-903)

Dimensions: 4" x 6" x 2" / 10 cm x 15 cm x 5 cm

Weight: 10 oz. / 284 g

Equipped with 12-foot (3.6-meter) cord. The foot pedal (REF 10-903) has no electrical connections.

### MyoSure® Tissue Removal Device Accessories

#### **Vacuum Source** – 200–650 mm Hg

Olympus Vacuum Pump Model KV-5 or equivalent in compliance with national version of safety standard, IEC 60601-1:1988-1995 (e.g., for USA, UL 60601-1:2003; for Europe, EN 60601-1:1990-1996; for Canada, CSA C22.2 No. 601.1:1998, etc.)

#### **Vacuum Canister & Tissue Trap**

Bemis 3000 cc Hi-Flow Canister Model 3002 055 or equivalent  
Bemis Specimen Collection Adapter 533810 or equivalent

## WARRANTY, SERVICE, AND REPAIR

### WARRANTY INFORMATION

Hologic warrants to the original purchaser of the MyoSure Hysteroscopic Tissue Removal System that it shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its instructions for use and maintenance instructions. The obligation of Hologic under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Hologic within one year from the date of purchase, if examination shall disclose to the satisfaction of Hologic that the product does not meet this warranty.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF HOLOGIC. HOLOGIC NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH THE SALE OF A MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM. THIS WARRANTY SHALL NOT APPLY TO A MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM OR ANY OTHER PART THEREOF WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, NOR TO ANY MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM THAT HAS BEEN REPAIRED OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED

HOLOGIC SERVICE PERSON. HOLOGIC MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM AND NOT SUPPLIED AND MANUFACTURED BY HOLOGIC. THE TERM "ORIGINAL PURCHASER", AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM WAS SOLD BY HOLOGIC. THIS WARRANTY MAY NOT BE ASSIGNED OR TRANSFERRED IN ANY MANNER.

### TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

Contact Hologic Technical Support if the MyoSure Hysteroscopic Tissue Removal System fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable. Return the MyoSure Hysteroscopic Tissue Removal System according to the instructions provided by Technical Support. Be sure to clean and sterilize the product before returning it and include all accessories in the box with the returned unit.

Return used or opened product according to the instructions provided with the Hologic-supplied biohazard kit.

Hologic and its distributors and customers in the European Community are required to comply with the Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC). Hologic is dedicated to meeting country specific requirements related to the environmentally sound treatment of its products. Hologic's objective is to reduce the waste resulting from the disposal of its electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE to potential reuse, treatment, recycling, or recovery to minimize the amount of hazardous substances entering the environment. Hologic customers in the European Community are responsible for ensuring that medical devices marked with the following symbol, indicating that the WEEE Directive applies, are not placed into a municipal waste system unless authorized to do so by local authorities.



Contact Hologic Technical Support to arrange for proper disposal of the control unit in accordance with the WEEE Directive.

### Hologic Technical Support

United States

Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA

Phone: 1.800.442.9892 (toll-free) or 1.508.263.2900

Fax: 1.508.229.2795

**EC REP** European Representative

Hologic UK Ltd

Link 10 Napier Way, Crawley, West Sussex, RH10 9 RA UK

Phone: +44 (0) 1293 522 080

**Electromagnetic Safety Guidance**

The following tables provide information on the electromagnetic environment that the MyoSure® Hysteroscopic Tissue Removal System is capable of operating in safely. Use of this equipment in an environment that exceeds these limits may cause the device to stop working, change cutting speed, or produce other unknown behavior. It is the responsibility of the person installing the Hologic MyoSure® Hysteroscopic Tissue Removal System to insure the electromagnetic environment does not exceed the specification set forth below in Tables 1–4.

**Table 1 – Guidance and manufacturer's declaration – electromagnetic emissions**

Guidance and manufacturer's declaration – electromagnetic emissions		
The MyoSure® Hysteroscopic Tissue Removal System is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoSure® Hysteroscopic Tissue Removal System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The MyoSure® Hysteroscopic Tissue Removal System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MyoSure® Hysteroscopic Tissue Removal System is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

**Table 2 – Guidance and manufacturer's declaration – electromagnetic immunity**

Guidance and manufacturer's declaration – electromagnetic immunity			
The MyoSure® Hysteroscopic Tissue Removal System is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoSure® Hysteroscopic Tissue Removal System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 s	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MyoSure® Hysteroscopic Tissue Removal System requires continued operation during power mains interruptions, it is recommended that the MyoSure® Hysteroscopic Tissue Removal System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels typical for commercial or hospital environments.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

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Table 3 – Guidance and manufacturer's declaration – electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The MyoSure® Hysteroscopic Tissue Removal System is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoSure® Hysteroscopic Tissue Removal System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MyoSure® Hysteroscopic Tissue Removal System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance (in meters)</b>  $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MyoSure® Hysteroscopic Tissue Removal System is used exceeds the applicable RF compliance level above, the MyoSure® Hysteroscopic Tissue Removal System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MyoSure® Hysteroscopic Tissue Removal System.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

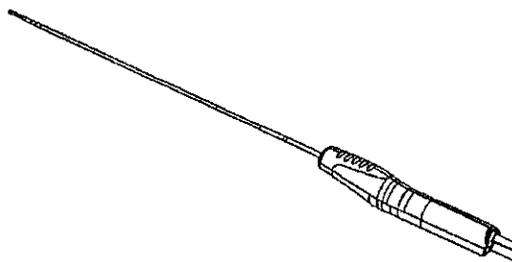
Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the MyoSure® Hysteroscopic Tissue Removal System

Recommended separation distances between portable and mobile RF communications equipment and the MyoSure® Hysteroscopic Tissue Removal System			
The MyoSure® Hysteroscopic Tissue Removal System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MyoSure® Hysteroscopic Tissue Removal System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MyoSure® Hysteroscopic Tissue Removal System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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# MyoSure® Hysteroscopic Tissue Removal System

## Instructions for Use



# HOLOGIC®

**PLEASE READ ALL INFORMATION CAREFULLY.**

**R<sub>X</sub> ONLY**

### Description

The MyoSure® Tissue Removal System consists of the following procedural components:

- Control Unit
- Tissue Removal Device (Single Use)
- Foot Pedal

The sterile, disposable, hand-held tissue removal device is used to hysteroscopically remove intrauterine tissue. It is connected via a flexible drive shaft to a motorized control unit. A foot pedal allows the user to control the tissue removal device by turning the motor in the control unit on and off.

### Indications for Use

The MyoSure Tissue Removal System is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue including submucous myomas and endometrial polyps.

### Contraindications

The MyoSure Tissue Removal System should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

### Warnings and Precautions

The brief operating instructions in this guide will make the system easier to use. As with any surgical instrument, there are important health and safety considerations. These are as follows:

- Before using the MyoSure Tissue Removal System for the first time, please review all available product information.
- Before using the MyoSure Tissue Removal System, you should be experienced in hysteroscopic surgery with powered instruments. Healthy uterine tissue can be injured by improper use of the tissue removal device. Use every available means to avoid such injury.

- Use only the MyoSure® Control Unit to connect to the MyoSure® Tissue Removal Device. Use of any other drive mechanism may result in failure of the device to operate or lead to patient or physician injury.
- If visualization is lost at any point during a procedure, stop cutting immediately.
- Periodic irrigation of the tissue removal device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.
- Ensure that vacuum pressure >200 mm Hg is available before commencing surgery.
- **DANGER:** Risk of explosion if used in the presence of flammable anesthetics.
- **WARNING - Exercise extreme caution when resecting tissue in patients who have implants that extend into the uterine cavity.**
- Do not use the MyoSure Tissue Removal Device to resect tissue that is adjacent to an implant. When resecting tissue in patients that have implants, assure that:
  - the MyoSure Tissue Removal Device's cutting window is facing away from (i.e., 180° opposite) the implant;
  - the visual field is clear; and
  - the MyoSure Tissue Removal Device's cutting window is engaged in tissue and is moved away from the implant as tissue resection proceeds.
- In the event an implant becomes entangled with a MyoSure cutter, the following steps are recommended:
  - cease cutting immediately;
  - kink the MyoSure Tissue Removal Device's outflow tube to prevent a loss of uterine distension;
  - disconnect the MyoSure Tissue Removal Device's drive cable from the control box;
  - grasp the end of the MyoSure Tissue Removal Device drive cable with a hemostat or other clamping device;
  - hold the drive cable hub and tissue removal device to prevent twisting;
  - open the tissue removal device's cutting window by manually twisting the hemostat counterclockwise; and
  - gently pull the MyoSure Tissue Removal Device into the hysteroscope to detach the MyoSure device from the implant.

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- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment in the patient vicinity not complying with the equivalent medical safety requirements of this equipment may lead to a reduced level of safety of the resulting system. The use of accessory equipment outside the patient vicinity not complying with medical or otherwise appropriate safety requirements may lead to a reduced level of safety of the resulting system.
- Use of an accessory, transducer, or cable, other than those specified by Hologic may result in increased emissions or decreased immunity of the MyoSure Hysteroscopic Tissue Removal System.

### Precautions

**R**X U.S. Federal law restricts this device to sale by or on the order of a physician.

- The tissue removal device should be stored at room temperature, away from moisture and direct heat.
- Do not use after expiration date.
- Do not use the device if the sterile package is open or appears compromised. Do not use the device if damage is observed.
- To assure optimal performance, replace the tissue removal device after 2 hours of cutting time.
- The tissue removal device is intended for single use only. Do not re-sterilize. Do not lubricate tissue removal device. Discard tissue removal device assembly after use.
- Use of a reprocessed, single-use tissue removal device may permanently damage, impede performance, or cause failure of the MyoSure Hysteroscopic Tissue Removal System. Use of such products may render any warranties null and void.
- DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or kinked drive cable may cause the control unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the control unit and the tissue removal device to allow the drive cable to hang in a large arc with no bends, loops, or kinks.
- DO NOT rotate the tissue removal device  $>180^\circ$  if the tissue removal device is not running. The cutting window may open up which will lead to inability to maintain distension. If such situation occurs, just tap the foot pedal once or twice to run the tissue removal device; the cutting window will then close automatically.
- If it appears that the tissue removal device's cutter blade has stopped rotating during a procedure, check to ensure that all connections to the tissue removal device and the control unit (both mechanical and electrical) are secure and that the drive cable has not wrapped into a loop.
- Exercise care when inserting or removing the device. Insertion and removal of the device should be performed under direct visualization at all times.
- To avoid perforation, keep the device tip under direct visualization and exercise care at all times when maneuvering it or cutting tissue close to uterine wall. Never use the device tip as a probe or dissecting tool.
- Exercise care when inserting or removing the device. Excessive bending of the device distal tip can cause the tissue removal device's cutter to come out of the cutting window. If such damage occurs, replace the device immediately.
- Do not allow the rotating portion of the tissue removal device to touch any metallic object such as a hysteroscope or sheath. Damage to both instruments is likely. Damage to the tissue removal device can range from a slight distortion or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures, or dulling, or if you have any other reason to suspect a tissue removal device is damaged, replace it immediately.
- Do not operate the tissue removal device in the open air for an extended period, as the lack of irrigation may cause the tissue removal device to overheat and seize.
- Excessive leverage on the tissue removal device does not improve cutting performance and, in extreme cases, may result in wear, degradation, and seizing of the inner assembly.
- Do not sterilize or immerse the control unit in disinfectant.
- Do not cool the tissue removal device by immersing it in cold water.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

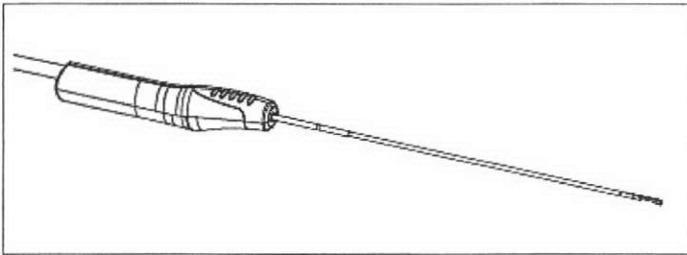
### Electromagnetic Safety

- The MyoSure Tissue Removal System needs special precautions regarding electromagnetic safety and needs to be installed and put into service according to the electromagnetic safety information provided in the system's Operating Manual.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- All equipment performance is considered safety-related performance. That is, the failure or degradation of the performance specified in this manual may pose a safety risk to the patient or operator of this equipment.
- **Note: If the MyoSure Tissue Removal System is put into service in accordance to the safety instruction in this manual, the product should remain safe and provide the performance listed above. If the product fails to provide this level of performance, the procedure should be aborted and the biomedical staff alerted to the observed problem. The problem needs to be corrected before continuing or starting a new procedure.**
- Portable and mobile RF communications equipment, including cellular telephones and other wireless devices can affect medical electrical equipment. To insure safe operation of the MyoSure Hysteroscopic Tissue Removal System, do not operate communications equipment or cellular telephones at a distance closer than specified in Table 4 of the Operating Manual.
- The MyoSure Tissue Removal System is not designed to work with or in the vicinity of electrical surgical equipment. If electrical surgical equipment must be used in the same area as the MyoSure Hysteroscopic Tissue Removal System, the MyoSure Tissue Removal System should be observed for proper operation before performing a procedure. This includes operating the electrical surgical equipment in its active mode at a power level suitable for the procedure.

- For more information regarding the electromagnetic safety of this product, please see Tables 1–4 in the back of the Operating Manual.

**Tissue Removal Device: 10-401**

The MyoSure Tissue Removal Device is shown in Figure 1. It is a hand-held unit which is connected to the control unit via a 6-foot (1.8-meter) flexible drive cable and to a collection canister via a 10-foot (3-meter) vacuum tube. Cutting action is activated by a foot pedal. The tissue removal device is a single-use device designed to hysteroscopically remove intrauterine tissue.



**FIGURE 1. MYOSURE® TISSUE REMOVAL DEVICE**

The flexible drive cable is inserted into the drive cable connection on the front panel of the MyoSure Control Unit.

The proximal end of the vacuum tubing is connected to a collection canister. The vacuum pressure draws fluid and resected tissue through the tissue removal device's cutting window.

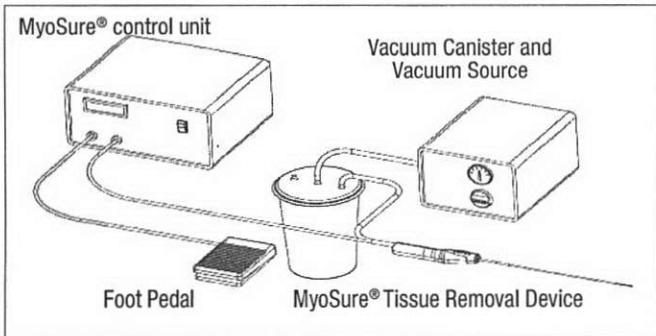
**Set-up**

The tissue removal device is EtO sterilized. Verify that the tissue removal device is sterile prior to use. Do not use if the package is opened or damaged. Discard all opened, unused devices.

**CAUTION: The tissue removal device is intended for single use only. DO NOT RE-STERILIZE. DO NOT REUSE. Do not lubricate tissue removal device. Discard tissue removal device after use. Dispose of the tissue removal device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.**

**WARNING-DANGER: Risk of explosion if used in the presence of flammable anesthetics.**

1. Review the System Configuration Diagram in Figure 2 for set-up outline.

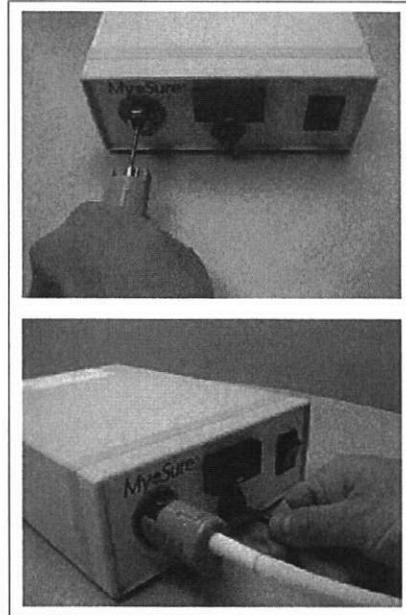


**FIGURE 2. SYSTEM CONFIGURATION**

2. Place the control unit on top of a cart or other stable work surface. Plug the control unit power cord into the rear panel connector and a grounded AC power source.
3. Connect the foot pedal tube to the connector on the front of the control unit panel.

**Connecting Tissue Removal Device to the Control Unit**

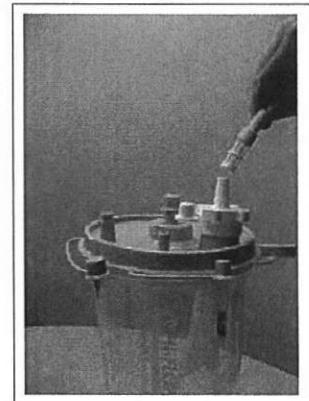
1. Remove the tissue removal device (REF 10-401) from the sterile package.
2. Sterile person hands the flexible drive cable and vacuum tubing to the non-sterile person.
3. Non-sterile person inserts the flexible cable into the corresponding connection on the control unit as shown in Figure 3.
4. The tissue removal device flexible drive cable has a keyed feature that serves to align the handpiece cable to the control unit connector. The metal tab on the connector is pushed down, the flexible cable inserted and then the tab is released.



**FIGURE 3. INSERT DRIVE CABLE AND FOOT PEDAL INTO CONTROL UNIT**

**CAUTION: DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or kinked drive cable may cause the control unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the control unit and the tissue removal device to allow the drive cable to hang in a large arc with no bends, loops, or kinks.**

5. Non-sterile person attaches the tissue removal device vacuum tubing to the corresponding connection on the tissue trap of the collection canister as shown in Figure 4.



**FIGURE 4. ATTACH VACUUM TUBE TO COLLECTION CANISTER**

## Operation

1. Push the power switch to the ON (I) position. *S7 17FEB2012*
2. The foot pedal activates tissue removal device operation. ~~Since the tissue removal device operates in only one direction and speed, the foot pedal merely turns the motor ON and OFF.~~ Once the foot pedal is depressed, the tissue removal device accelerates and rotates to the set speed and continues until the foot pedal is released.
3. Press the foot pedal and observe the tissue removal device action to verify that the motor runs and that the cutting window is closed as shown in Figure 5.

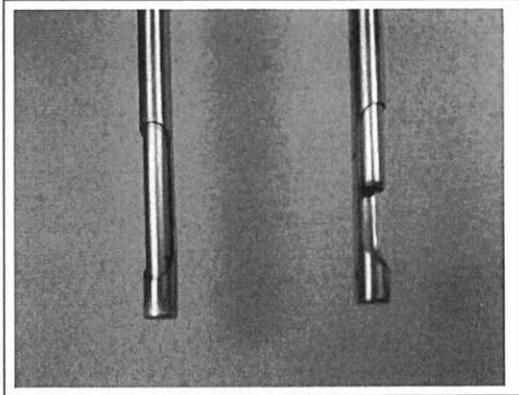


FIGURE 5. CLOSED TISSUE REMOVAL DEVICE CUTTING WINDOW ON LEFT

**WARNING:** Periodic irrigation of the tissue removal device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.

1. Introduce the tissue removal device transvaginally through the straight 3 mm working channel of a previously placed hysteroscope.
5. Under direct hysteroscopic visualization, position the tissue removal device's side facing cutting window against target pathology.

**CAUTION:** Excessive leverage on the tissue removal device does not improve cutting performance and, in extreme cases, may result in wear, degradation, and seizing of the cutter assembly.

6. Press the foot pedal to activate the tissue removal device's cutting blade.
7. The tissue removal device's reciprocating action alternately opens and closes the device's cutting window to the vacuum flow thereby drawing tissue into the cutting window.
8. Cutting takes place when the tissue removal device cutting edge rotates and translates across the tissue removal device's cutting window.

**CAUTION:** If it appears that the blade has stopped rotating during a procedure, check to ensure that all connections to the tissue removal device and the control unit (both mechanical and electrical) are secure and that the drive cable has not wrapped into a loop.

**NOTE:** If system is turned off for any reason, wait at least 15 seconds before turning power back on.

### Storage

The tissue removal device should be stored at room temperature, away from moisture and direct heat. Do not use after expiration date.

### Sterility

The tissue removal device is EtO sterilized. DO NOT RE-STERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

### Disposal

Disconnect the tissue removal device from the control unit. Dispose of the tissue removal device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.

**CAUTION:** The tissue removal device contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

### Troubleshooting

The MyoSure® Tissue Removal System is very simple to operate. The control unit is switched ON using the front panel power switch. If the unit does not operate, check the following:

1. Unit is plugged into wall outlet.
2. Wall outlet has power.
3. Power cord is attached to back of control unit.
4. Foot pedal has been connected to front panel.
5. Vacuum pressure is available.
6. Vacuum tubing is connected.

If excess force or bend is applied to the tissue removal device, the control unit will shut off the timer display to protect the system. In this event, switch the main power switch located in the front panel of the control unit to OFF, wait for 15 seconds and then switch the main power switch to ON to resume operation of the MyoSure® Tissue Removal System.

**NOTE:** If the system is turned off for any reason, wait at least 15 seconds before turning the power back on.

## Technical Specifications

### Tissue Removal Device: 10-401

Sterile, single use device

Length: 25.25" / 64.14 cm

OD: 3 mm

Weight: 17 oz. / 482 g

### Tissue Removal Device Accessories

#### Vacuum Source – 200–650 mm Hg

Olympus Vacuum Pump Model KV-5 or equivalent in compliance with national version of safety standard, IEC 60601-1:1988-1995 (e.g., for USA, UL 60601-1:2003; for Europe, EN 60601-1:1990-1996; for Canada, CSA C22.2 No. 601.1:1998, etc)

#### Vacuum Canister & Tissue Trap

Bemis 3000 cc Hi-Flow Canister Model 3002 055 or equivalent  
Bemis Specimen Collection Adapter 533810 or equivalent

**WARRANTY, SERVICE, AND REPAIR**

**WARRANTY INFORMATION**

Hologic warrants to the original purchaser of the MyoSure® Hysteroscopic Tissue Removal System that it shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its instructions for use and maintenance instructions. The obligation of Hologic under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Hologic within one year from the date of purchase, if examination shall disclose to the satisfaction of Hologic that the product does not meet this warranty.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF HOLOGIC. HOLOGIC NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH THE SALE OF A MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM. THIS WARRANTY SHALL NOT APPLY TO A MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM OR ANY OTHER PART THEREOF WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, NOR TO ANY MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM THAT HAS BEEN REPAIRED OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED HOLOGIC SERVICE PERSON. HOLOGIC MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM AND NOT SUPPLIED AND MANUFACTURED BY HOLOGIC. THE TERM "ORIGINAL PURCHASER", AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM WAS SOLD BY HOLOGIC. THIS WARRANTY MAY NOT BE ASSIGNED OR TRANSFERRED IN ANY MANNER.

**TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION**

Contact Hologic Technical Support if the MyoSure Hysteroscopic Tissue Removal System fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable. Return the MyoSure Hysteroscopic Tissue Removal System according to the instructions provided by Technical Support. Be sure to clean and sterilize the product before returning it and include all accessories in the box with the returned unit.

Return used or opened product according to the instructions provided with the Hologic-supplied biohazard kit.

**Hologic Technical Support**

United States  
 Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA  
 Phone: 1.800.442.9892 (toll-free) or 1.508.263.2900  
 Fax: 1.508.229.2795

**EC/REP** European Representative

Hologic UK, Ltd.  
 Link 10 Napier Way, Crawley, West Sussex RH10 9 RA UK  
 Phone: +44 (0) 1293 522 080

**Symbols Used on Labeling**

Authorized Representative in the European Community	
Batch code, Lot code	
Catalogue number, Part number, or reorder number	
Caution, consult accompanying documents	
Contents	
Do not reuse	
Do not use if package is damaged	
Use by	
Manufacturer	
ON Main electrical power on.	
OFF Main electrical power off.	
Patient contact parts do not contain phthalates	
Serial number	
Sterilized using ethylene oxide	
U.S. federal law restricts this device to sale by or on the order of a physician	

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## **14 STERILIZATION**

The proposed changes do not affect any of the sterilization parameters of the cleared device (K100559). Therefore, the sterilization information that has already been submitted, and is on file at Hologic, Inc, remains identical.

;

## **15 BIOCOMPATIBILITY**

The proposed changes do not affect any material components of the cleared device (K100559). Therefore, the biocompatibility testing and information that has already been submitted, and is on file at Hologic, Inc, remains identical.

## 16. SOFTWARE

### Software Level of Concern Analysis

FDA has previously determined that software used to control the Myosure Hysteroscopic Tissue Removal System (K091100, K100559) (b)(4) Trade Secret Process - Software

Confidential

### Software Design Description

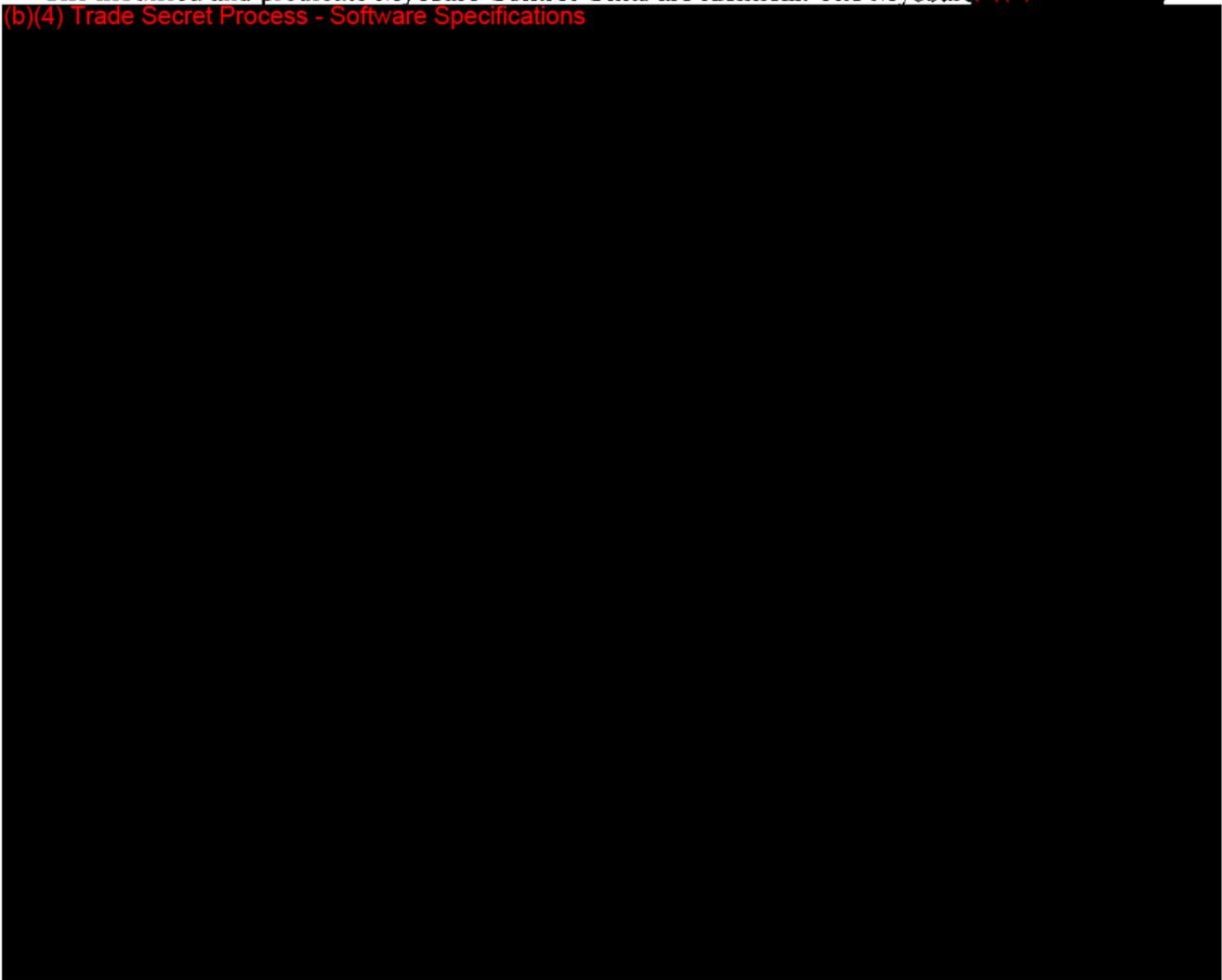
#### Functional Overview

Firmware present in the predicate Myosure Hysteroscopic Tissue Removal System (K100559) has been updated to allow the motor to move bidirectionally.

