



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K052917 - 334 pages
COMPANY: HOWMEDICA OSTEONICS CORP (HOWMOSTEB)
PRODUCT: PROSTHESIS, KNEE PATELLOFEMOROTIBIAL, PARTIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER (NPJ)
SUMMARY: Product: STRYKER COMPARTMENTAL KNEE SYSTEM

DATE REQUESTED: May 14, 2012

DATE PRINTED: May 14, 2012

Note: Printed



DEC 27 2005

**510(k) Summary of Safety and Effectiveness
Stryker® Compartmental Knee System**

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission: Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430

For Information contact: Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5581 Fax: (201) 831-6038

Date Summary Prepared: December 9, 2005

Device Identification

Proprietary Name: Stryker® Compartmental Knee System
Common Name: Knee Prosthesis Components
Proposed Regulatory Class: Class II

Classification Name, Reference and Product Code:

Knee Joint, Femorotibial, Polymer/Metal, Semi-constrained, Cemented Prosthesis, 21 CFR §888.3530, 87 NPJ
Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis, 21 CFR 888.3540, 87 KRR
Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer, 21 CFR 888.3520, 87 HSX
Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer, 21 CFR §888.3530, 87 HRY

Description:

The Stryker® Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and unicompartmental arthroplasty. The system allows the physician to choose the most appropriate option to treat the patient with patellofemoral arthroplasty and/or unicompartmental arthroplasty as needed.

Indications for Use

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicompartmental arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartmental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis, or

- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

Substantial Equivalence:

The device is substantially equivalent to its predicates for patellofemoral arthroplasty and femorotibial arthroplasty in regards to intended use, design, materials, and operational principles. The analyses demonstrate that the components from these systems are compatible when used for patellofemoral and/or femorotibial replacement.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2005

Ms. Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K052917
Trade/Device Name: Stryker Compartmental Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: NPJ, KRR, HSX, HRY
Dated: December 13, 2005
Received: December 13, 2005

Dear Ms. Kelly:

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

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

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

Page 2 – Ms. Vivian Kelly

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson

Acting Director

Division of General, Restorative and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Stryker® Compartmental Knee System

Indications for Use:

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicompartmental arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

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- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

Prescription Use X

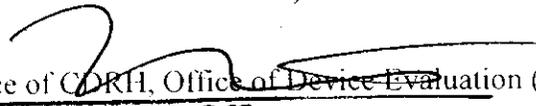
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 807 Subpart C)

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

Concurrence of  Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K052917



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2005

Ms. Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K052917
Trade/Device Name: Stryker Compartmental Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: NPJ, KRR, HSX, HRY
Dated: December 13, 2005
Received: December 13, 2005

Dear Ms. Kelly:

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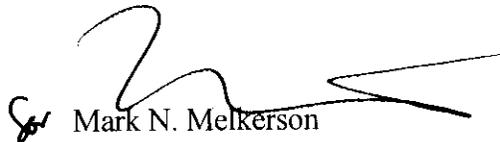
Page 2 – Ms. Vivian Kelly

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Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Stryker® Compartmental Knee System

Indications for Use:

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- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

Prescription Use X AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of  Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K052917

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

December 01, 2005

HOWMEDICA OSTEONICS CORP
 325 CORPORATE DR.
 MAHWAH, NJ 07430
 ATTN: VIVIAN KELLY

510(k) Number: K052917
 Product: STRYKER
 COMPARTMENTAL
 KNEE SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified 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>

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

October 19, 2005

HOWMEDICA OSTEONICS CORP
 325 CORPORATE DR.
 MAHWAH, NJ 07430
 ATTN: VIVIAN KELLY

510(k) Number: K052917
 Received: 18-OCT-2005
 Product: STRYKER
 COMPARTMENTAL KNEE
 SYSTEM

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 any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/oivd/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
 Supervisory Consumer Safety Officer
 Office of Device Evaluation

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

October 17, 2005

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

HOWMEDICA OSTEONICS CORP
 325 CORPORATE DR.
 MAHWAH, NJ 07430
 ATTN: VIVIAN KELLY

510(k) Number: K052917
 Received: 17-OCT-2005
 Product: STRYKER
 User Fee ID Number: 6022901L KNEE
 SYSTEM

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 any 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 Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. 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
 (314) 418-4983

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) 594-2977 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 <http://www.fda.gov/oc/mdufma>.

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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 an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

R052917

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: MD6022901-956733 Write the Payment Identification number on your check.	
completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken properly submit your application and fee payment:			
1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.htm#3a . You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) HOWMEDICA OSTEONICS CORP 325 CORPORATE DR MAHWAH NJ 07430 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 222183590		2. CONTACT NAME Vivian Kelly 2.1 E-MAIL ADDRESS vivian.kelly@stryker.com 2.2 TELEPHONE NUMBER (include Area code) 201-831-5581 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 201-831-6038	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <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)		3.1 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. 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, parents, and partner firms <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	
6. 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	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) \$3,833.00 Replaces MD6021605-956733 (2005)			
			06-Oct-2005

Form FDA 8601 (08/2003)

Close Window

Print Cover sheet

Call

45 OR II



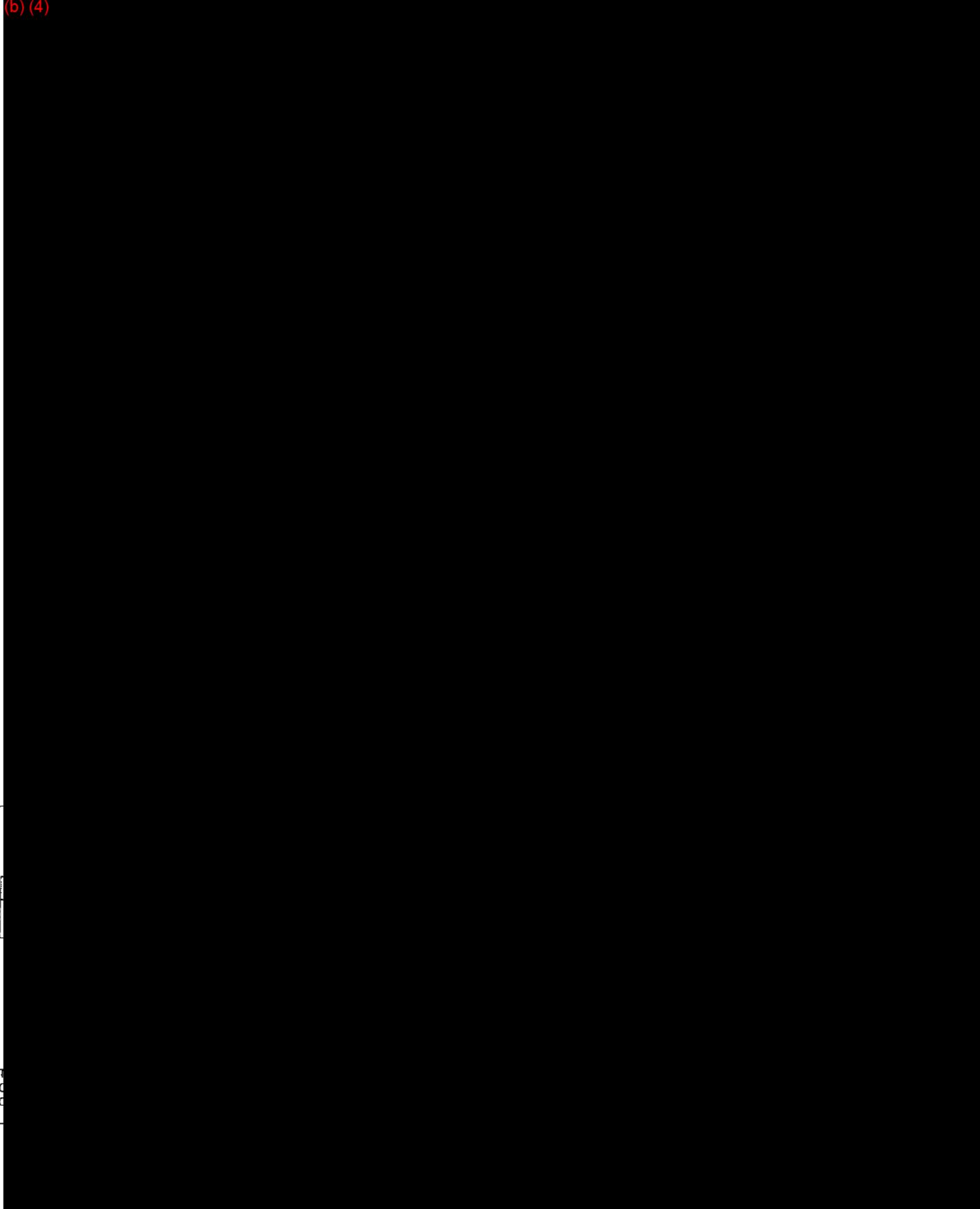
VENDOR NO.	VENDOR NAME
24109	FOOD AND DRUG ADMIN

325 Corporate Drive
Mahwah, NJ 07430

Orthopaedics

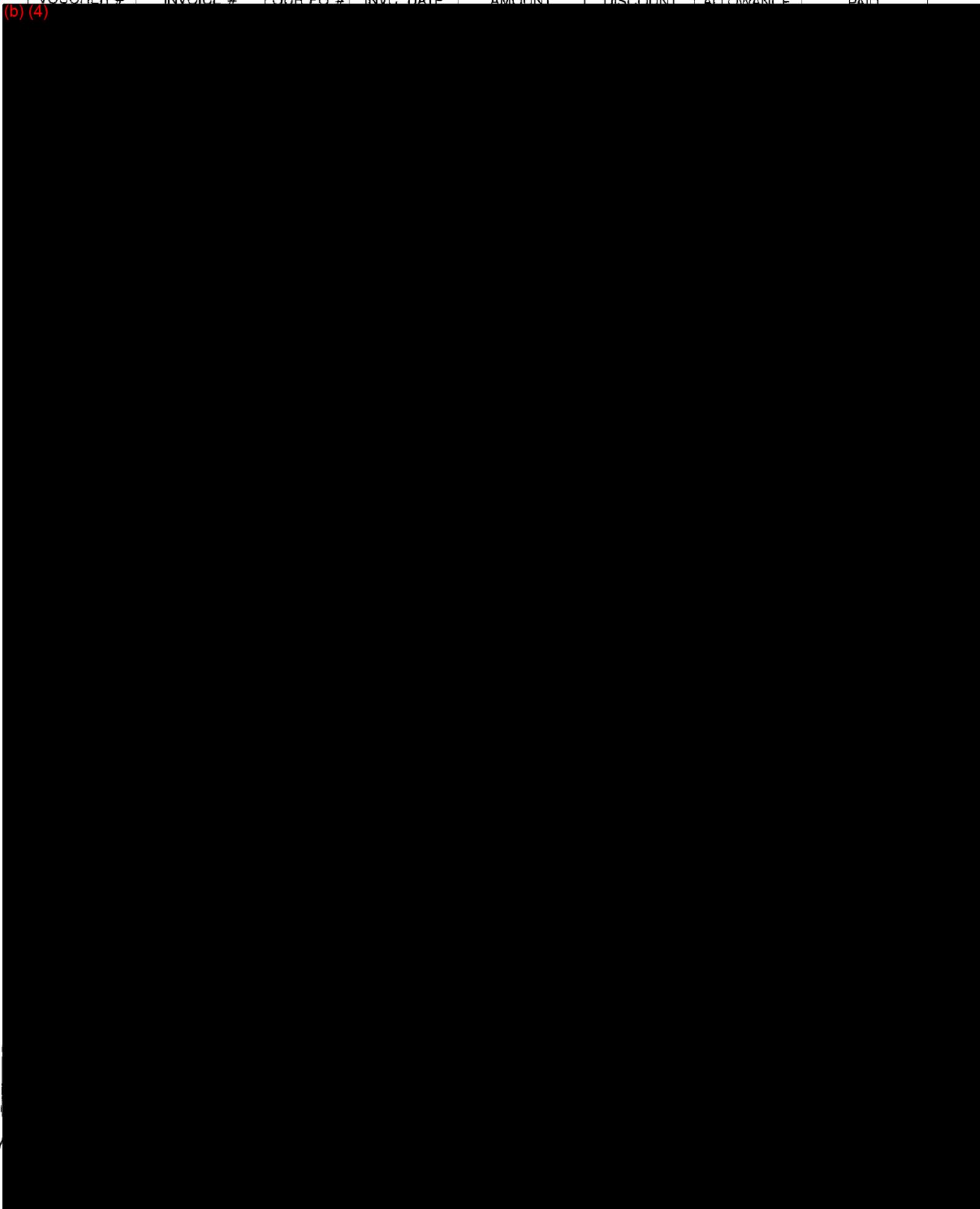
VOUCHER #	INVOICE #	OUR PO #	INVC. DATE	AMOUNT	DISCOUNT	ALLOWANCE	PAID
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(b) (4)



VENDOR NO.	Records processed under FOIA Request 2011-5983; Released 5/30/2018	stryker 325 Corporate Drive Mahwah, NJ 07430
	VENDOR NAME	
24109	FOOD AND DRUG ADMIN	Orthopaedics

VOUCHER #	INVOICE #	OUR PO #	INVC DATE	AMOUNT	DISCOUNT	ALLOWANCE	PAID
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(b) (4)

stryker
Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

October 14, 2005

Via Federal Express

Office of Device Evaluation (510(k))
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Traditional Premarket Notification: Stryker® Compartmental Knee System

Dear Sir or Madam:

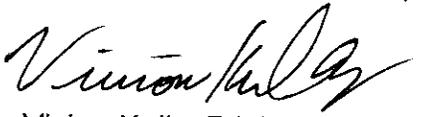
In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and Title 21 CFR §807, Subpart E, this traditional 510(k) Premarket Notification is being submitted in duplicate for the Stryker® Compartmental Knee System. The Truthful and Accurate Statement immediately follow this letter. The Indications for Use Statement is included in Appendix E.

This submission contains methods, data, and analysis of these data, which Howmedica Osteonics Corp. considers "Trade Secret" and commercially privileged and confidential to Howmedica Osteonics Corp. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act.

Although we claim that the subject device is substantially equivalent to the predicate device within the meaning of Section 513(i)(1)(A) of the Federal Food, Drug and Cosmetic Act, nothing in this submission in any way reflects upon the completely unrelated federal patent law "doctrine of equivalents" or makes any claims in regards to trademark names.

If there are any questions, or if further information is needed, please contact the undersigned below at (201) 831-5581.

Sincerely,
Howmedica Osteonics Corp.


Vivian Kelly, RAC
Regulatory Affairs Specialist

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Premarket Notification
Truthful and Accurate Statement

[as required by 21 CFR §807.87k)]

I certify that, in my capacity as Regulatory Affairs Specialist of Howmedica Osteonics Corp., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been willfully omitted.



Vivian Kelly

Regulatory Affairs Specialist

Date: 10/14/05

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PREMARKET NOTIFICATION:
STRYKER® COMPARTMENTAL KNEE SYSTEM

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

October 14, 2005

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**TRADITIONAL 510(k)
STRYKER® COMPARTMENTAL KNEE SYSTEM
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510(k) Summary of Safety and Effectiveness
Stryker® Compartmental Knee System

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission:

Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430

For Information contact:

Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5581 Fax: (201) 831-6038

Date Summary Prepared:

October 14, 2005

Device Identification

Proprietary Name:

Stryker® Compartmental Knee System

Common Name:

Knee Prosthesis Components

Classification Name and Reference:

Knee Joint, Femorotibial, Polymer/Metal, Semi-constrained,
Cemented Prosthesis
21 CFR §888.3530

Proposed Regulatory Class:

Class II

Device Panel/Product Code:

OR (87) NPJ, Prosthesis, Knee, Patellofemorotibial, Partial,
Semi-constrained, Cemented, Polymer/Metal/Polymer

Description:

The Stryker® Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and unicondylar arthroplasty. The system allows the physician to choose the most appropriate option to treat the patient with patellofemoral arthroplasty and/or unicondylar arthroplasty as needed.

Indications for Use

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartmental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

Substantial Equivalence:

The device is substantially equivalent to its predicates for patellofemoral arthroplasty and femorotibial arthroplasty in regards to intended use, design, materials, and operational principles. The analyses demonstrate that the components from these systems are compatible when used for patellofemoral and/or femorotibial replacement.

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SECTION I
ADMINISTRATIVE INFORMATION

Stryker® Compartmental Knee

Traditional 510(k)

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

Name and Address of the Manufacturer(s) of the Device:

Howmedica International S. de R.L.
Raheen Business Park
Limerick, Ireland
Est. Reg. Number: 9610726

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430
Est. Reg. Number: 2249697

Stryker, Ireland, LTD. Osteonics
Carrigtwohill Industrial Estate
Carrigtwohill, County Cork, Ireland
Est. Reg. Number: 9616680

Name and Address of the Distributor of the Device:

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Est. Reg. Number: 2249697

Contact Person:

Vivian Kelly
Phone (201) 831-5581
Fax (201) 831-6038
Email: Vivian.Kelly@stryker.com

Device Identification

Proprietary Name:	Stryker® Compartmental Knee System
Common Name:	Knee prosthesis components
Classification Name and Reference:	Knee Joint, Femorotibial, Polymer/Metal, Semi-constrained, Cemented Prosthesis 21 CFR §888.3530
Proposed Regulatory Class:	Class II
Device Panel/Product Code:	OR (87) NPJ, Prosthesis, Knee, Patellofemorotibial, Partial, Semi-constrained, Cemented, Polymer/Metal/Polymer

Stryker® Compartmental Knee

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SECTION II
DEVICE DESCRIPTIVE INFORMATION

Stryker® Compartmental Knee

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Introduction

This 510(k) submission is to introduce a compartmental knee system. The Stryker® Compartmental Knee System is a system of different knee components to replace either the patellofemoral and/or condyle regions of the femoral knee joint. All of the components in the Stryker® Compartmental Knee System were cleared as part of the knee systems listed below and are discussed in the Device Description Section:

- Avon® Patello-femoral Joint (PFJ) Prosthesis (K010100, K020841, K041160, and K051948 currently pending review and the Scorpio® X3™ Patella cleared in K051977),
- EIUS® Unicompartmental Knee System (K992287 & K033769),
- SCR® Unicompartmental Knee Prosthesis (K896856 & K911373), and
- UNIX™ Unicompartmental Knee System (K923011).

Intended Use

The Stryker® Compartmental Knee System consists of sterile, single-use devices intended for replacement of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The Stryker® Compartmental Knee System includes Avon® Patellofemoral Joint components for reconstruction of the patellofemoral joint and the EIUS®, SCR® and UNIX™ Unicompartmental Knee Prostheses.

Indications for Use

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,

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- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartmental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are sterile, single use only and are intended for implantation with bone cement. See Appendix E for the Indications for Use Statement.

Device Description

The Stryker® Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and unicompartmental arthroplasty. The system allows the physician to choose the most appropriate option to treat the patient with patellofemoral arthroplasty and/or unicompartmental arthroplasty as needed.

A description of each component is provided below and a list of the components and representative engineering drawings are included in Appendix A.

Patellofemoral Components

The patellofemoral components in the Stryker® Compartmental Knee System for replacement of the patellofemoral regions the femoral knee joint were cleared as part of the Avon® Patello-femoral Joint (PFJ) Prosthesis. These components will not be modified and are described below.

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Femoral Components

The femoral component is for resurfacing the patellar groove on the femur for patellofemoral arthroplasty and articulates with a patellar component as described below. It is available in four sizes: extra small, small, medium, and large. The small, medium and large sizes were determined substantially equivalent via 510(k) K010100, while the extra small component was cleared in K041160. All of these components are fabricated from cobalt chromium alloy per ASTM F-75.

Patellar Components

The patellar components for patellofemoral arthroplasty articulate with the above referenced femoral components and were cleared as part of different knee systems including the Avon®, Kinemax®, Duracon®, Scorpio® and Triathlon® Knee Systems. These components will not be modified. They are fabricated from Ultra-High Molecular Weight Polyethylene (UHMWPE) per ASTM F-648, and are available in various sizes and styles. Each patella design is described below.

Avon® Polyethylene Patellas

The polyethylene patellar components were cleared in K020841. They are available in small, medium and large sizes.

Kinemax® Patellar Components

The Kinemax® and Kinemax® Plus patellar components in small, medium and large sizes were cleared for use with the femoral components in K010100.

Duracon® Patellar Components

The patellas from the Duracon® Knee System to be used with the patellofemoral components were cleared in K961483 and K965173. The 510(k) K051948 is pending review to add these patellas to the Avon® Patello-femoral Joint (PFJ) Prosthesis product line. They are available in six sizes ranging from 27mm to 39mm in the interior-superior dimension and are 8mm to 11mm in thickness (b) (4)

(b) (4)

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Scorpio® Patellar Components

The patellar components from the Scorpio® Knee System are available in six sizes with thickness of 8mm and 10mm in diameters ranging from 30mm to 38mm. The design features are the same as the predicate Scorpio® patellas cleared in K972967 in regards to articular geometry, fixation peg location, location and number of pegs. 510(k) K051948 is pending review to add these patellas to the Avon® Patello-femoral Joint (PFJ) Prosthesis product line.

(b) (4)

Scorpio® X3™ UHMWPE Patellar Components

These patellas were recently cleared in K051977 to modify the current Scorpio® Patellar material. They will be manufactured from a modified sequentially cross-linked and annealed Ultra High Molecular Weight Polyethylene (UHMWPE) material. The design of the component has not changed.

(b) (4)

Triathlon® Patellar Components

Triathlon® Patellar components are available in six diameters (27mm, 29mm, 31mm, 33mm, 36mm, and 39mm) and four thicknesses (8mm, 9mm, 10mm, and 11mm). The design

(b) (4)

These patellas are similar in design to the Duracon® Symmetric Patellar component cleared in K961483 (see above) or the patellar components cleared as part to the Triathlon® CR Total Knee System in K040267 or the Triathlon® X3™ components recently cleared in K051146. 510(k) K051948 is pending review to add these patellas to the Avon® Patello-femoral Joint (PFJ) Prosthesis product line.

(b) (4)

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Femorotibial Components

The femorotibial components were cleared in various 510(k)s as part of the EUIS® , SCR® and UNIX™ Unicompartmental Knee Systems. The Stryker® Compartmental Knee System includes different styles of uni-compartment knee components so the physician can choose the most appropriate type of femorotibial components, i.e., a resurfacing or resectioning design to address both right and left compartmental needs. It is important to note that the different components in the system cannot be mixed. See Table 1 for the list of compatible components. A EUIS® femoral component must be used with an EUIS® tibial component and so on. Each system and its components will not be modified and are described below.

EUIS® Components

The EIUS® Unicompartmental Knee System consists of a distal femoral resurfacing component and proximal tibial resurfacing component for unicompartmental arthroplasty for medial or lateral compartments of the knee joint. The system was originally determined substantially equivalent via 510(k) K992287 and was cleared under the name of the “First Step Uni Knee.” A line extension was submitted for additional tibial components in K033769.

The cast cobalt chromium femoral components are available in extra small, small, medium, large and extra large sizes in left medial/right lateral and right medial/left lateral. The tibial component is fabricated from UHMWPE and is available in 6mm, 8mm, 9mm, 10mm and 12mm thicknesses for the left medial/right lateral and/or right medial/left lateral compartments. The underside of the tibial components contains a cement recess and a keel. An alternate design includes inserts in 6mm, 8mm, 9mm, 10mm, 12mm thicknesses without a keel for the left medial / right lateral and/or right medial / left lateral compartments.

SCR® Components

The SCR® Unicompartmental Knee Prosthesis was cleared under the name “MOD-ML Unicompartmental Knee” via 510(k) K896856 and K911373 (b) (4) [REDACTED]. It is a modular, unicondylar knee prosthesis for reconstructive replacement of the deficient knee

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compartment for the right and/or left knee in both medial and lateral designs.

There are four sizes (5, 7, 9 and 11) of femoral components and five sizes (5, 7, 9, 11 and 13) of tibial trays to address size variations in the patient population in right and left configurations. The medial and lateral femoral components are manufactured from cobalt-chrome alloy. The tibial component is fabricated from cobalt-chrome alloy with a polyethylene tibial insert, fabricated from ultra-high molecular weight polyethylene (UHMWPE). The tibial insert is available in 7, 8, 9, 10 or 12mm thicknesses in right and left configurations in sizes 5, 7, 9 and 11(which also fits in the size 13 tray).

UNIX™ Components

The Osteonics® UNIX™ Unicompartmental Knee is a modular, unicondylar knee prosthesis available in right and left knee designs for reconstructive replacement of the deficient knee compartment(s). It was found substantially equivalent via K923011.

The Osteonics® UNIX™ Unicompartmental Knee System's femoral components are manufactured from cobalt-chromium alloy and the cobalt chromium tibial tray has a modular UHMWPE tibial bearing insert. The femoral and tibial components are available four sizes (Sizes 1, 2, 3 and 4) in right and left configurations. The tibial inserts are available in 8mm, 10mm, 12mm and 15mm thicknesses for each tibial tray.

Table 1: Compatibility Chart of Subject Components

	Polyethylene Patellas	EIUS® Tibial Components	SCR® Tibial Components	UNIX™ Tibial Component	UNIX™ Tibial Insert Component
Avon® Femoral Components	✓				
EIUS® Femoral Components		✓			
SCR® Femoral Components			✓		
UNIX™ Femoral Component				✓	✓
UNIX™ Tibial Component					✓

✓ = Compatible

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Materials

The subject patellar and polyethylene tibial components are fabricated from ultra-high molecular weight polyethylene (UHMWPE) meeting the requirements of ASTM F-648 and the patellofemoral, femoral and cobalt chromium tibial components meet ASTM F-75 for cast cobalt chrome alloy. Both materials have a long successful history of use in orthopaedic implant surgery. The material properties of the UHMWPE tibial components meet the material properties of (b) (4).

Labeling

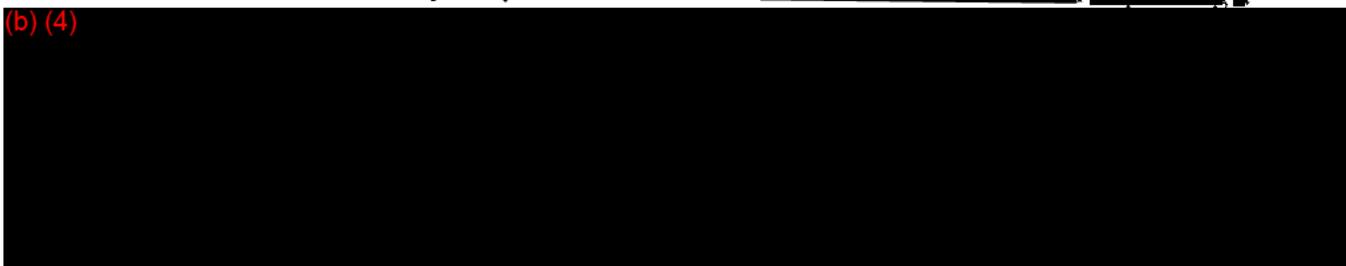
The draft labels for the subject device are presented in Appendix B-1. A draft package insert for the system is presented in Appendix B-2. An updated draft package insert is included in Appendix B-3 to create a generic insert for all unicondylar knee systems. Appendix B-4 contains the revised insert for the patellofemoral prosthesis, which was also included in K051948 currently pending review. A draft surgical technique is included in Appendix B-5. Additionally, the following warning will be included in the labeling and on the outer carton of the cemented components:

Warning: This Device Is Intended For Cemented Use Only in USA.

Testing

In order to assess if the patellofemoral components will not infringe on the femorotibial components, an engineering analysis was conducted. (b) (4)

(b) (4)

**Sterility Information**

The components are single use devices and are provided sterile. The implants are sterilized to a Sterility Assurance Level (SAL) of 10^{-6} using:

- Method: Gamma Irradiation

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- Source: Cobalt 60
- Dose: 25kGy
- Validation: ANSI/AAMI/ISO 11137

Pyrogenicity testing: (b) (4)

(b) (4)

Packaging Information

The subject components will be packaged as described in their associated premarket notifications: (b) (4)

(b) (4)

The components are packaged in a double blister tray then placed in the cardboard container, sealed via the primary package labels, and enveloped in shrink-wrap.

(b) (4)

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SECTION III
SUBSTANTIAL EQUIVALENCE INFORMATION

Stryker® Compartmental Knee

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Substantial Equivalence Information

The device is substantially equivalent to its predicates for patellofemoral arthroplasty and femorotibial arthroplasty in regards to intended use, design, materials, and operational principles. The following list includes the predicate devices that will be used to support the substantial equivalence claim of the Stryker® Compartmental Knee System. A comparison to these predicate devices is presented below. Supporting literature is provided in Appendix D.