#### Software Operating Environment

The modified and predicate Myosure Control Units are identical. The Myosure (b)(4) Trade

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**Software Interfaces**

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**Programming Language**

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**Summary of Firmware Functional Requirements**

The Myosure System (b)(4) performs the same functions as the predicate software, cleared by FDA in K100559, by driving the motor mechanism in the handpiece.

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In addition to the logic above, set other Maxon motor controller (b)(4) Trade Secret Process - Software Specifications:

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The Full Software Design Specification and Software Requirements Specification have been included in this section of the submission.

**Risk/Hazard Analysis**

In accordance with Hologic's design control procedures, the following documents were reviewed and revised as necessary based on changes proposed for the modified Myosure Hysteroscopic Tissue Removal System:

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The referenced documents are on file at Hologic, Inc.

**Traceability Matrix**

The table tracing requirements, specifications, hazards, mitigations and verification & validation testing for the Myosure System (b)(4) Trade Secret Process - Software Specifications

**Software Revision Level History**

(b)(4) Trade Secret Process - Software Specifications

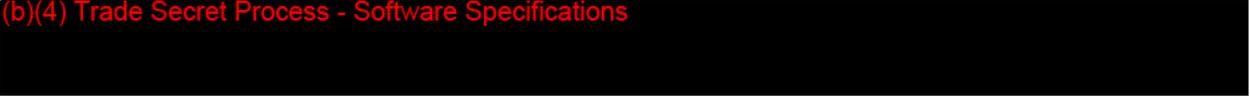
**Software Verification**

Verification of the modified Myosure System (b)(4) Trade Secret Process - Software Specifications was performed with same verification & validation test protocols as the predicate (b)(4) Trade Secret Process - Software Specifications cleared by FDA in K100559.

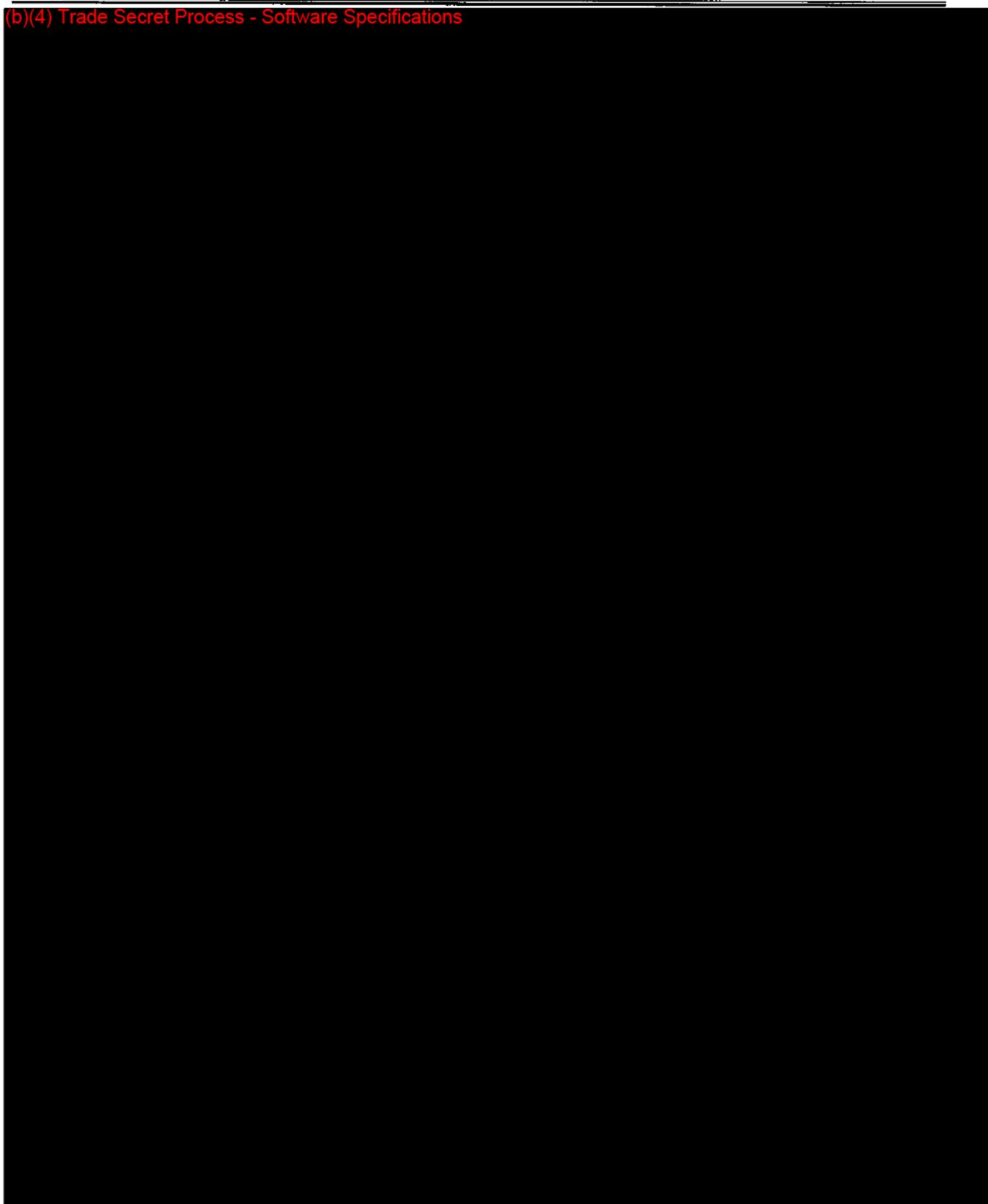
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**Unresolved Bugs and Anomalies**

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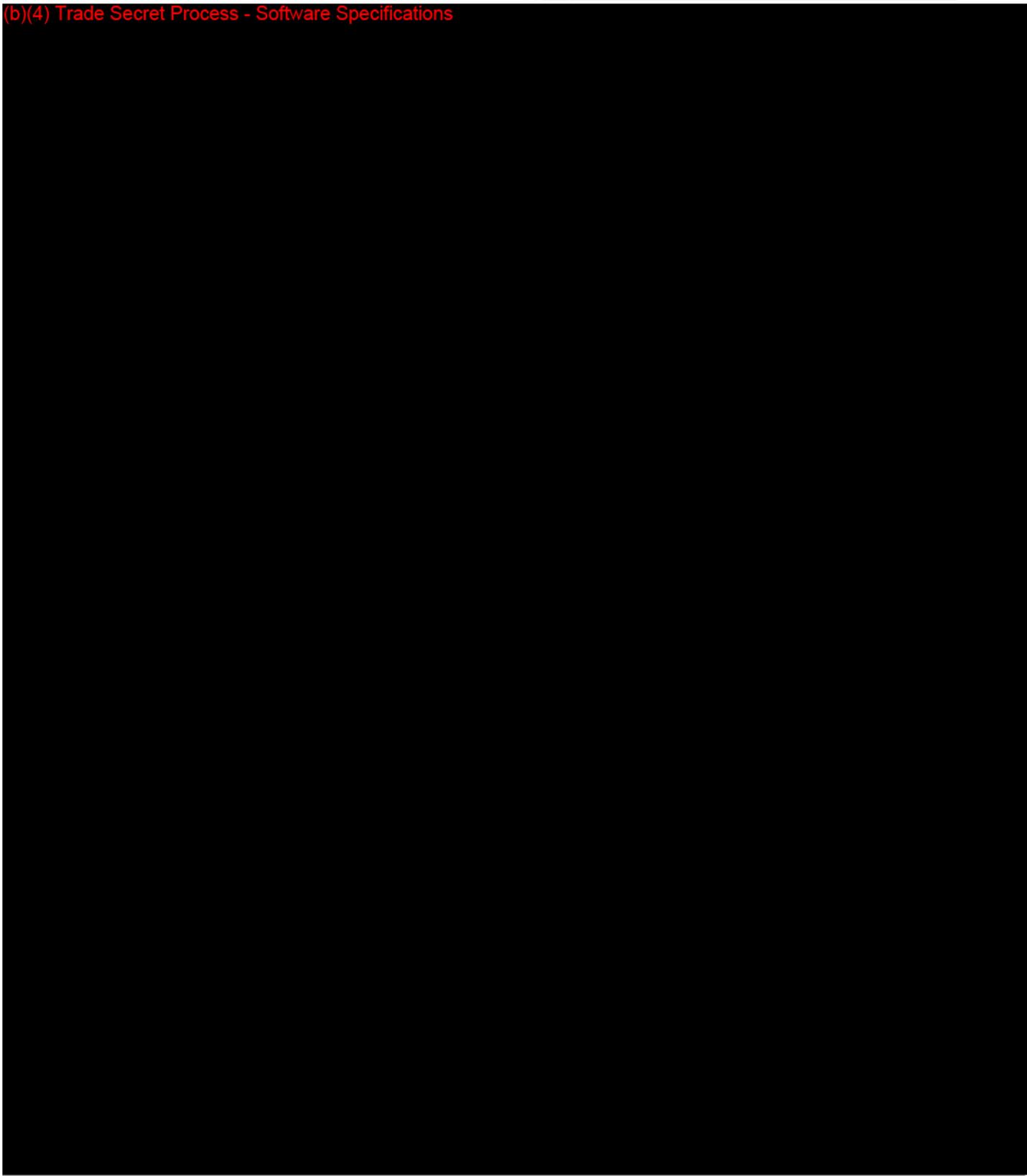
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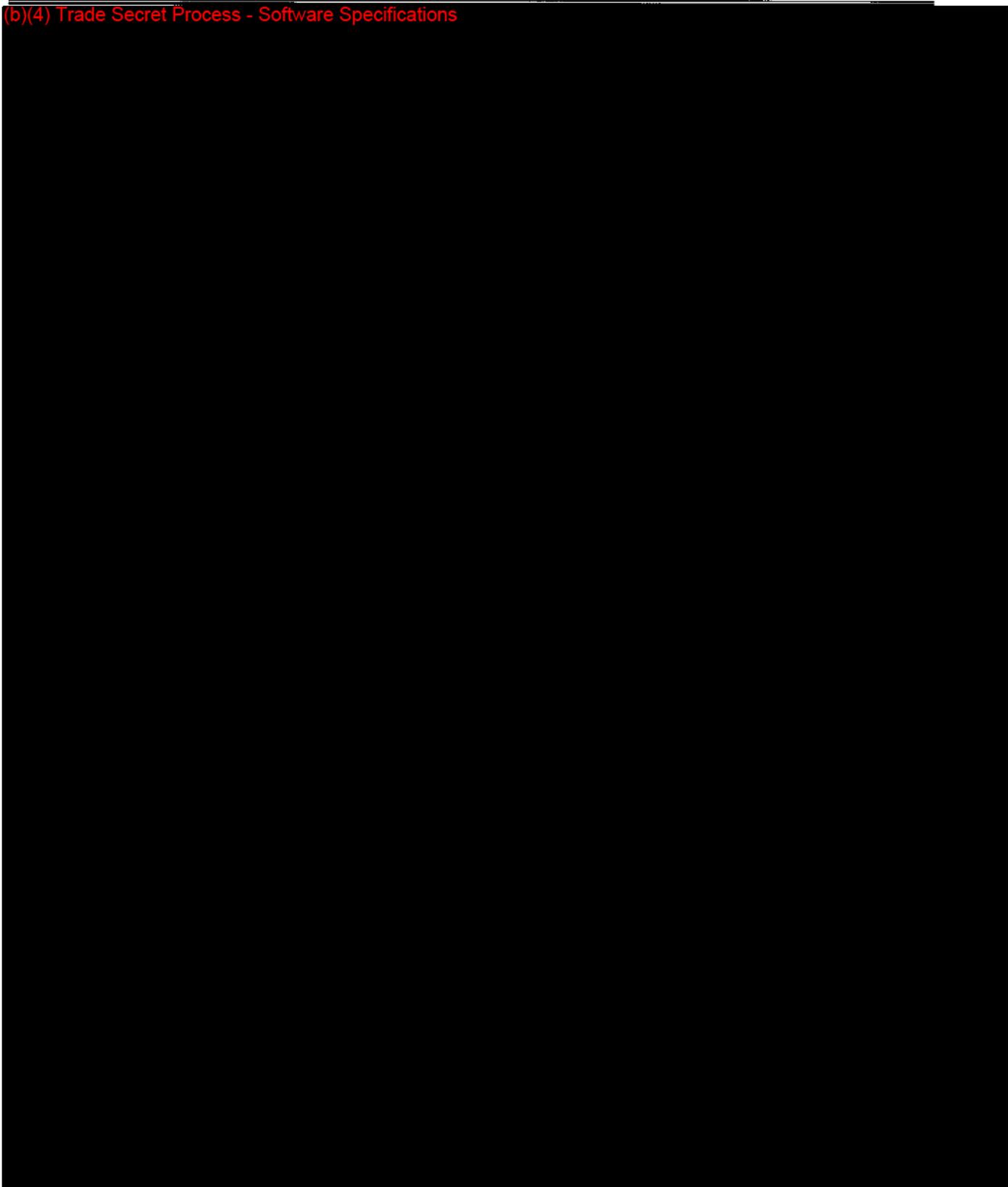
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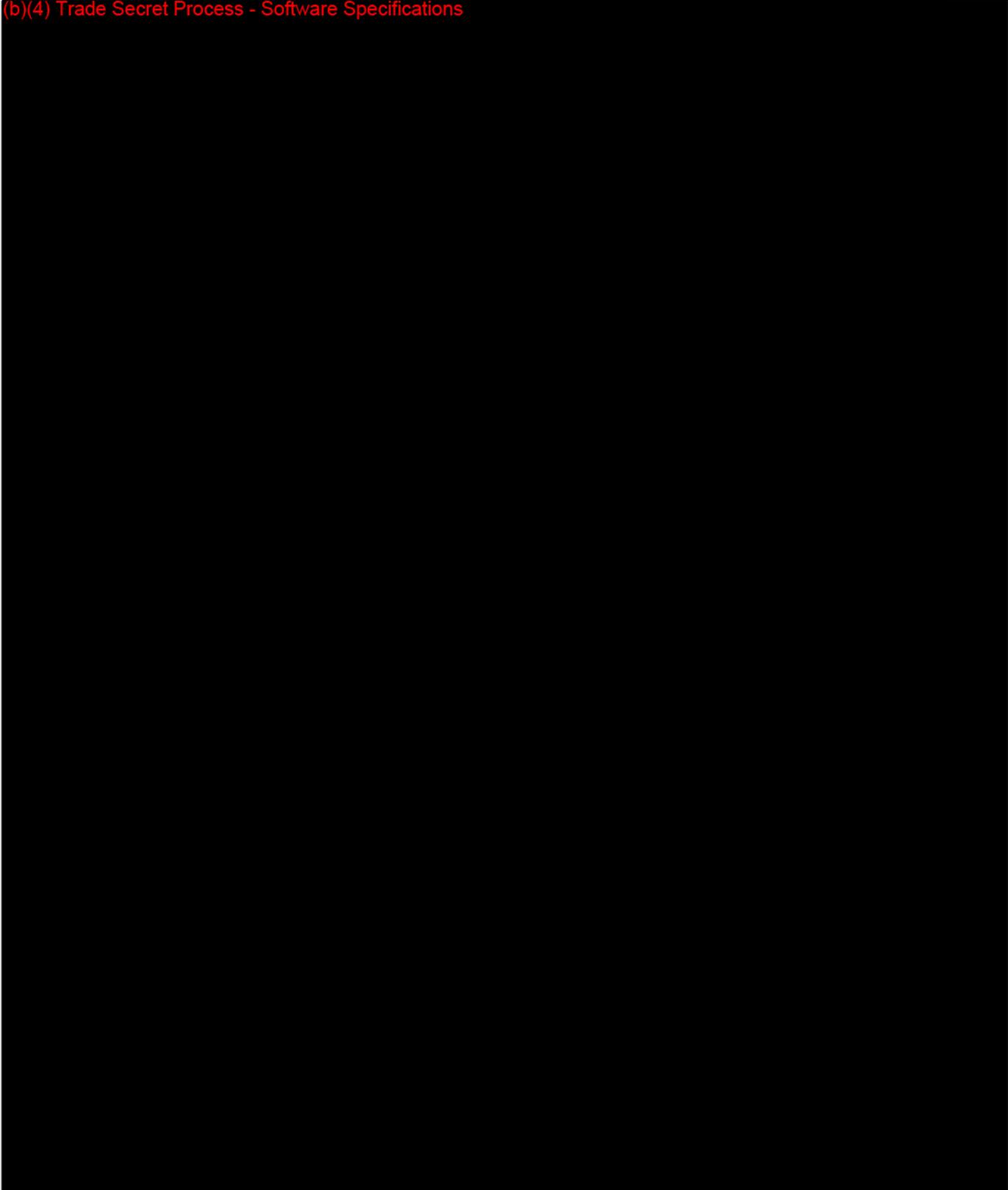
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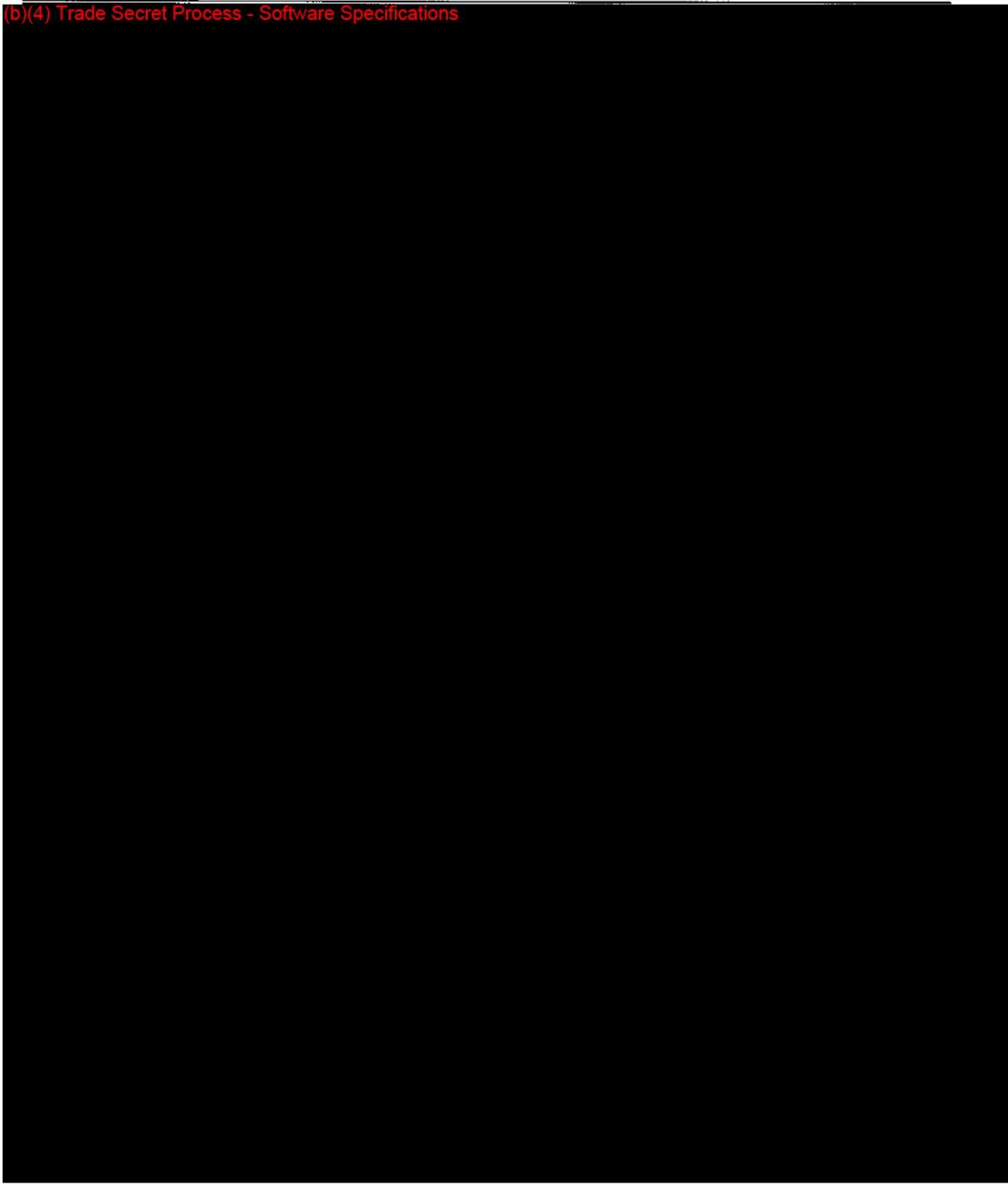
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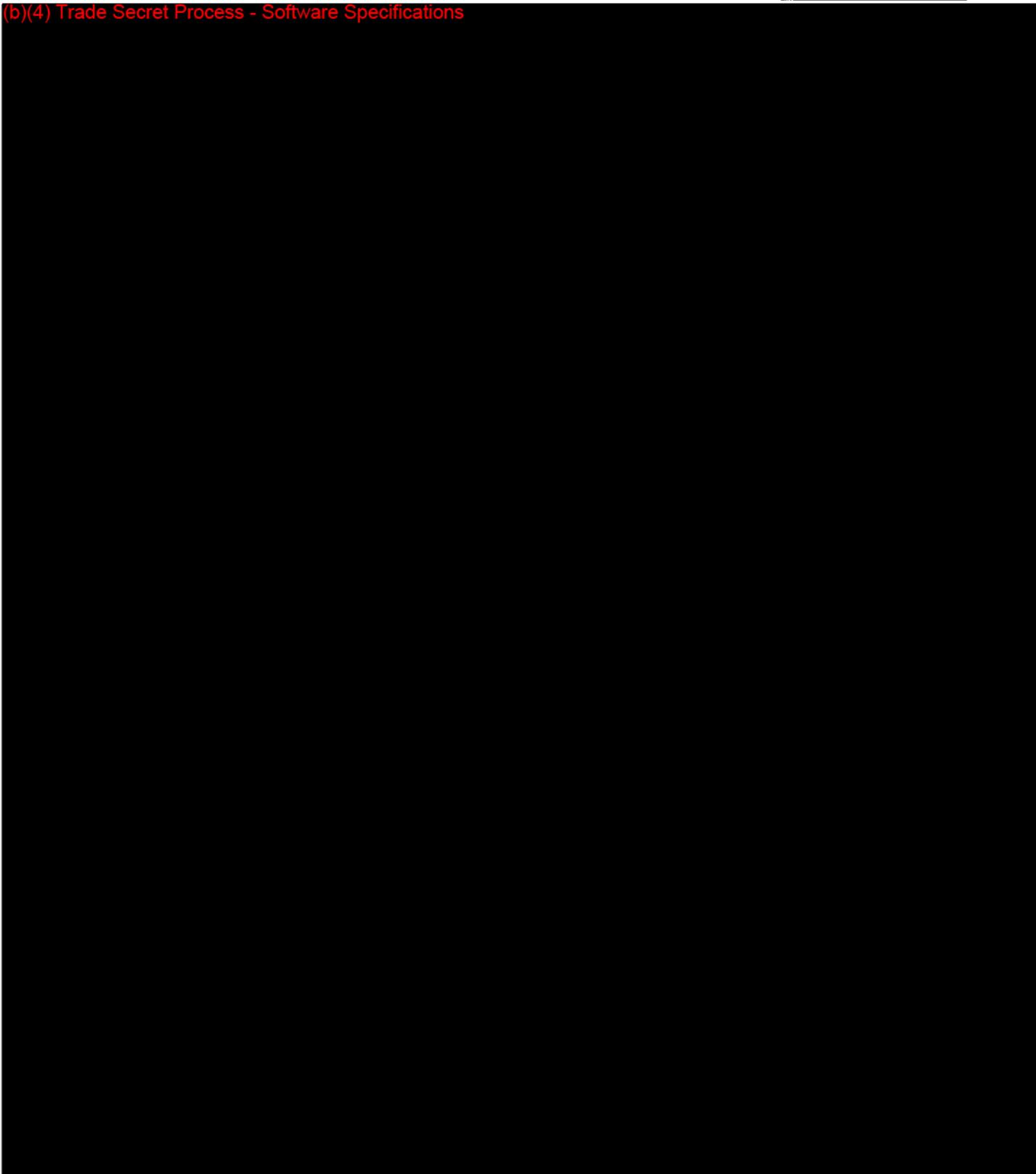
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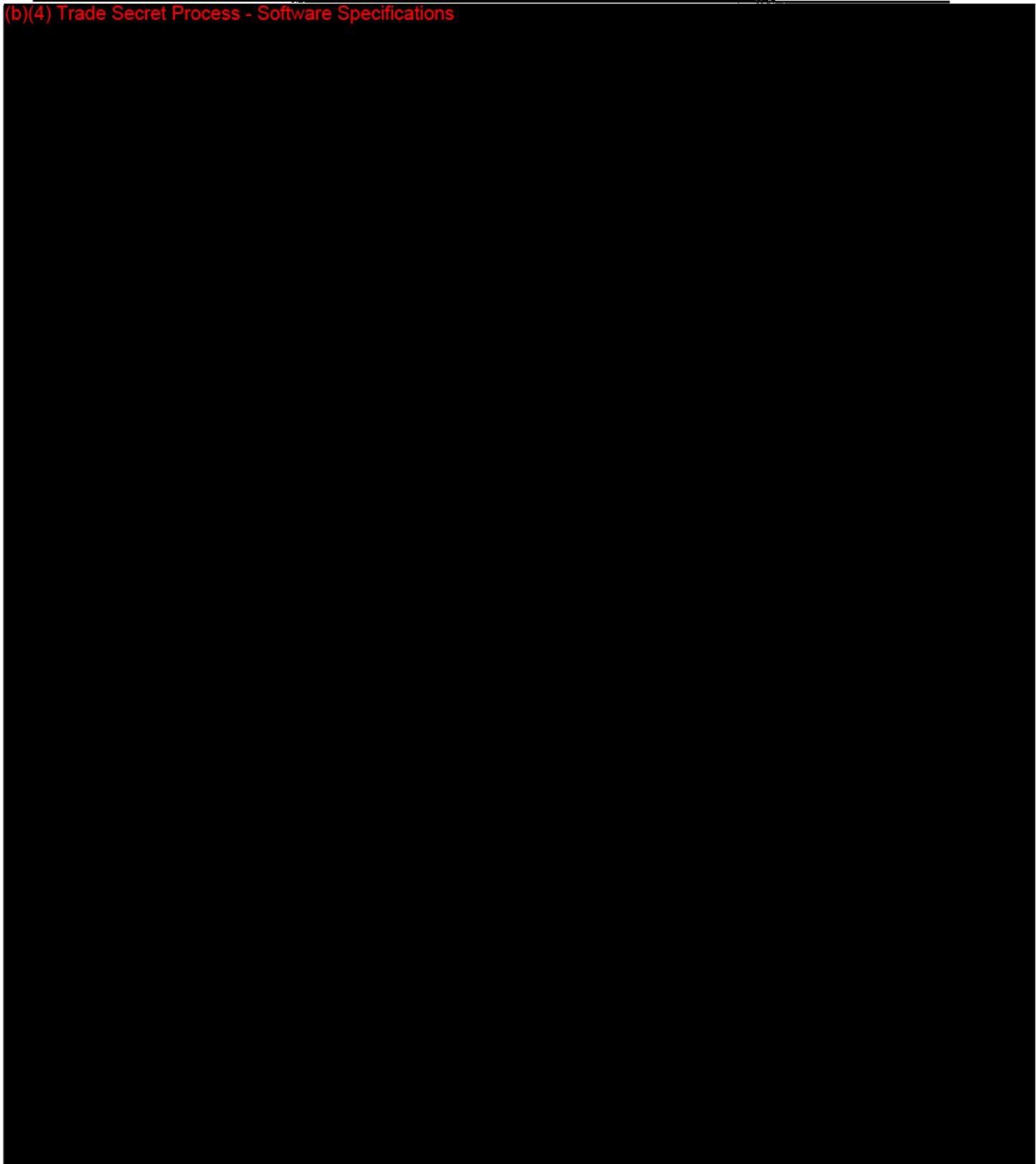
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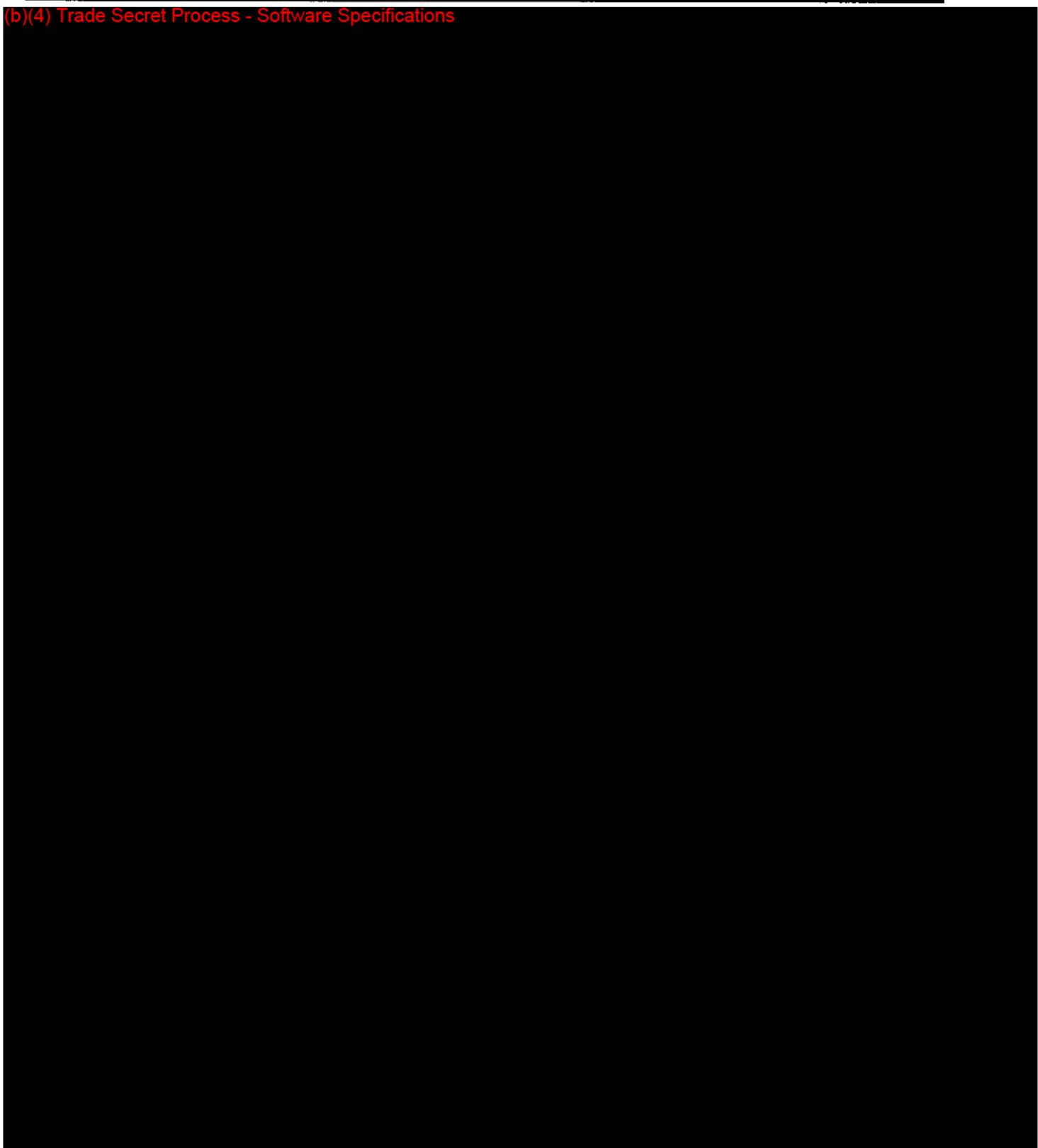
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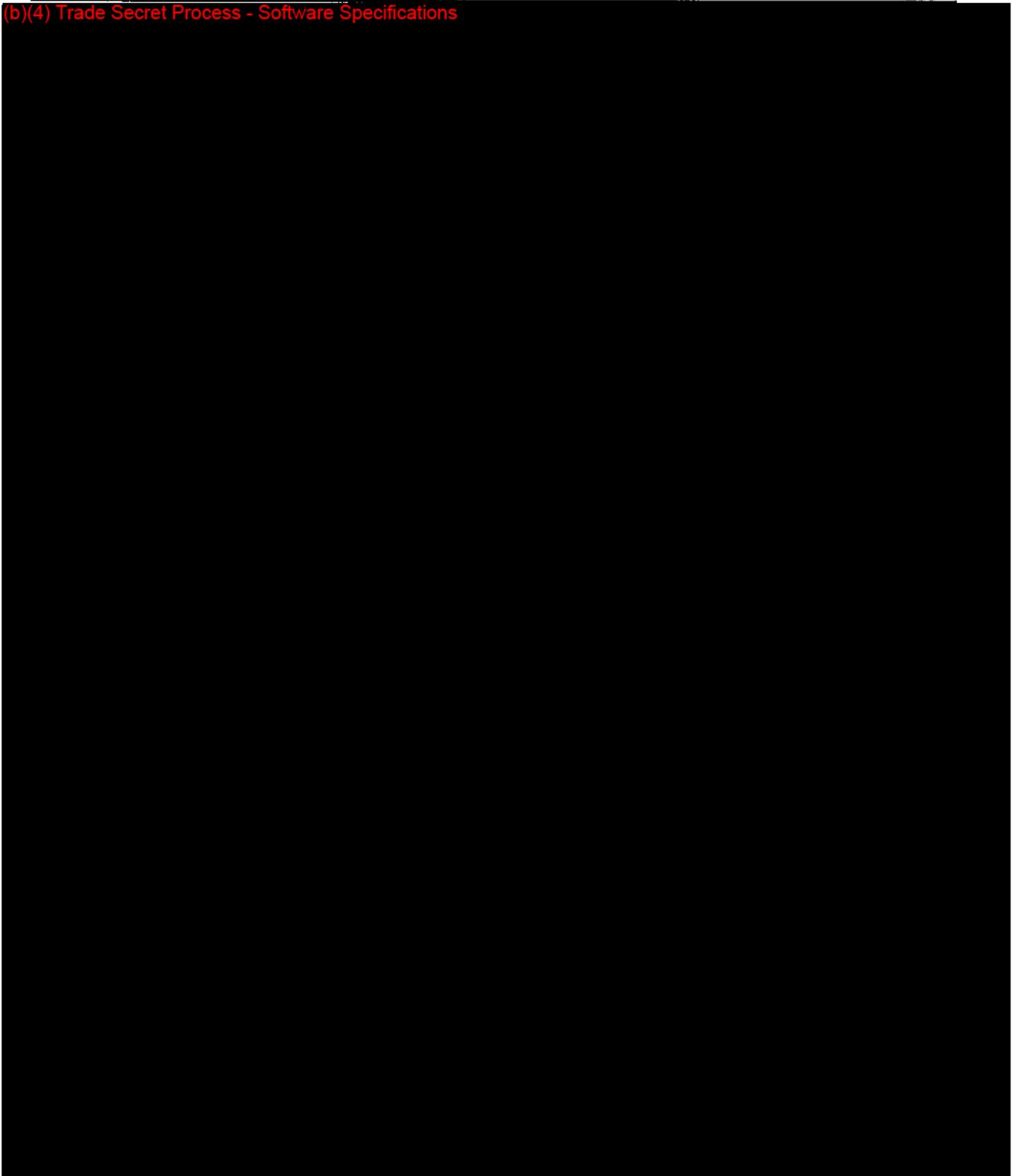
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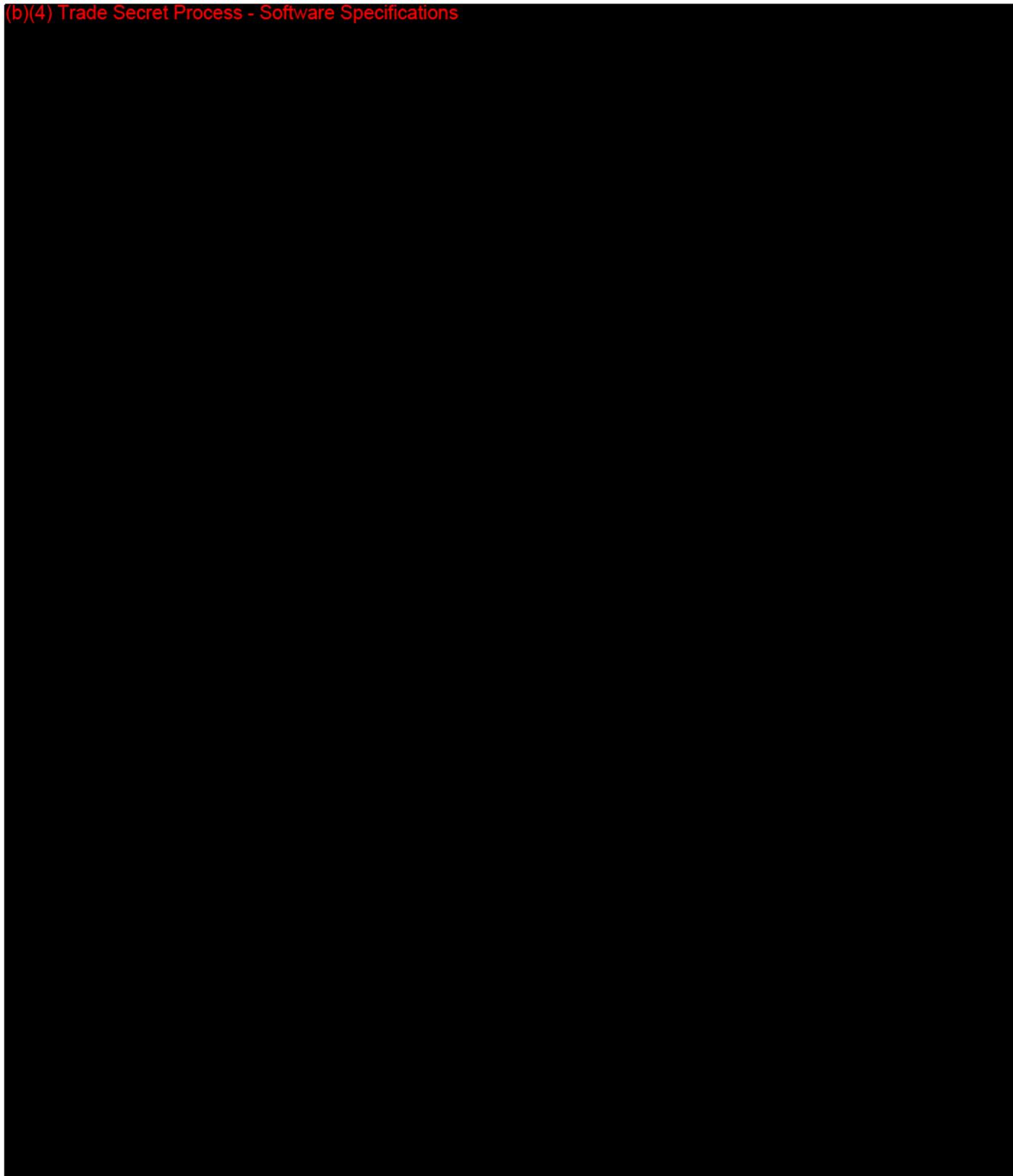
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(b)(4) Trade Secret Process - Software Specifications

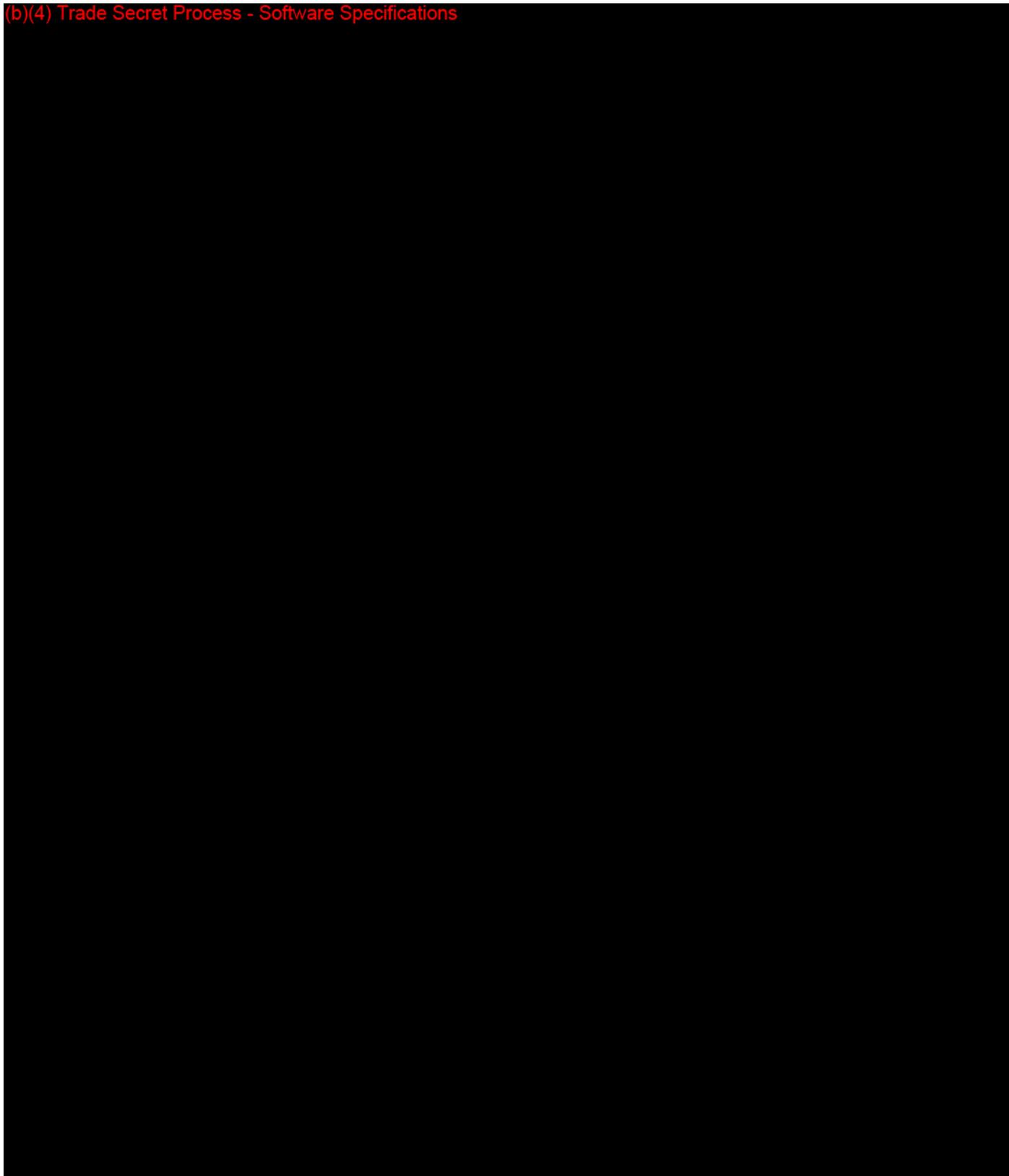


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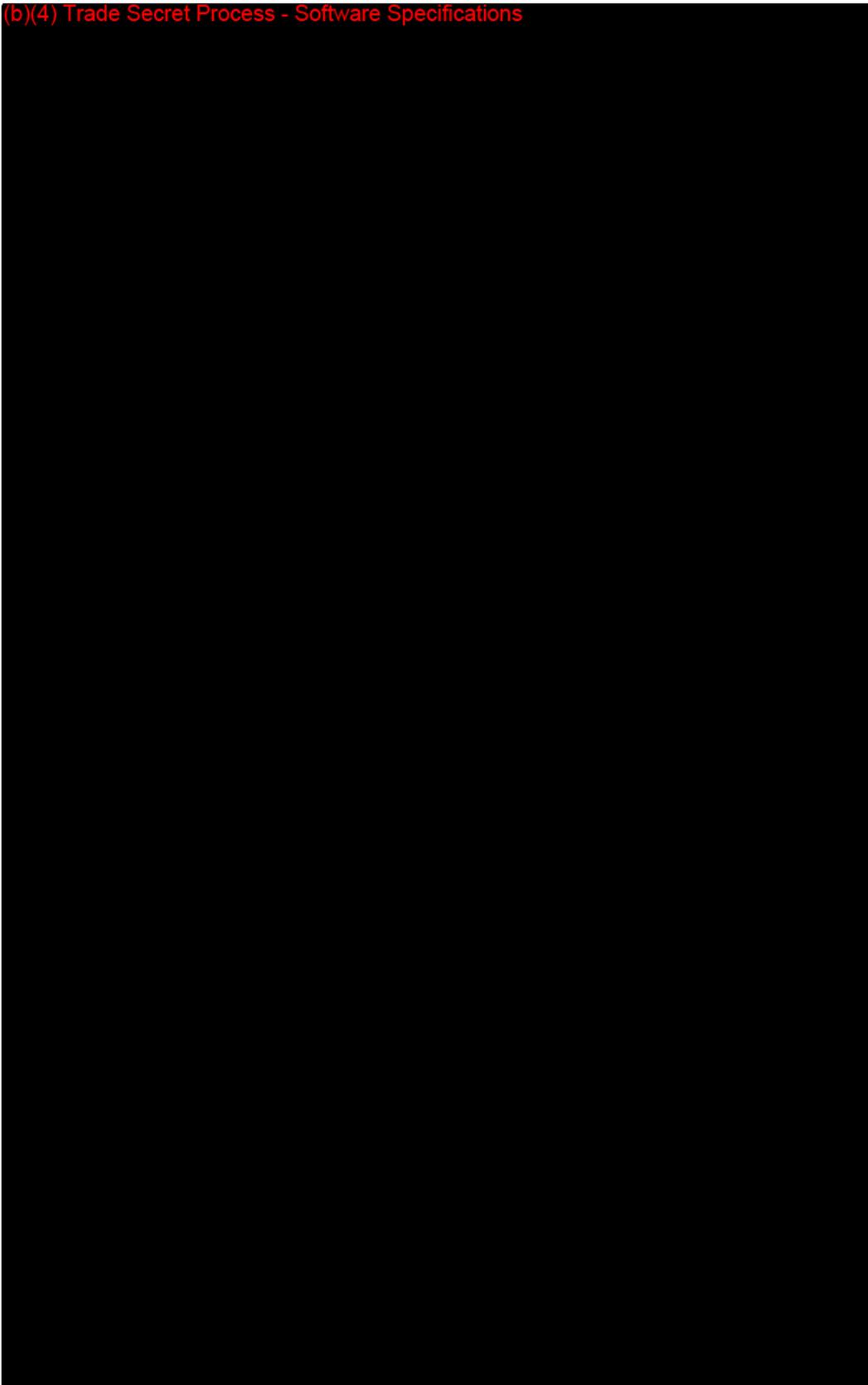


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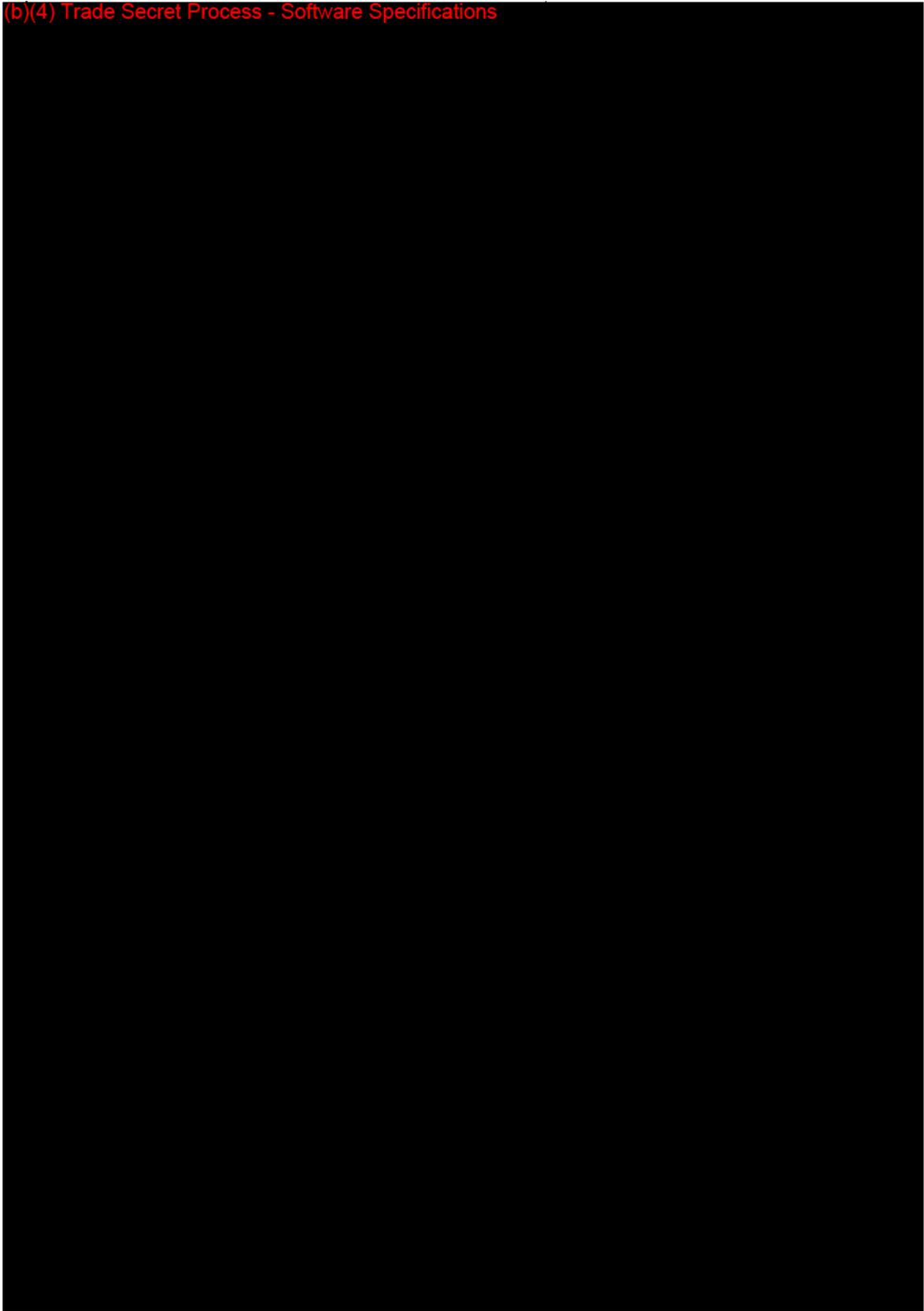
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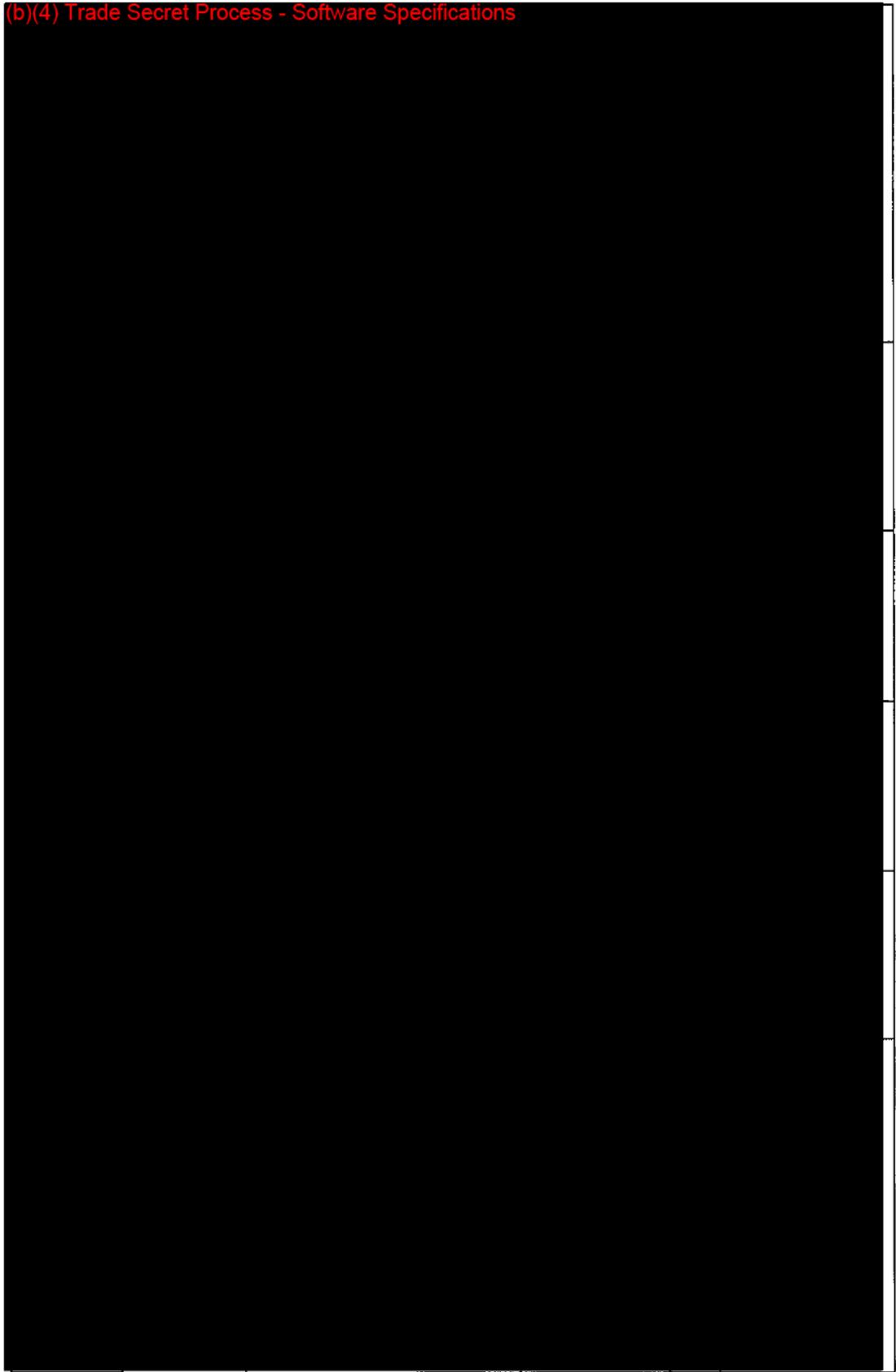