- Smith & Nephew Hybrid Knee Femoral Components (K042896)
- Avon® Patello-femoral Joint Prosthesis (K010100, K020841 & K041160)
- EIUS® Unicompartamental Knee System (K992287 & K033769)
- SCR® Unicompartamental Knee Prosthesis (K896856 & K911373)
- UNIX™ Unicompartamental Knee System (K923011)
- PCA® Unicompartamental Knee Prosthesis System (K831143)

Intended Use

The intended use for the subject components is the same as the previously cleared, individual tibial, femoral and patellofemoral components. The components of Avon® Patello-femoral Joint Prosthesis are currently used to perform patellofemoral arthroplasty while the EIUS®, SCR® and UNIX™ components are indicated for unicondylar arthroplasty.

As a system, the intended use is similar to the Smith & Nephew Hybrid Knee Femoral Components, which includes components for patellofemoral and femorotibial arthroplasty. This device may be used when the patient's condition cannot be treated by a single compartment device such as an unicondylar or patellofemoral prosthesis. With this device, the surgeon can implant a device to treat more than one compartment of the knee.

It is also similar in intended use to the PCA® Unicompartamental Knee Prosthesis System cleared via K831143. This prosthesis consists of a femoral resurfacing component and a tibial resurfacing component comprised of a tibial tray and polyethylene insert for both the medial

Stryker® Compartmental Knee

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and lateral sides to address both left and right compartment needs. The system is intended to replace damaged femoral and tibial bearing surfaces of the medial and/or lateral compartments of knee with moderate to severe damage as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, avascular necrosis and other knee conditions. It also recommends arthroplasty to resurface the patellofemoral joint if pathology of the joint is present or anticipated at the time of surgery. This predicate device is intended to treat the same patient population as the subject device.

Based on a review of the intended uses of the predicate devices, the Stryker® Compartmental Knee System is substantially equivalent to the above referenced predicate devices. The use of the device falls with the same scope of these devices to treat various conditions of the knee when patellofemoral and/or femorotibial arthroplasty is required.

Design

The designs of the individual predicate components from the Avon®, EIUS®, SCR® and UNIX™ Systems have not been modified for this submission. Therefore, the subject components are substantially equivalent to the predicate devices in regards to design. The subject and predicate components are all used to perform either patellofemoral or unicondylar arthroplasty.

Materials

The subject device is fabricated from cast cobalt chrome and Ultra-High Molecular Weight Polyethylene (UHMWPE). The predicates are also manufactured from these same materials, which has a long history of use for orthopaedic implants.

Operational Principles

The basic operational principle for the predicate devices, as well as the subject device is for patellofemoral and/or femorotibial arthroplasty. The method of site preparation and insertion are similar for all devices. Relative indications for use are also similar. All components are intended for use with bone cement.

Stryker® Compartmental Knee

Traditional 510(k)

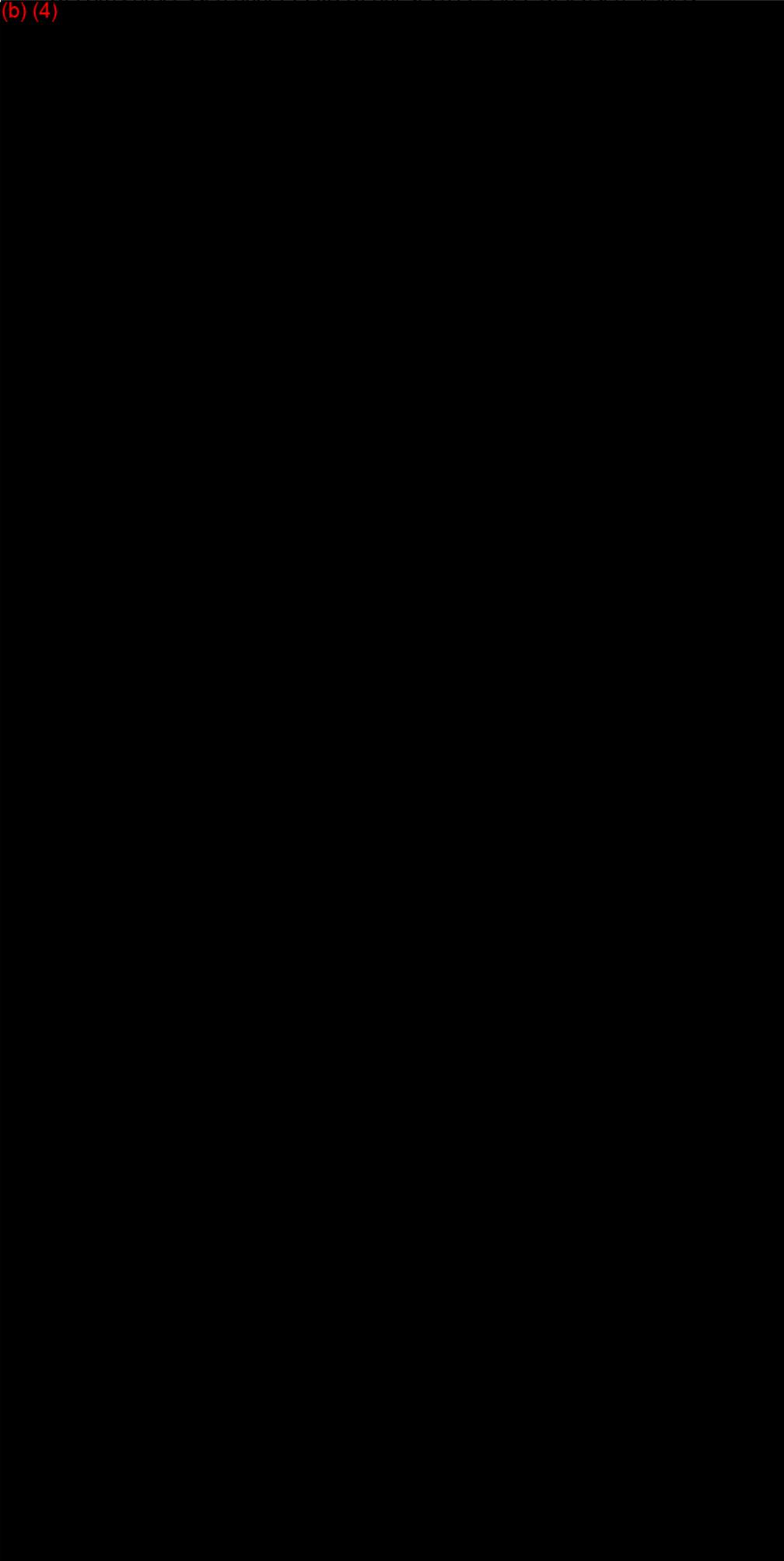
In conclusion, the subject device is substantially equivalent to the predicate devices when used for patellofemoral and/or femorotibial replacement. The engineering analysis provided in Appendix C and the supporting predicate device information included in Appendix D have sufficiently demonstrated the equivalence of the subject devices to the predicate devices. The Substantial Equivalence Table outlining the basis of equivalency follows.

(b) (4)

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Substantial Equivalence Table



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APPENDICES

APPENDIX A COMPONENT INFORMATION

APPENDIX B PACKAGING INFORMATION

APPENDIX C TEST REPORT

APPENDIX D PREDICATE DEVICE INFORMATION

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APPENDIX A
COMPONENT INFORMATION

A-1 Component List

A-2 Engineering Drawing

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**APPENDIX A-1
Component List
Patellofemoral Components**

Cat. No.	Description
	Femoral Components
6430-0-050	Femoral Component, Extra Small
6430-0-100	Femoral Component, Small
6430-0-200	Femoral Component, Medium
6430-0-300	Femoral Component, Large
	Patellar Components
6430-0-020	Patellar Component, Small
6430-0-030	Patellar Component, Medium
6430-0-040	Patellar Component, Large
6479-4-900	Kinemax® Patella, Small
6479-4-910	Kinemax® Patella, Med
6479-4-920	Kinemax® Patella, Large
6479-3-900	Kinemax® Plus Patella, Small
6479-3-910	Kinemax® Plus Patella, Med
6479-3-920	Kinemax® Plus Patella, Large
6642-2-600	Duracon® Symmetric Patella S27mm x 8mm
6642-2-610	Duracon® Symmetric Patella S29mm x 8mm
6642-2-620	Duracon® Symmetric Patella S31mm x 9mm
6642-2-630	Duracon® Symmetric Patella S33mm x 9mm
6642-2-640	Duracon® Symmetric Patella S36mm x 10mm
6642-2-645	Duracon® Symmetric Patella S39mm x 11mm
73-3308	Scorpio® Symmetric Patella 30mm x 8mm
73-3508	Scorpio® Symmetric Patella 32mm x 8mm
73-3708	Scorpio® Symmetric Patella 34mm x 8mm
73-3710	Scorpio® Symmetric Patella 34mm x 10mm
73-3910	Scorpio® Symmetric Patella 36mm x 10mm
73-3110	Scorpio® Symmetric Patella 38mm x 10mm

(b) (4)

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Patellofemoral Components Continued

Cat. No.	Description
5550-L-278	Triathlon® Symmetric Patella S27mm x 8mm
5550-L-298	Triathlon® Symmetric Patella S29mm x 8mm
5550-L-319	Triathlon® Symmetric Patella S31mm x 9mm
5550-L-339	Triathlon® Symmetric Patella S33mm x 9mm
5550-L-360	Triathlon® Symmetric Patella S36mm x 10mm
5550-L-391	Triathlon® Symmetric Patella S39mm x 11mm
5550-G-278	Triathlon® X3™ Symmetric Patella – 27mm x 8mm
5550-G-298	Triathlon® X3™ Symmetric Patella – 29mm x 8mm
5550-G-319	Triathlon® X3™ Symmetric Patella – 31mm x 9mm
5550-G-339	Triathlon® X3™ Symmetric Patella – 33mm x 9mm
5550-G-360	Triathlon® X3™ Symmetric Patella – 36mm x 10mm
5550-G-391	Triathlon® X3™ Symmetric Patella – 39mm x 11mm
73-20-3308	Scorpio® X3™ Symmetric Patella 30mm x 8mm
73-20-3508	Scorpio® X3™ Symmetric Patella 32mm x 8mm
73-20-3708	Scorpio® X3™ Symmetric Patella 34mm x 8mm
73-20-3710	Scorpio® X3™ Symmetric Patella 34mm x 10mm
73-20-3910	Scorpio® X3™ Symmetric Patella 36mm x 10mm
73-20-3110	Scorpio® X3™ Symmetric Patella 38mm x 10mm

Femorotibial Components

Cat. No.	Description
EIUS® Femoral Components	
6636-2-001	Extra Small, Left Medial/Right Lateral
6636-2-002	Small, Left Medial/Right Lateral
6636-2-003	Medium Left Medial/Right Lateral
6636-2-004	Large, Left Medial/Right Lateral
6636-2-005	Extra Large, Left Medial/Right Lateral
6636-2-011	Extra Small, Right Medial/ Left Lateral
6636-2-012	Small, Right Medial/ Left Lateral
6636-2-013	Medium Right Medial/ Left Lateral
6636-2-014	Large, Right Medial/ Left Lateral
6636-2-015	Extra Large, Right Medial/ Left Lateral
EIUS® Tibial Components	
6636-2-308	Tib X-Small 8MM LM/RL
6636-2-309	Tib X-Small 9MM LM/RL
6636-2-310	Tib XSmall 10MM LM/RL
6636-2-312	Tib XSmall 12MM LM/RL
6636-2-318	Tib XSmall 8mmM RM/LL
6636-2-319	Tib XSmall 9mm RM/LL

Stryker® Compartmental Knee

Traditional 510(k)

6636-2-320	Tib XSmall 10mm RM/LL
6636-2-322	Tib XSmall 12mm RM/LL
6636-2-408	Tib Small 8mmLM/RL
6636-2-409	Tib Small 9mm LM/RL
6636-2-410	Tib Small 10mm LM/RL
6636-2-412	Tib Small 12mm LM/RL
6636-2-418	Tib Small 8mm RM/LL
6636-2-419	Tib Small 9mm RM/LL
6636-2-420	Tib Small 10mm RM/LL
6636-2-422	Tib Small 12mm RM/LL
6636-2-508	Tib Medium 8mm LM/RL
6636-2-509	Tib Medium 9mm LM/RL
6636-2-510	Tib Medium 10mm LM/RL
6636-2-512	Tib Medium 12mm LM/RL
6636-2-518	Tib Medium 8mm RM/LL
6636-2-519	Tib Medium 9mm RM/LL
6636-2-520	Tib Medium 10mm RM/LL
6636-2-522	Tib Medium 12mm RM/LL
6636-2-608	Tib Large 8mm LM/RL
6636-2-609	Tib Large 9mm LM/RL
6636-2-610	Tib Large 10mm LM/RL
6636-2-612	Tib Large 12mm LM/RL
6636-2-618	Tib Large 8mm RM/LL
6636-2-619	Tib Large 9mm RM/LL
6636-2-620	Tib Large 10mm RM/LL
6636-2-622	Tib Large 12mm RM/LL
6636-2-708	Tib XLarge 8mm LM/RL
6636-2-709	Tib XLarge 9mm LM/RL
6636-2-710	Tib XLarge 10mm LM/RL
6636-2-712	Tib XLarge 12mm LM/RL
6636-2-718	Tib XLarge 8mm RM/LL
6636-2-719	Tib XLarge 9mm RM/LL
6636-2-720	Tib XLarge 10mm RM/LL
6636-2-722	Tib XLarge 12mm RM/LL
EIUS® Tibial Components with Keel	
6636-2-306	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 6mm
6636-2-406	Tibial Component Small, LM /RL, 6mm
6636-2-506	Tibial Component Medium, LM /RL, 6mm
6636-2-606	Tibial Component Large, LM /RL, 6mm
6636-2-706	Tibial Component X-Large, LM /RL, 6mm
6636-2-316	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 6mm
6636-2-416	Tibial Component Small, RM /LL, 6mm
6636-2-516	Tibial Component Medium, RM /LL, 6mm
6636-2-616	Tibial Component Large, RM /LL, 6mm
6636-2-716	Tibial Component X-Large, RM /LL, 6mm

(b) (4)

Stryker® Compartmental Knee

Traditional 510(k)

EIUS® Tibial Components without Keel	
6636-0-306	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 6mm
6636-0-406	Tibial Component Small, LM /RL, 6mm
6636-0-506	Tibial Component Medium, LM /RL, 6mm
6636-0-606	Tibial Component Large, LM /RL, 6mm
6636-0-706	Tibial Component X-Large, LM /RL, 6mm
6636-0-316	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 6mm
6636-0-416	Tibial Component Small, RM /LL, 6mm
6636-0-516	Tibial Component Medium, RM /LL, 6mm
6636-0-616	Tibial Component Large, RM /LL, 6mm
6636-0-716	Tibial Component X-Large, RM /LL, 6mm
6636-0-308	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 8mm
6636-0-408	Tibial Component Small, LM /RL, 8mm
6636-0-508	Tibial Component Medium, LM /RL, 8mm
6636-0-608	Tibial Component Large, LM /RL, 8mm
6636-0-708	Tibial Component X-Large, LM /RL, 8mm
6636-0-318	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 8mm
6636-0-418	Tibial Component Small, RM /LL, 8mm
6636-0-518	Tibial Component Medium, RM /LL, 8mm
6636-0-618	Tibial Component Large, RM /LL, 8mm
6636-0-718	Tibial Component X-Large, RM /LL, 8mm
6636-0-309	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 9mm
6636-0-409	Tibial Component Small, LM /RL, 9mm
6636-0-509	Tibial Component Medium, LM /RL, 9mm
6636-0-609	Tibial Component Large, LM /RL, 9mm
6636-0-709	Tibial Component X-Large, LM /RL, 9mm
6636-0-319	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 9mm
6636-0-419	Tibial Component Small, RM /LL, 9mm
6636-0-519	Tibial Component Medium, RM /LL, 9mm
6636-0-619	Tibial Component Large, RM /LL, 9mm
6636-0-719	Tibial Component X-Large, RM /LL, 9mm
6636-0-310	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 10mm
6636-0-410	Tibial Component Small, LM /RL, 10mm
6636-0-510	Tibial Component Medium, LM /RL, 10mm
6636-0-610	Tibial Component Large, LM /RL, 10mm
6636-0-710	Tibial Component X-Large, LM /RL, 10mm
6636-0-320	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 10mm
6636-0-420	Tibial Component Small, RM /LL, 10mm
6636-0-520	Tibial Component Medium, RM /LL, 10mm
6636-0-620	Tibial Component Large, RM /LL, 10mm
6636-0-720	Tibial Component X-Large, RM /LL, 10mm
6636-0-312	Tibial Component X-Small, Left Medial (LM), Right Lateral (RL), 12mm
6636-0-412	Tibial Component Small, LM /RL, 12mm
6636-0-512	Tibial Component Medium, LM /RL, 12mm
6636-0-612	Tibial Component Large, LM /RL, 12mm
6636-0-712	Tibial Component X-Large, LM /RL, 12mm

(b) (4)

Stryker® Compartmental Knee

Traditional 510(k)

6636-0-322	Tibial Component X-Small, Right Medial (RM), Left Lateral (LL), 12mm
6636-0-422	Tibial Component Small, RM /LL, 12mm
6636-0-522	Tibial Component Medium, RM /LL, 12mm
6636-0-622	Tibial Component Large, RM /LL, 12mm
6636-0-722	Tibial Component X-Large, RM /LL, 12mm
SCR® Components	
4010-005	Femoral Component, Medial, Right or Left, Size 5
4010-007	Femoral Component, Medial, Right or Left, Size 7
4010-009	Femoral Component, Medial, Right or Left, Size 9
4010-011	Femoral Component, Medial, Right or Left, Size 11
4050-005	Femoral Component, Lateral, Right or Left, Size 5
4050-007	Femoral Component, Lateral, Right or Left, Size 7
4050-009	Femoral Component, Lateral, Right or Left, Size 9
4050-011	Femoral Component, Lateral, Right or Left, Size 11
4020-0005	Tibial Component, Medial, Size 5
4020-0007	Tibial Component, Medial, Size 7
4020-0009	Tibial Component, Medial, Size 9
4020-0011	Tibial Component, Medial, Size 11
4020-0013	Tibial Component, Medial, Size 13
4060-0005	Tibial Component, Lateral, Size 5
4060-0007	Tibial Component, Lateral, Size 7
4060-0009	Tibial Component, Lateral, Size 9
4060-0011	Tibial Component, Lateral, Size 11
4060-0013	Tibial Component, Lateral, Size 13
4040-05xx	Tibial Insert, Size 5, xx = 07, 08, 09, 10 or 12
4040-07xx	Tibial Insert, Size 7, xx = 07, 08, 09, 10 or 12
4040-09xx	Tibial Insert, Size 9, xx = 07, 08, 09, 10 or 12
4040-11xx	Tibial Insert, Size 11, xx = 07, 08, 09, 10 or 12

(b) (4)

Stryker® Compartmental Knee

Traditional 510(k)

UNIX™ Components		(b) (4)
4510-001L	Femoral Component, Size 1, Left	
4510-001R	Femoral Component, Size 1, Right	
4510-002L	Femoral Component, Size 2, Left	
4510-002R	Femoral Component, Size 2, Right	
4510-003L	Femoral Component, Size 3, Left	
4510-003R	Femoral Component, Size 3, Right	
4510-004L	Femoral Component, Size 4, Left	
4510-004R	Femoral Component, Size 4, Right	
4540-01xx	Tibial Insert, Size 1 xx= 8, 10, 12, 15mm	
4540-02xx	Tibial Insert, Size 2 xx= 8, 10, 12, 15mm	
4540-03xx	Tibial Insert, Size 3 xx= 8, 10, 12, 15mm	
4540-04xx	Tibial Insert, Size 4 xx= 8, 10, 12, 15mm	
4520-0001L	Tibial Component, Size 1, Medial/Left, Lateral /Right	
4520-0001R	Tibial Component, Size 1, Medial/Right, Lateral /Left	
4520-0002L	Tibial Component, Size 2, Medial/Left, Lateral /Right	
4520-0002R	Tibial Component, Size 2, Medial/Right, Lateral /Left	
4520-0003L	Tibial Component, Size 3, Medial/Left, Lateral /Right	
4520-0003R	Tibial Component, Size 3, Medial/Right, Lateral /Left	
4520-0004L	Tibial Component, Size 4, Medial/Left, Lateral /Right	
4520-0004R	Tibial Component, Size 4, Medial/Right, Lateral /Left	

Stryker® Compartmental Knee

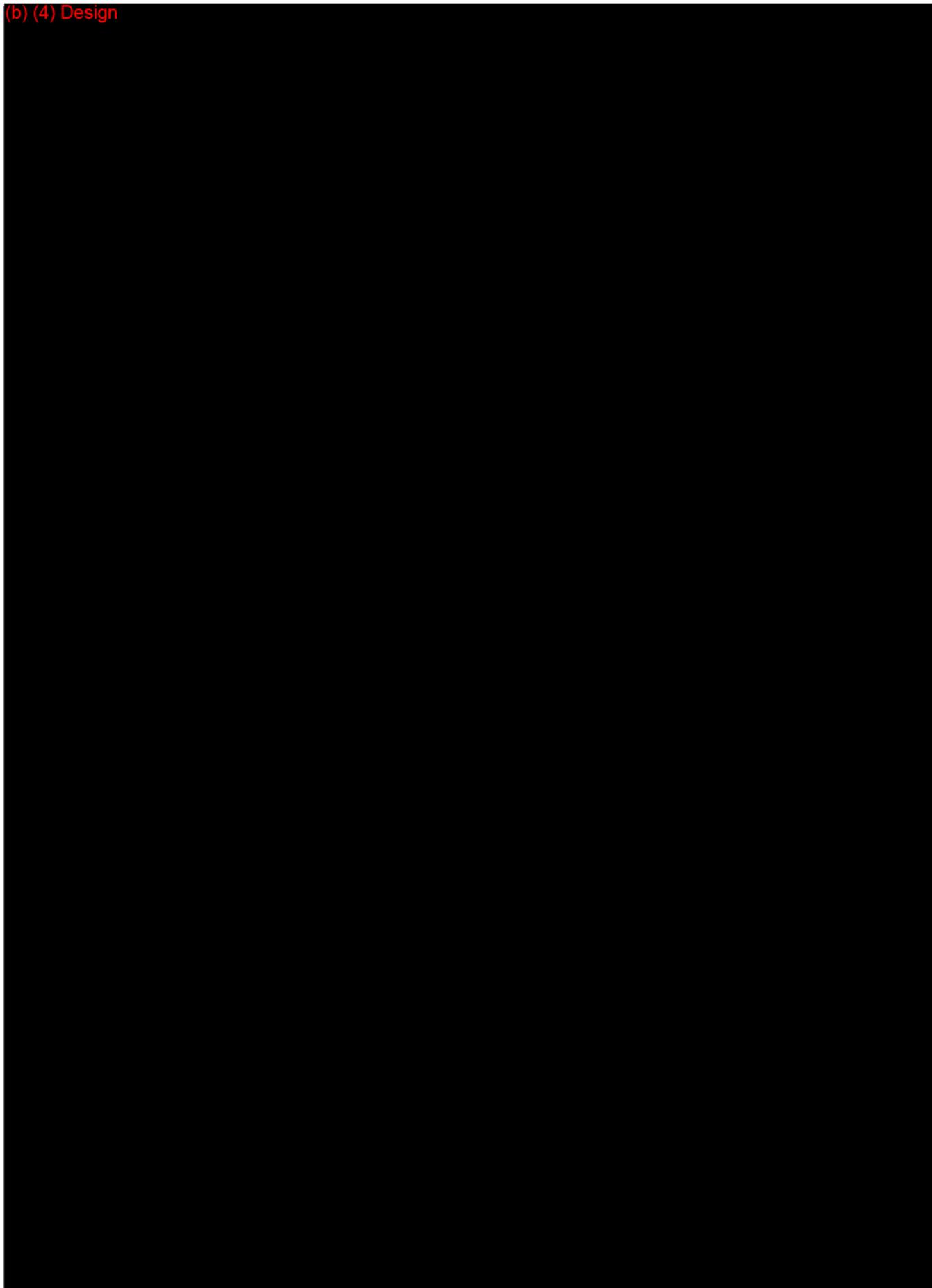
Traditional 510(k)

APPENDIX A-2
Engineering Drawings

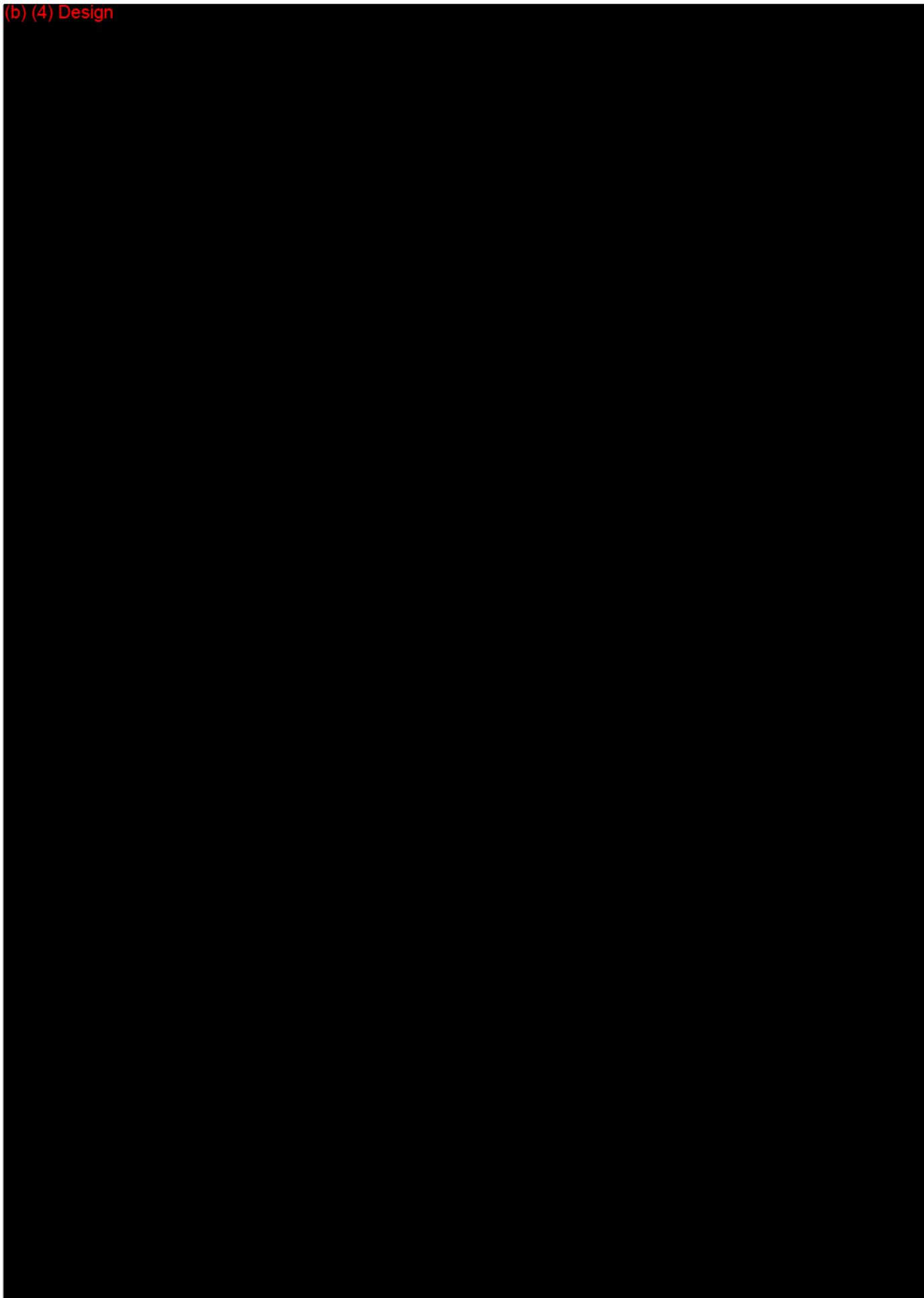
-CONFIDENTIAL-

Patellofemoral Components

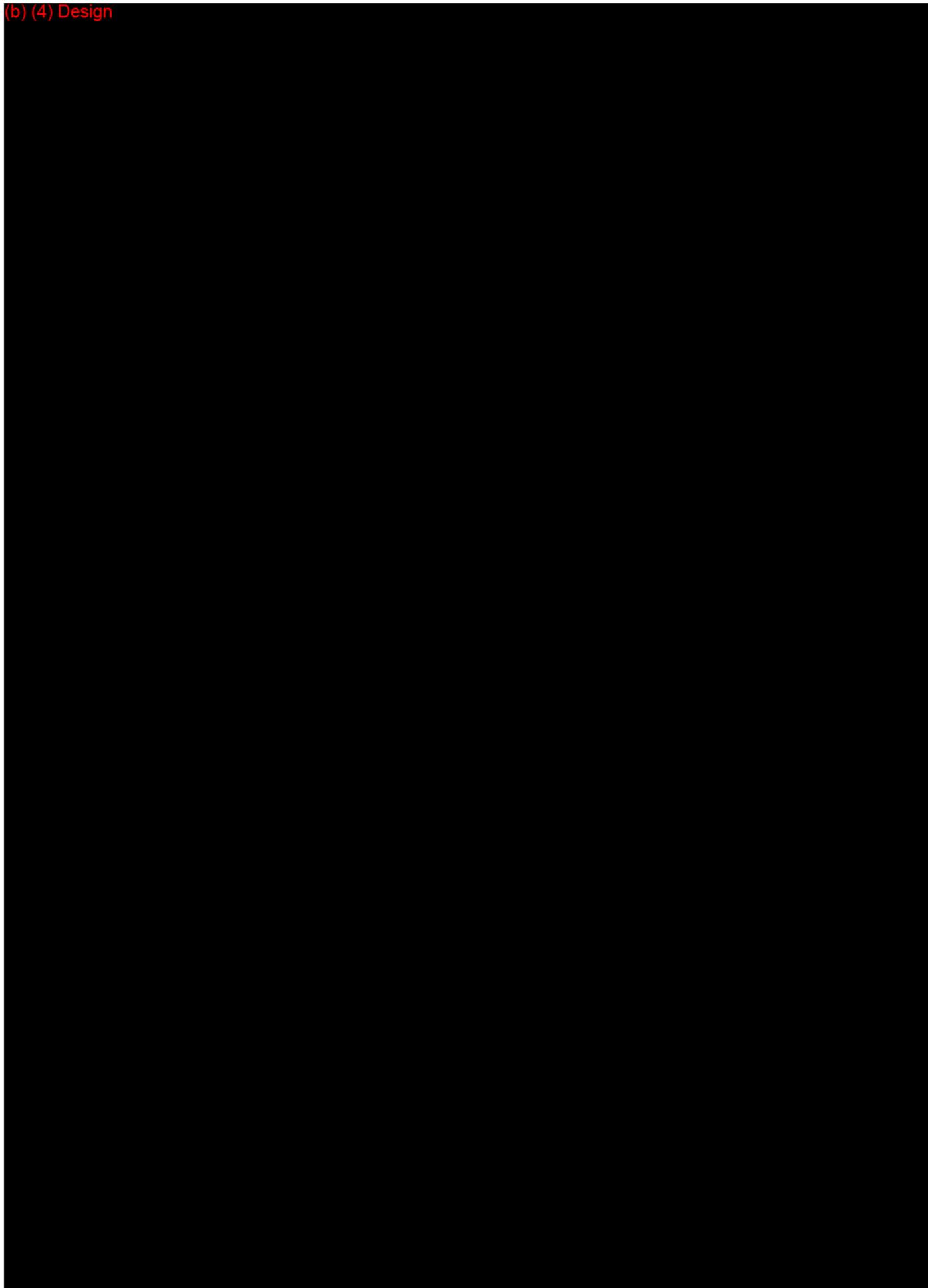
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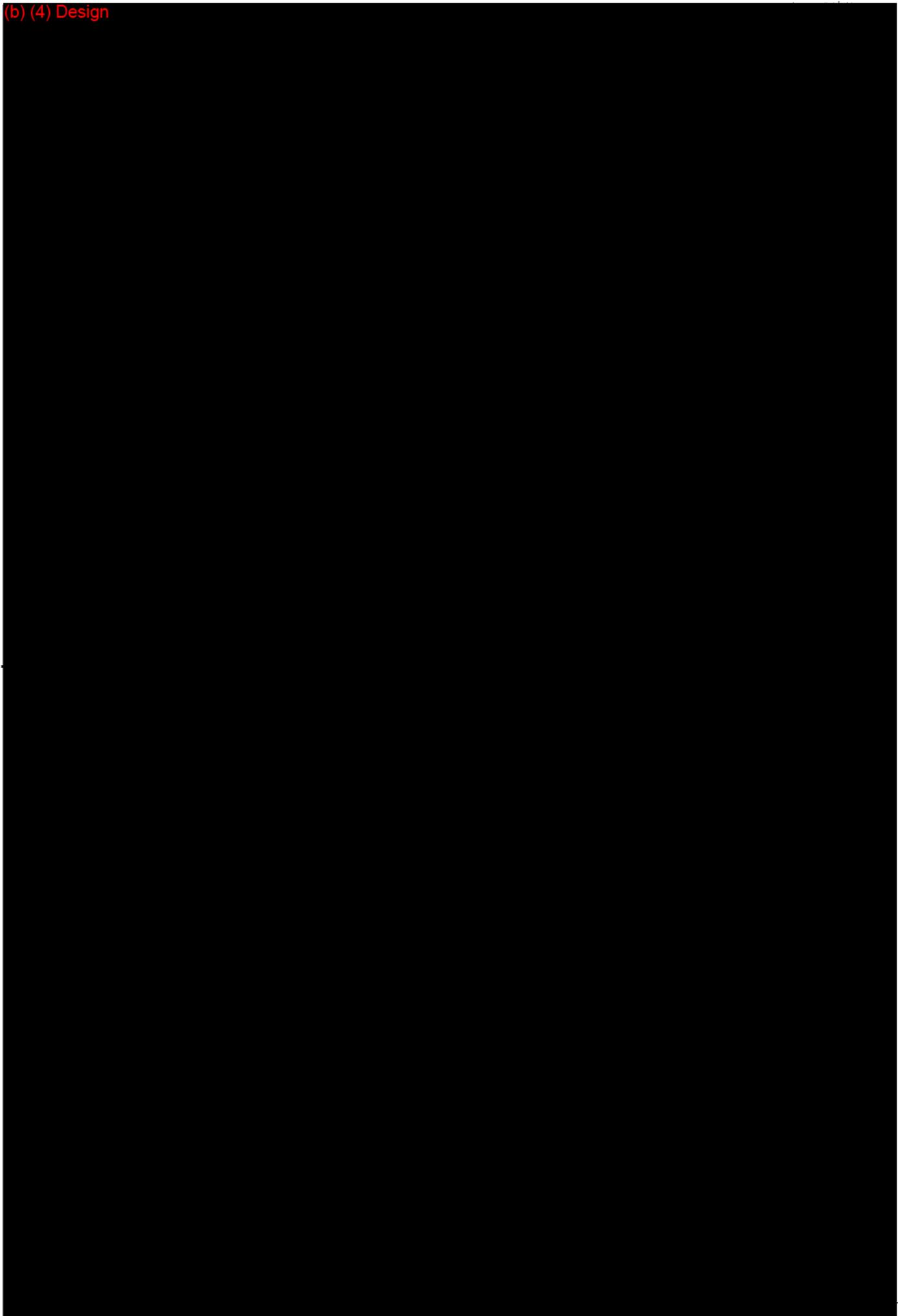
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(b) (4) Design

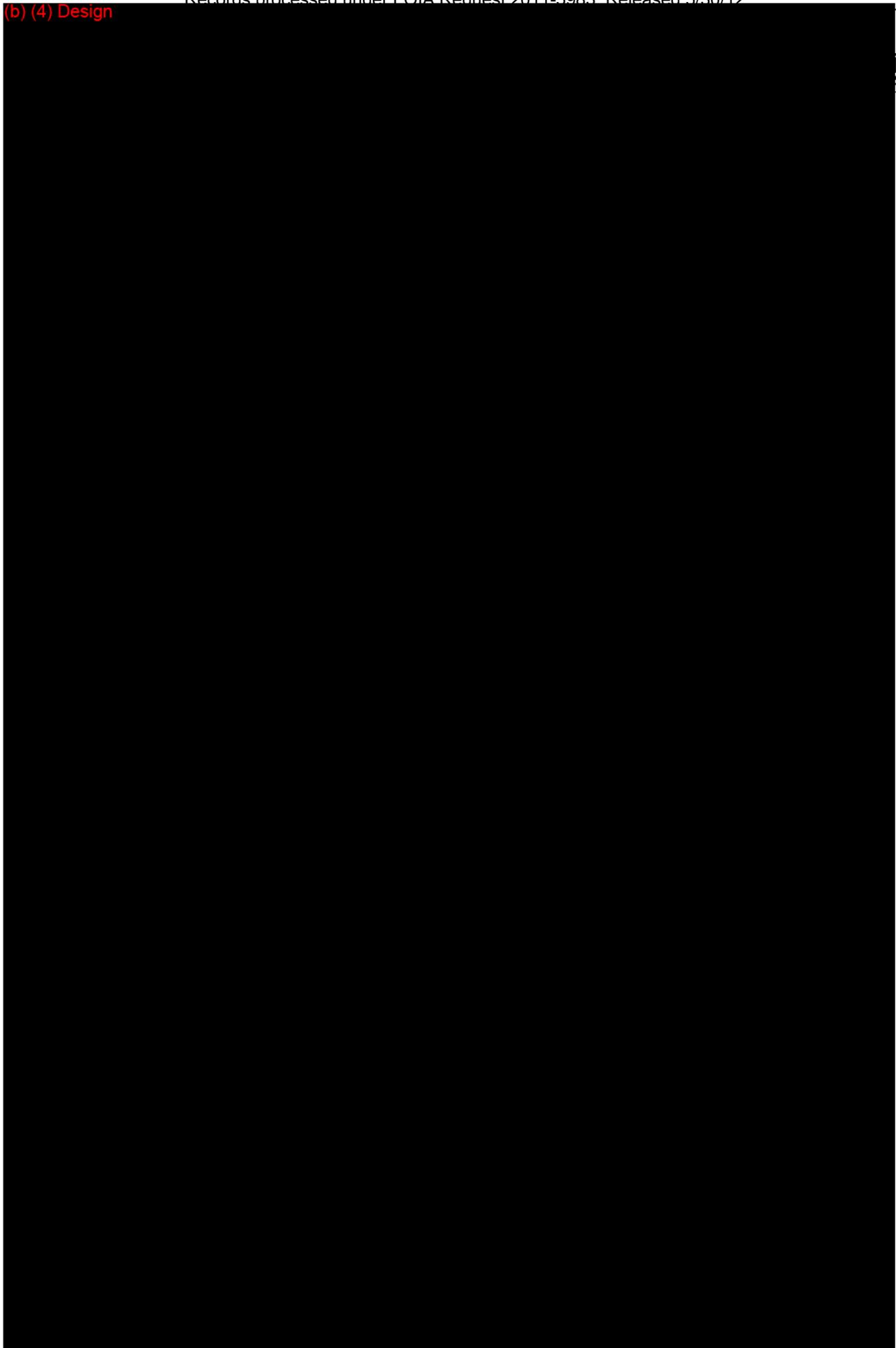


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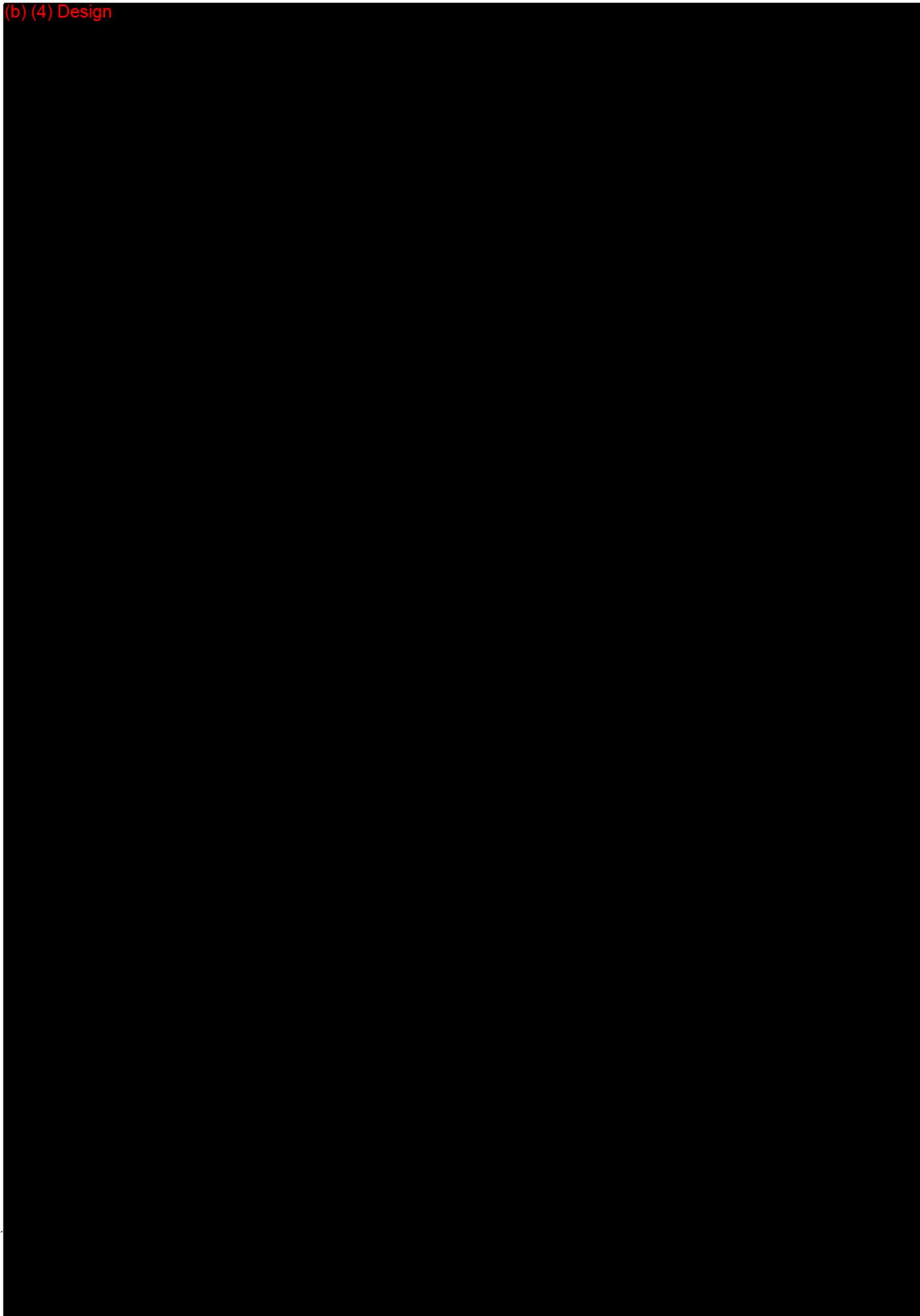
Avon® Patellar Components

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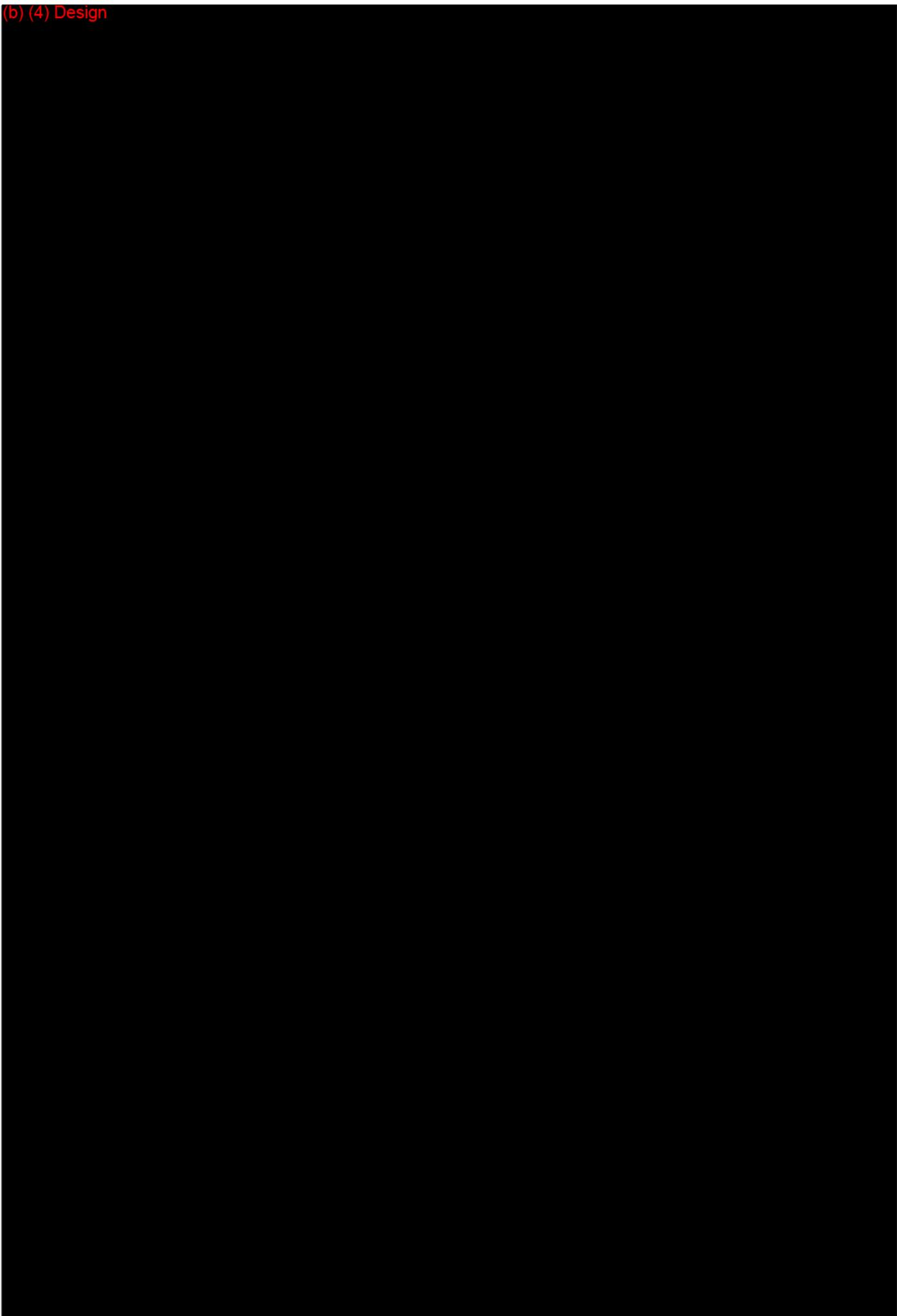
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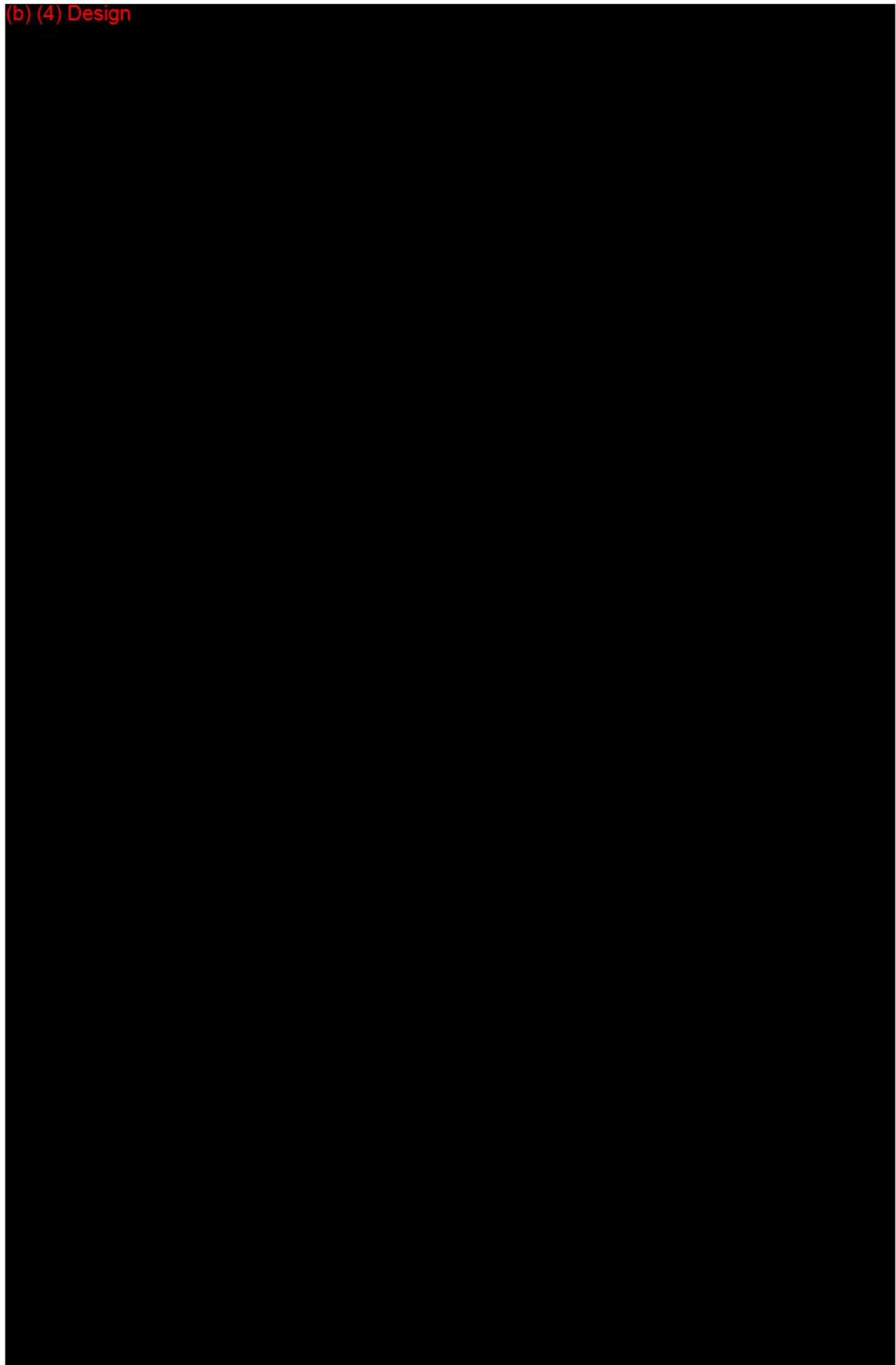
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(b) (4) Design



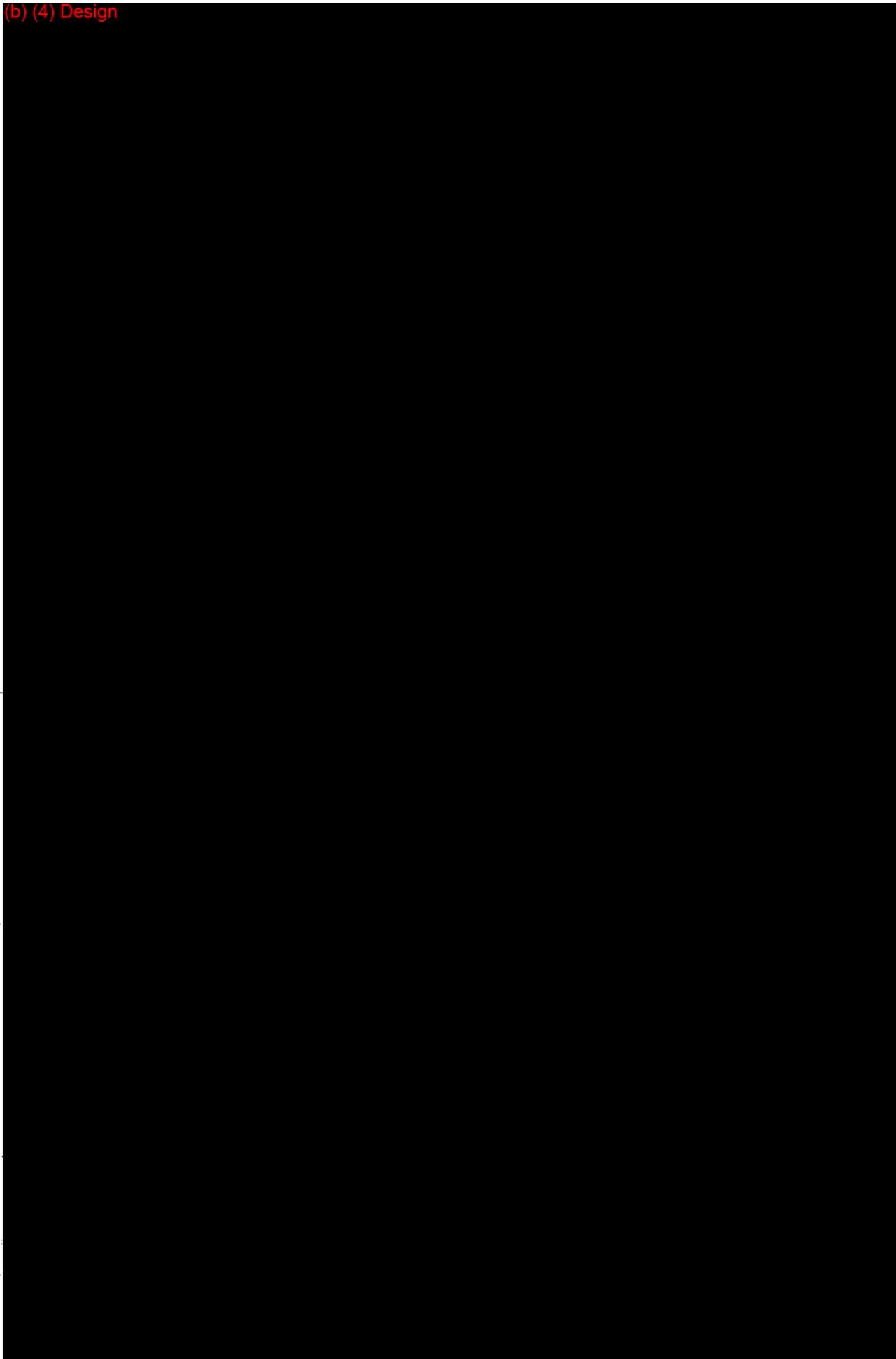
Kinemax[®] All Polyethylene Patella
(medium sizes)