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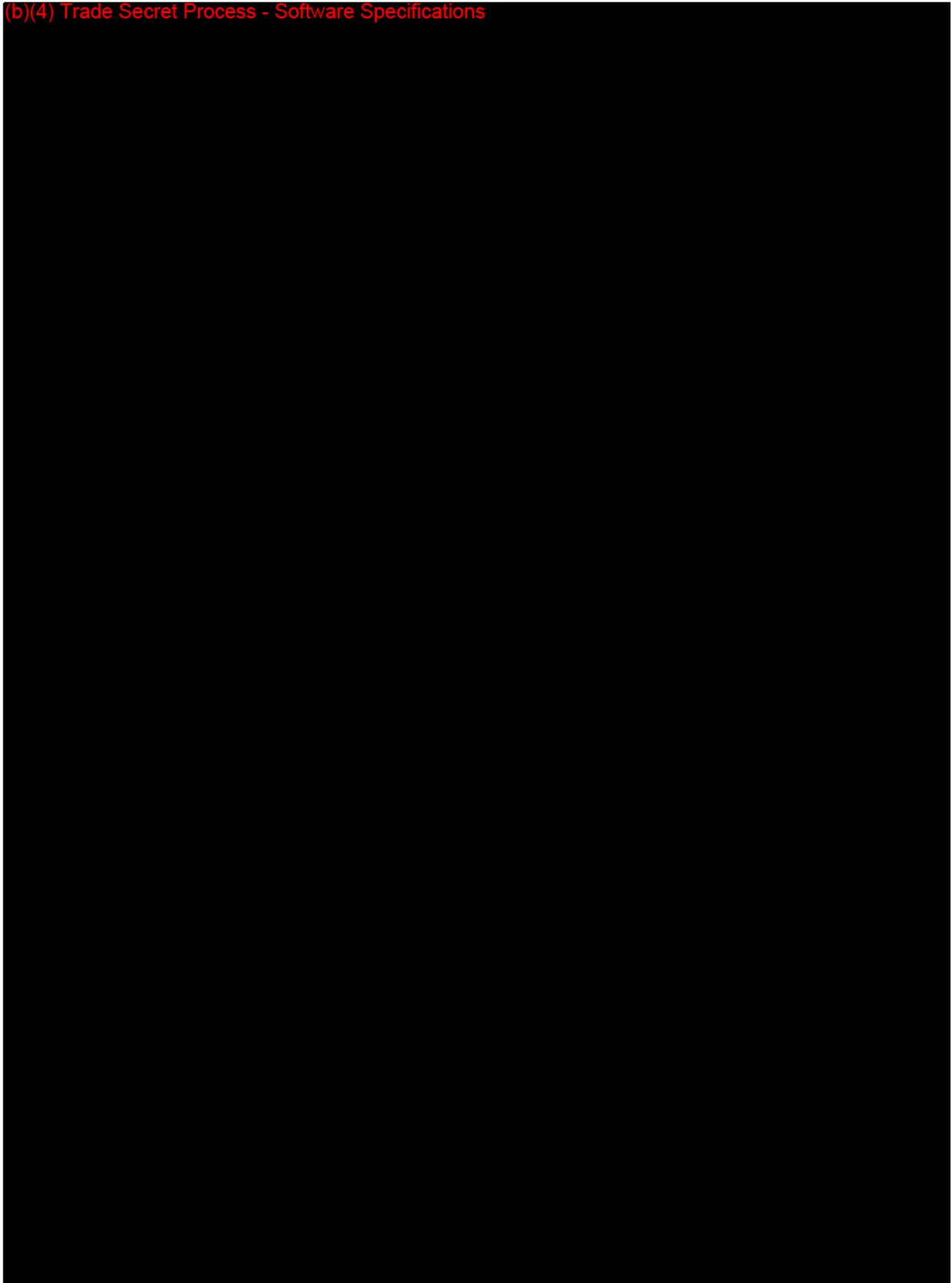


Requirements / Specifications / Hazards / Mitigations / V&V Testing Traceability Matrix

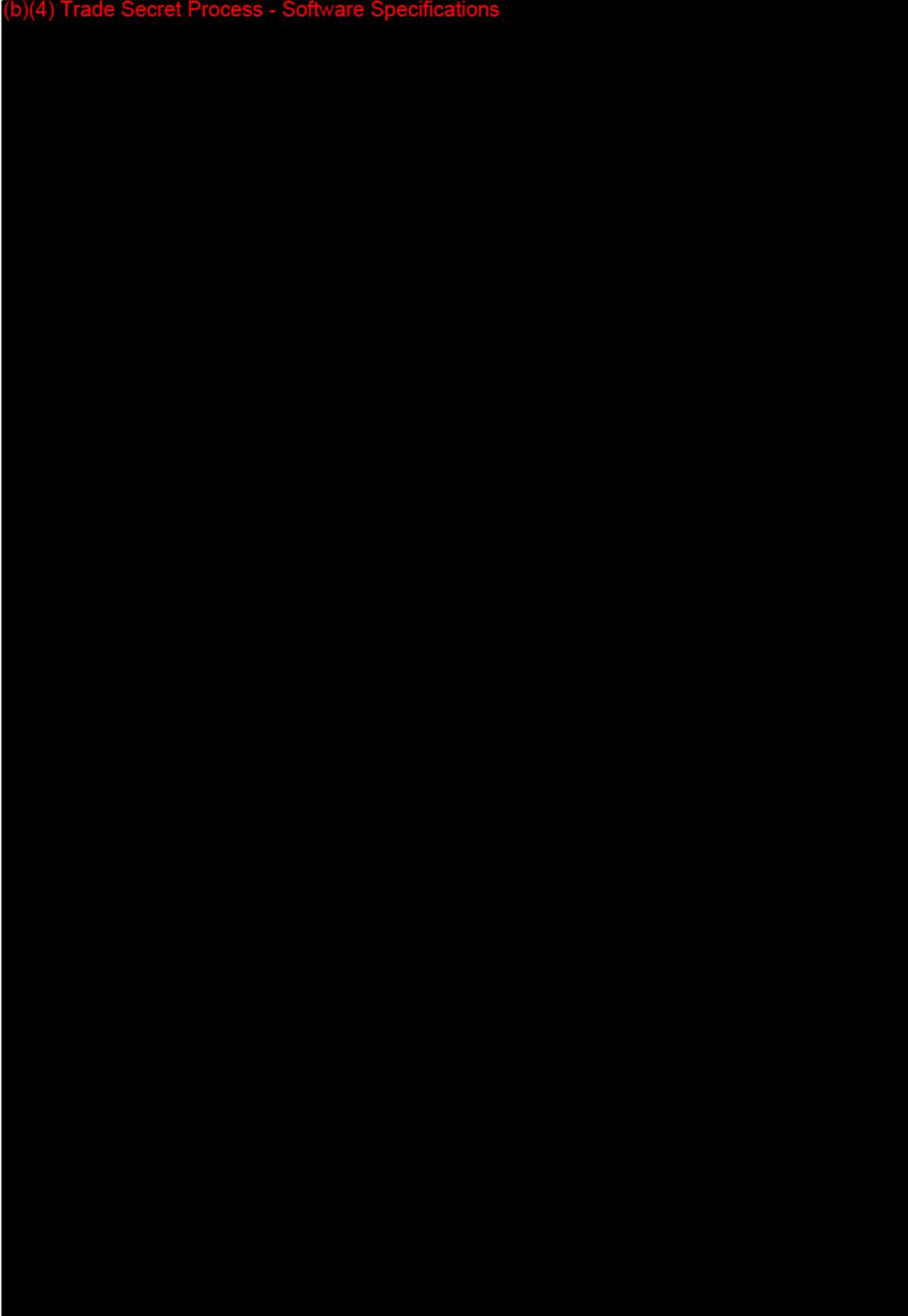
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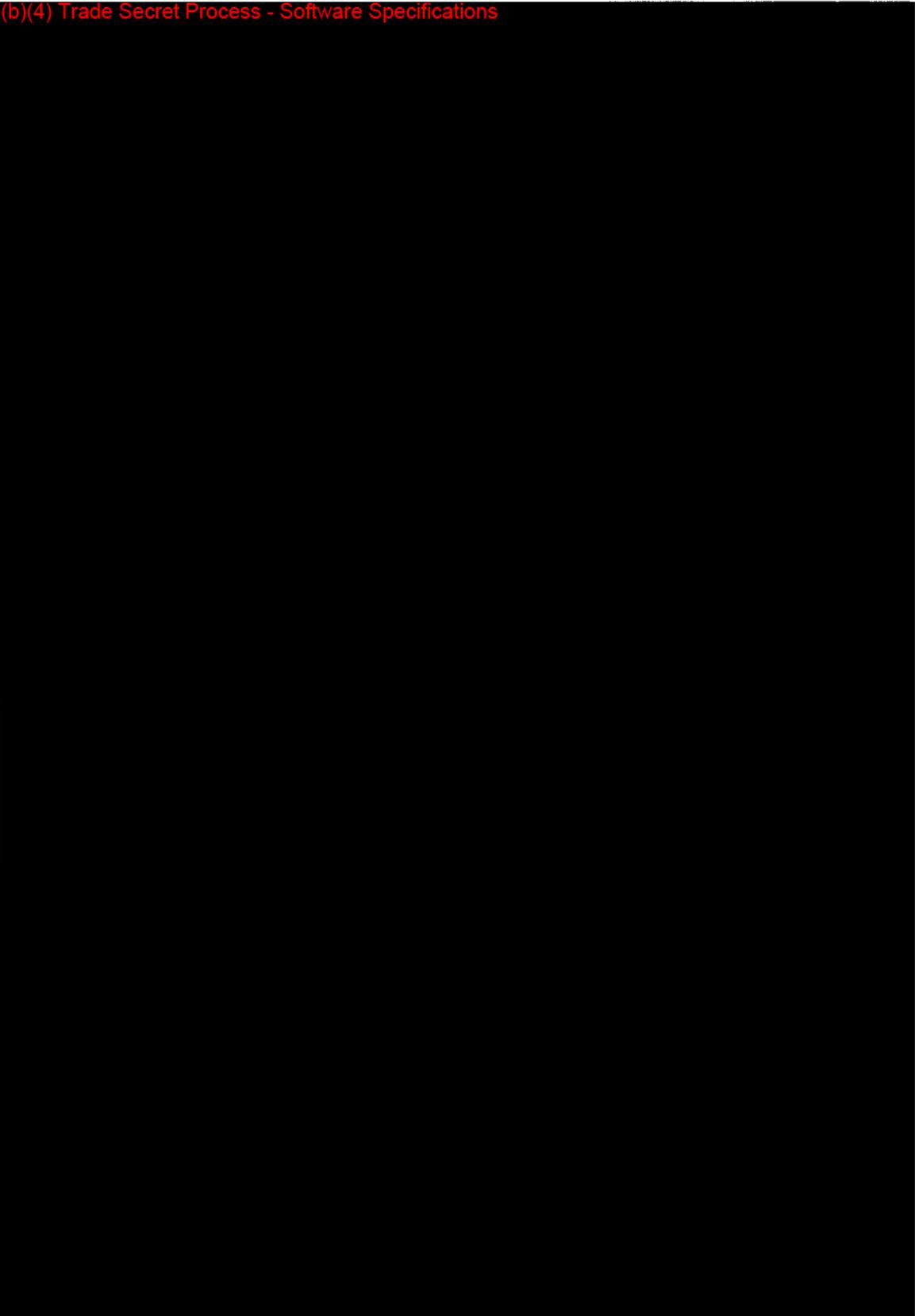
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(b)(4) Trade Secret Process - Software Specifications

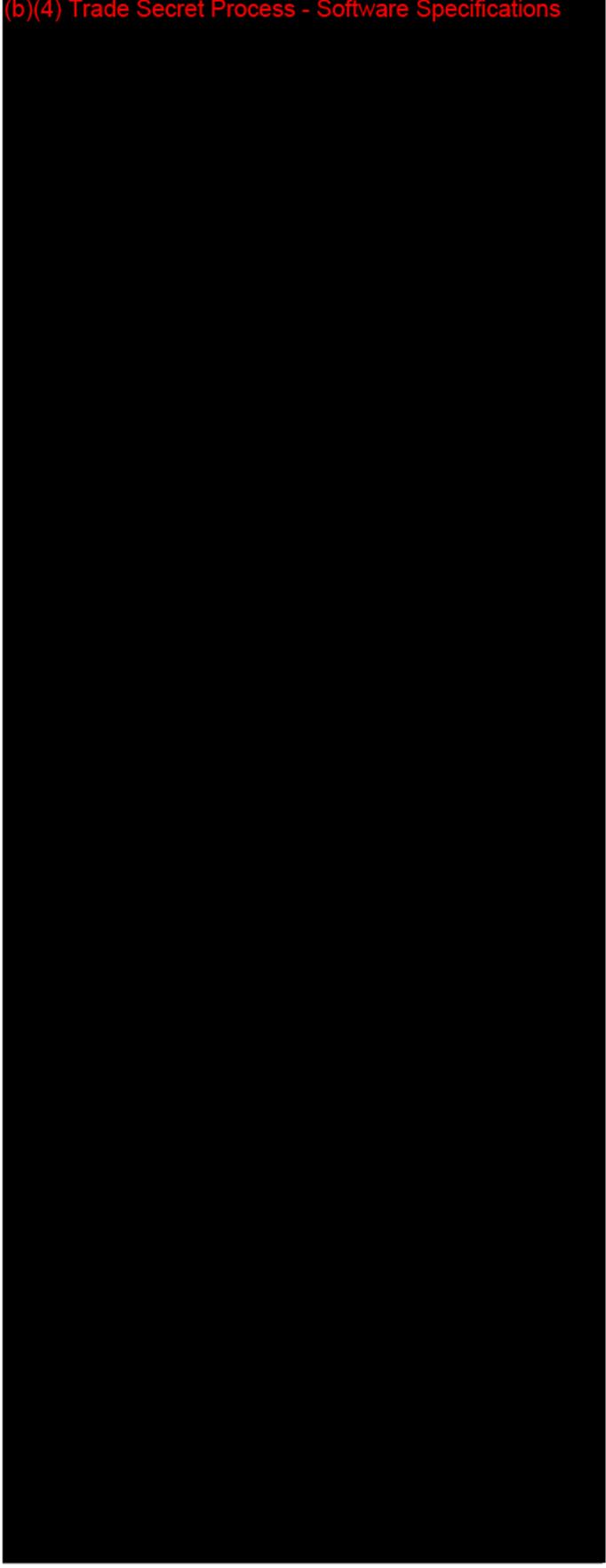


Requirements / Specifications / Hazards / Mitigations / V&V Testing Traceability Matrix

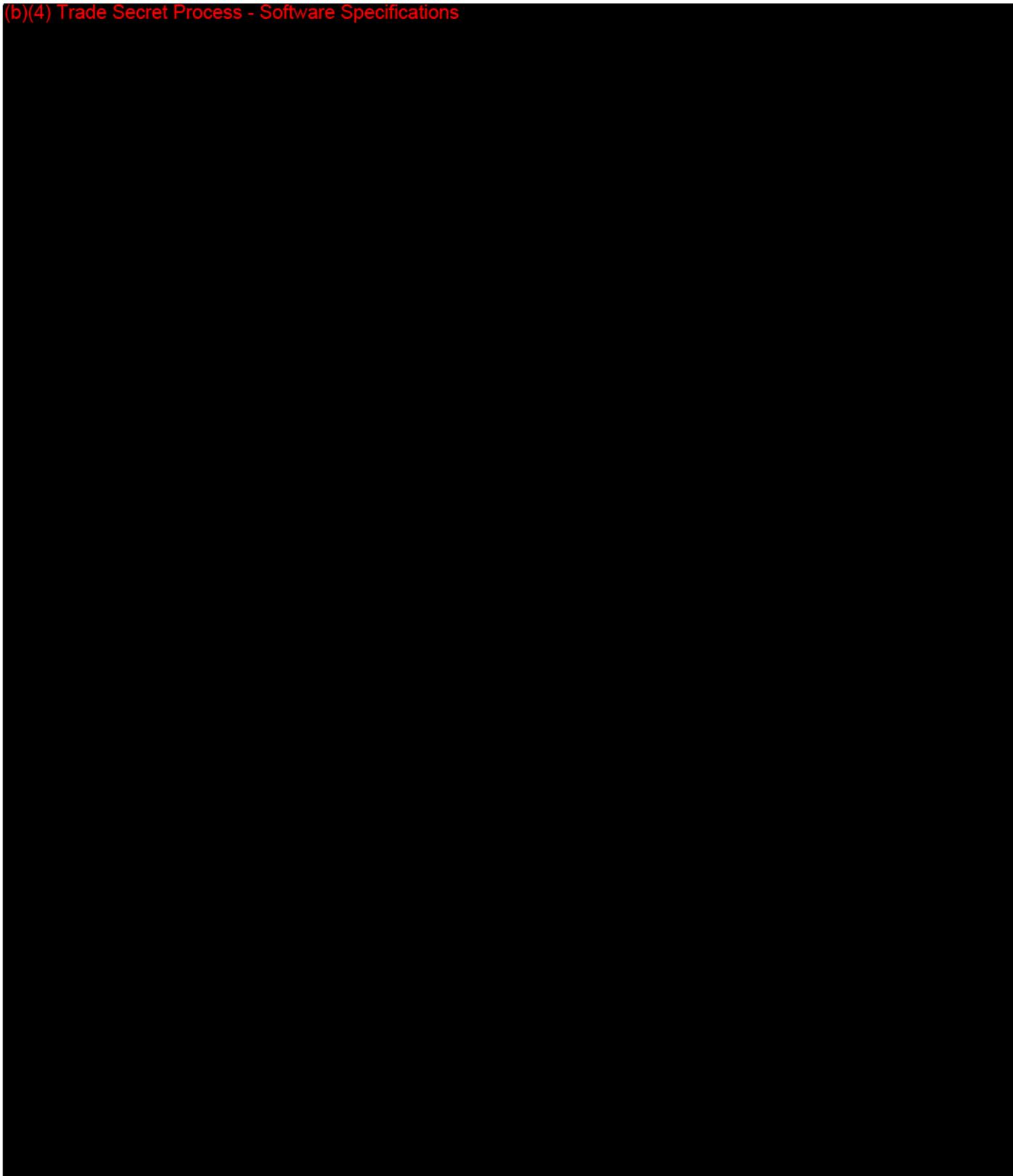
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Process - Software  
Specifications

**MyoSURE™ Software Revision History Record\_Bi-Directional Drive**

(b)(4) Trade Secret Process - Software Specifications

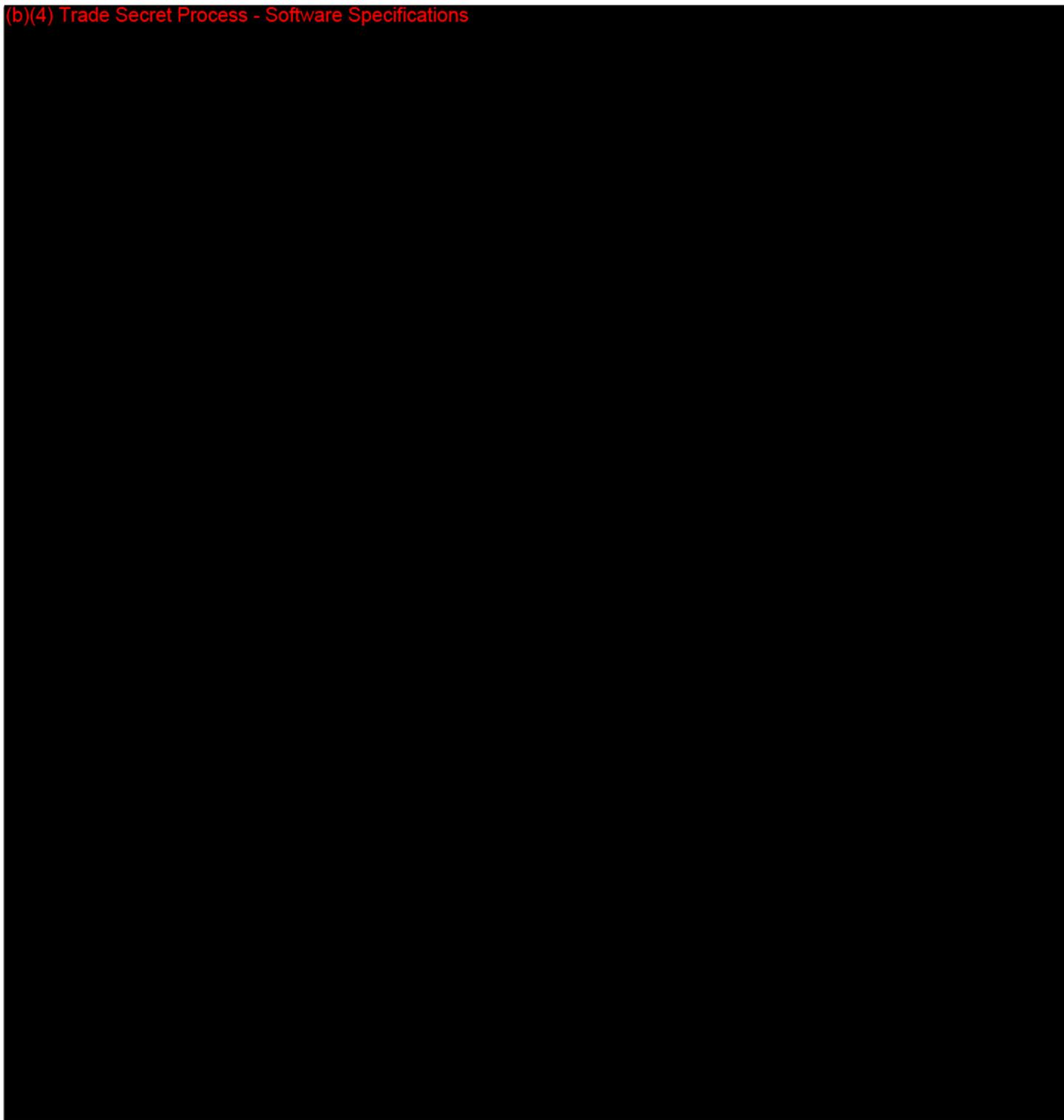


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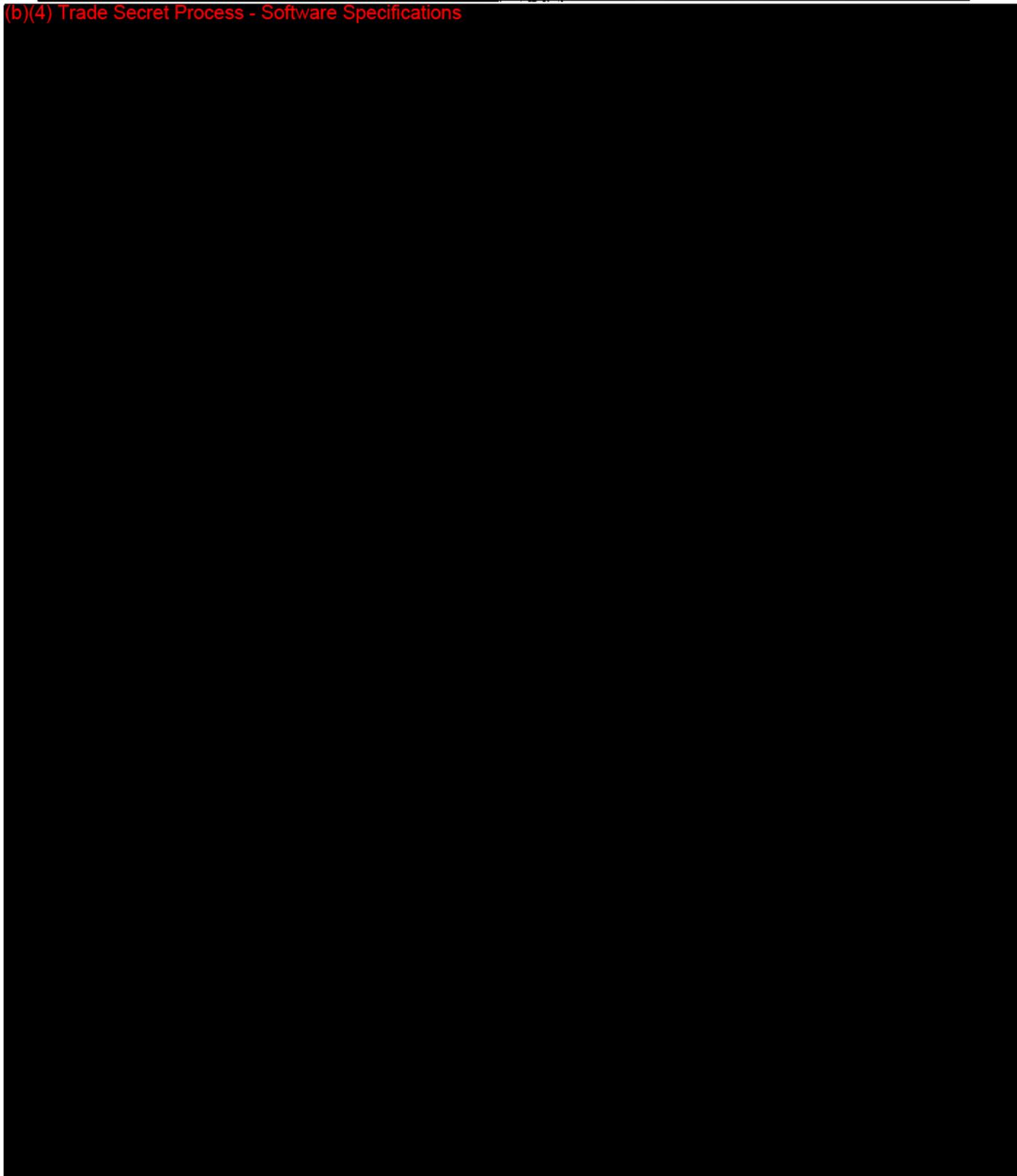


## Software Verification Testing

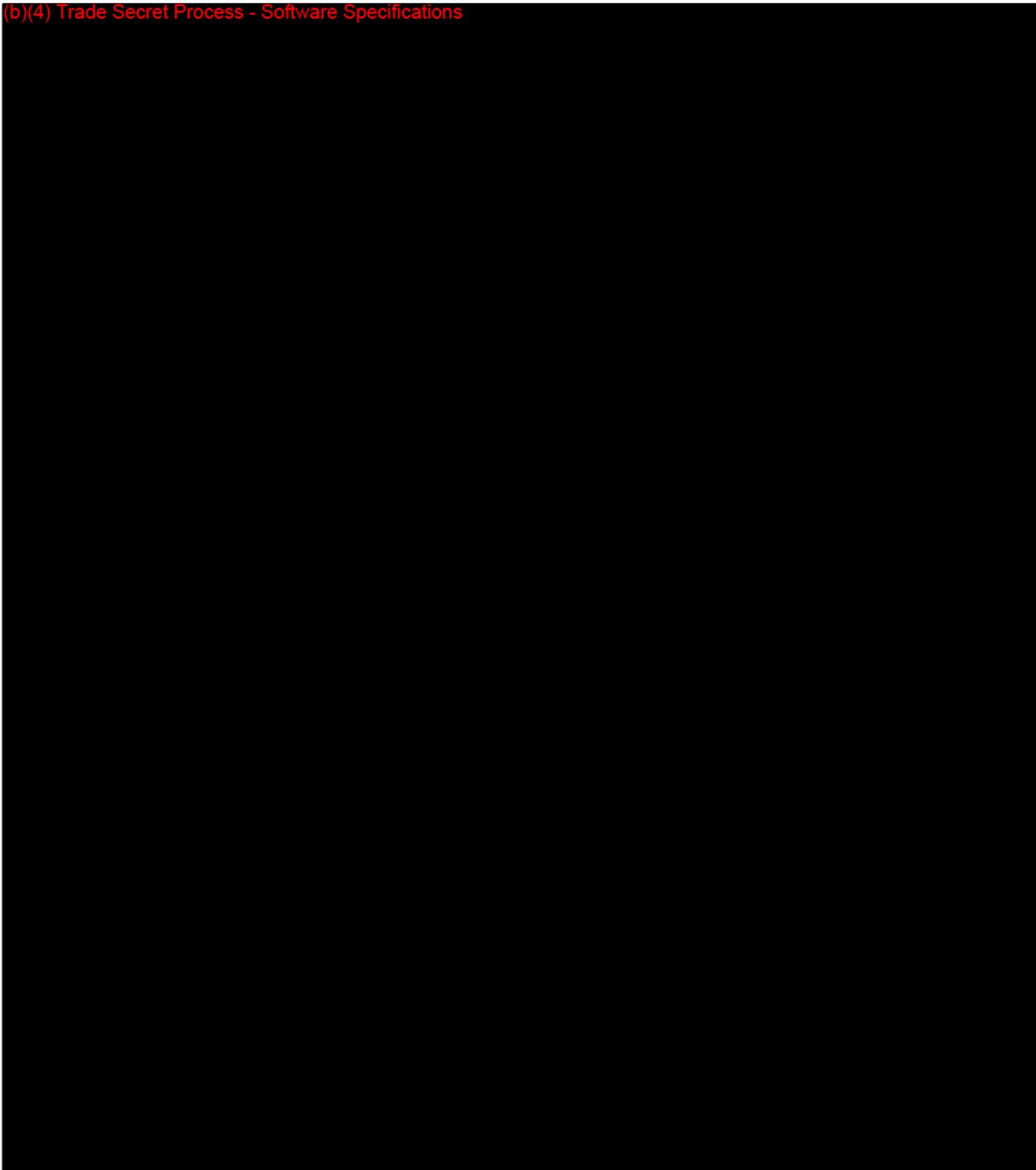
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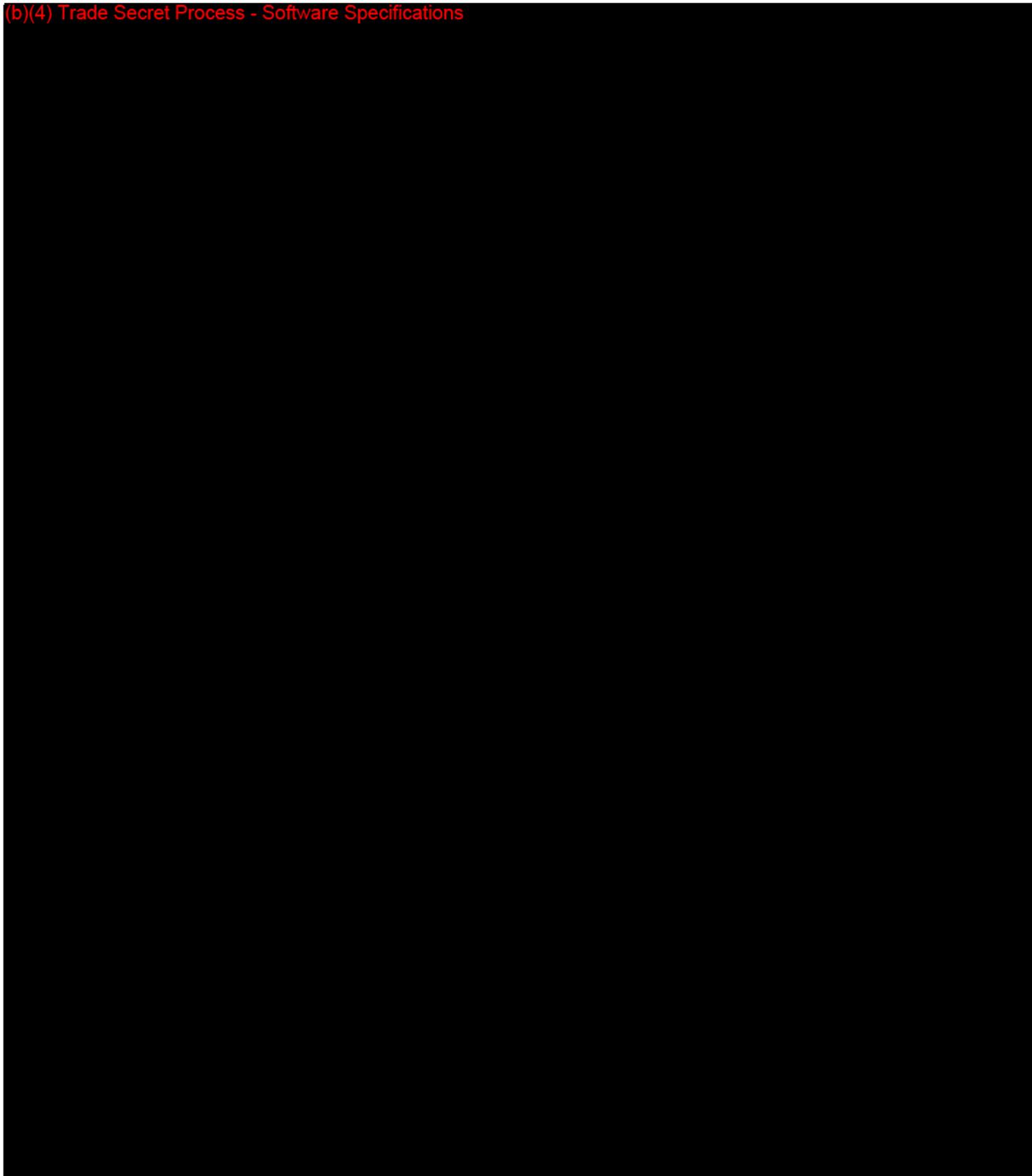
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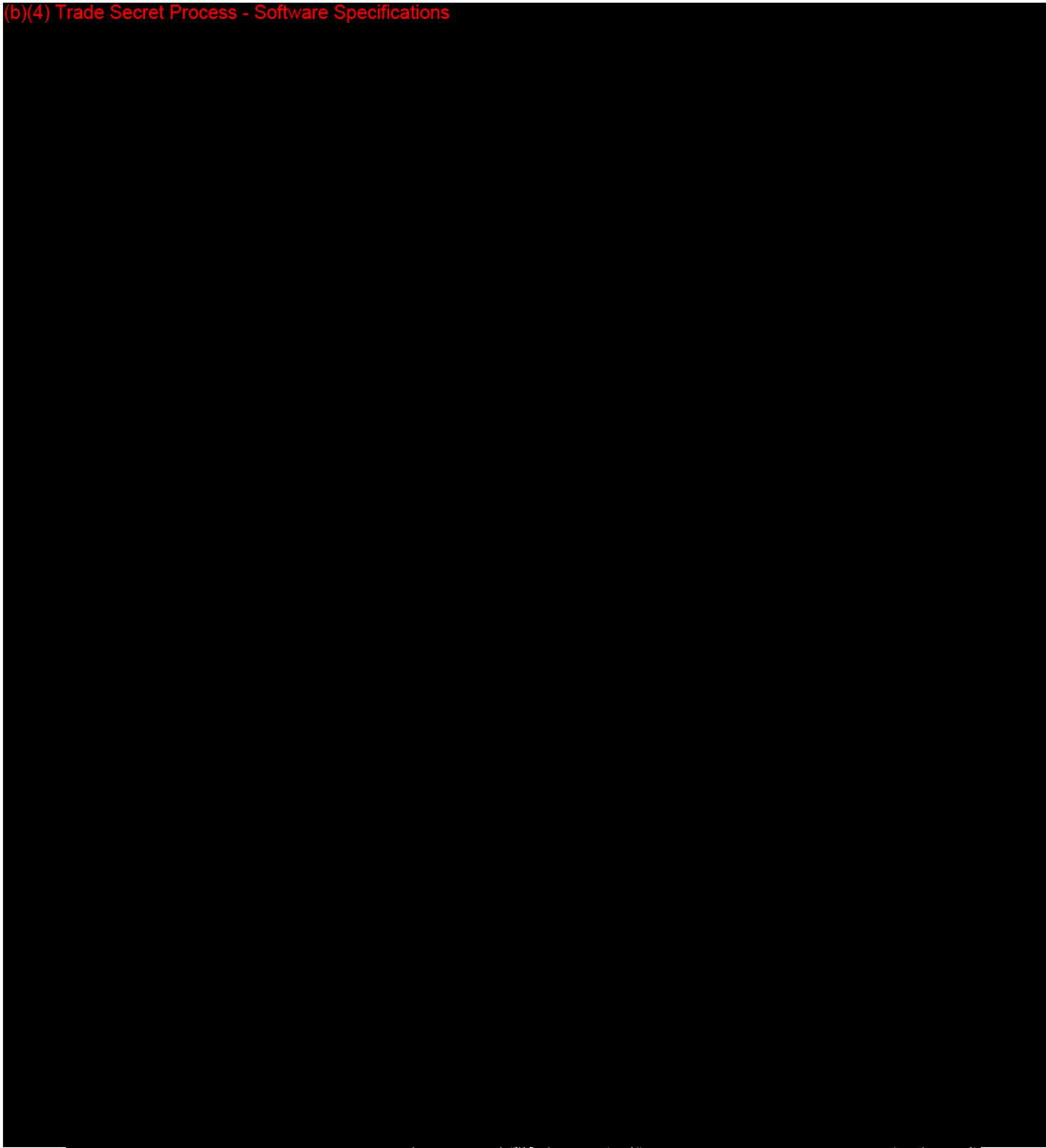
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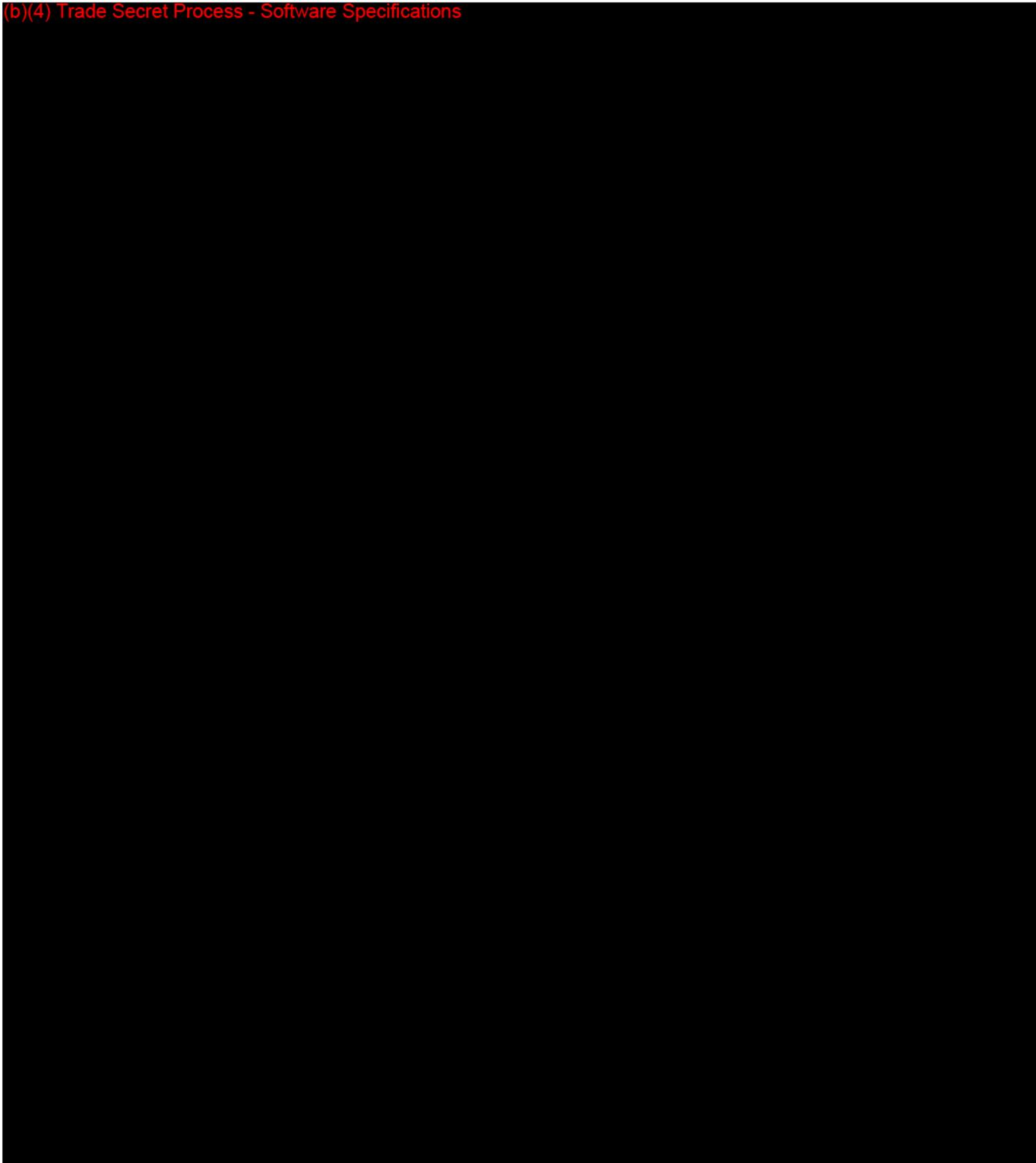
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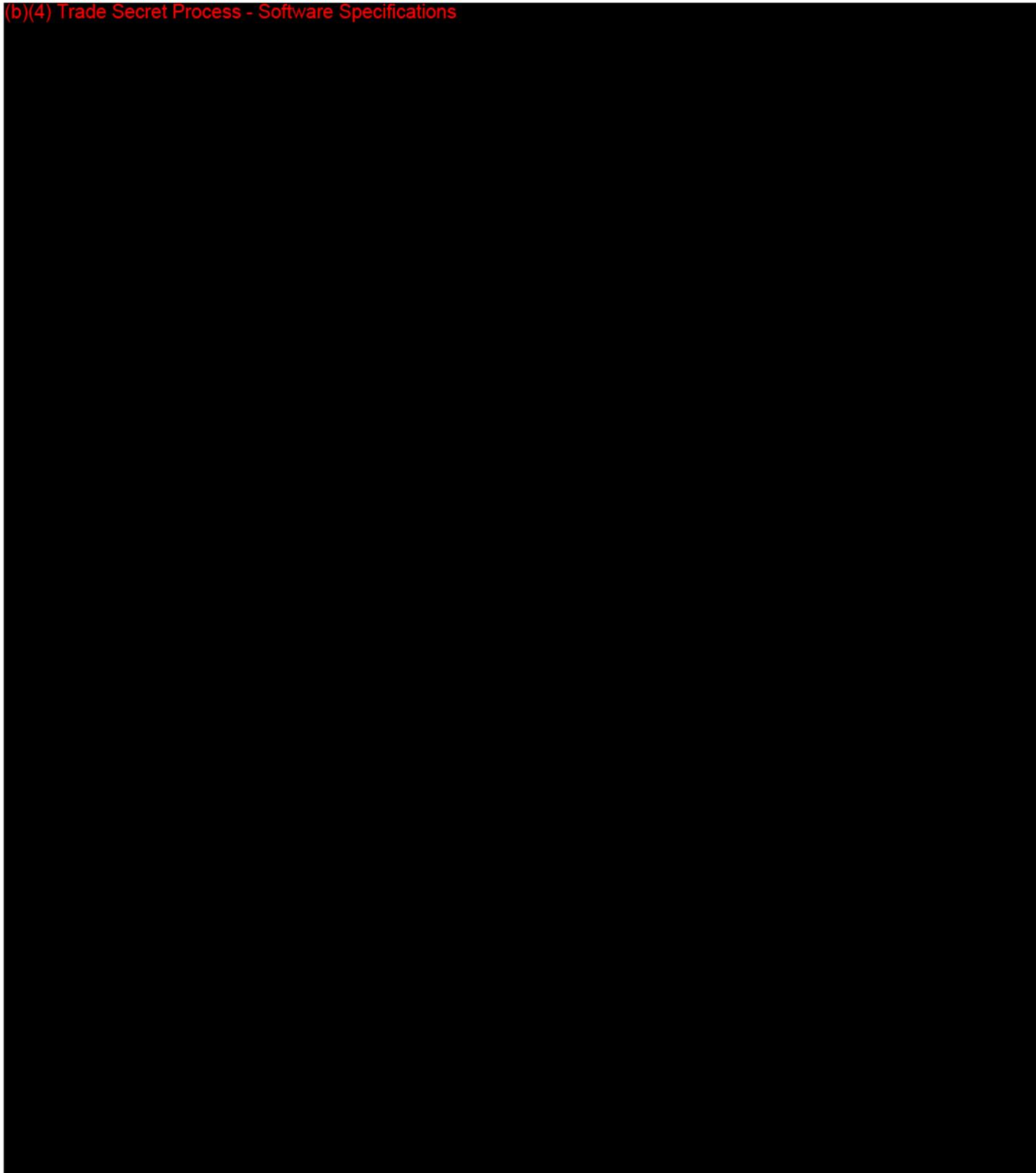
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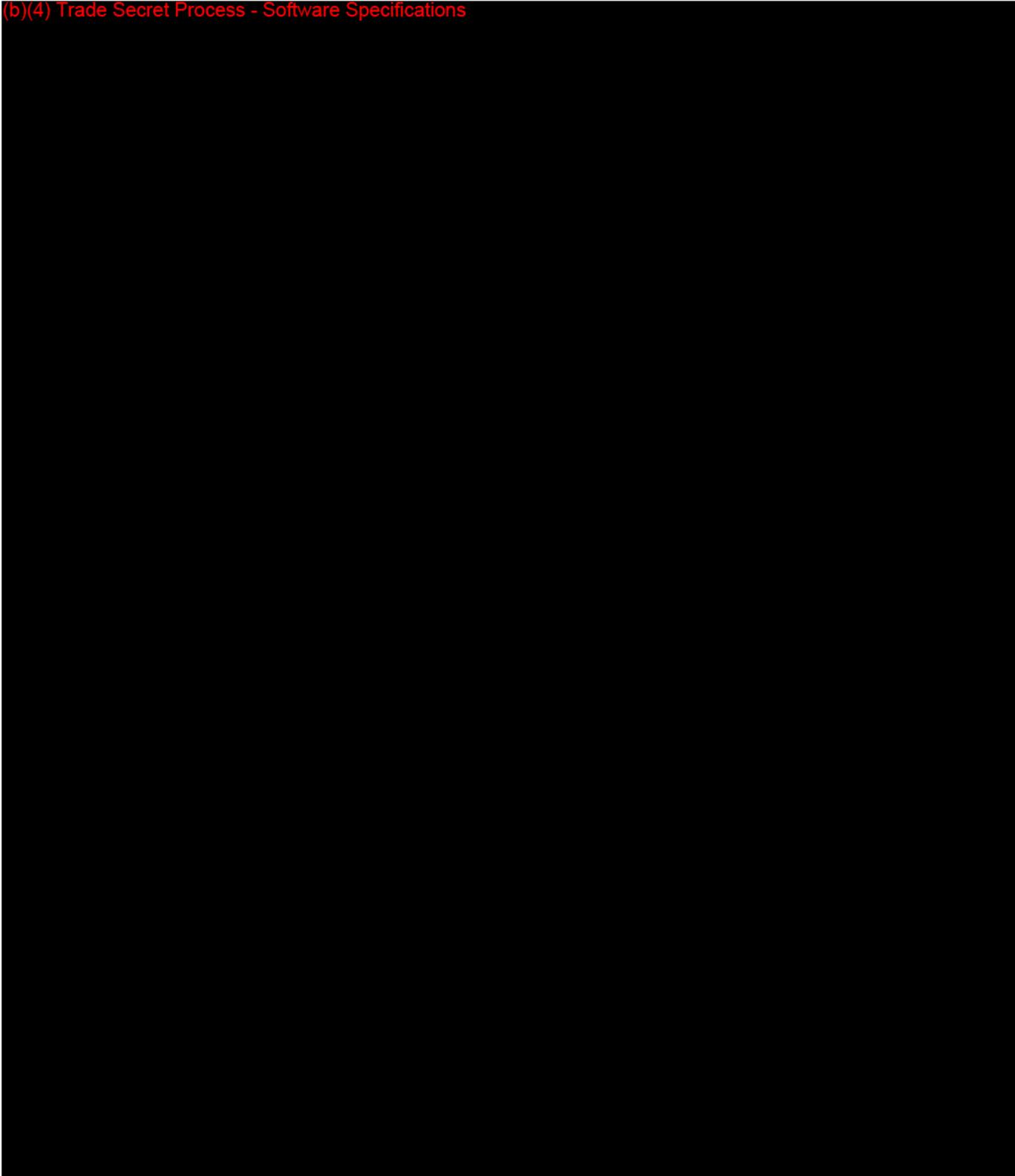
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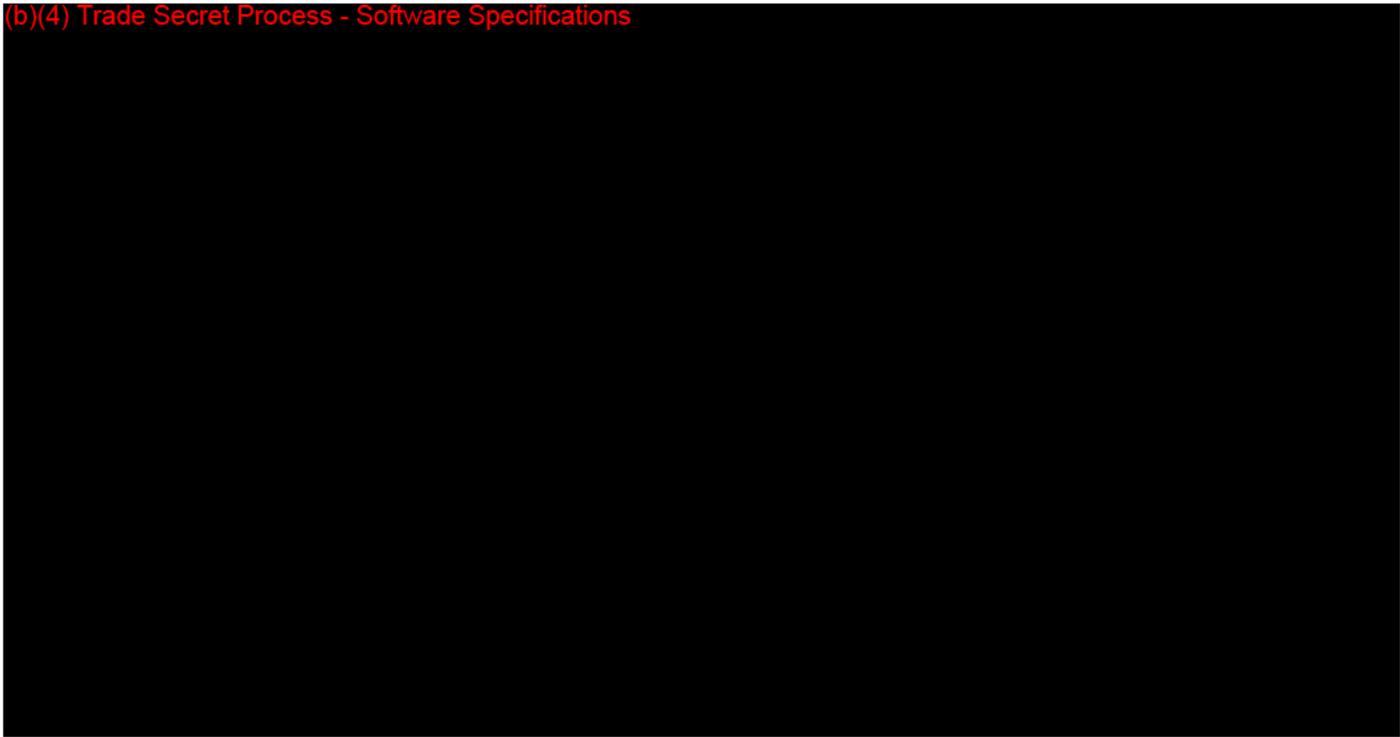
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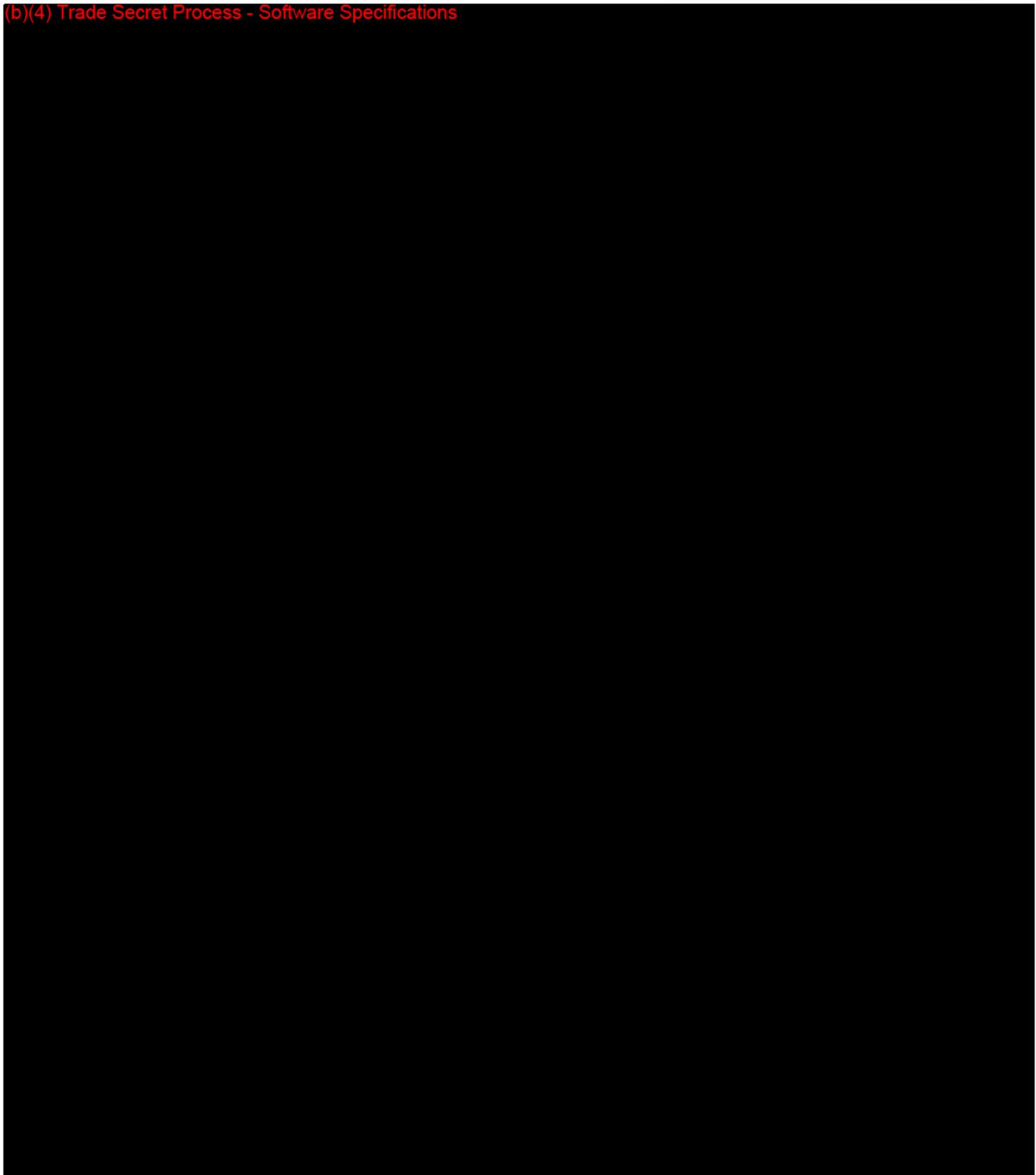
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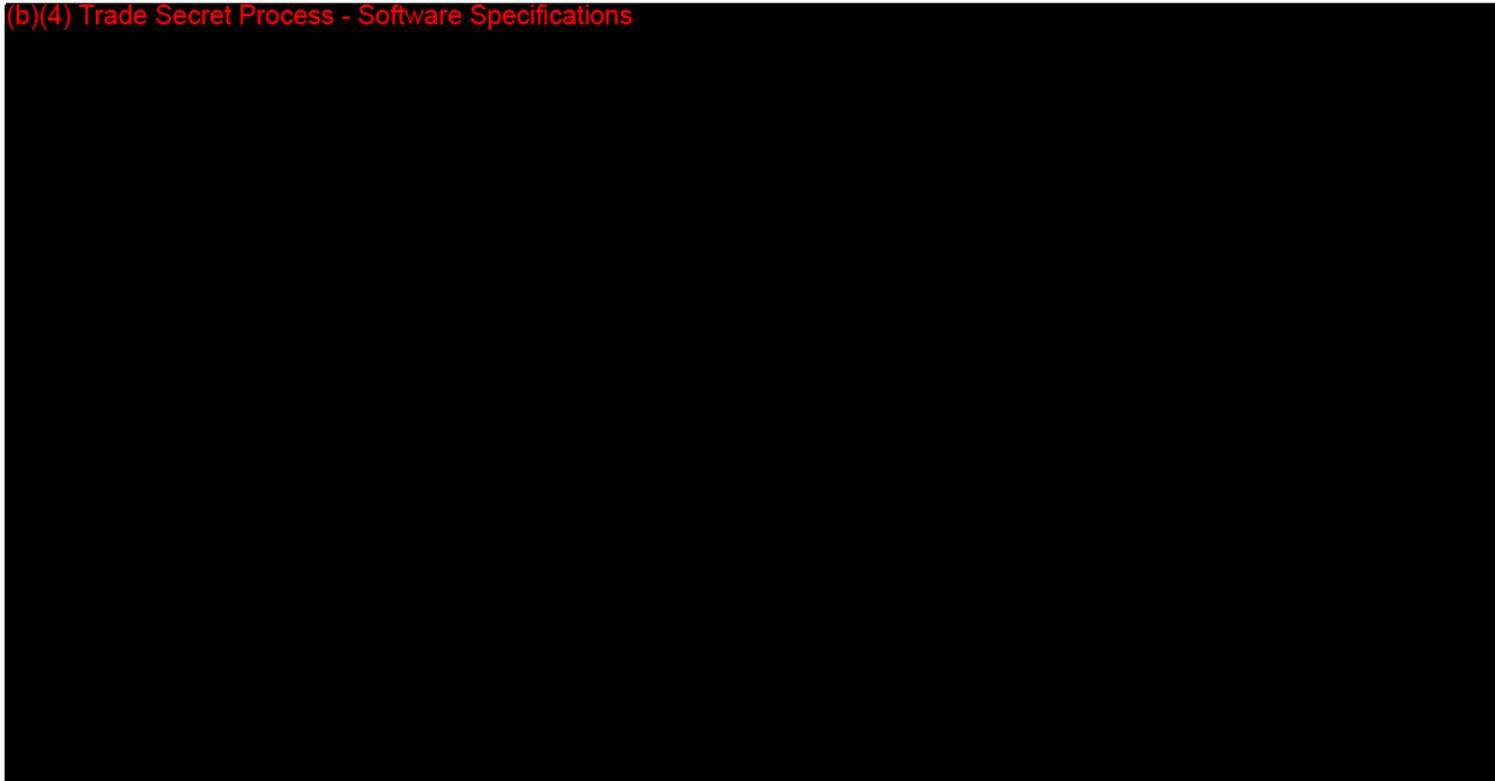
(b)(4) Trade Secret Process - Software Specifications