(b) (4) Design



89

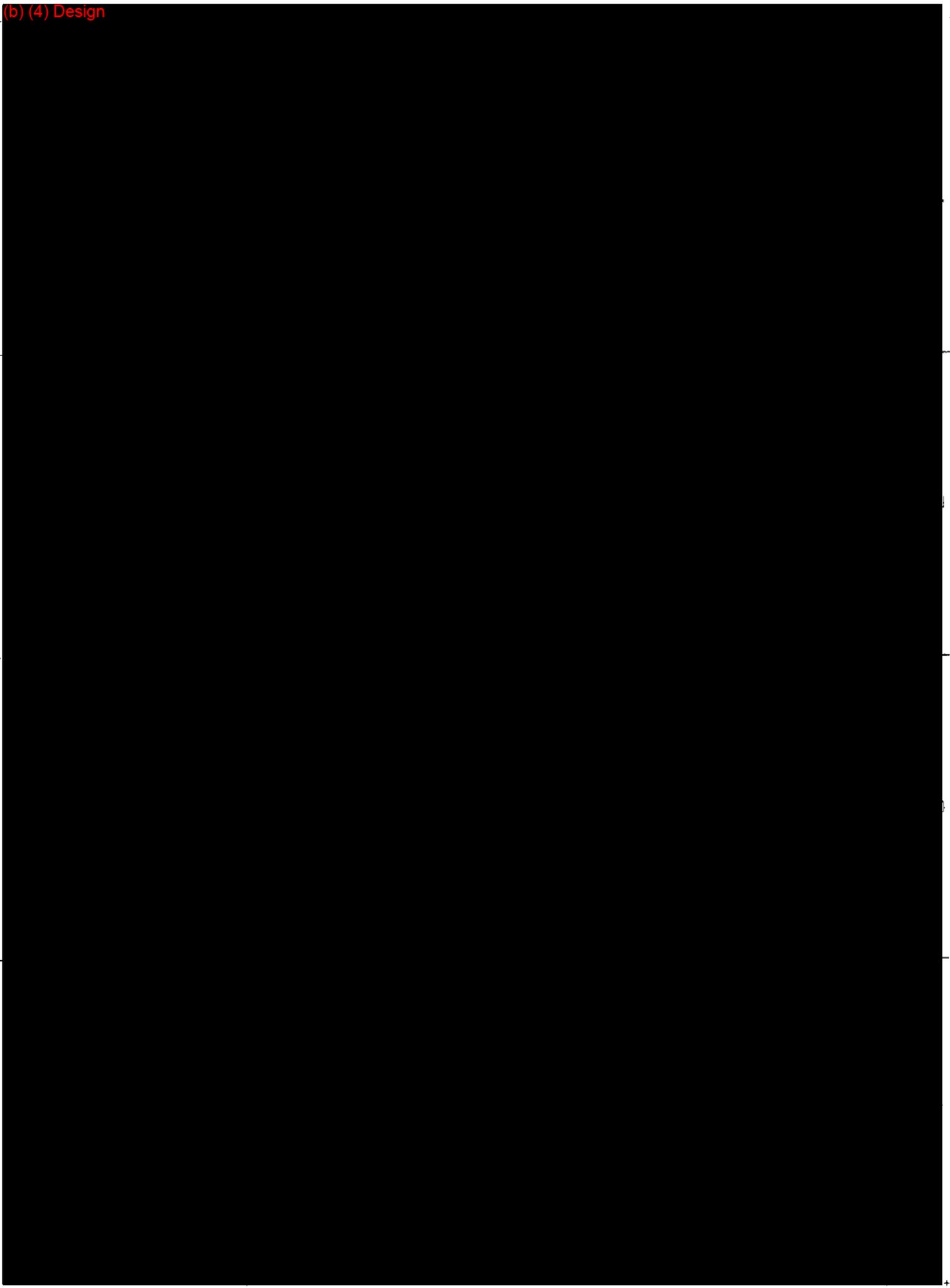
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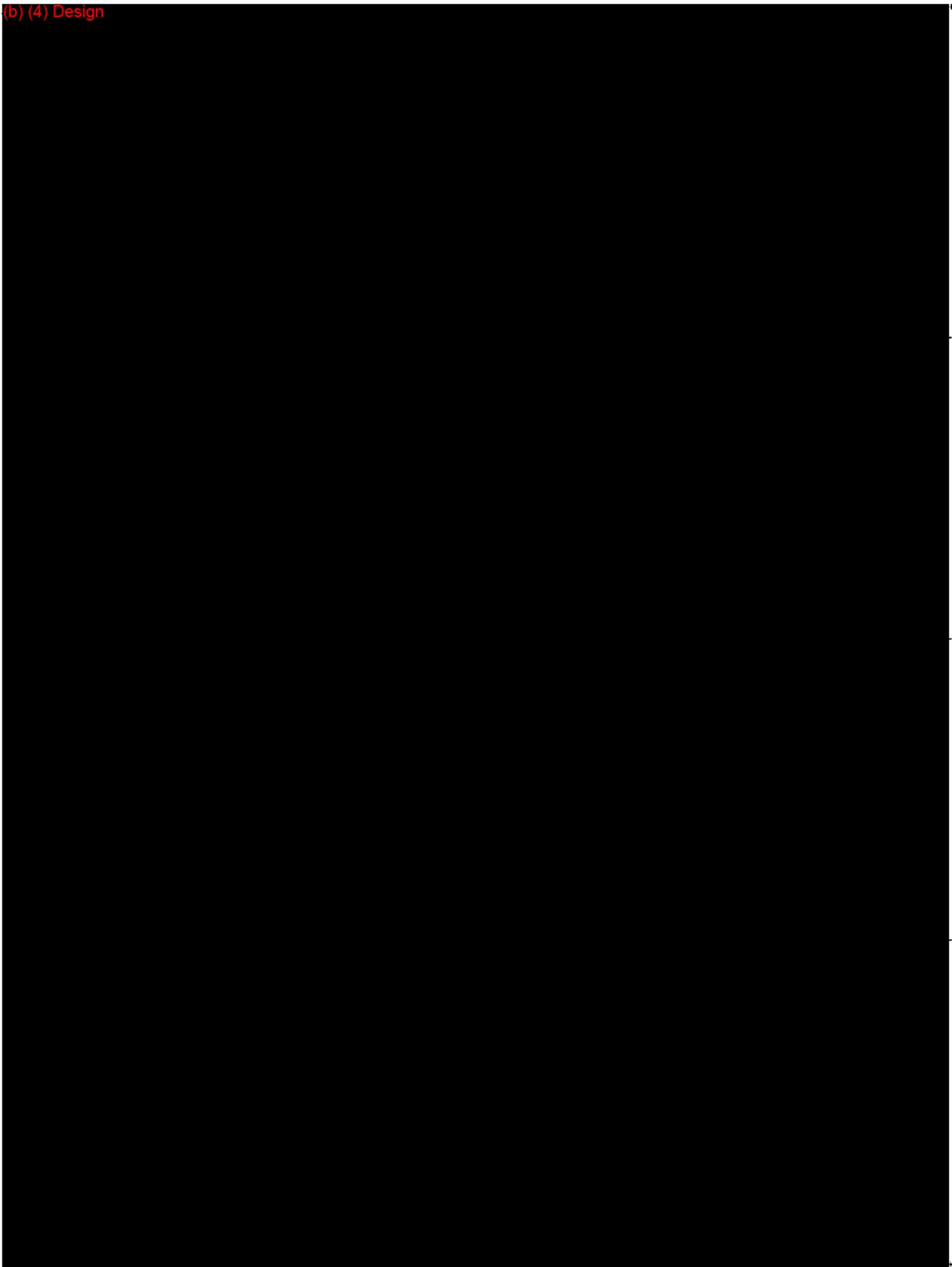
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Duracon[®] All Polyethylene Patella

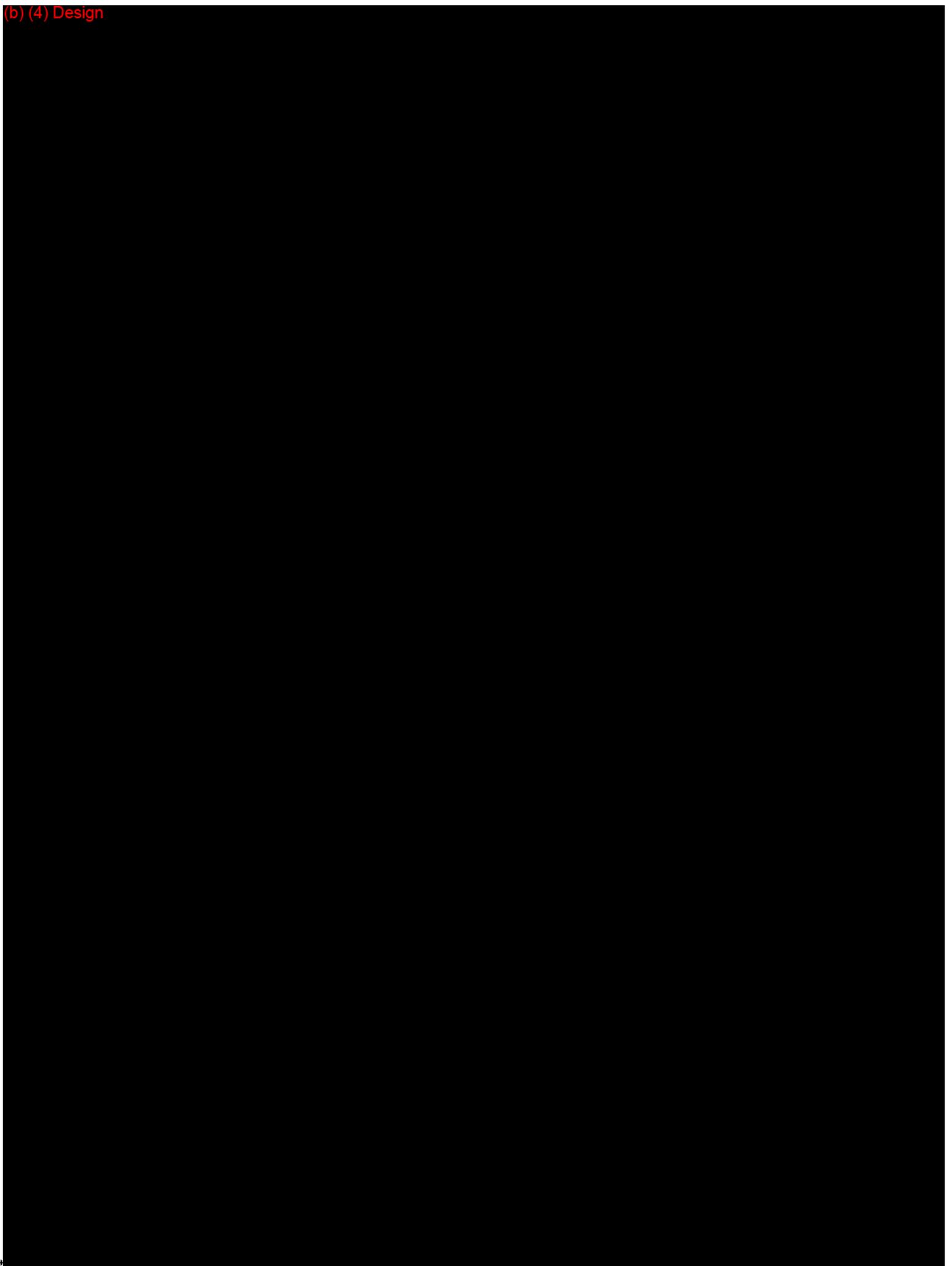
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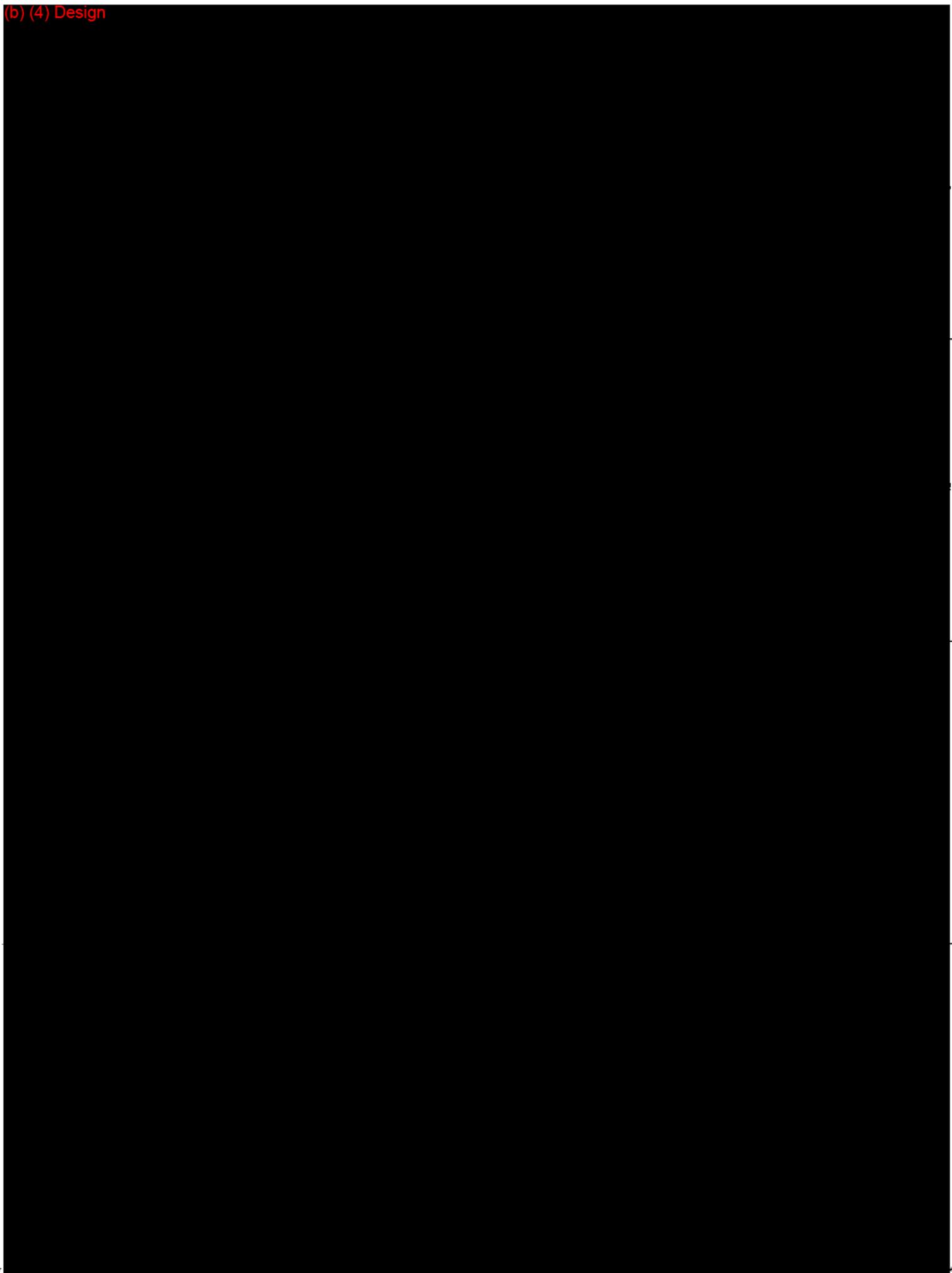
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(b) (4) Design

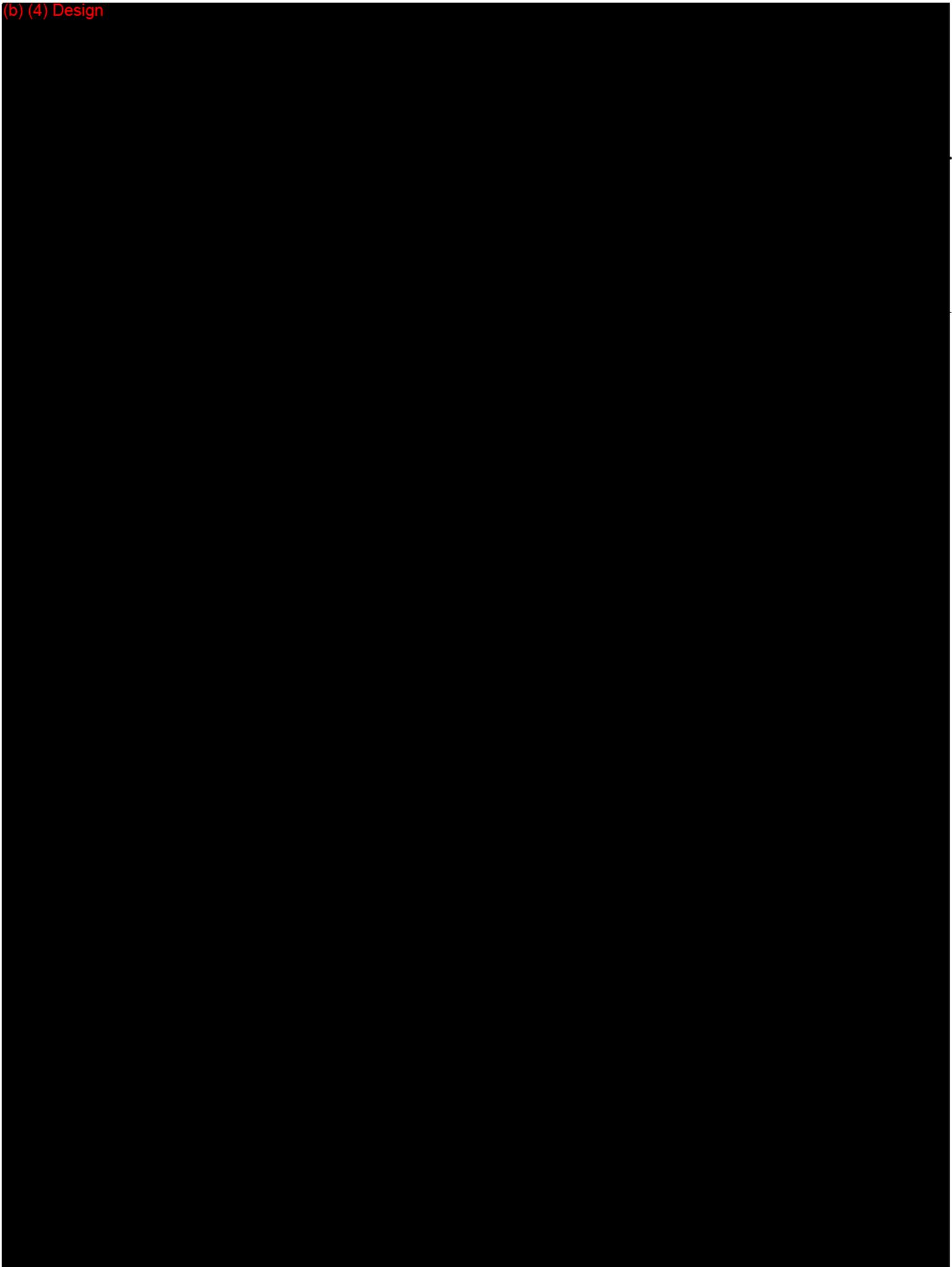


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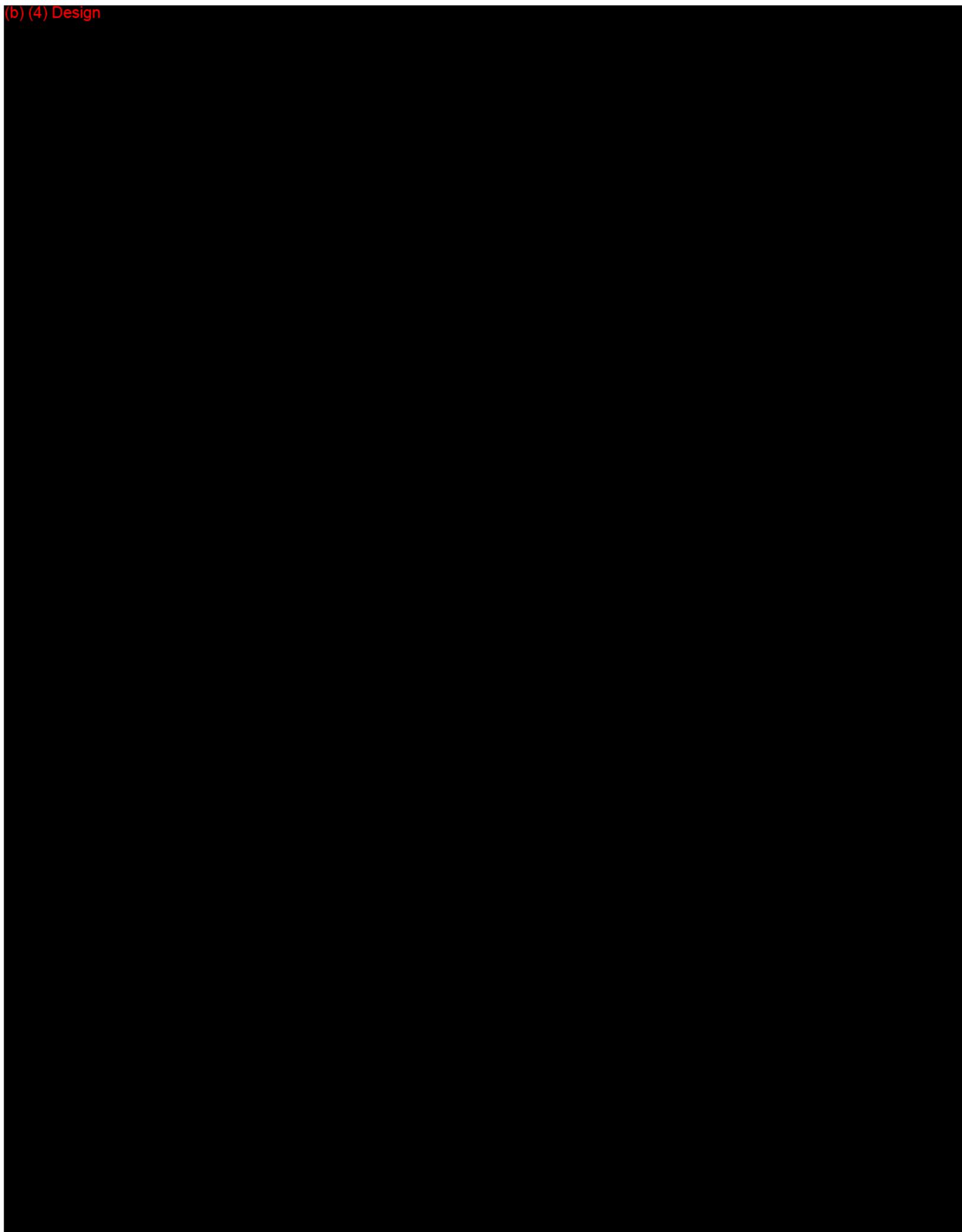


Scorpio[®] Components
(Standard and X3[™])

(b) (4) Design

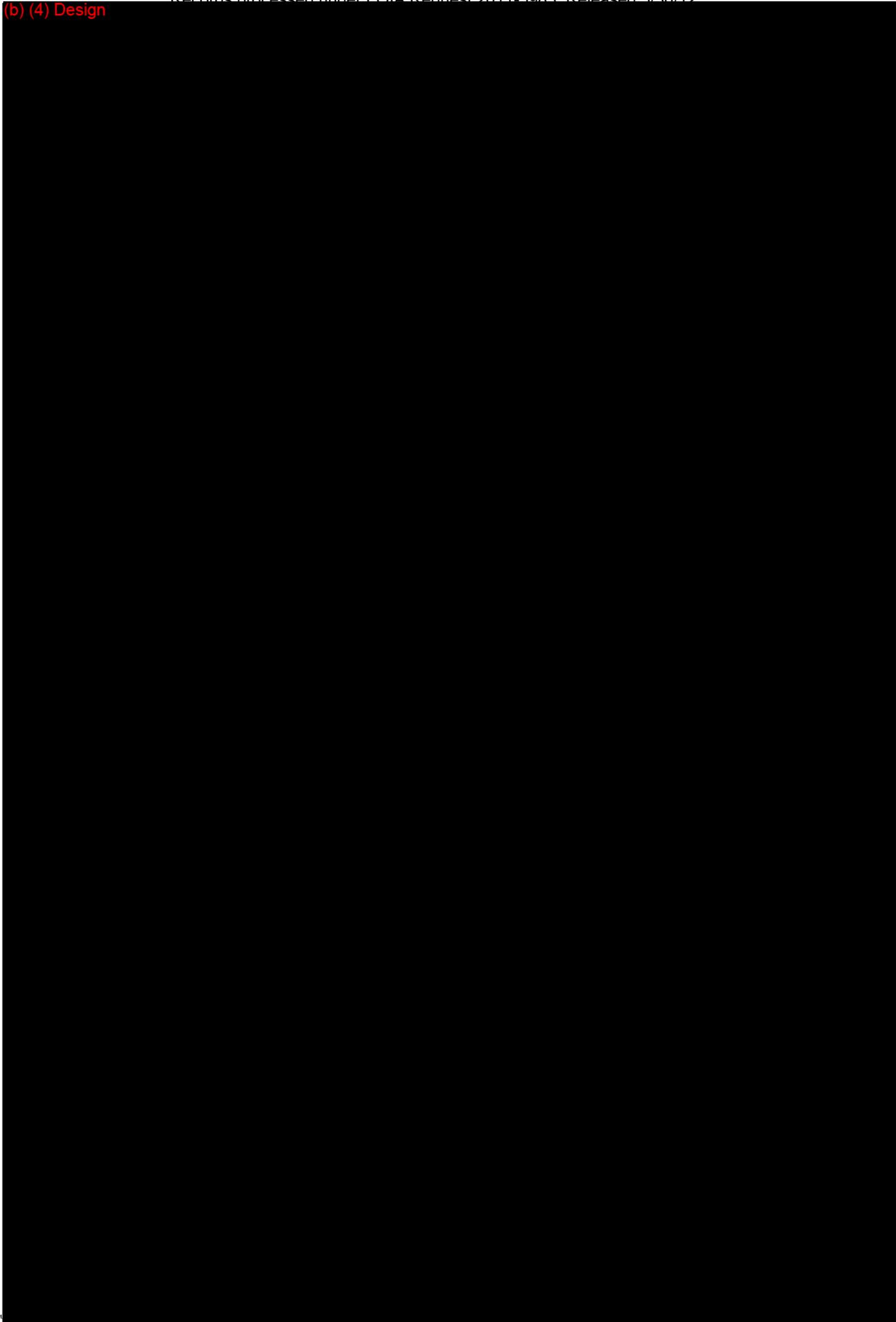


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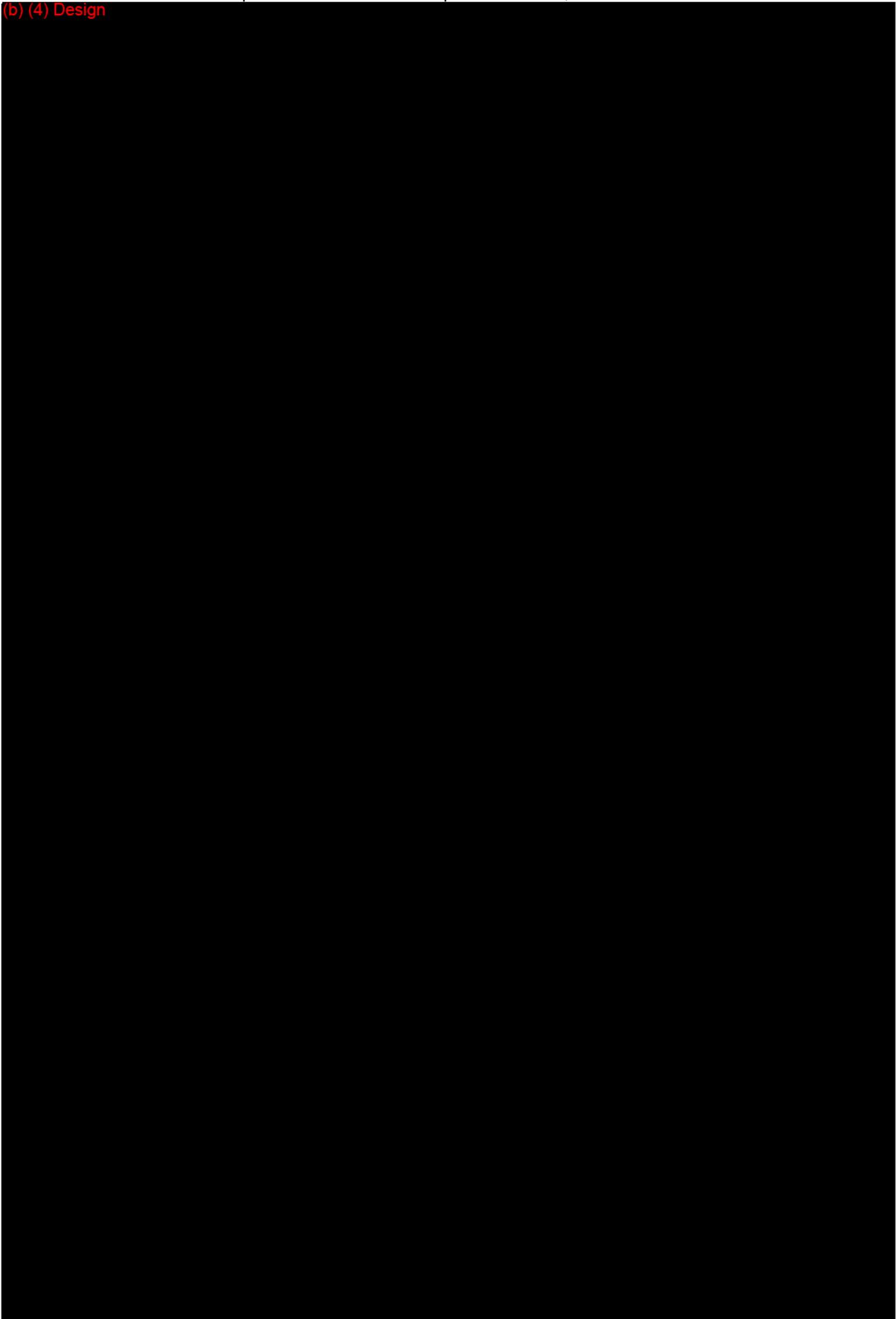


Triathlon® Knee System
(Standard and X3™)