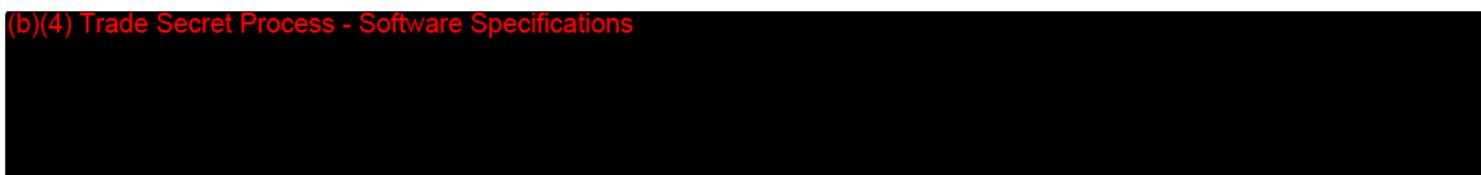
(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



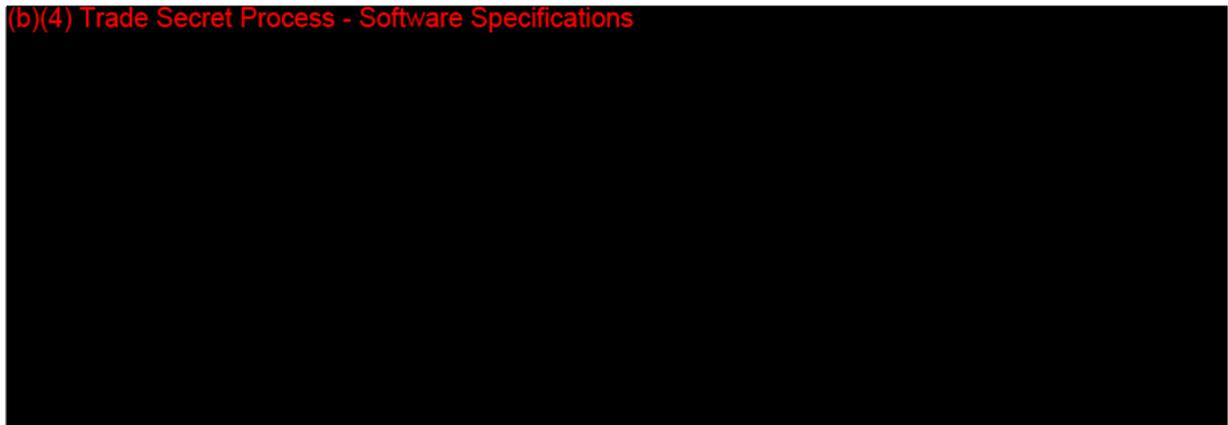
(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



(b)(4) Trade Secret Process - Software Specifications



## 17. **ELECTROMAGNETIC COMPATIBILITY / ELECTRICAL SAFETY**

The MyoSURE™ Hysteroscopic Tissue Removal System meets the following standards:

- IEC/EN 60601-1: (2004) Medical electrical equipment – Part 1: General requirements for safety.
- IEC/EN 60601-1-2: 2001 - Medical Electrical Equipment. General Requirements for Safety- Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC/EN 60601-2-18:1996 - Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment

The proposed modifications to the device do not affect the electrical safety verification or the electromagnetic compatibility verification (b)(4)

Trade  
Secret  
Process -

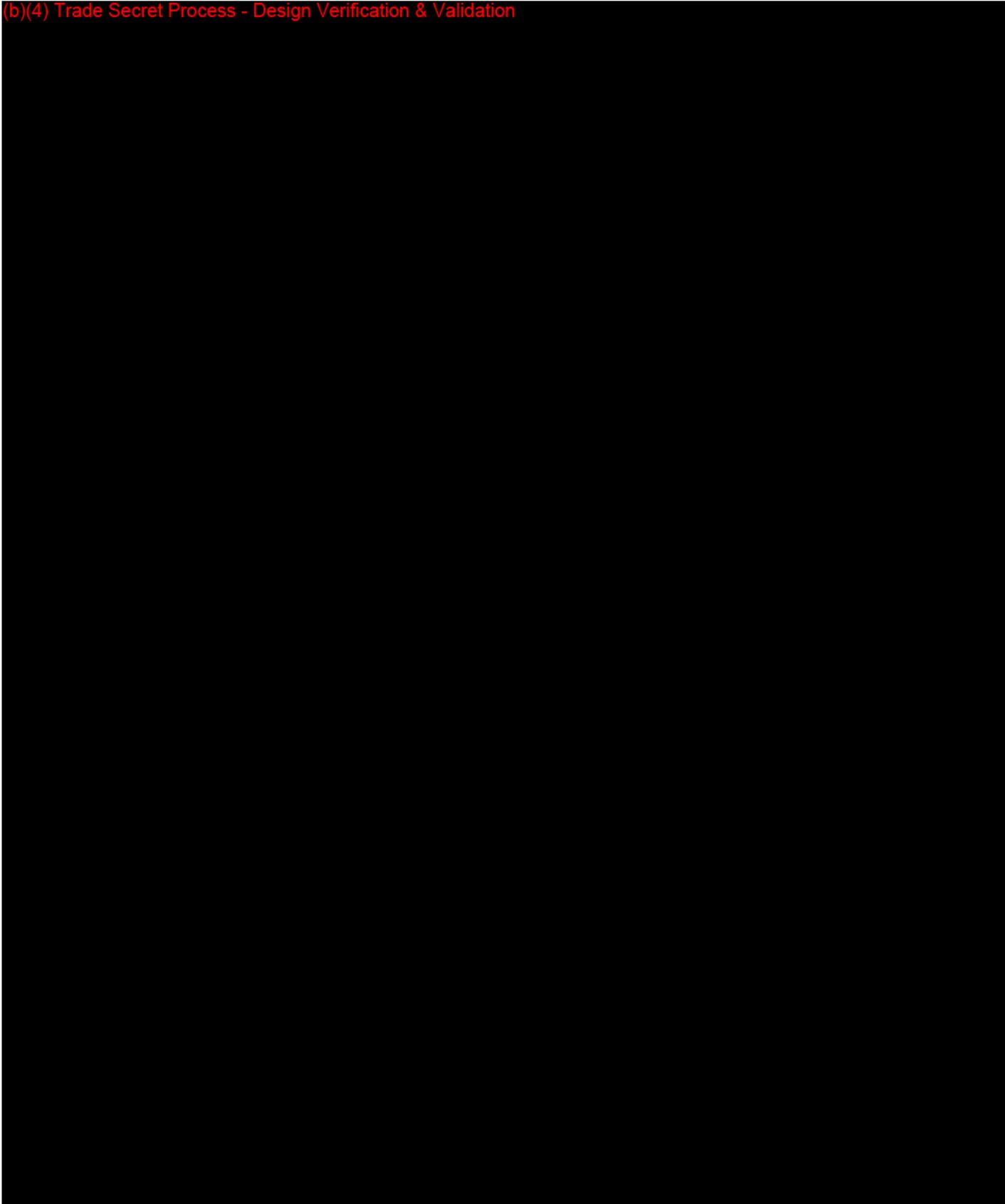
## 18. PERFORMANCE TESTING - BENCH

### Performance Testing Summary

Performance testing applicable to the modified Myosure Hysteroscopic Tissue Removal System was determined based on an analysis of risks and hazards posed by the proposed modifications to the device. No new hazards or risks were identified that relate to the proposed Myosure Hysteroscopic Tissue Removal System modifications. Accordingly, the following testing was performed to confirm functional equivalence of the modified and predicate Myosure Systems:

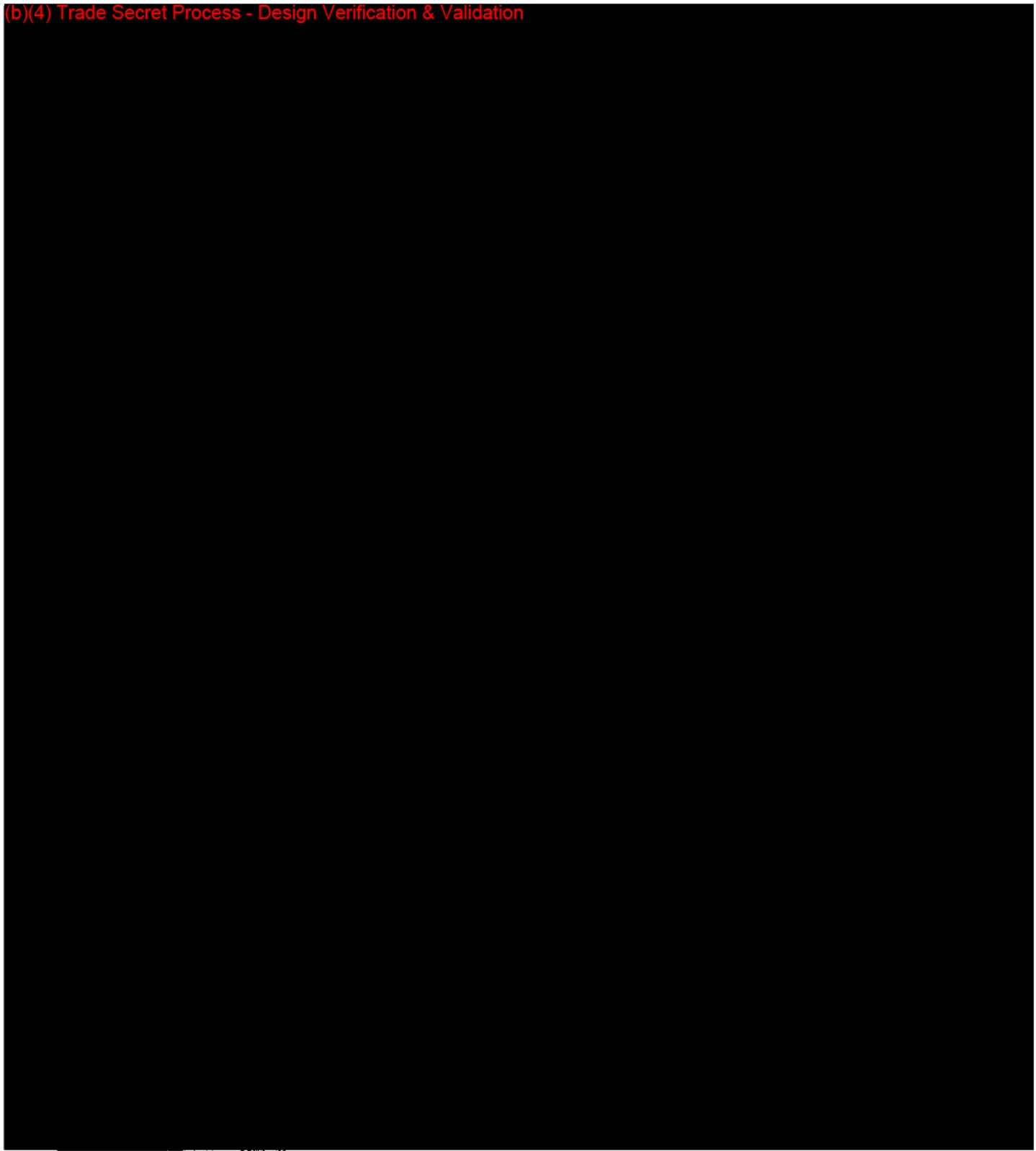
- Performance verification testing of the modified Myosure Hysteroscopic Tissue Removal System was completed using the same methodology as was used in support of the predicate Myosure System 510(k) submission (K100559). The Myosure Tissue Removal Devices and modified Control Units were used to cut extirpated fibroid tissue; each device was tested for a 30 minute duration test interval. Testing evaluated cutting functionality and heat generation over the test interval for the modified Myosure System. Test results for the predicate and modified Myosure Hysteroscopic Tissue Removal Systems were then compared. Results from this testing demonstrated that:
  - the modified Myosure System's fibroid cutting performance is equivalent to that of the predicate device under simulated worst case clinical conditions
  - cutter durability over time is equivalent for the modified and predicate Myosure Systems
  - heat generation over time is equivalent for the modified and predicate Myosure Systems and meets IEC 60601-1 thermal safety requirements.
- Verification/validation testing of the modified Myosure System was completed and confirmed that the modified Myosure System meets the same functional and performance specifications as the predicate Myosure System. The full test report has been included in this section of the submission.

(b)(4) Trade Secret Process - Design Verification & Validation

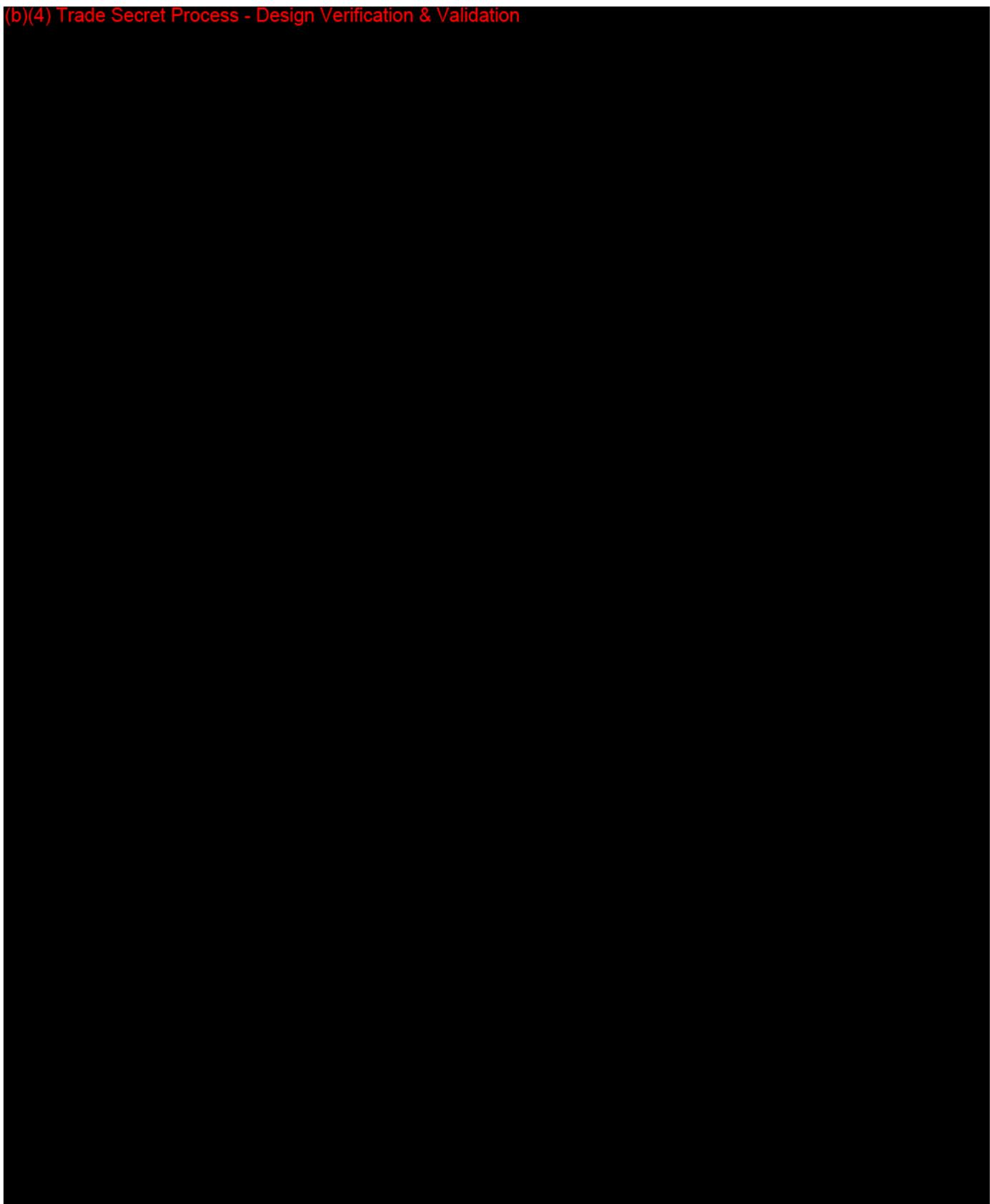


## Design Verification Testing

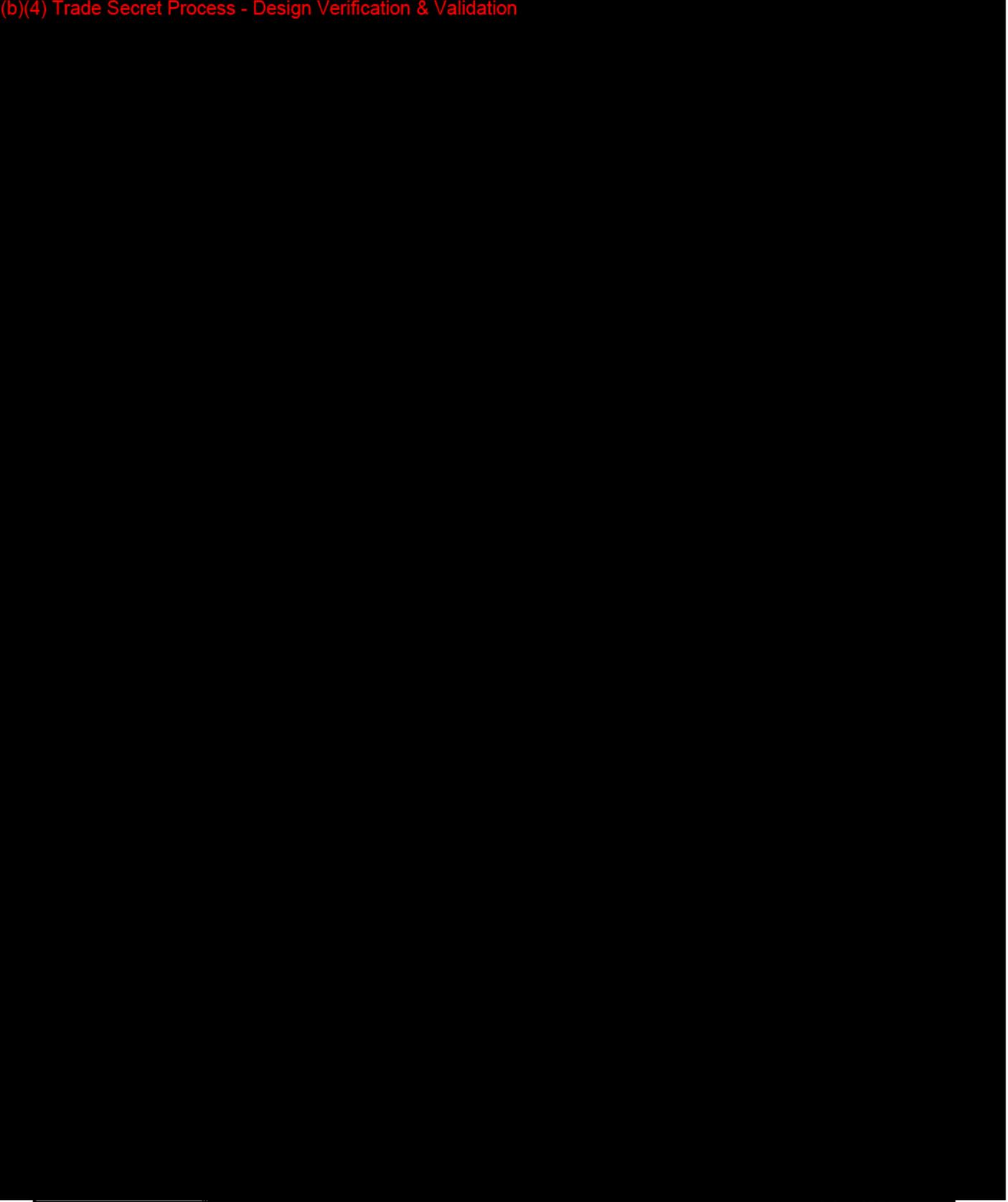
(b)(4) Trade Secret Process - Design Verification & Validation



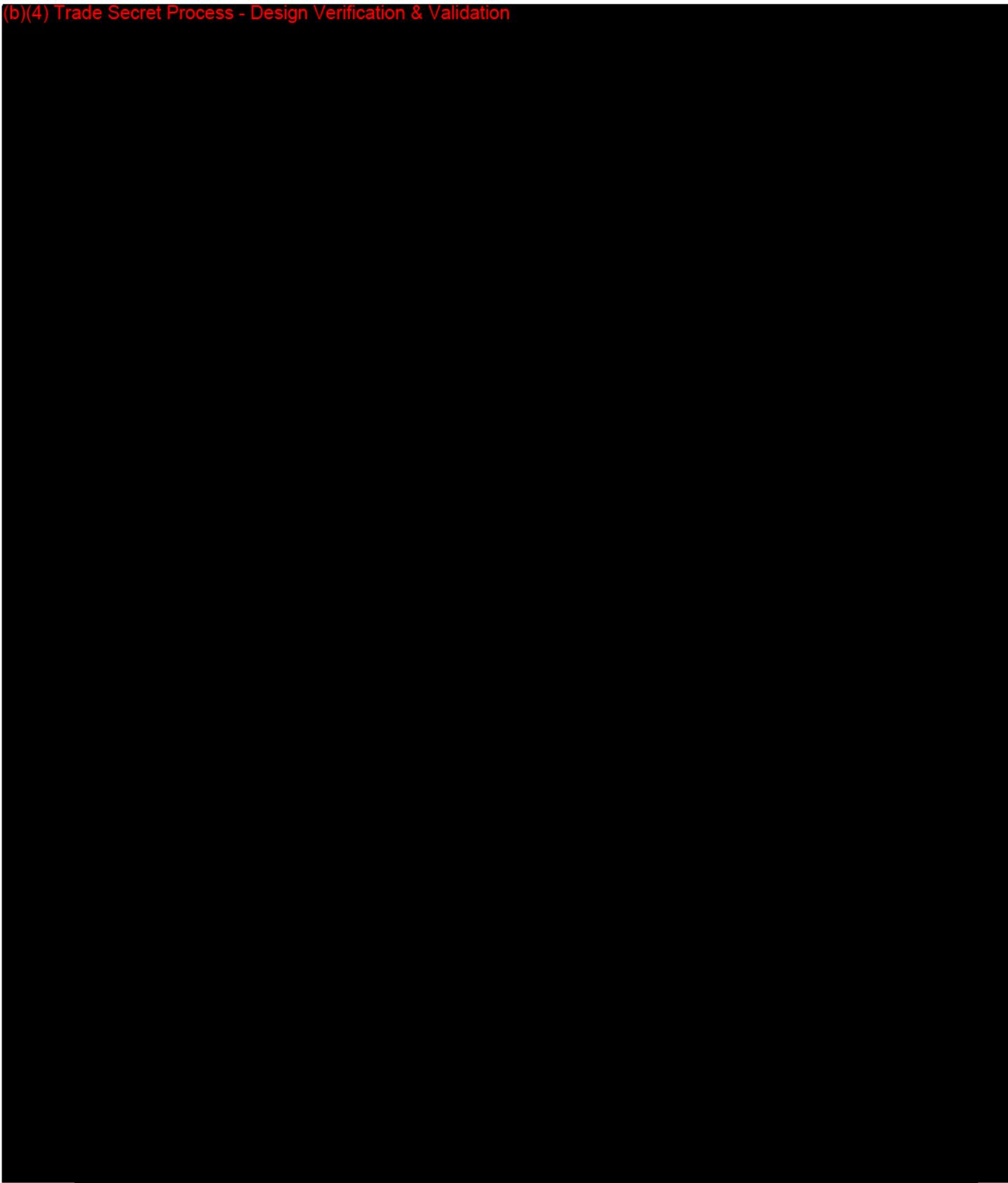
(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



(b)(4) Trade Secret Process - Design Verification & Validation



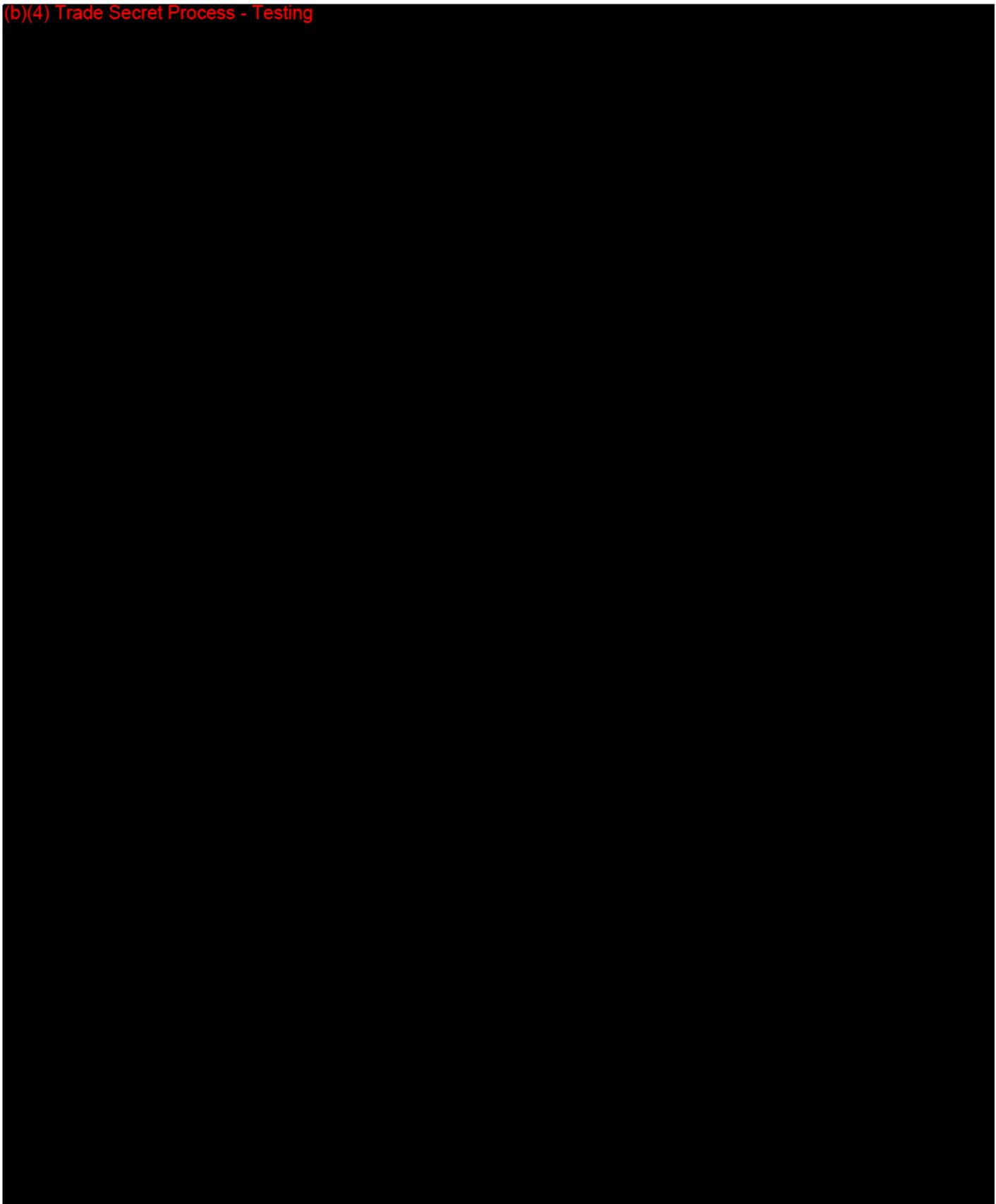
(b)(4) Trade Secret Process - Design Verification & Validation



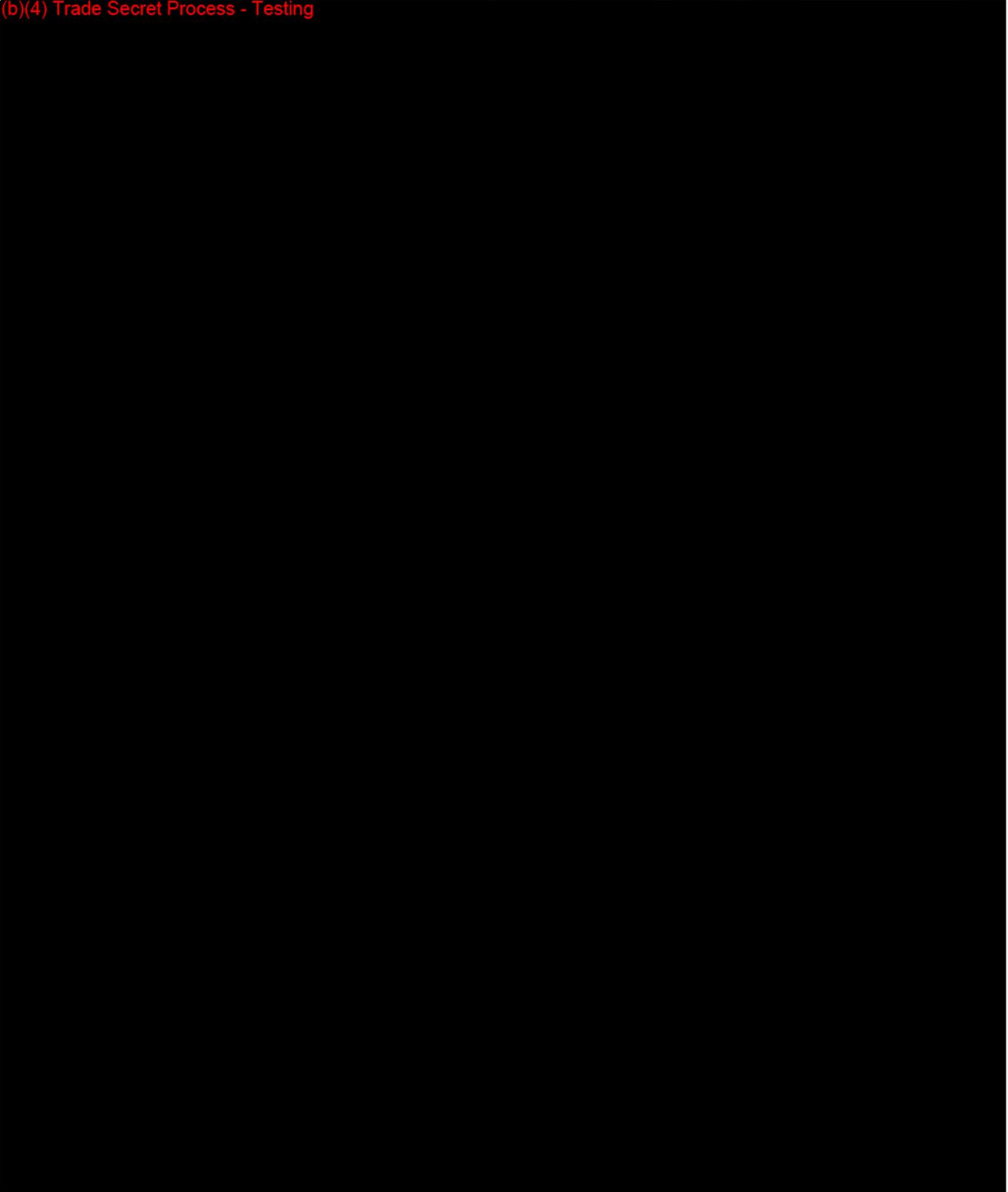
(b)(4) Trade Secret Process - Design Verification & Validation