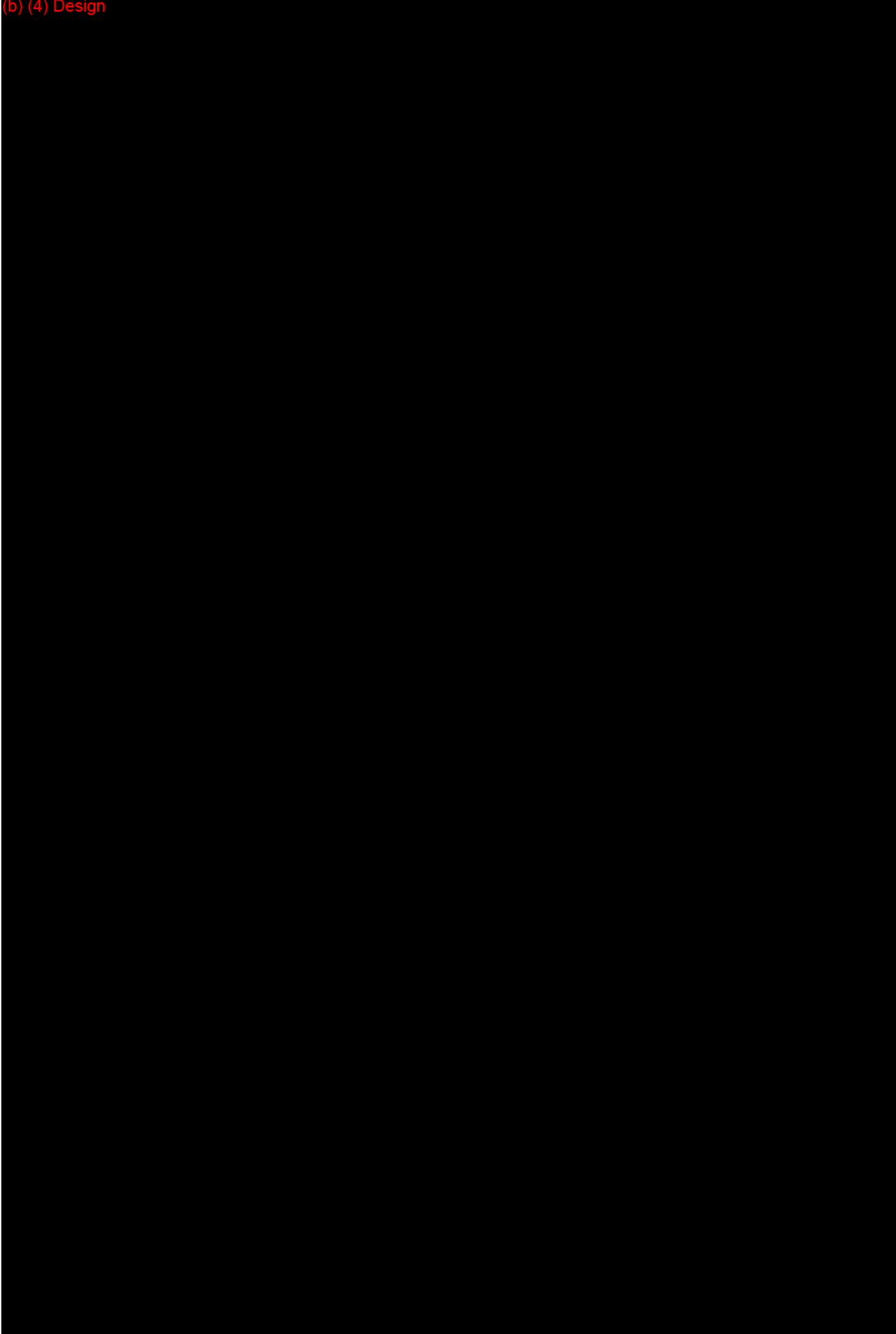
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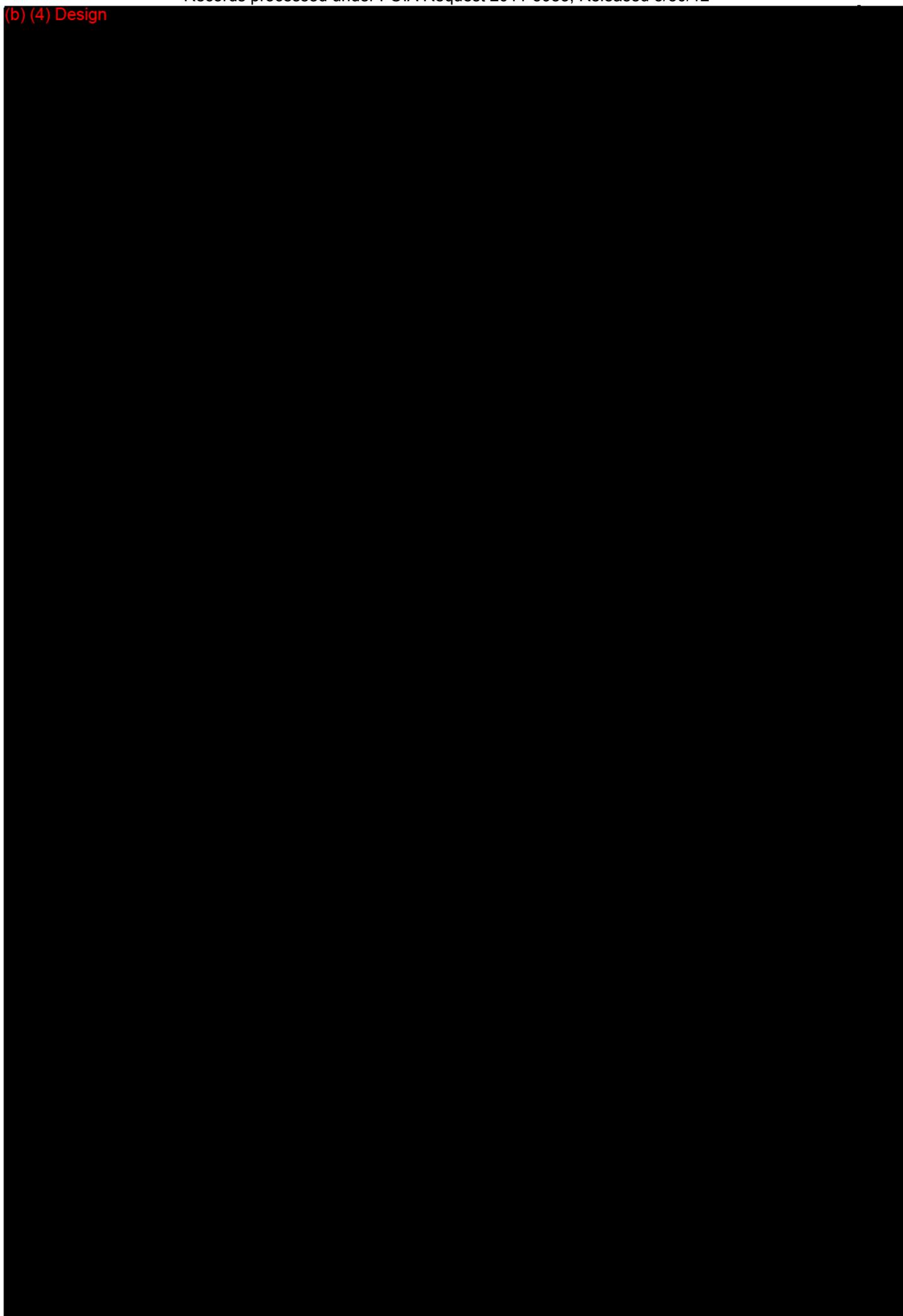
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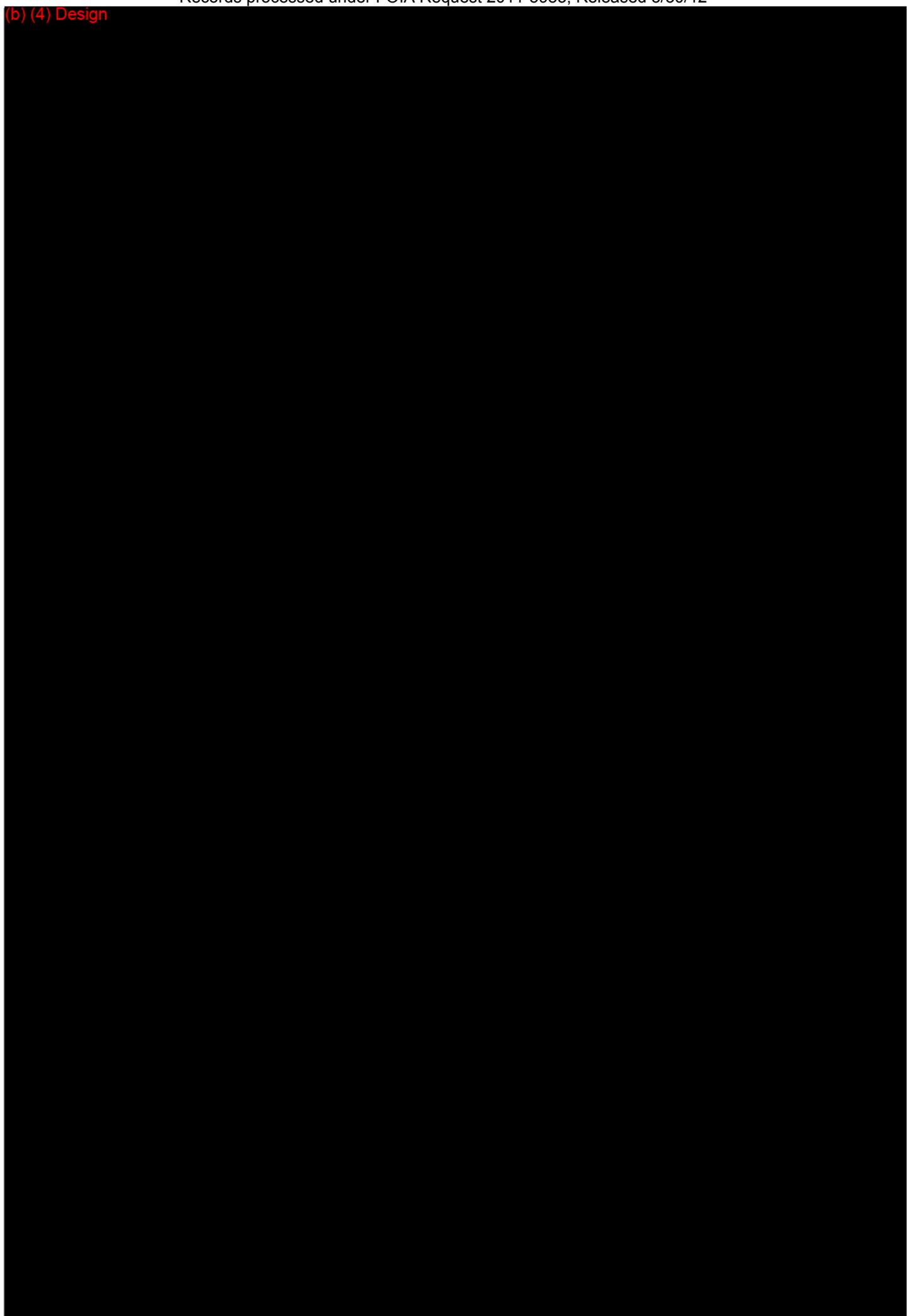
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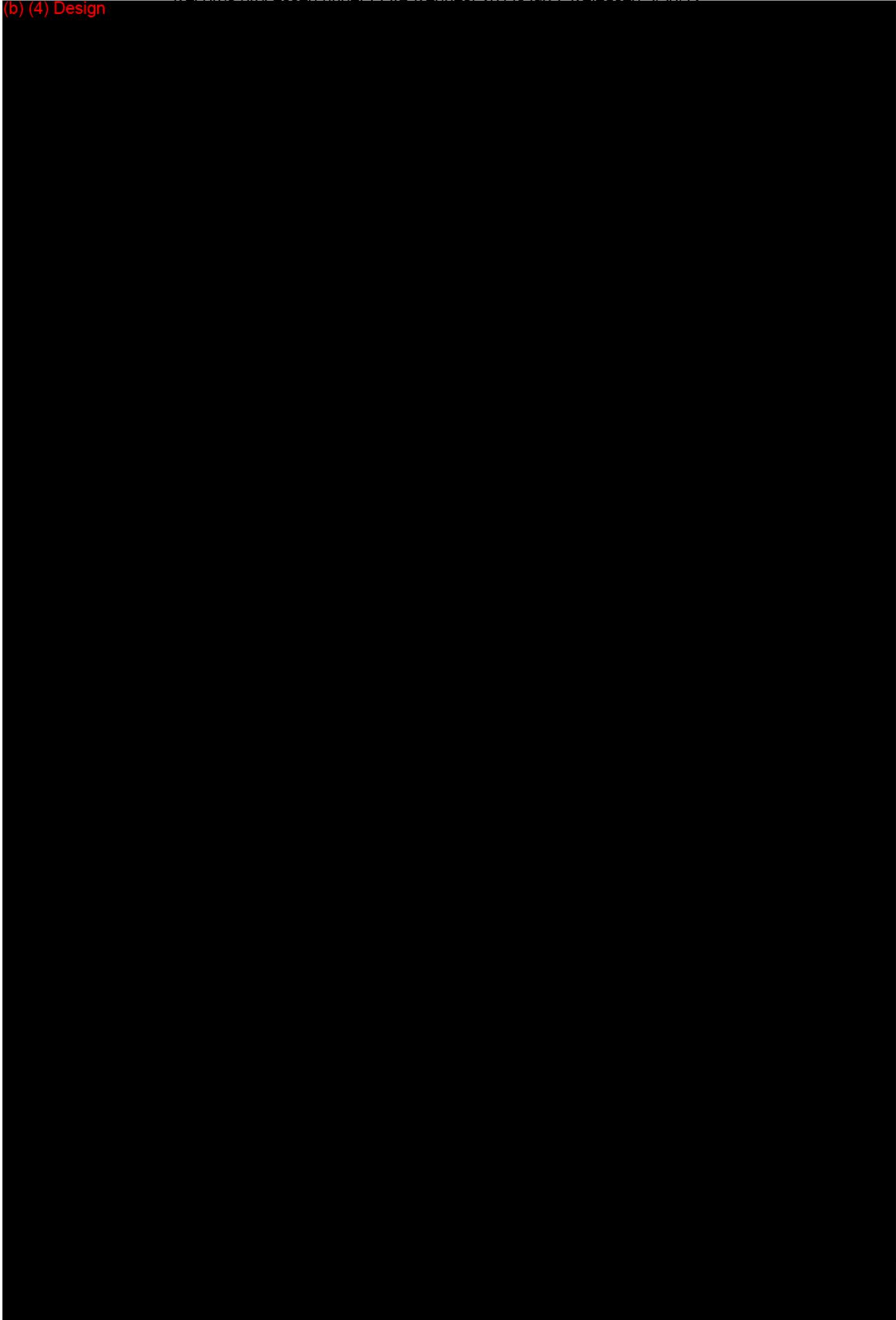
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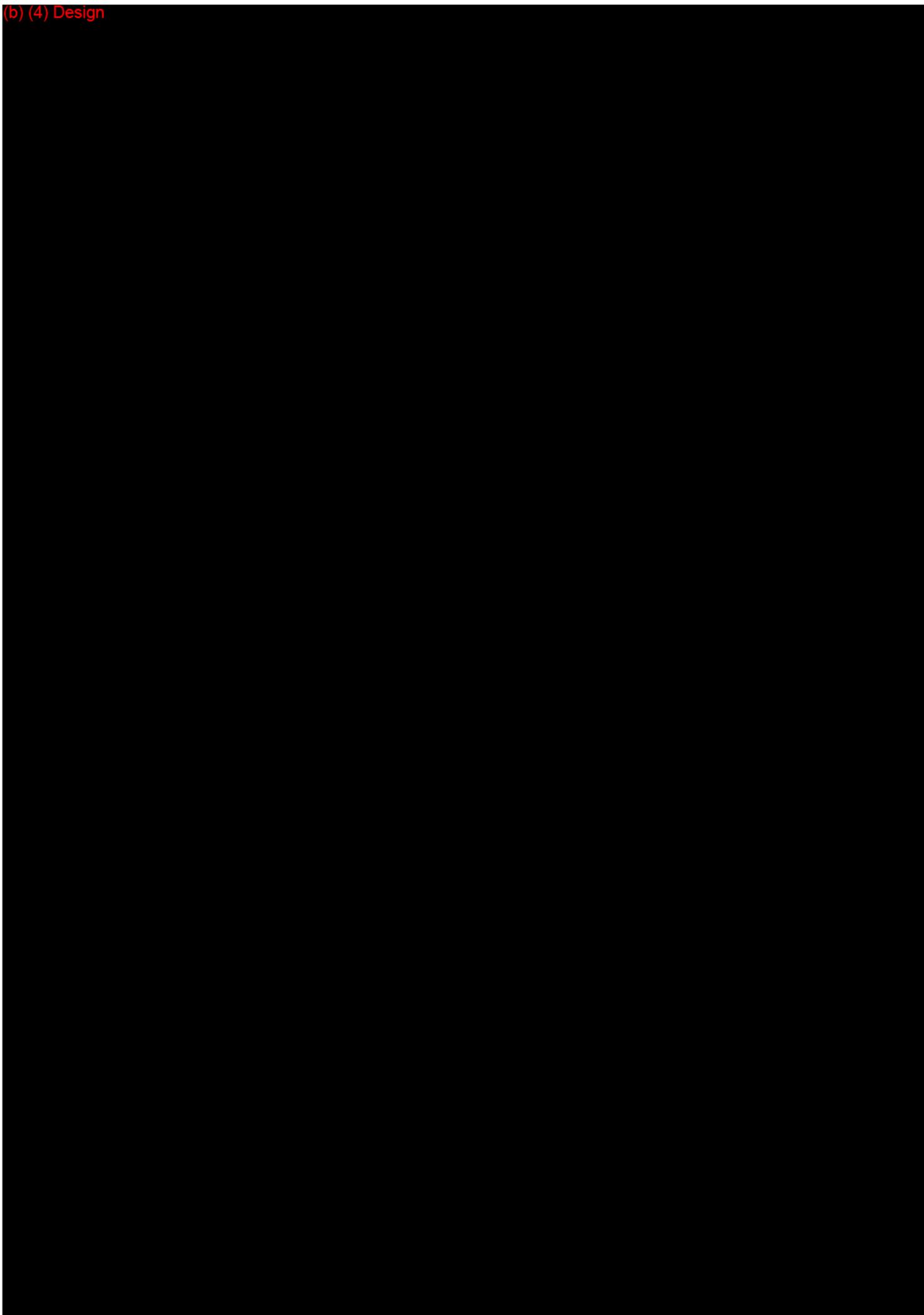
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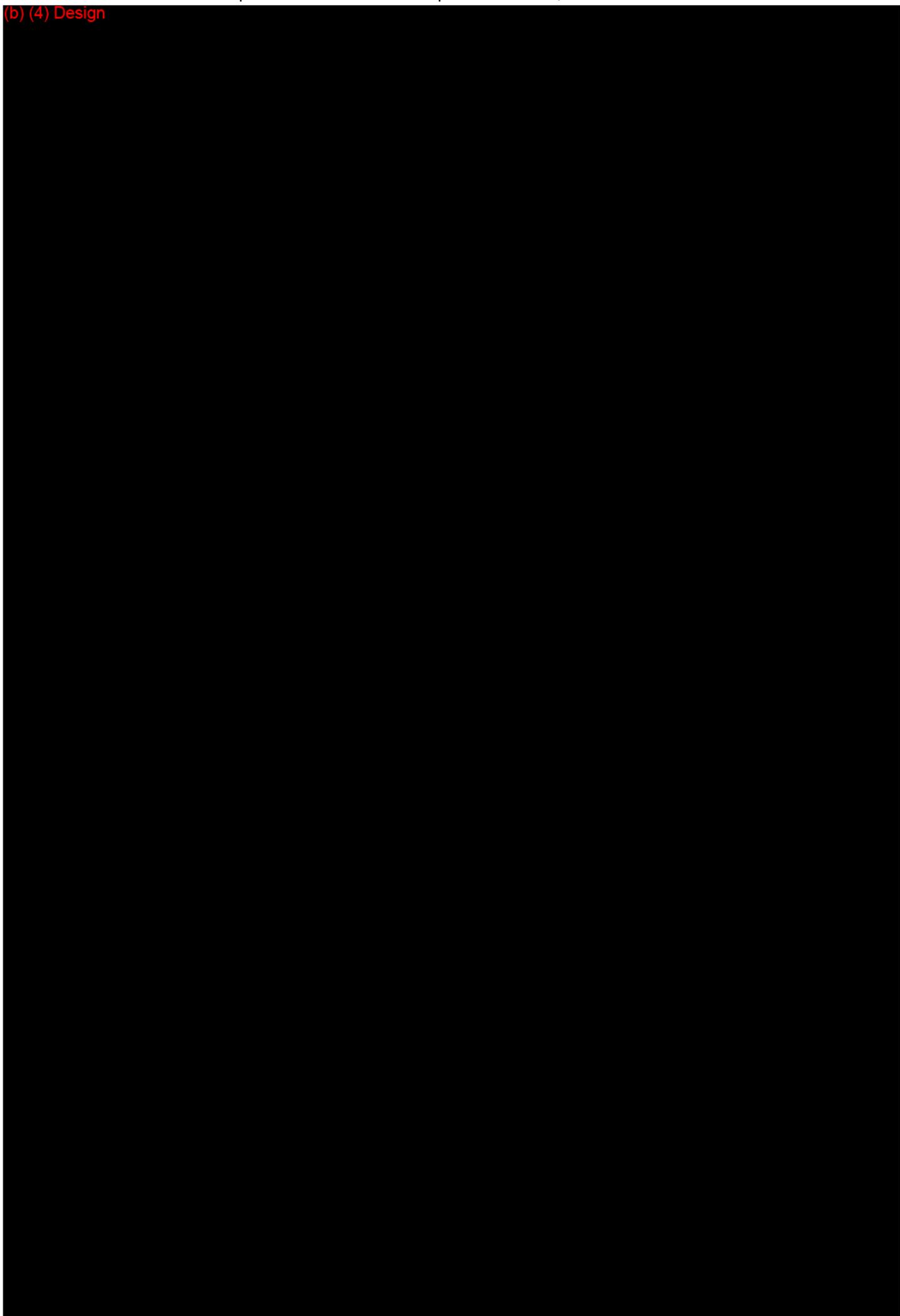
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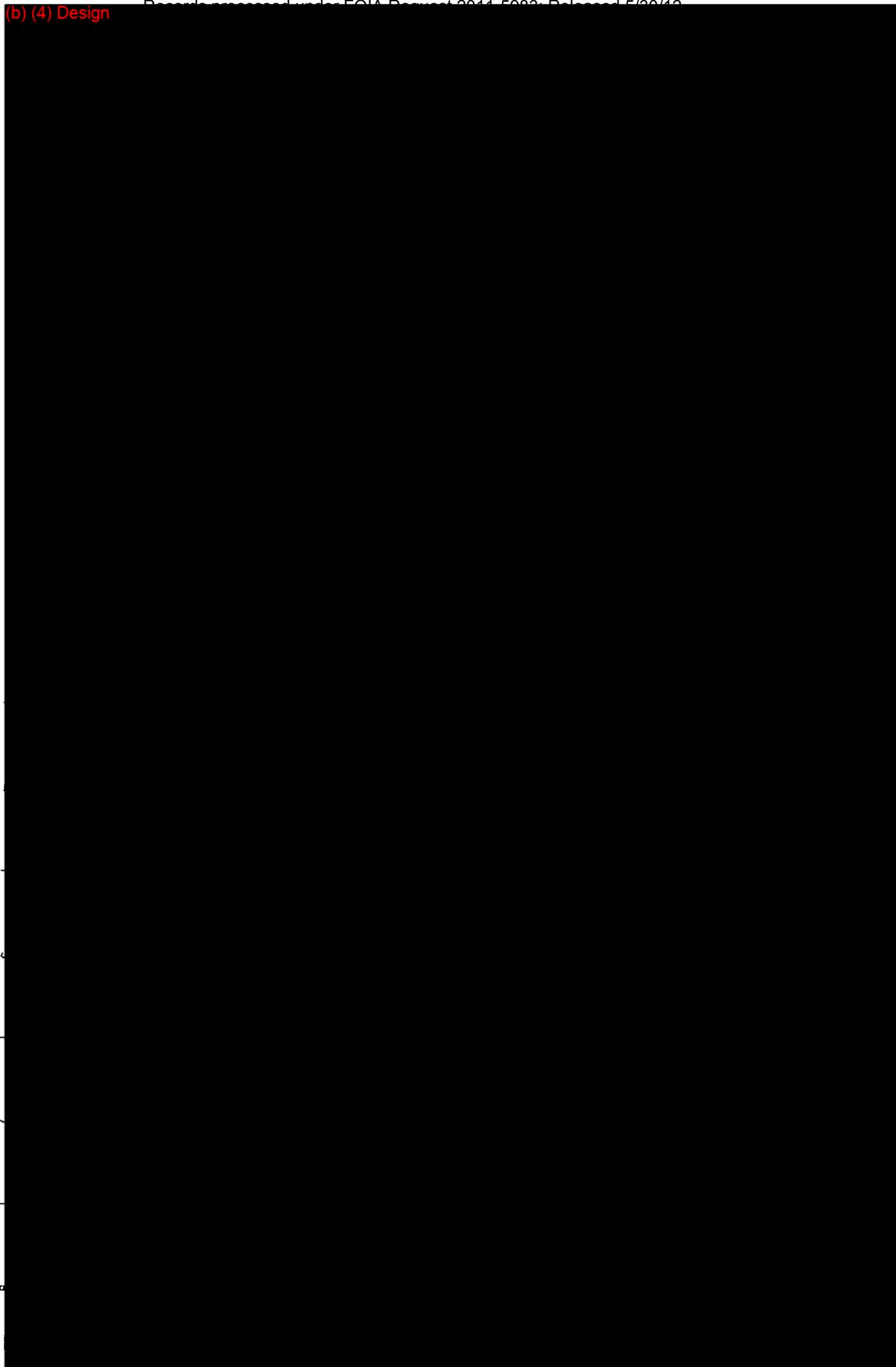
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(b) (4) Design

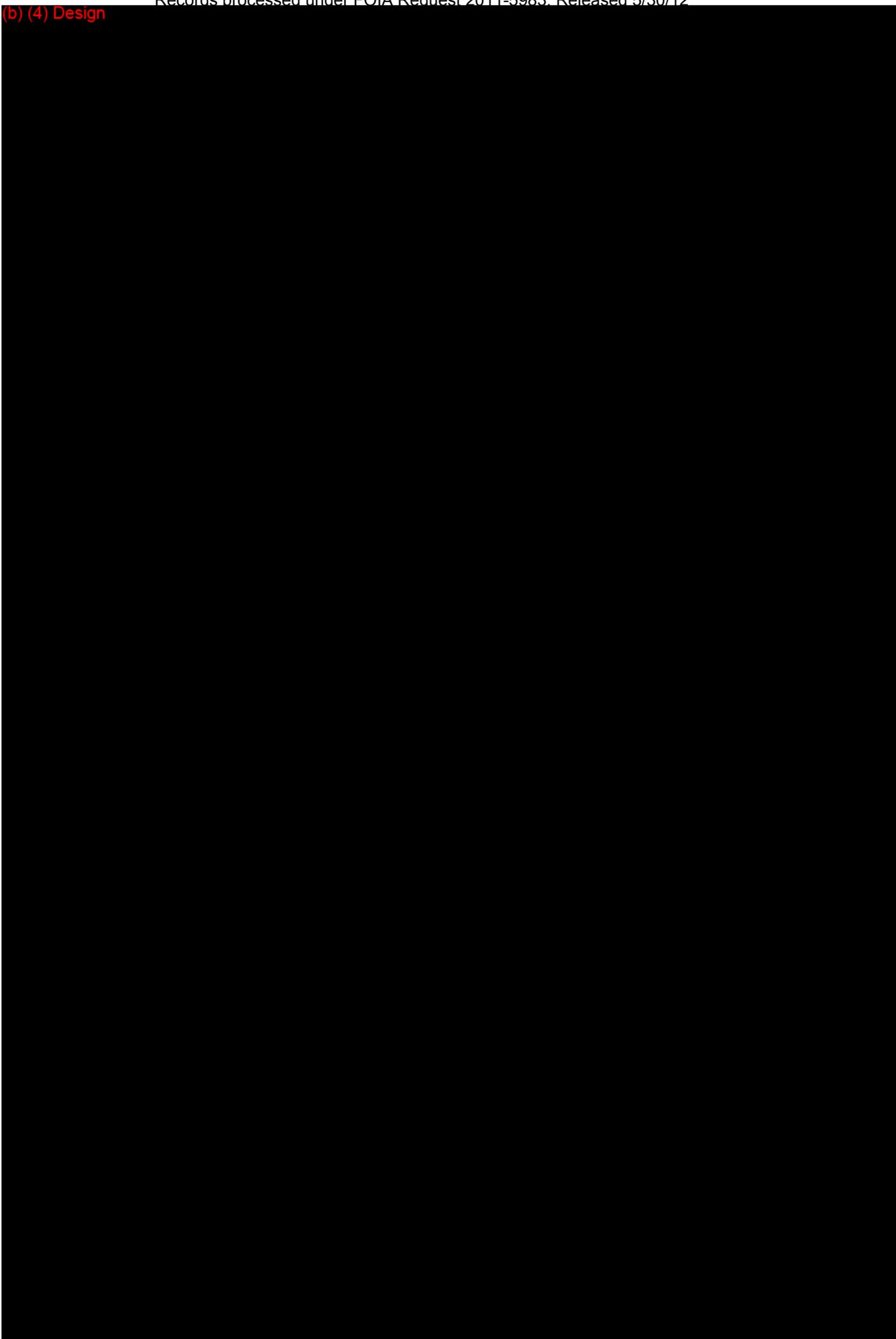


(b) (4) Design



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(b) (4) Design

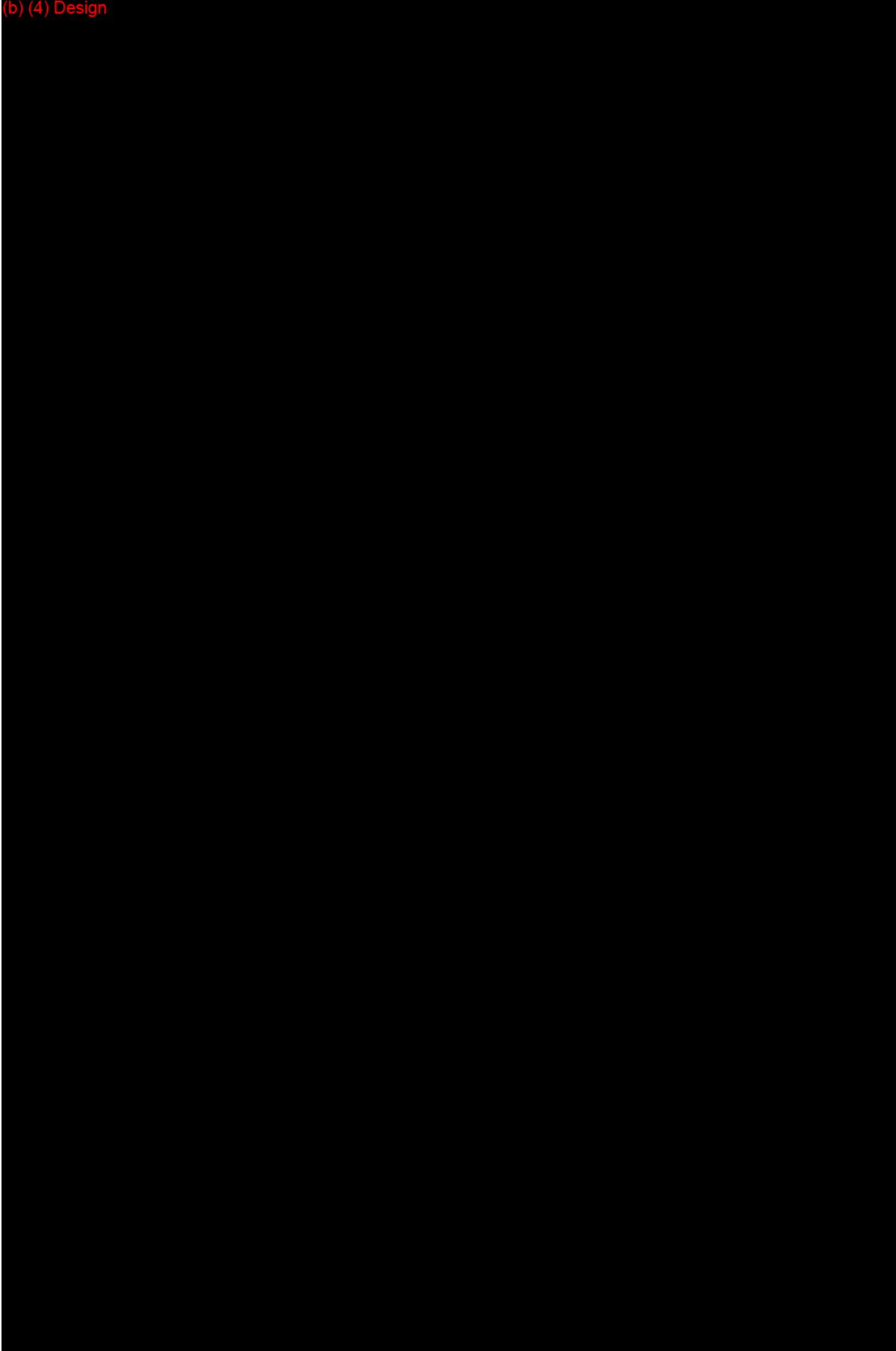


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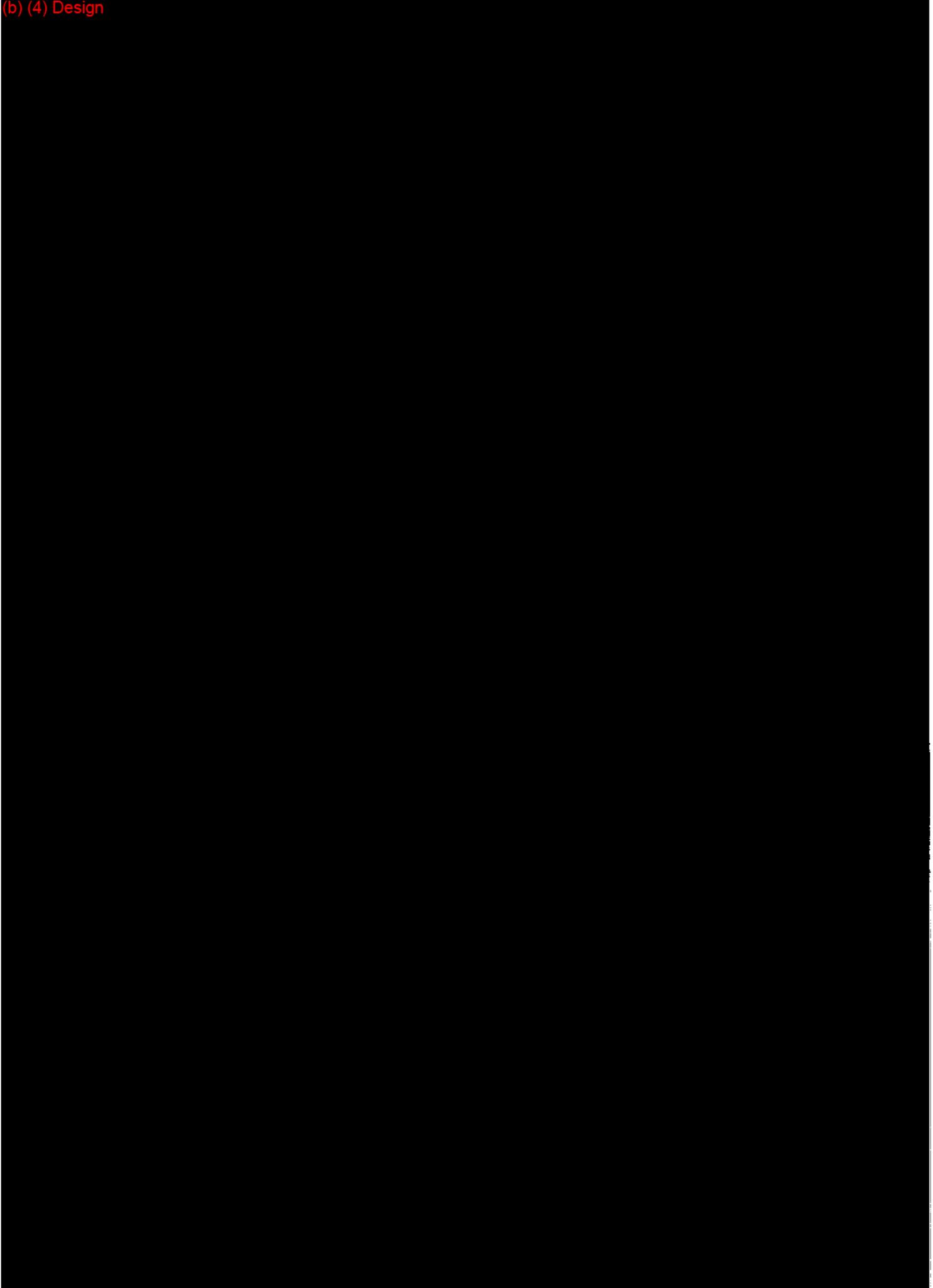
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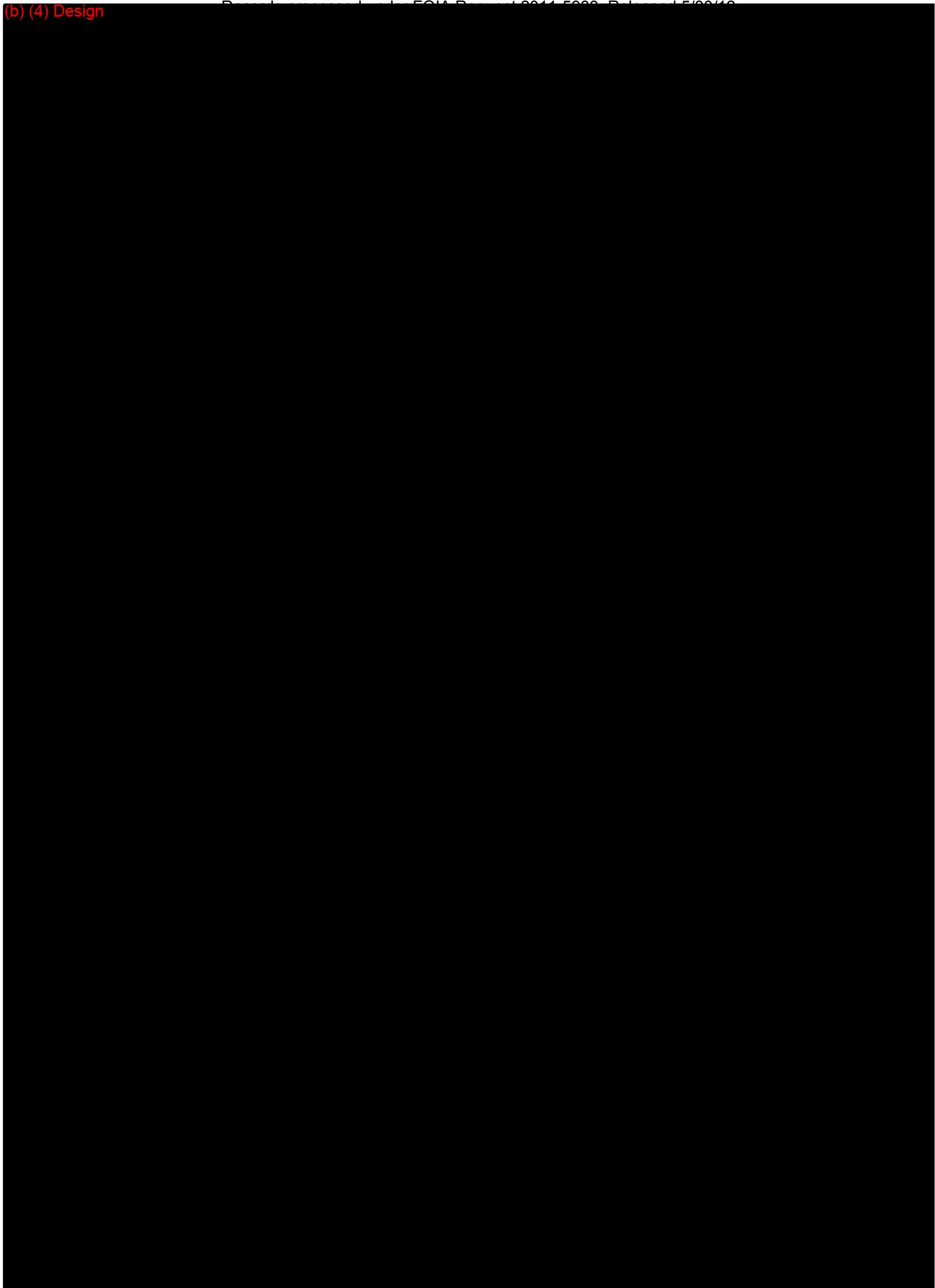
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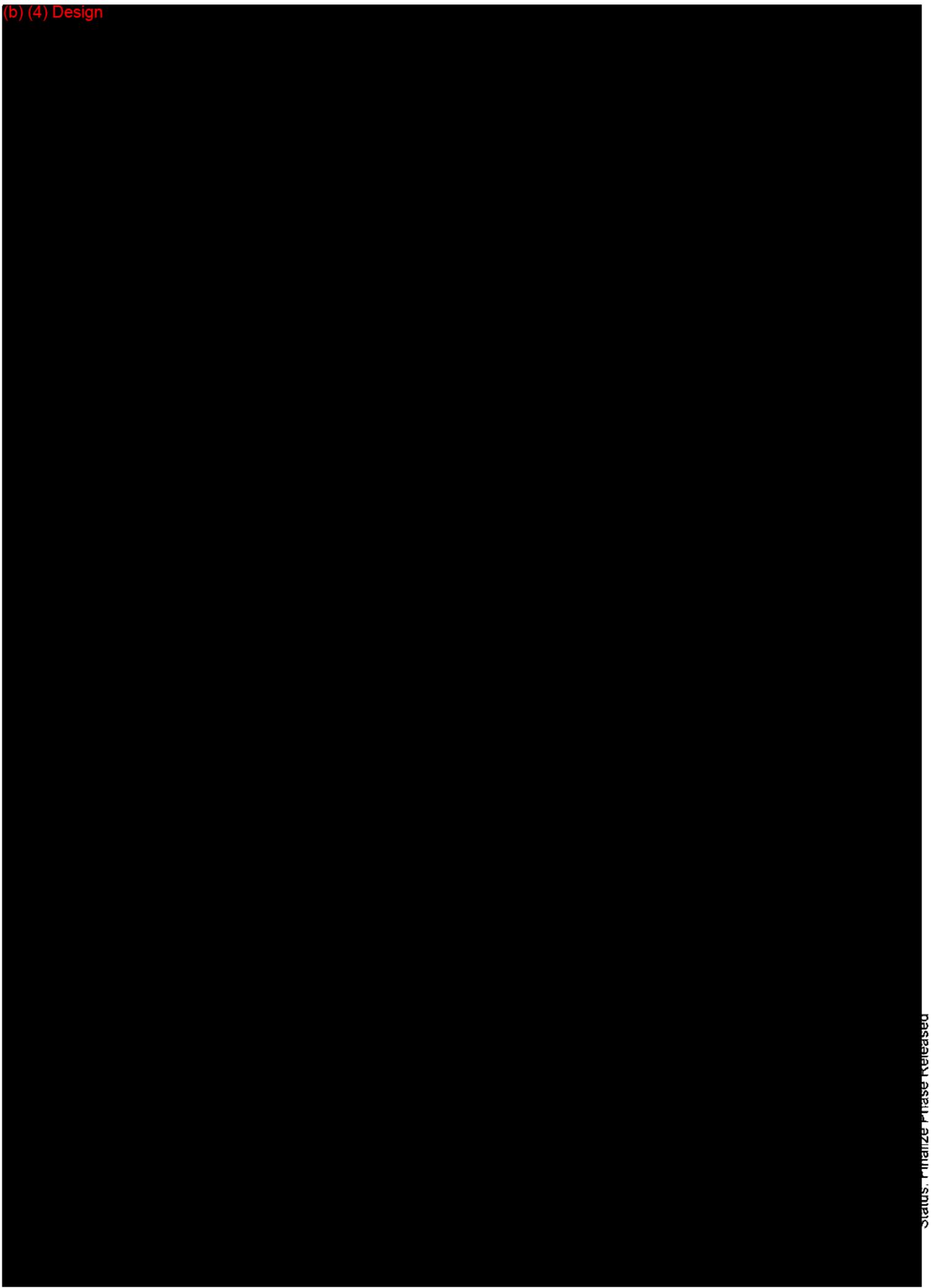
EIUS[®] Femoral Components

(b) (4) Design



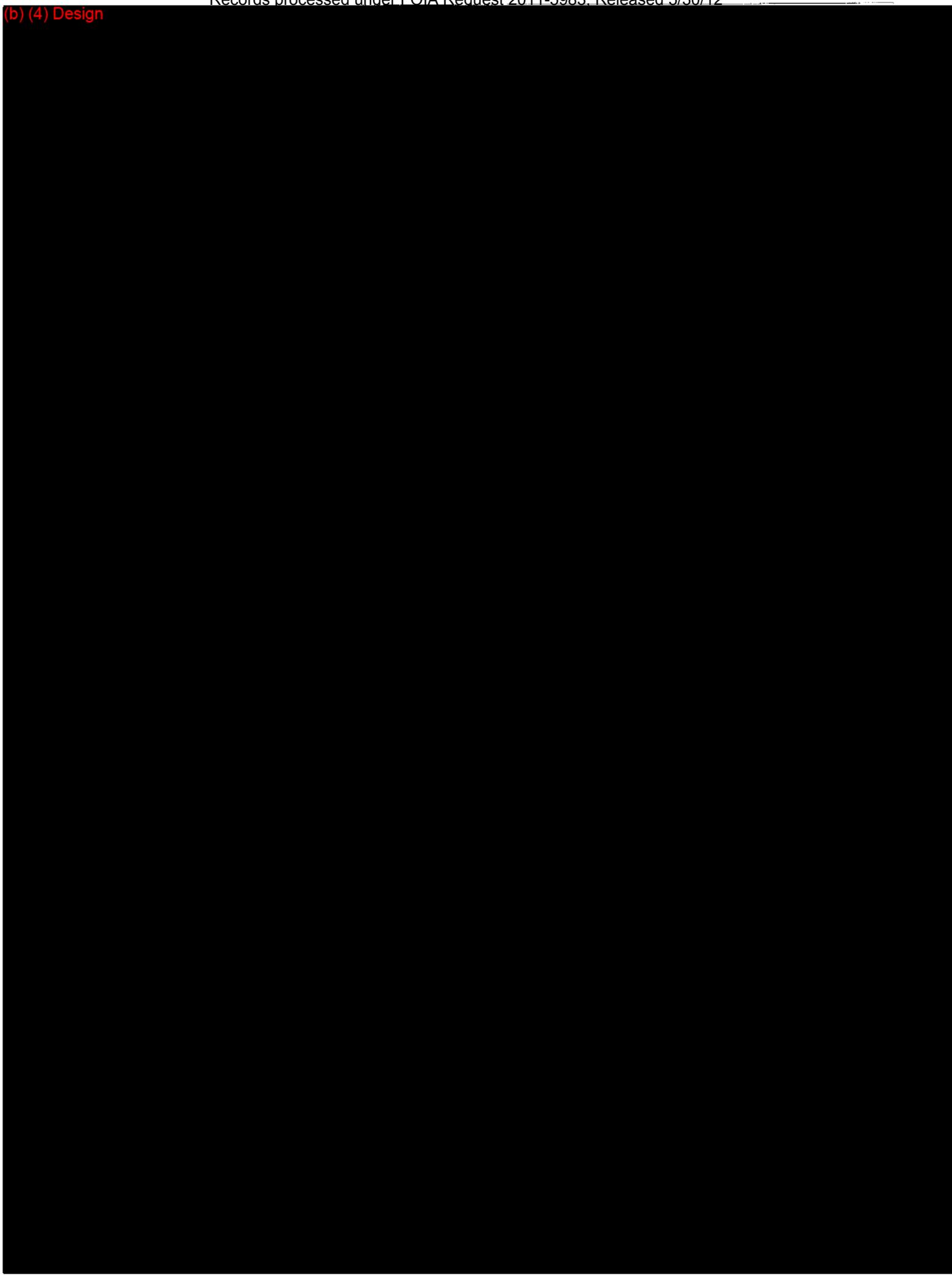


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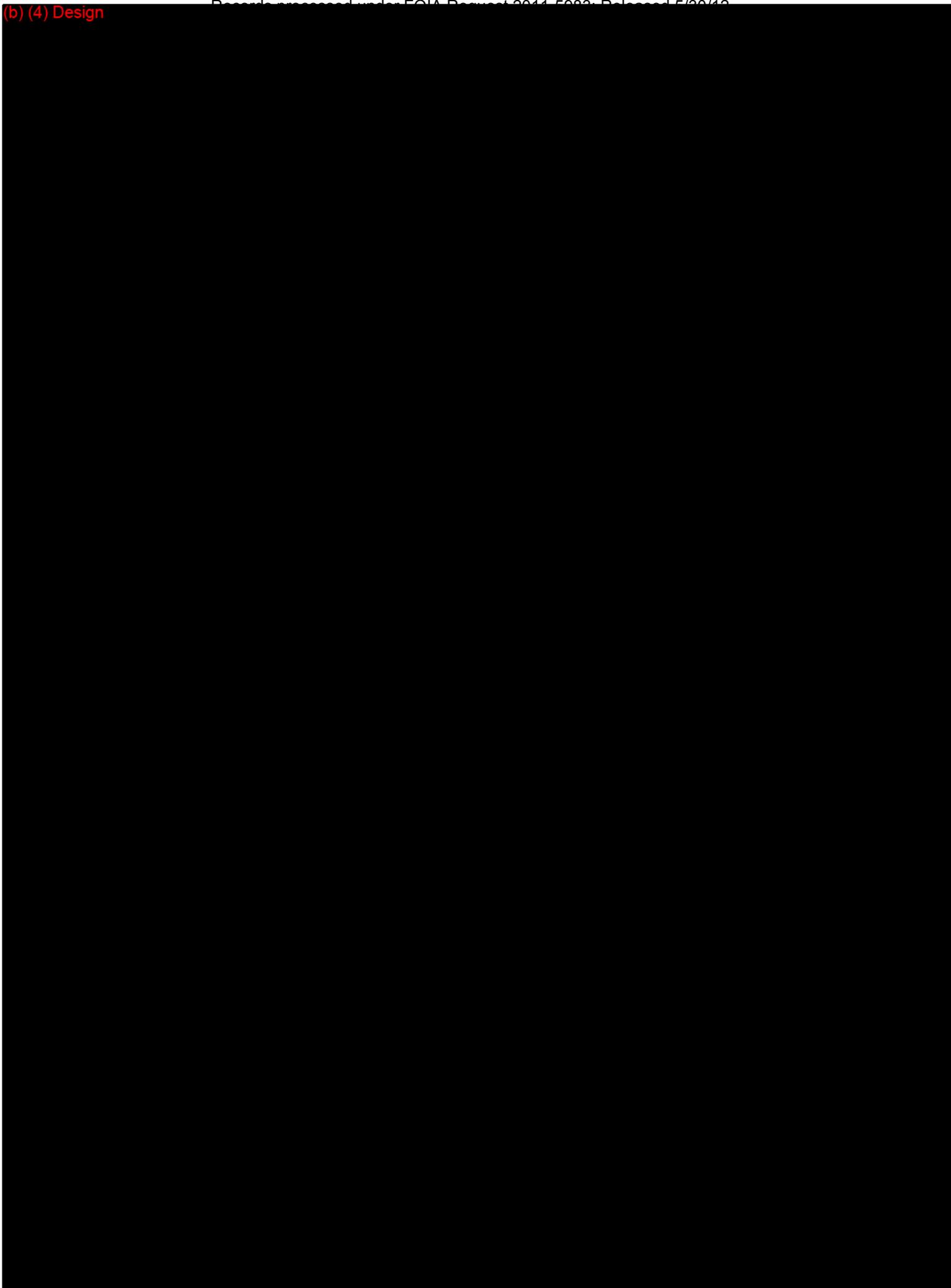


Status: Finalize Phase Released

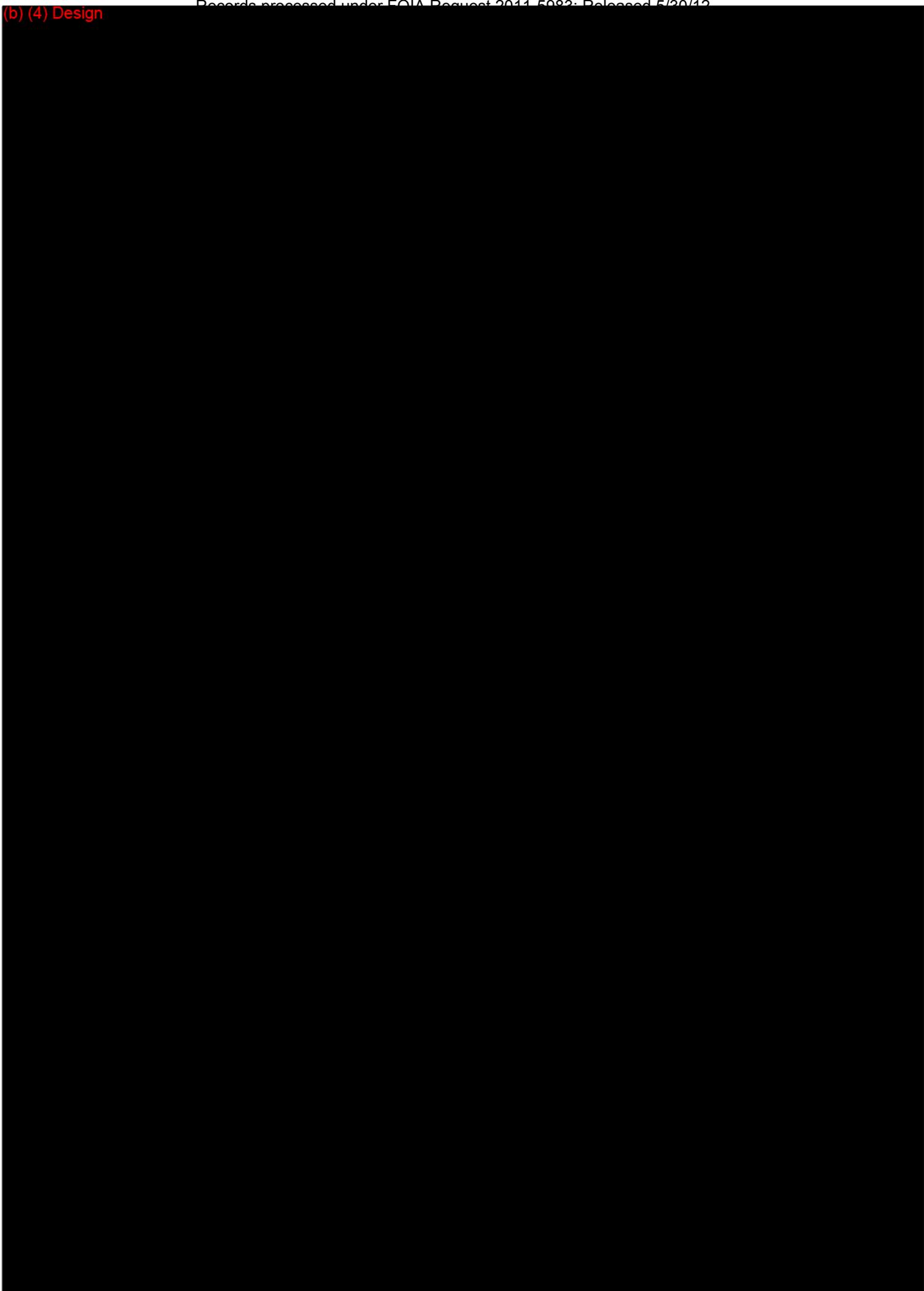
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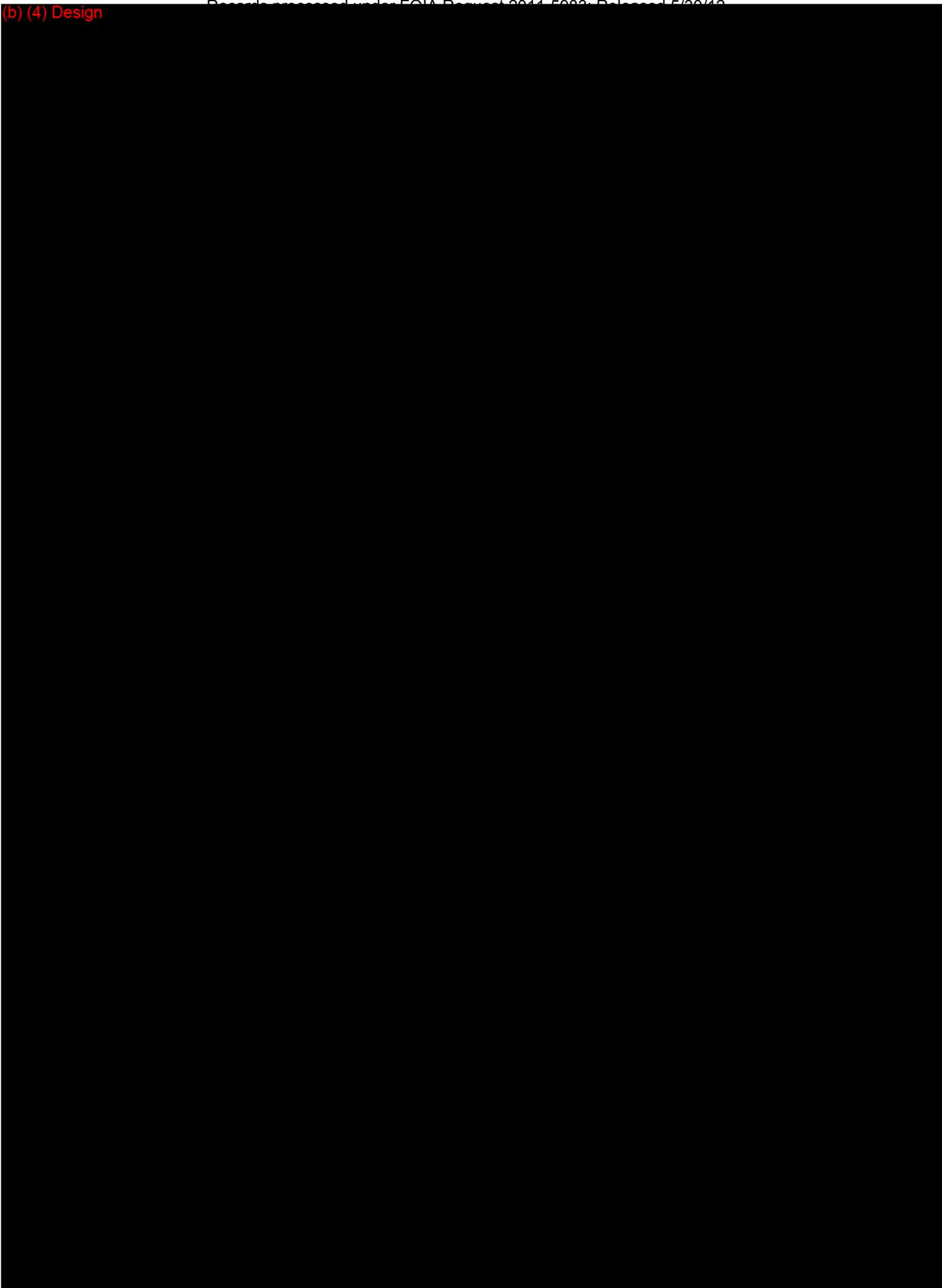
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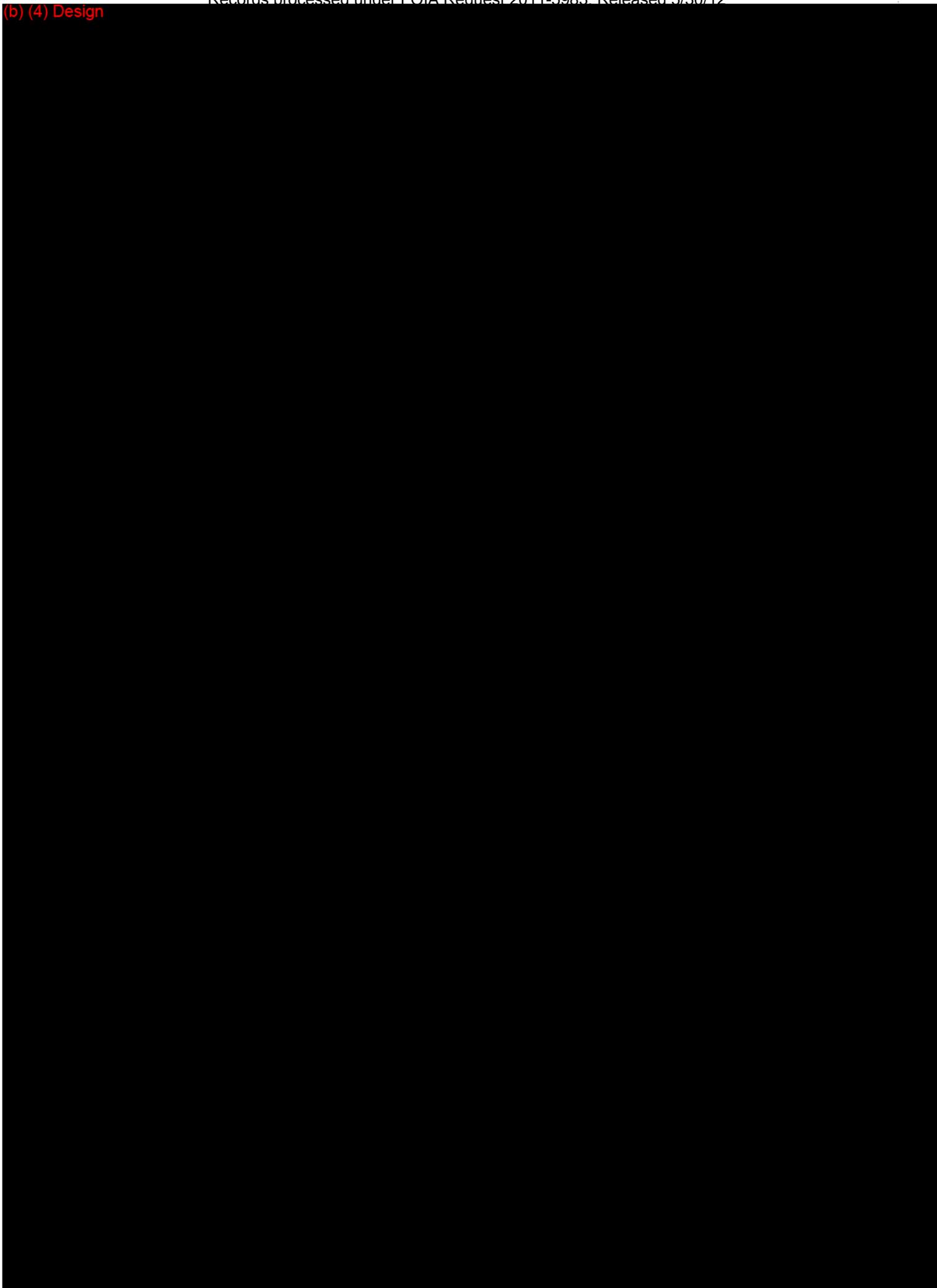
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(b) (4) Design