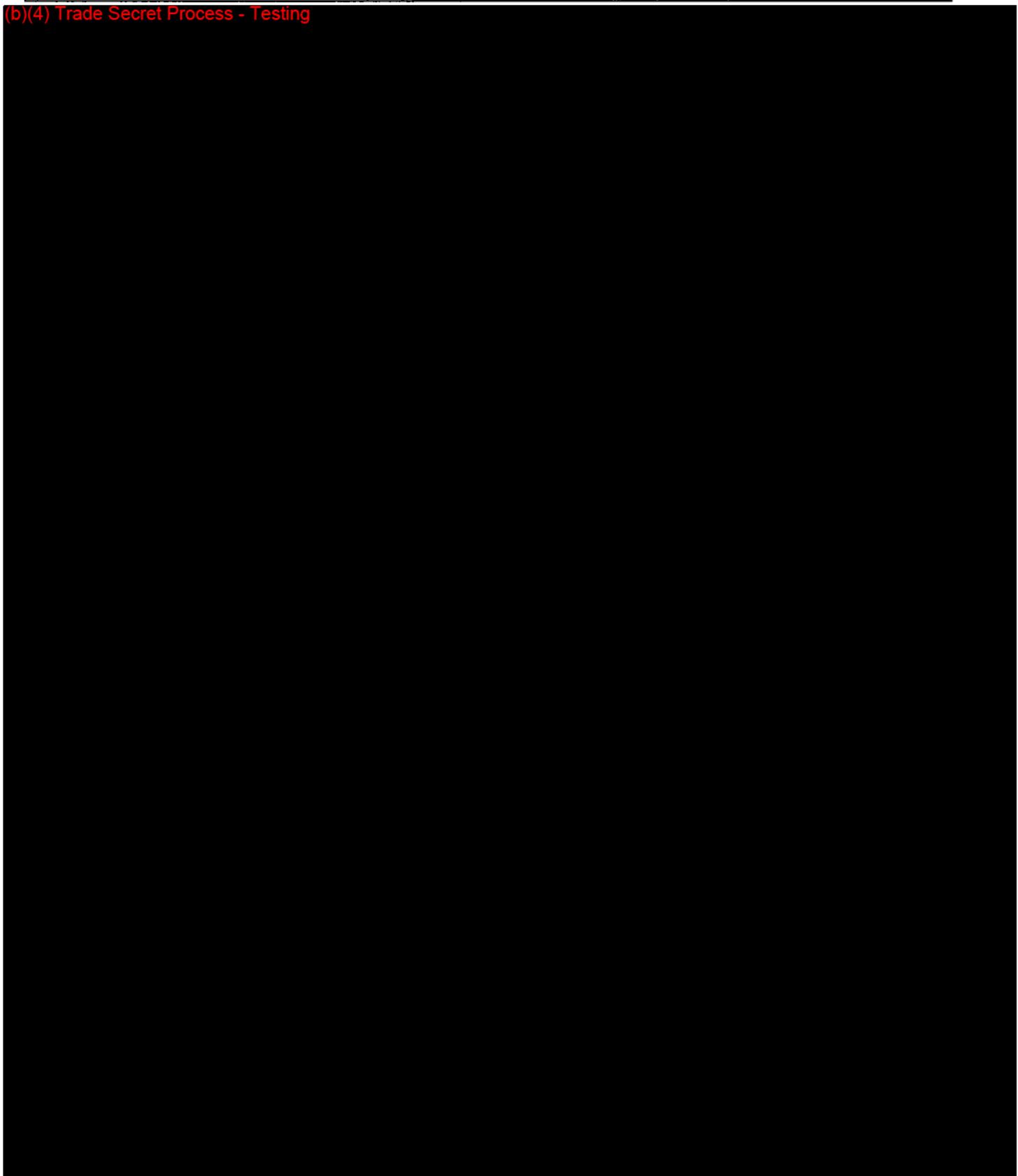
(b)(4) Trade Secret Process - Testing



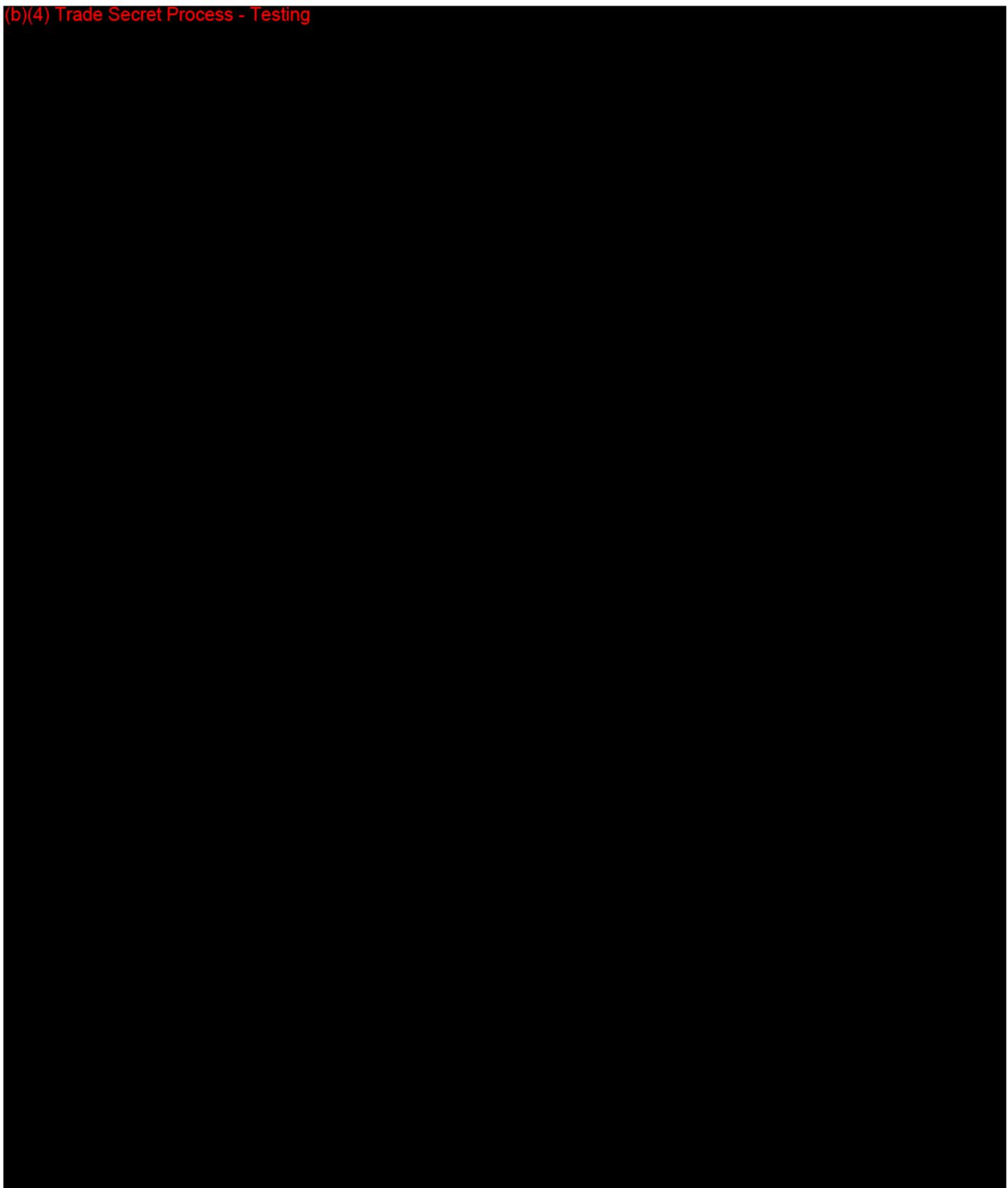
(b)(4) Trade Secret Process - Testing



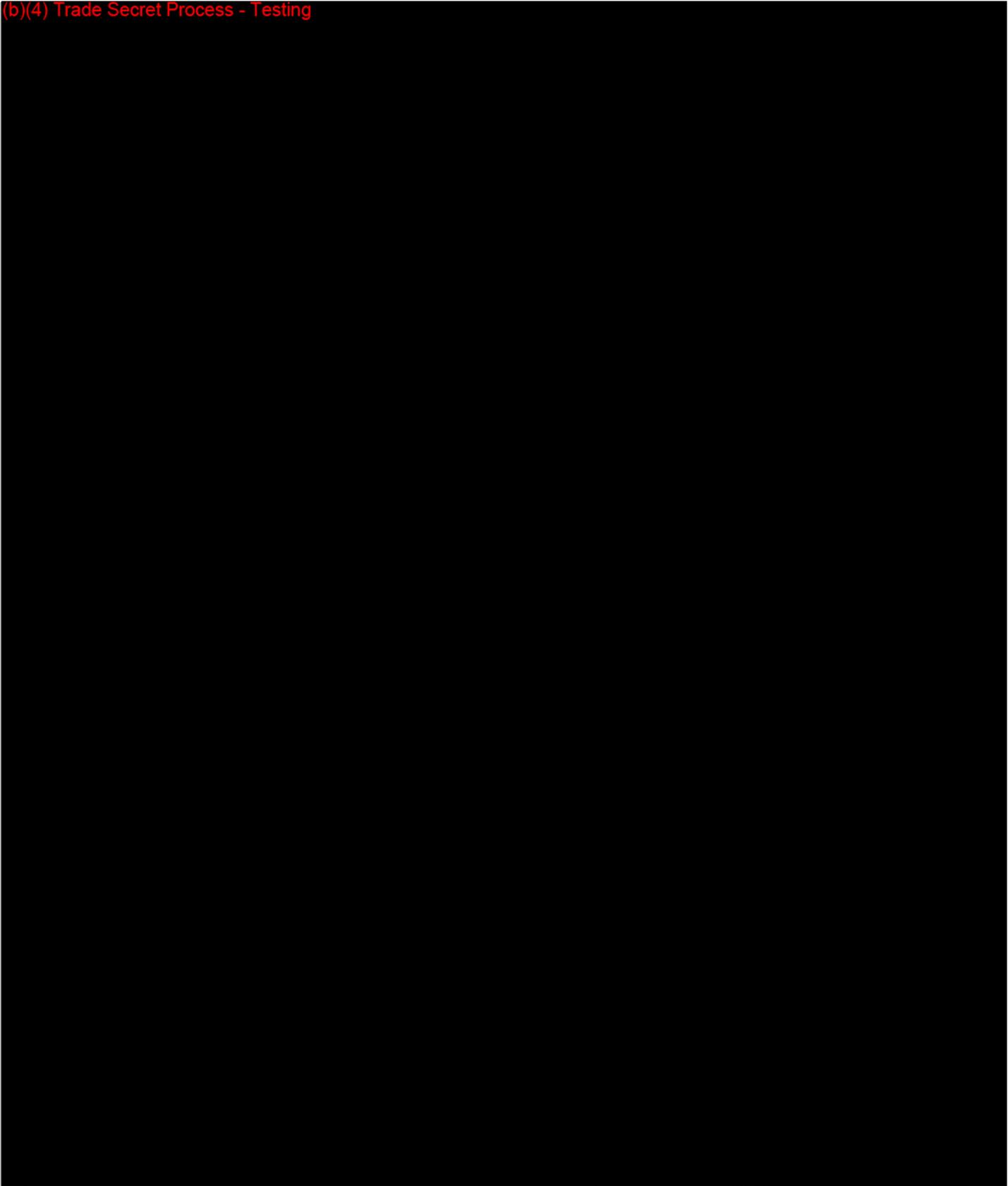
(b)(4) Trade Secret Process - Testing



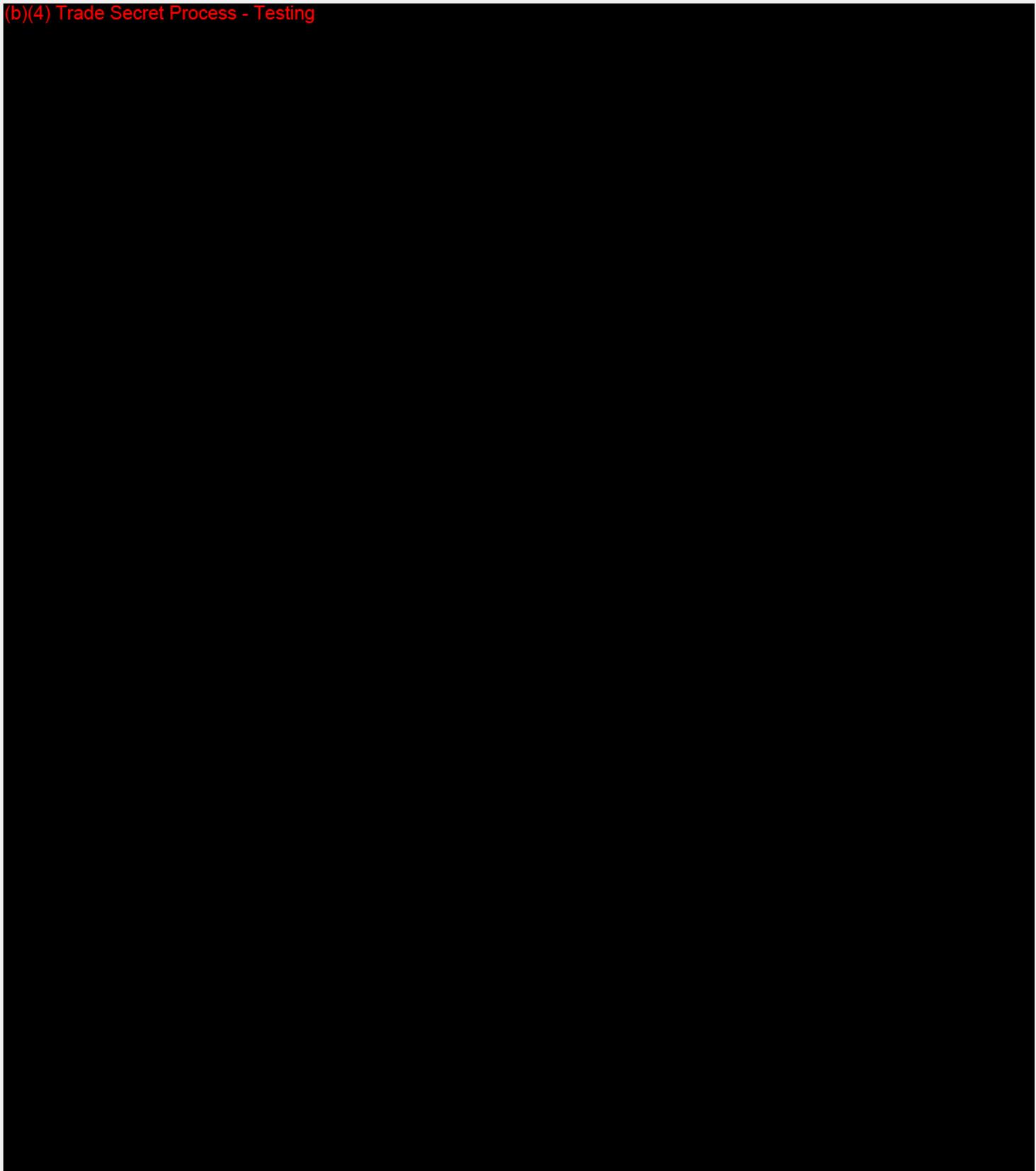
(b)(4) Trade Secret Process - Testing



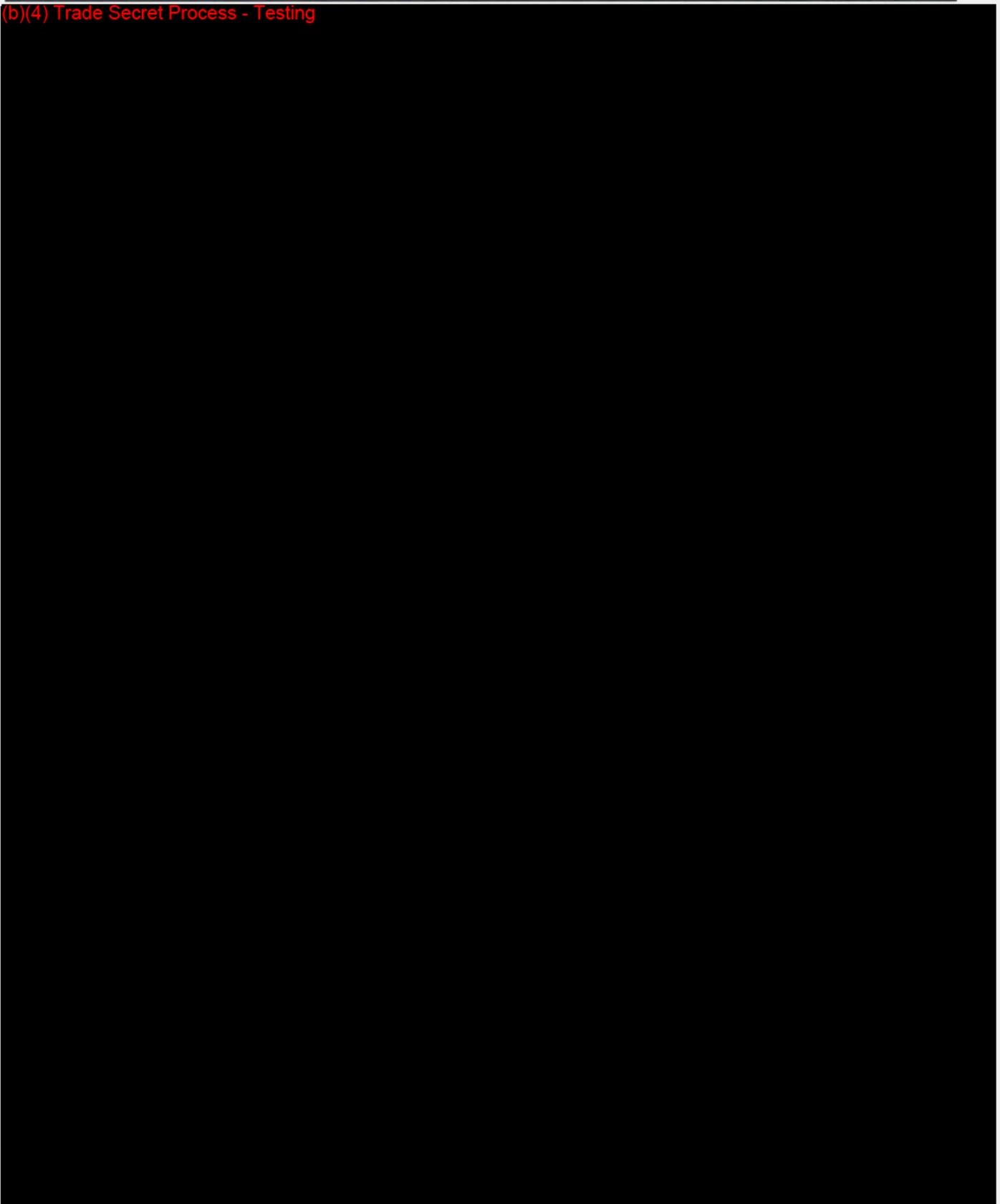
(b)(4) Trade Secret Process - Testing



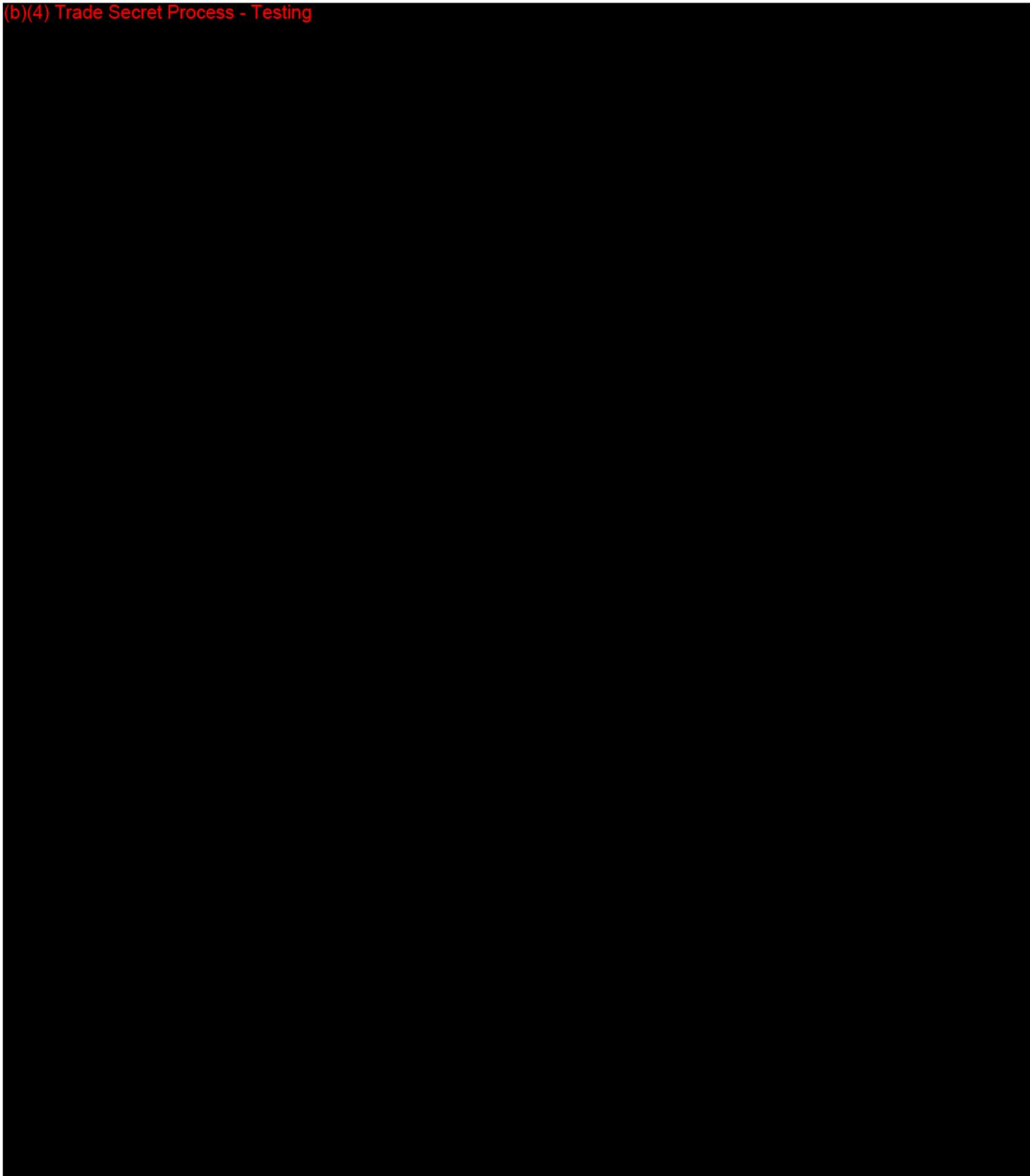
(b)(4) Trade Secret Process - Testing



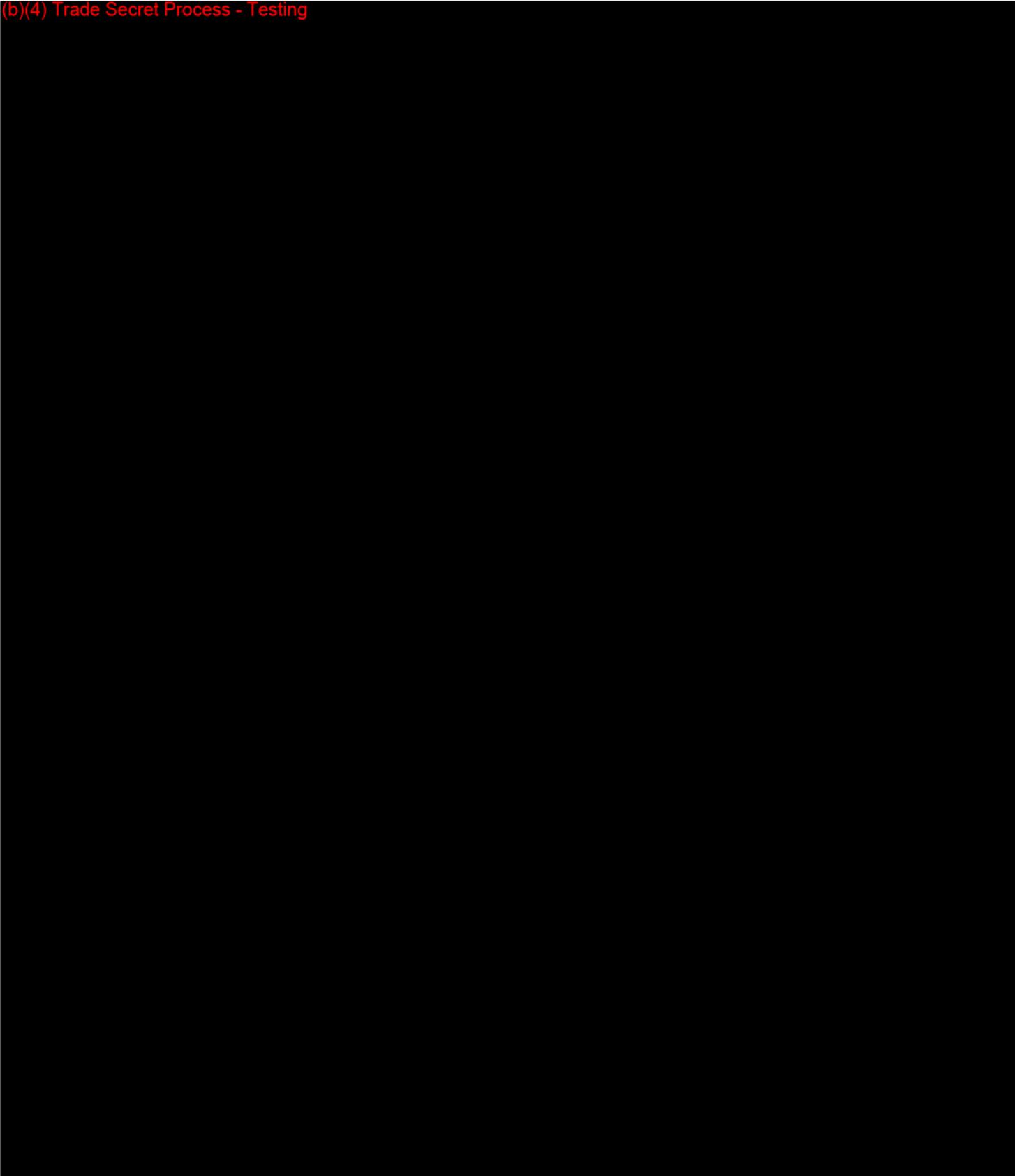
(b)(4) Trade Secret Process - Testing



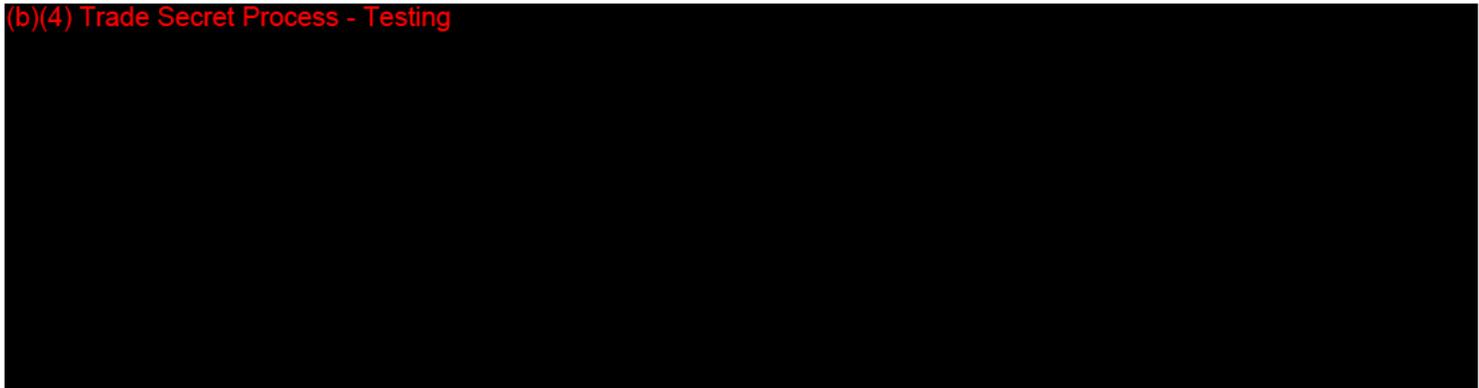
(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



**19. PERFORMANCE TESTING - ANIMAL**

(b)(4) Trade Secret Process - Testing

**20. PERFORMANCE TESTING - CLINICAL**

**Not applicable to this submission.**

**21. KIT CERTIFICATION**

**This device is not part of a kit. Not applicable to this submission.**



### COVER SHEET MEMORANDUM

*Kathy Daws-Kapp*

From: Reviewer Name

Subject: 510(k) Number

To: The Record

*K120593*

Please list CTS decision code *SE*

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

#### Not Substantially Equivalent (NSE) Codes

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

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

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC.



Regulation Number

884.1690

Class\*

II

Product Code

H1H

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

Additional Product Codes:

Review: Sharon Andrews  
for (Branch Chief)  
Elaine Blyskun

OGDB  
(Branch Code)

3/23/12  
(Date)

Final Review: Lynn M. Whyte  
dep (Division Director)

3/23/12  
(Date)



**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION**

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

1. Explain how the new indication differs from the predicate device's indication:  
The subject indication is NOT different from the predicate. See discussion above under Indications for Use.

3. Describe the new technological characteristics:  
The technological characteristics are NOT different from the predicate

5. Explain how descriptive characteristics are not precise enough:  
Descriptive characteristics ARE acceptable

8. Explain what performance data is needed:  
Testing is identified in risk analysis and performed. Per Special 510(k) policy, this data was not reviewed. The company indicates that the performance is comparable.

## Summary Information for K120593

### Device Description

This device is a hysteroscopic morcellator that is intended for use in removing tissue such as myomas and polyps from the uterus and cutting them into pieces small enough to be able to easily remove them. The device is introduced into the uterus through the working channel of a hysteroscope. This device has been modified from the previous version of the device which was cleared under K073690. The device includes the following components:

- \*Tissue removal device (Handpiece and Flexible cable)
- Motor control unit
- Foot pedal
- Power cord

The tissue removal device is provided sterile for single use only. Other components do not contact the patient.

#### Tissue Removal Device

The tissue removal device has the following dimensions: 3.0 mm outer diameter, 2.0 mm inner diameter, and 32 cm length. The tissue removal device is connected to the motor control unit by an integrated 6 foot flexible cable. This unit also has a 10 foot suction tube that extends from the proximal end of the handpiece. The distal end of the handpiece consists of a rotating and reciprocating inner tube encased in an outer stationary tube. The outer tube has a side facing window that allows for suction of tissue into the tube and the inner tube resects the tissue. Distention fluid and resected tissue are aspirated through the inner cutting tube and collected into an attached vacuum canister and tissue trap.

#### Motor Control Unit

The control unit has a power switch, connectors for morcellator flexible cable and foot pedal, reset button, and small display window. The display window is used for the display of elapsed time. The morcellator speed, direction of rotation, and reciprocation rate are fixed and cannot be changed by the user. The control unit includes software. Rotation and reciprocation movement is now translated through a wire core in the flexible cable.

#### Foot Pedal

The foot pedal is a single pedal model. Depressing the foot pedal toggles between on and off.

### Indications for Use

The indications are given as the following:

“The MyoSURE Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.”

This indications statement has not changed from K100559.

### Modifications

As compared to the predicate Interlace device (Hysteroscopic Morcellation system, K091100 and K100559) the following change has been made:

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

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

#### Discussion of Required Elements:

##### Table of Contents

The table of contents is missing, but this is not critical item.

##### Standards

Standards are mentioned, but only in reference to testing conducted on previous models. The company indicates that modification identified here does not impact electrical safety or electromagnetic compatibility (EMC). I might disagree with this statement (particularly in regard to EMC, but the impact would be minimal and effectiveness testing was conducted—they just did not repeat general safety and EMC standards testing.

##### Risk analysis

A software/firmware hazard analysis was provided. The analysis was not specific to the change, but does provide information on methods used and results.

Section 18 states that performance testing required was determined based on an analysis of risks and hazards posed by the proposed changes. They indicate no new risks were identified (and we agree). They list the following testing as that which was identified by the analysis (and provide results):

- Cutting performance 9extirpated uteri and beef tongue in g/min)
- Cutting durability (30 minutes constant use)
- Heat generation

Test protocols/results provided also include the following minor aspects: compatibility with distension media, noise creation, and bend test. Data provided compares the new version to the predicate. Temperature and cutting performance graphs show similar results for both subject and predicate. The cutting assembly is single use and does not require further durability testing.

**SCREENING CHECKLIST FOR SPECIAL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number:  K120593

**Section 1: Required Elements for a SPECIAL 510(k) submission:**

	Present or Adequate	Missing or Inadequate
<b>Medical Device User Fee Cover Sheet</b> <a href="http://www.fda.gov/oc/mdufma/coversheet.html">www.fda.gov/oc/mdufma/coversheet.html</a>	✓	
<b>Cover Letter</b> Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 <a href="http://www.fda.gov/cdrh/ode/guidance/1567.html">http://www.fda.gov/cdrh/ode/guidance/1567.html</a>	✓	
<b>Table of Contents</b>	✓	
<b>Truthful and Accurate Statement</b> Device Advice - <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_9">www.fda.gov/cdrh/devadvice/314312.html#link_9</a>	✓	
<b>Form FDA 3654 - Standards Data Report for 510(k)s –</b> <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a>  1: No standard used? = No Standards Form Required 2: Declaration of Conformity? = Yes Standards Form Required 3: Standard but no declaration? = Yes Standards Form Required	✓	
<b>Device's Trade Name, Device's Classification Name and Establishment Registration Number.</b>	✓	
<b>Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).</b>	✓	
<b>Proposed Labeling - Device Advice</b> <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_10">www.fda.gov/cdrh/devadvice/314312.html#link_10</a>	✓	
<b>Indications for Use Statement</b> Device Advice - <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_6">www.fda.gov/cdrh/devadvice/314312.html#link_6</a>	✓	
<b>Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.</b>	✓	
<b>510(k) Summary or 510(k) Statement</b> Device Advice - <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_7">www.fda.gov/cdrh/devadvice/314312.html#link_7</a>	✓	
<b>Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.</b>	✓	
<b>Identification of legally marketed predicate device. *</b>	✓	
<b>Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]</b>	NA	
<b>Class III Certification and Summary. **</b>	NA	

Class III Summary and Certification Form <a href="http://www.fda.gov/cdrh/manual/stmnciii.html">www.fda.gov/cdrh/manual/stmnciii.html</a>		
<b>Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study.</b> FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf</a> FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf</a> Financial Disclosure by Clinical Investigators <a href="http://www.fda.gov/oc/guidance/financialdis.html">www.fda.gov/oc/guidance/financialdis.html</a>	✓	
Kit Certification: Device Advice <a href="http://www.fda.gov/cdrh/ode/odecl874.html">http://www.fda.gov/cdrh/ode/odecl874.html</a>	NA	

\*- May not be applicable for Special 510(k)s.

\*\* - Required for Class III devices, only.

**Section 2: Required Elements for a SPECIAL 510(k) submission:**

	Present or Adequate	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	✓	
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met.? This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Items with checks in the Present or Adequate column do not require additional information from the sponsor. Items with checks in the Missing or Inadequate column must be submitted before substantive review of the document.

Passed Screening  Yes  No - Reviewer: *Kathryn S. DeWitt*

Concurrence by Review Branch: *Sharon Andrew* Date: *3/23/12*  
*for Elaine Blyskun*  
*Branch Chief, OSD B*

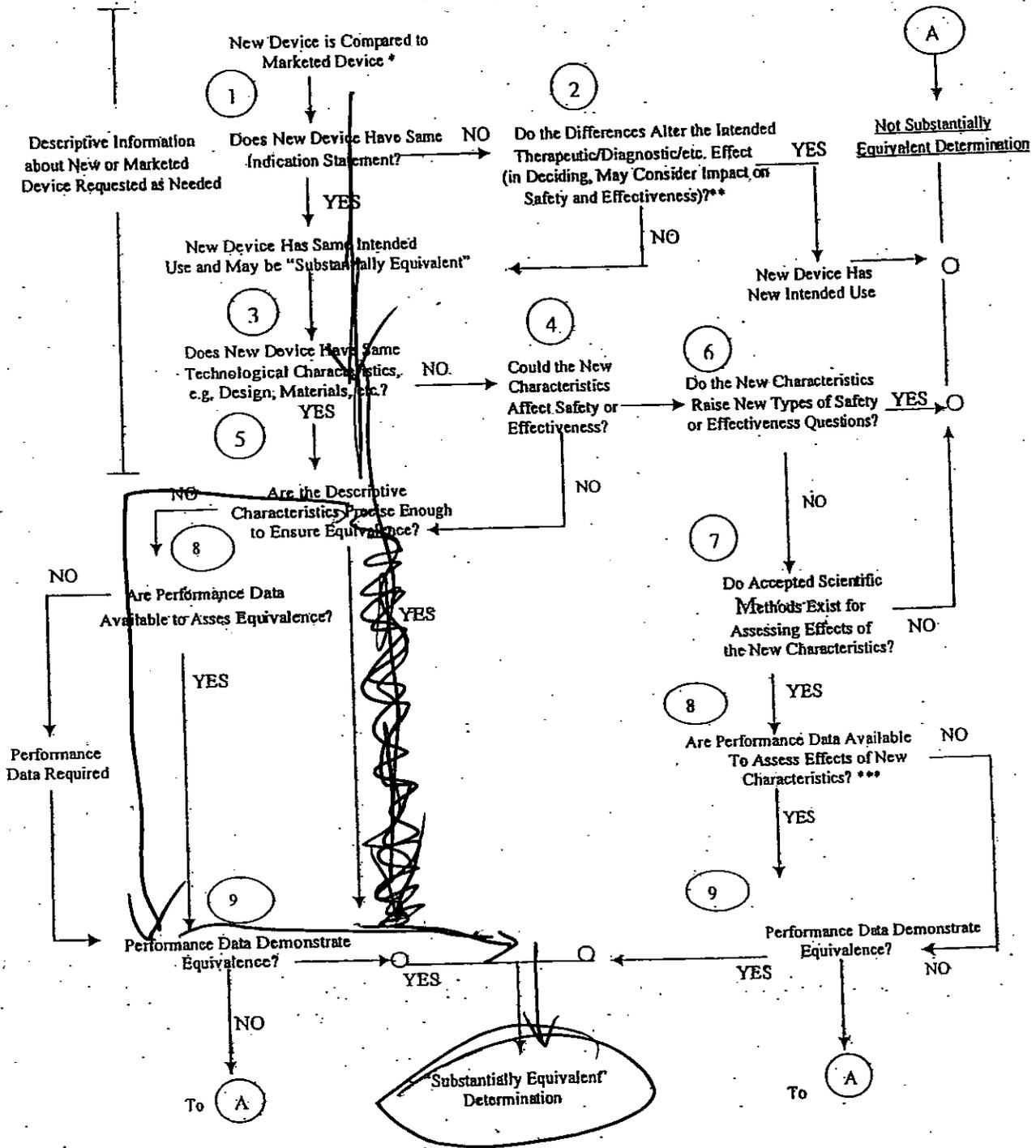
The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug,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

respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the A Suggested Approach to Resolving Least Burdensome Issues document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

*Form Last Updated: Brandi Stuart 9/4/08*

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



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

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

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