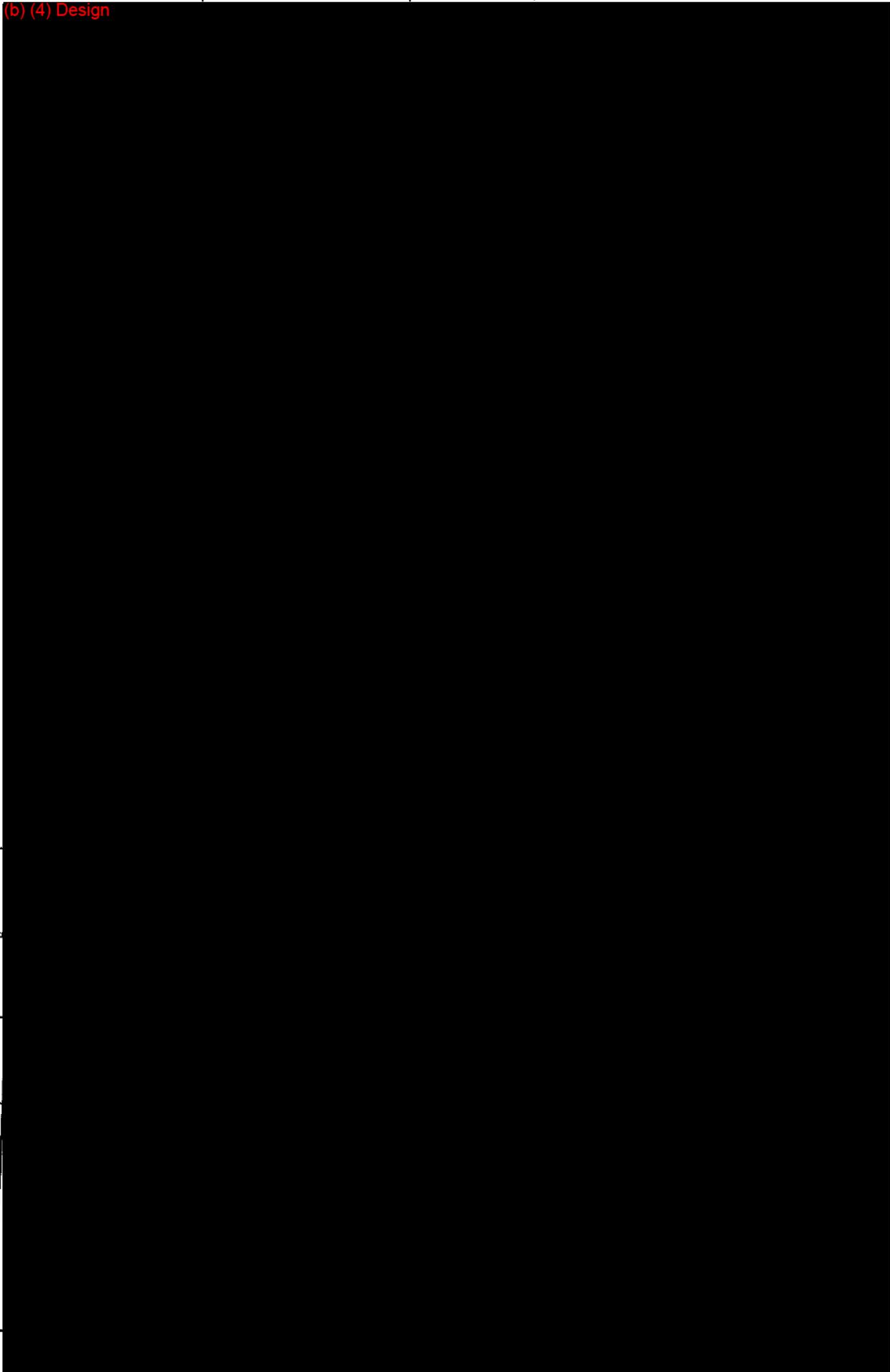


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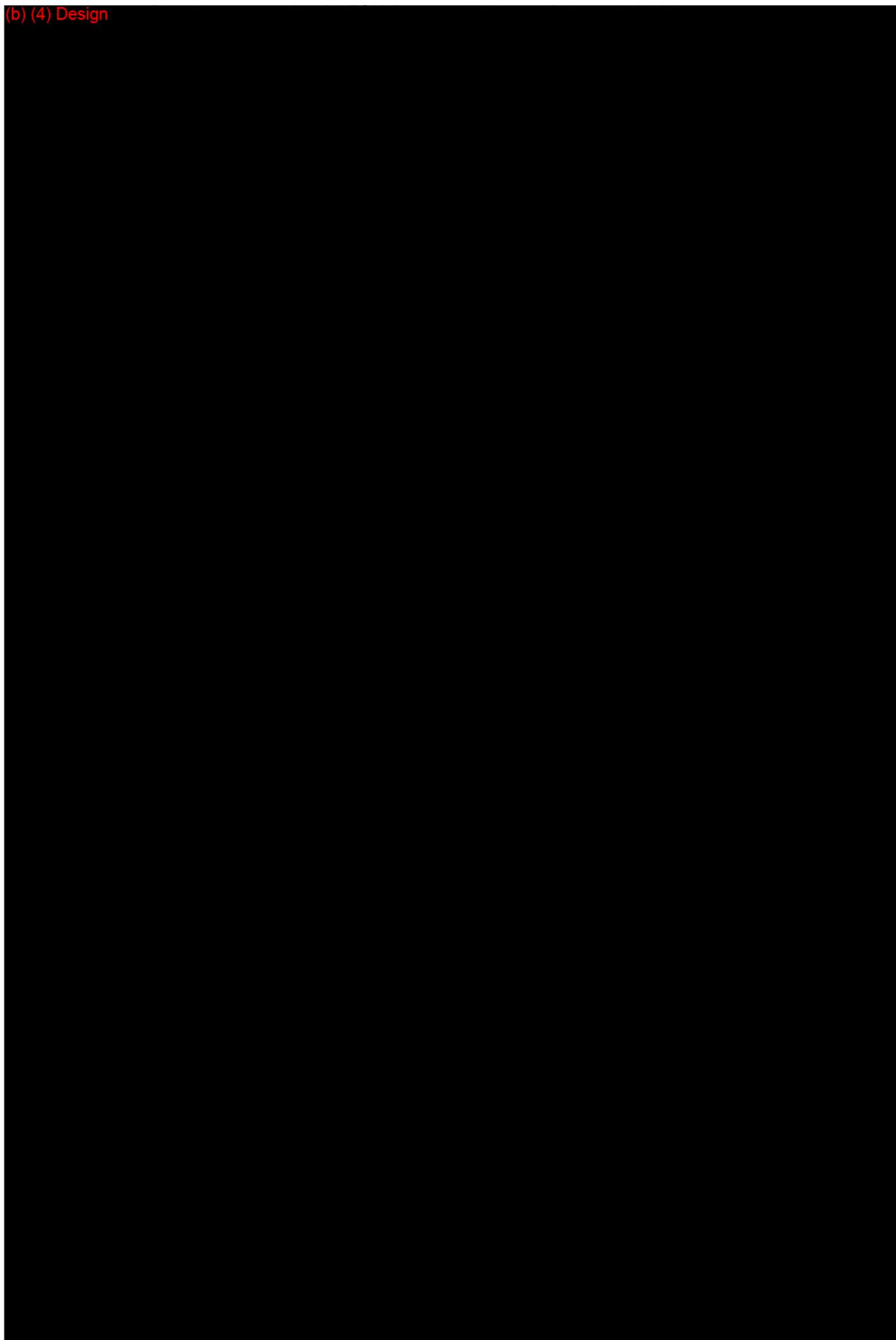


EIUS[®] Tibial Components

(b) (4) Design

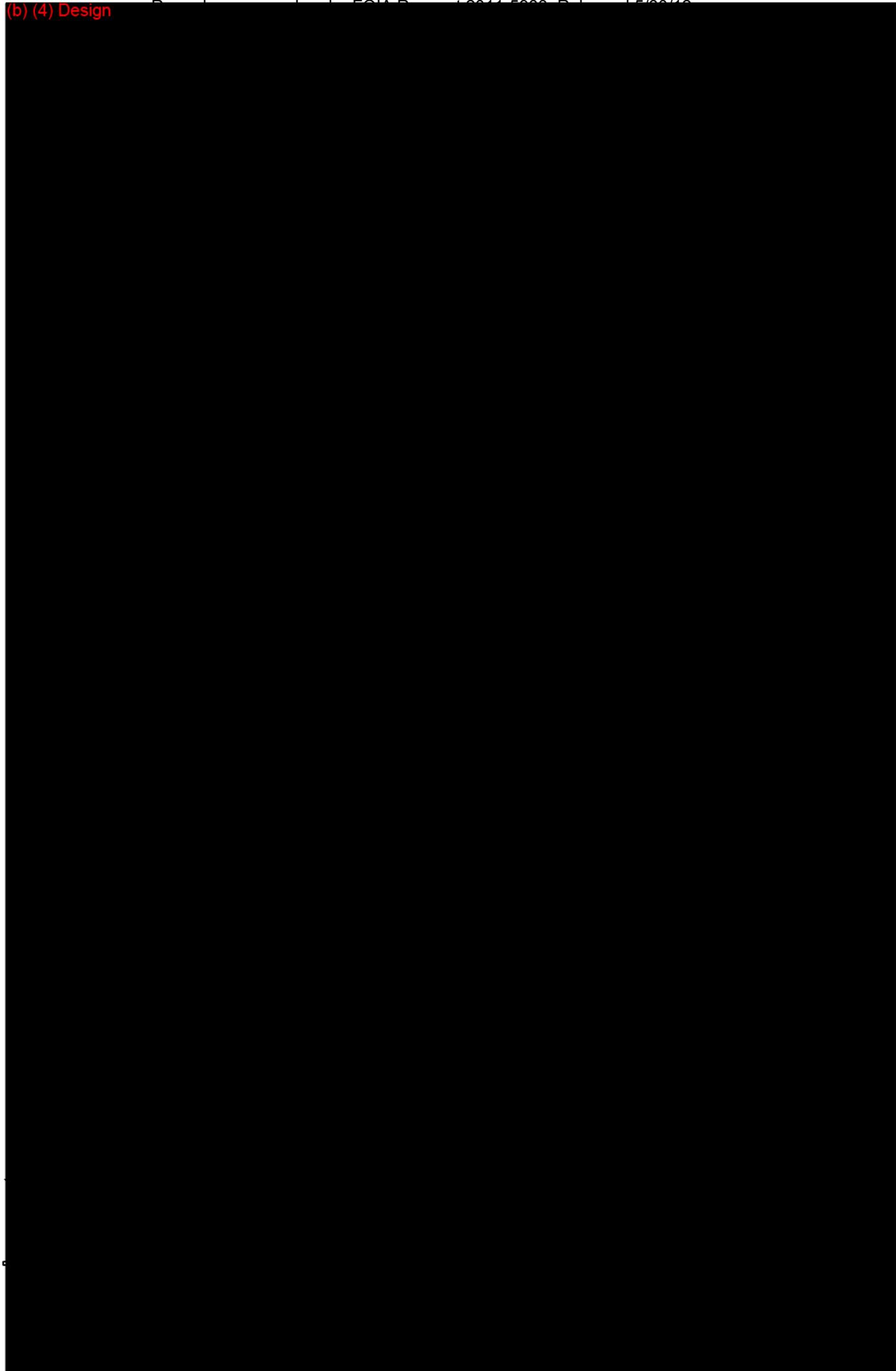


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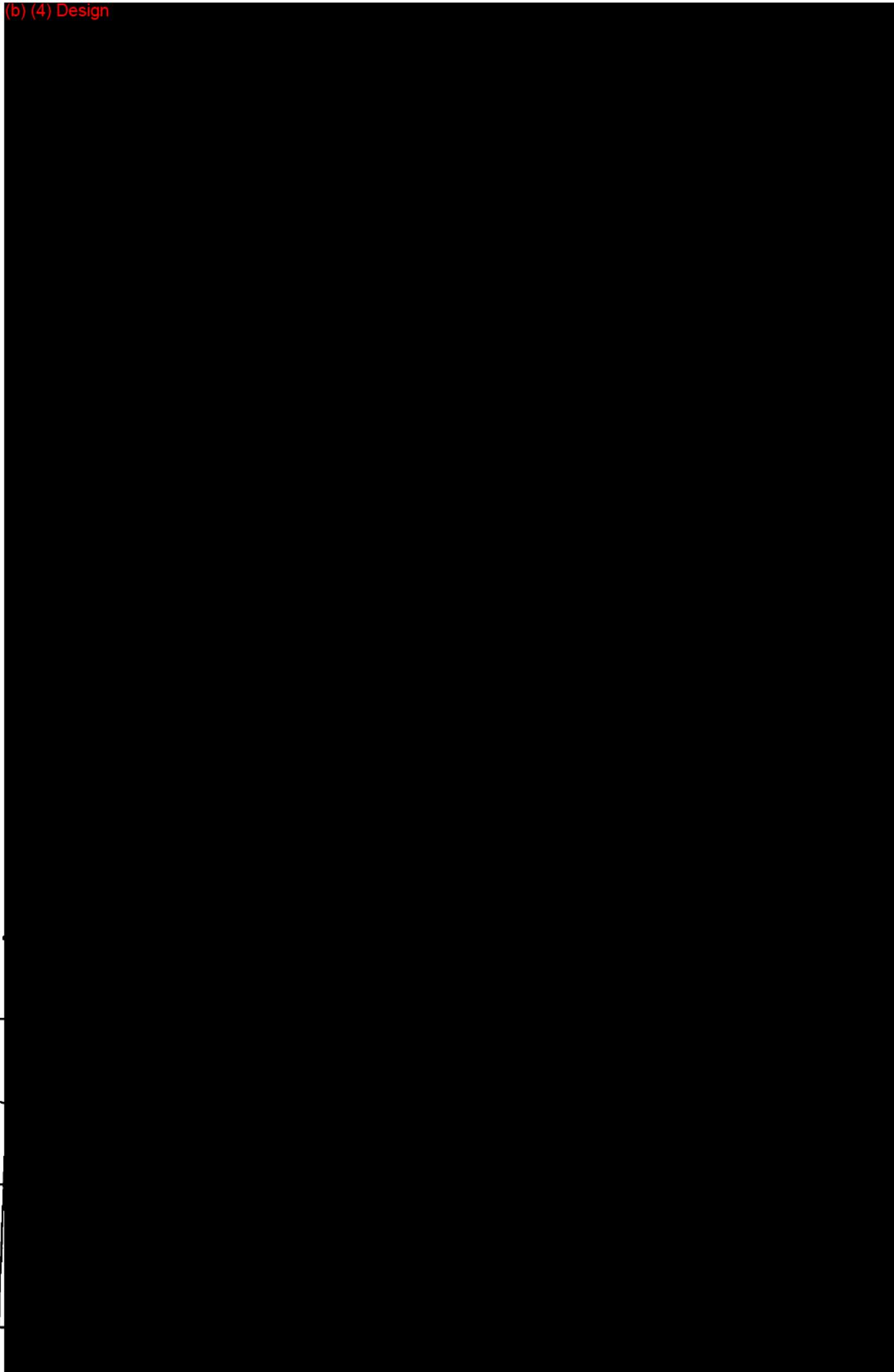
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Product Name: [REDACTED] QM# [REDACTED] 10011-5000-01 Rev. 15/2016



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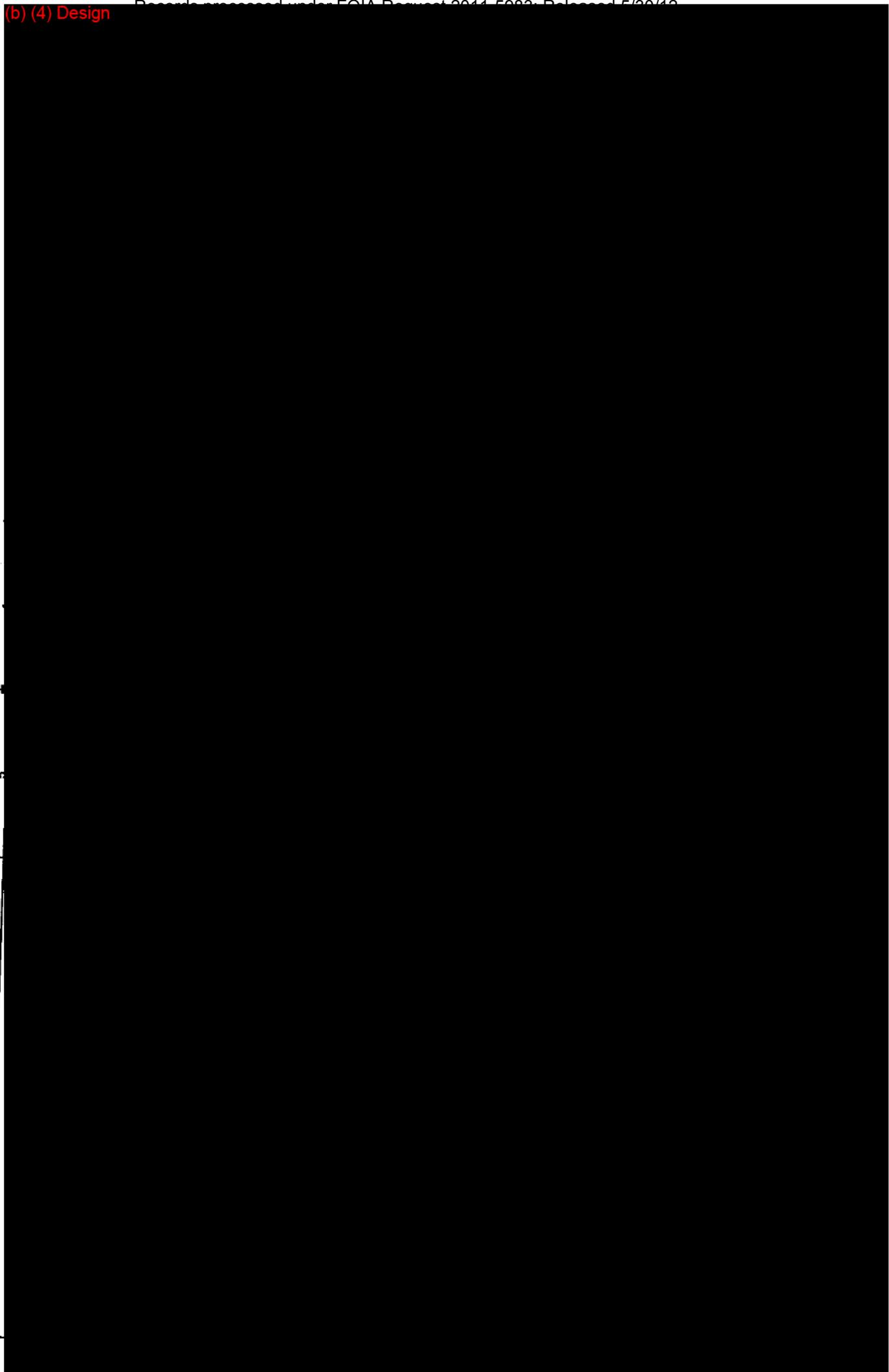




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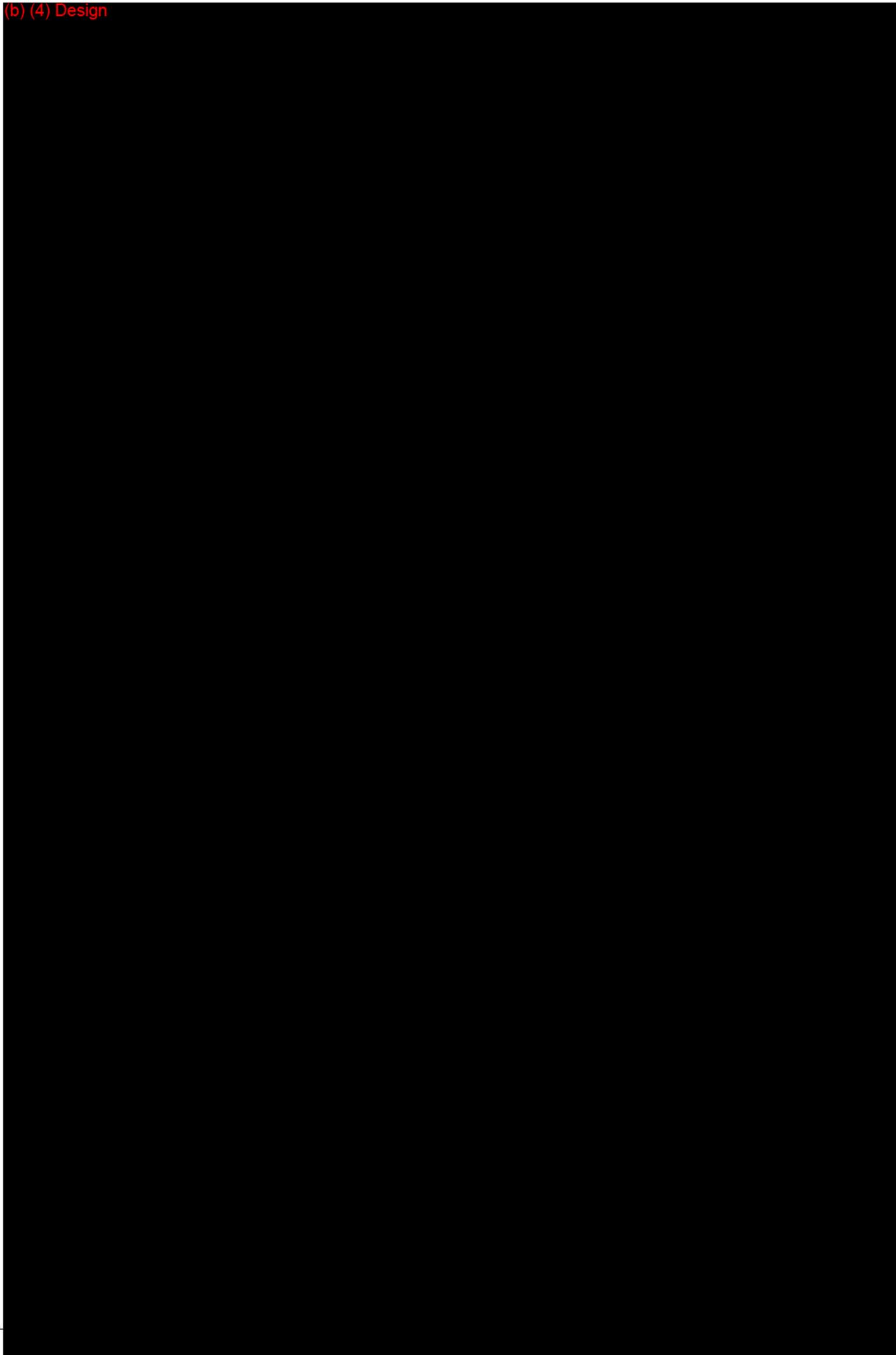
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Records processed under FOIA Request 2014-5082, Released 5/20/19

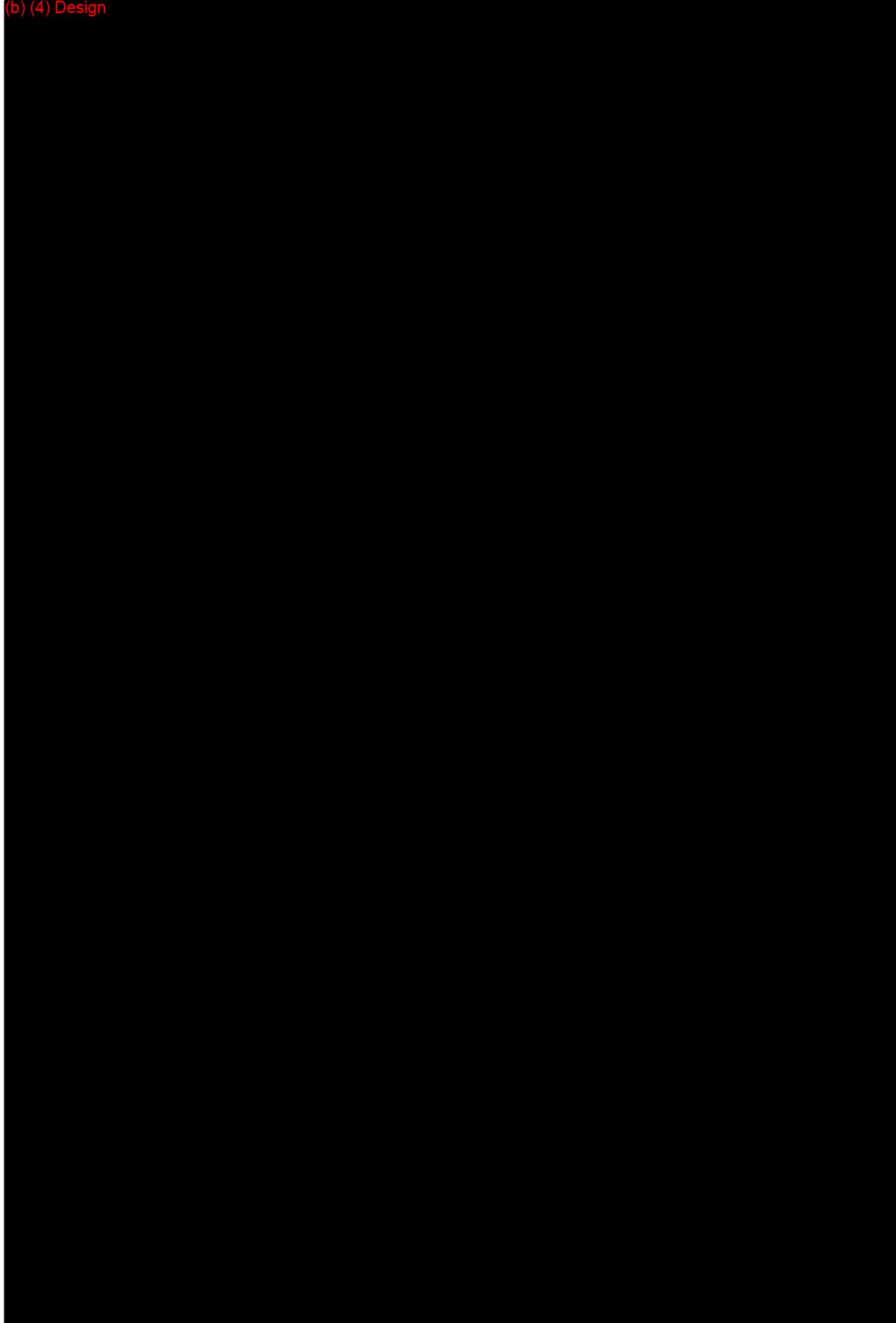


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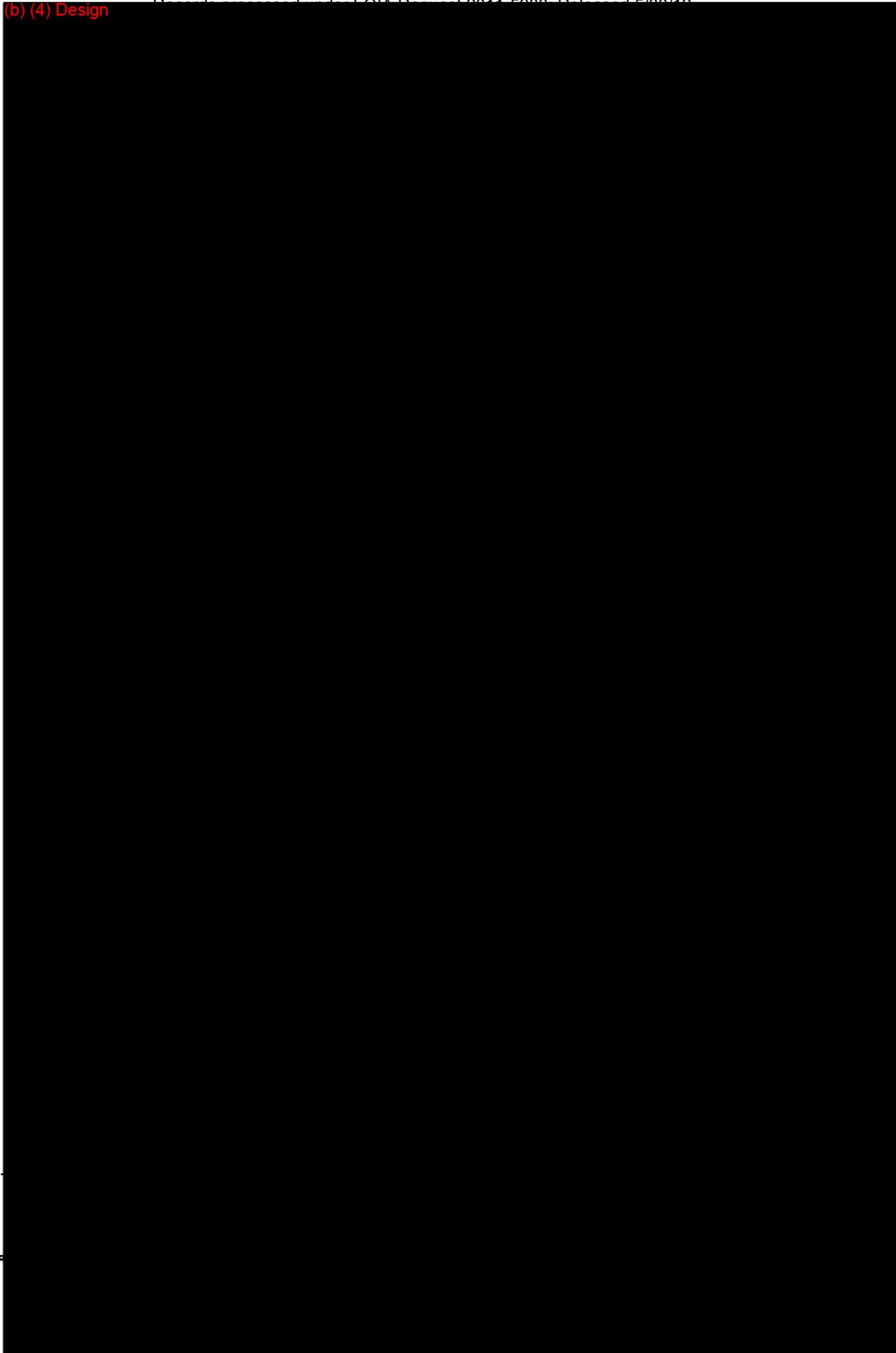


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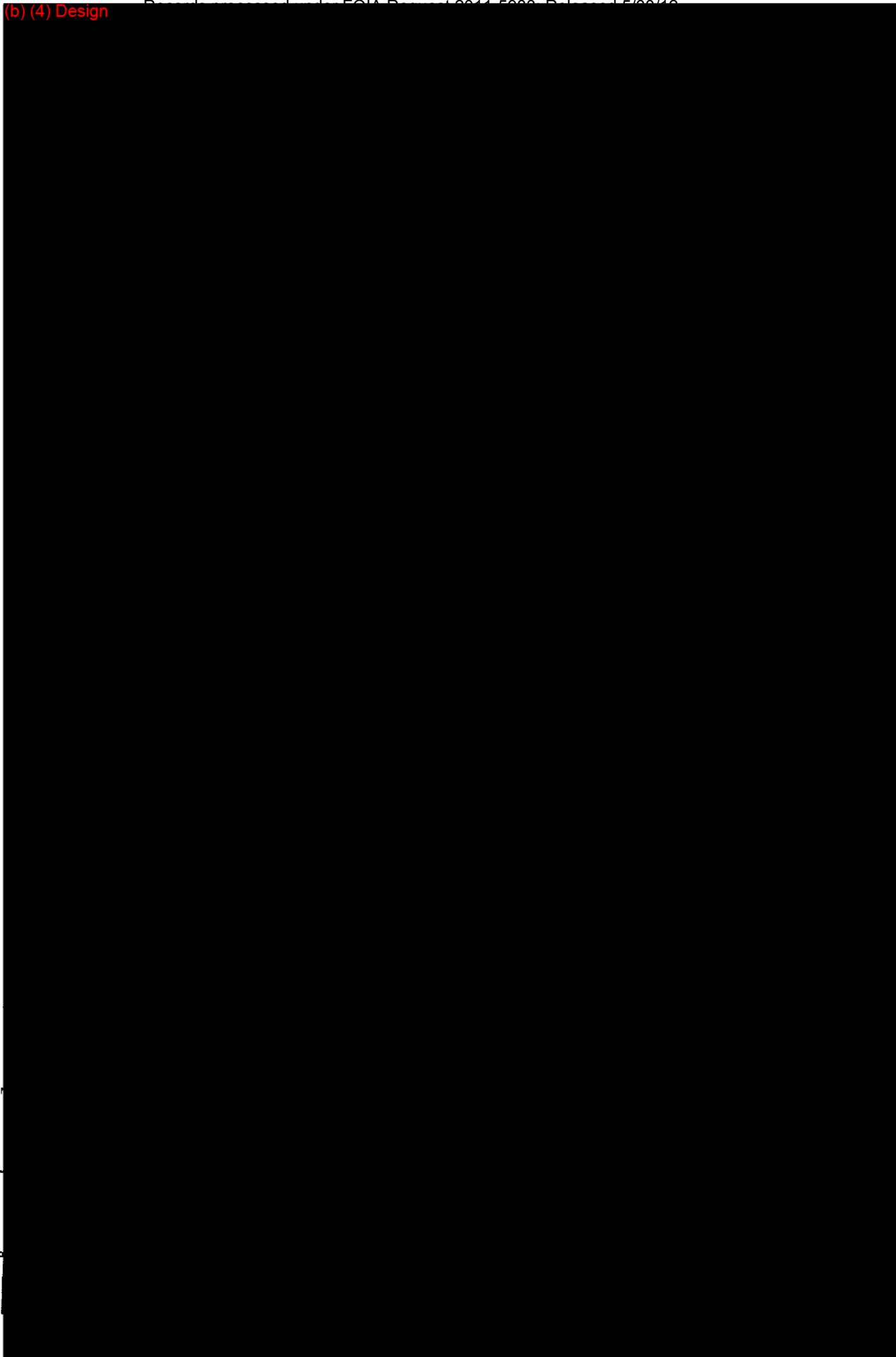


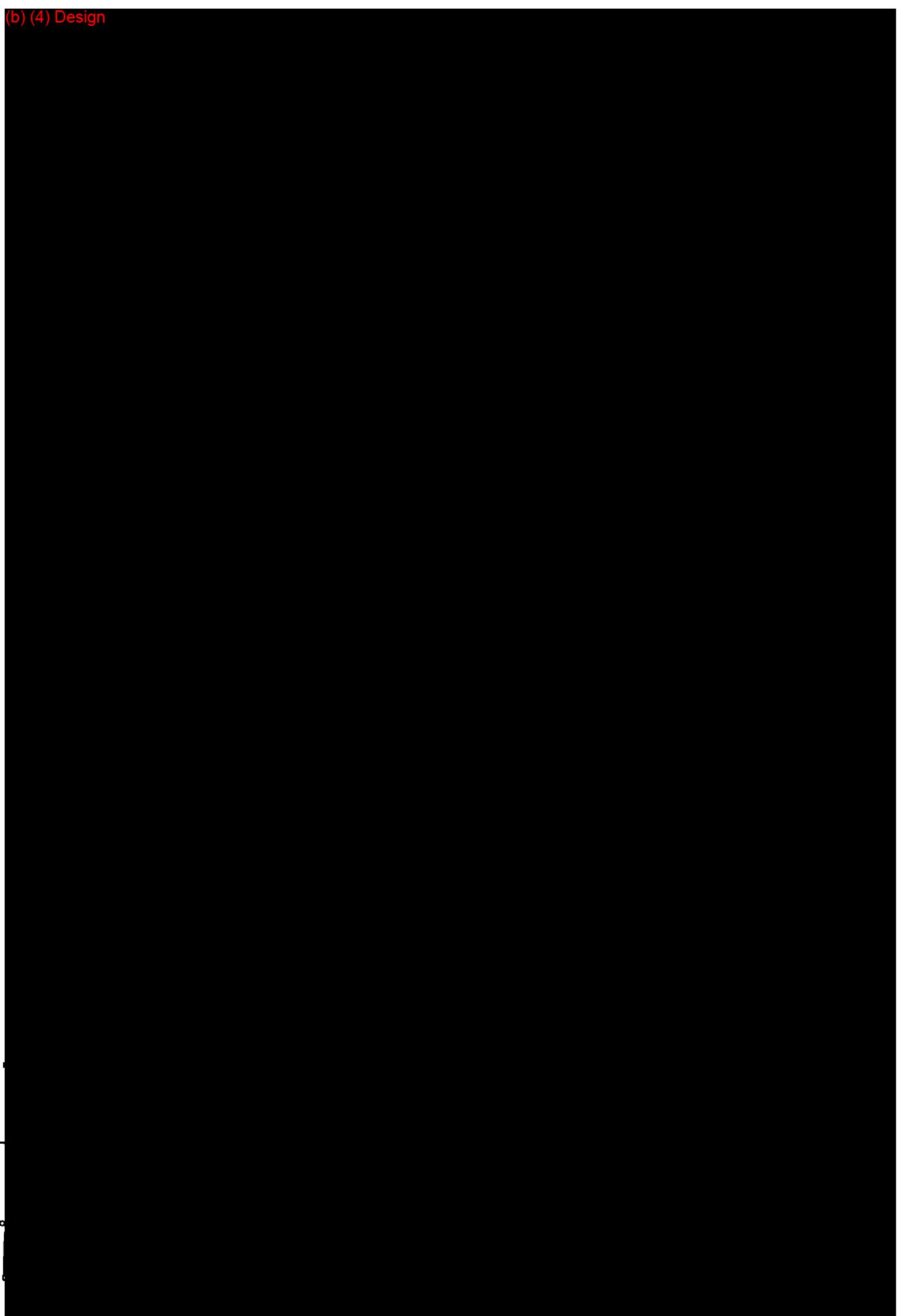
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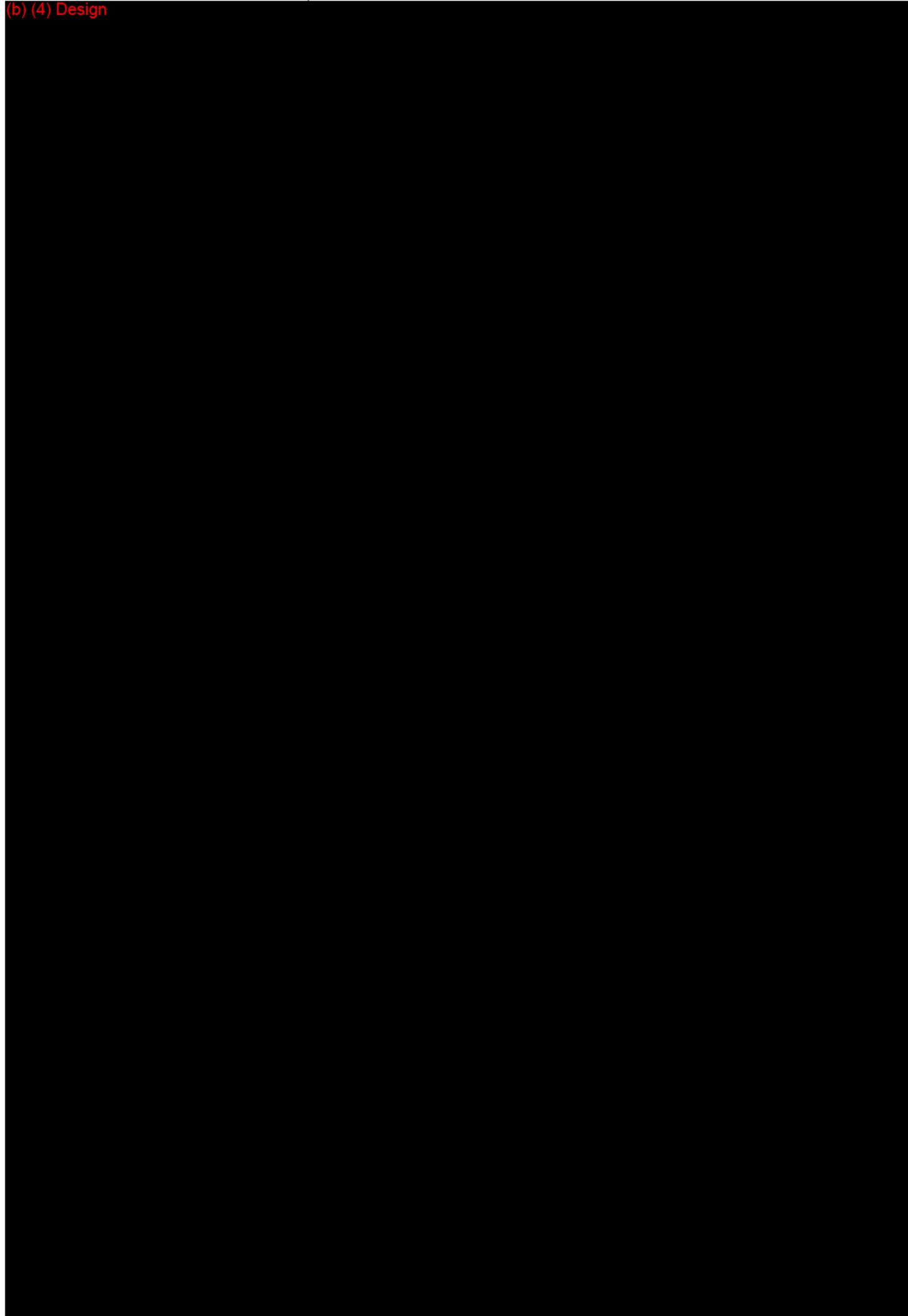


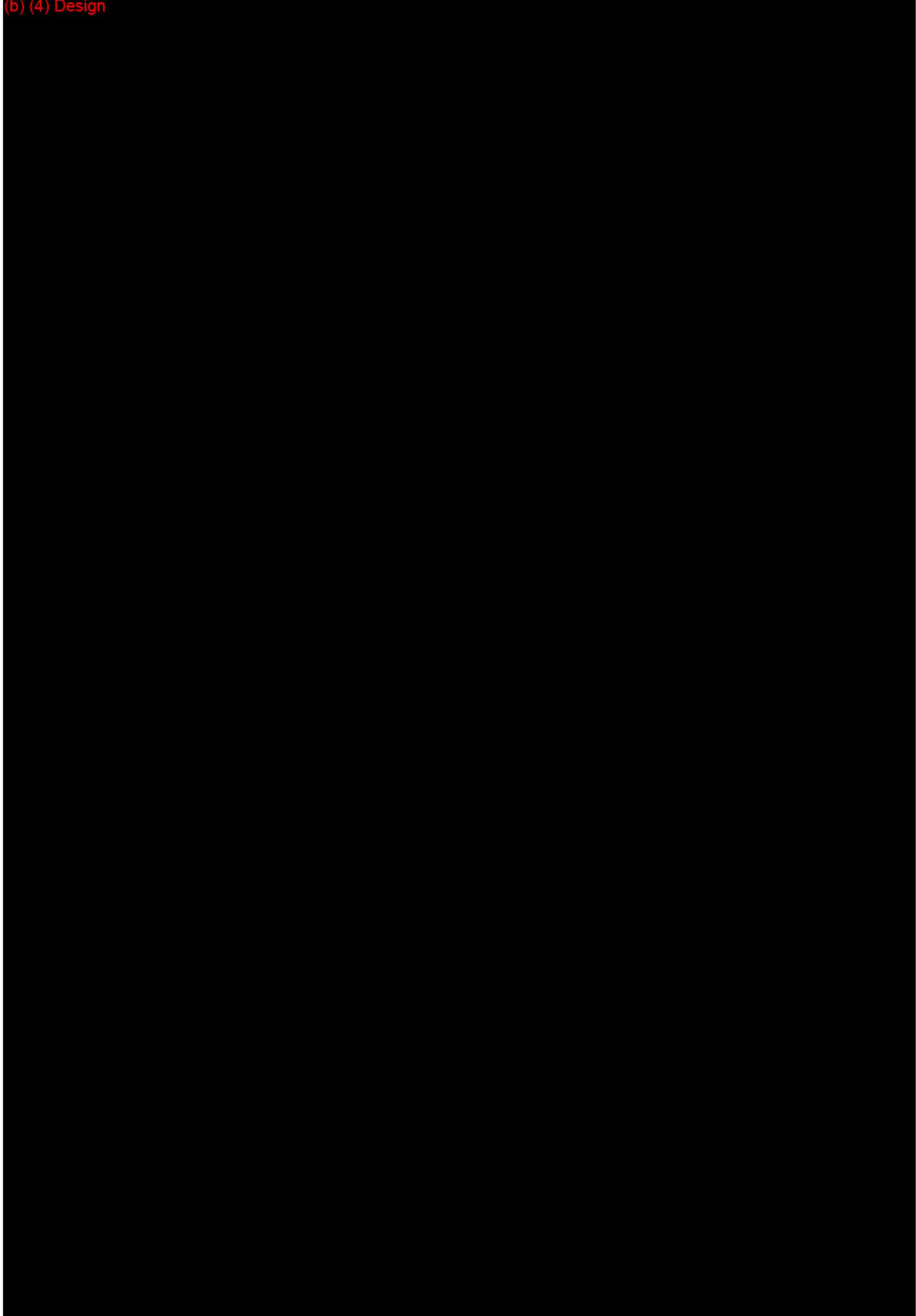
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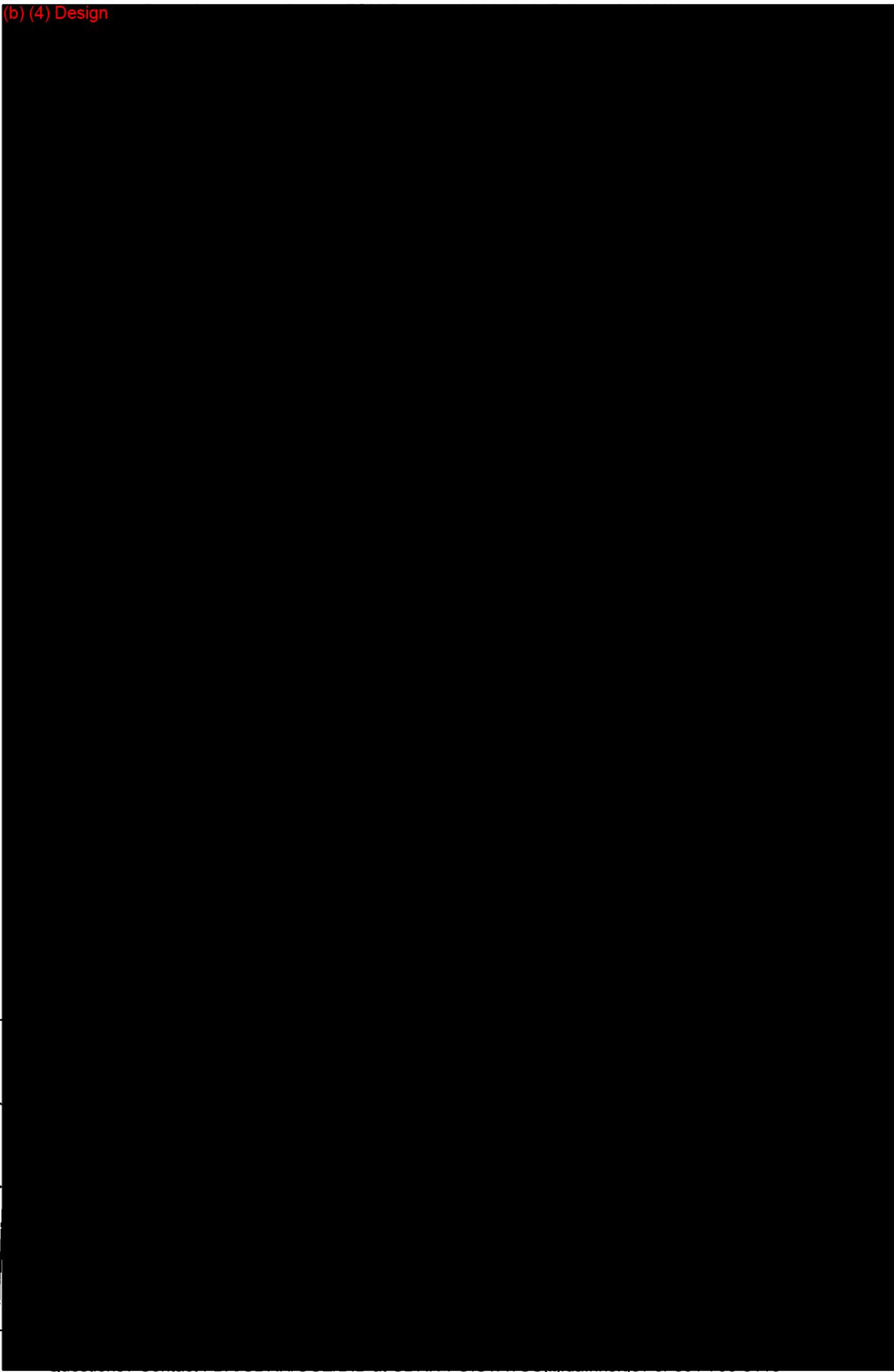




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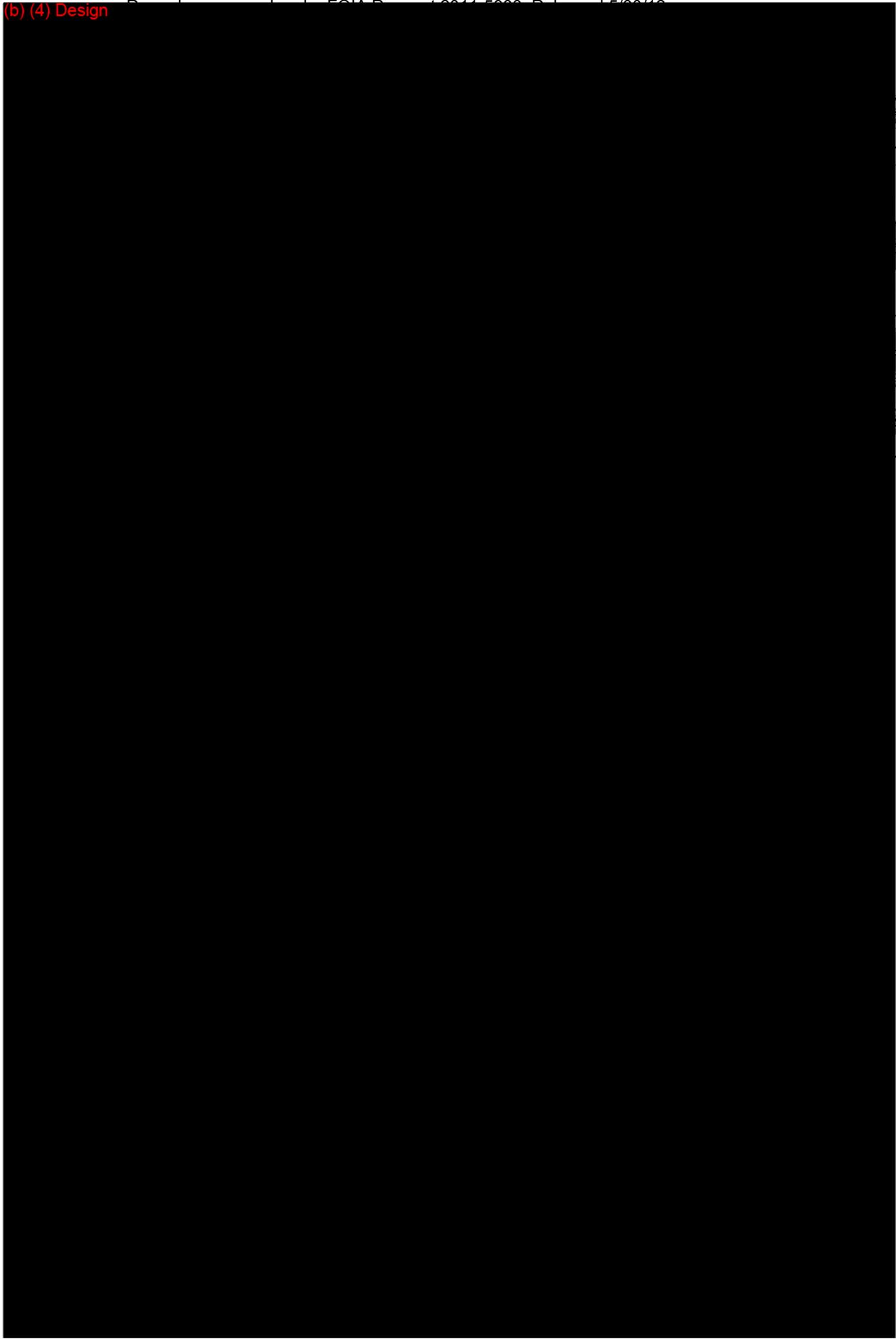


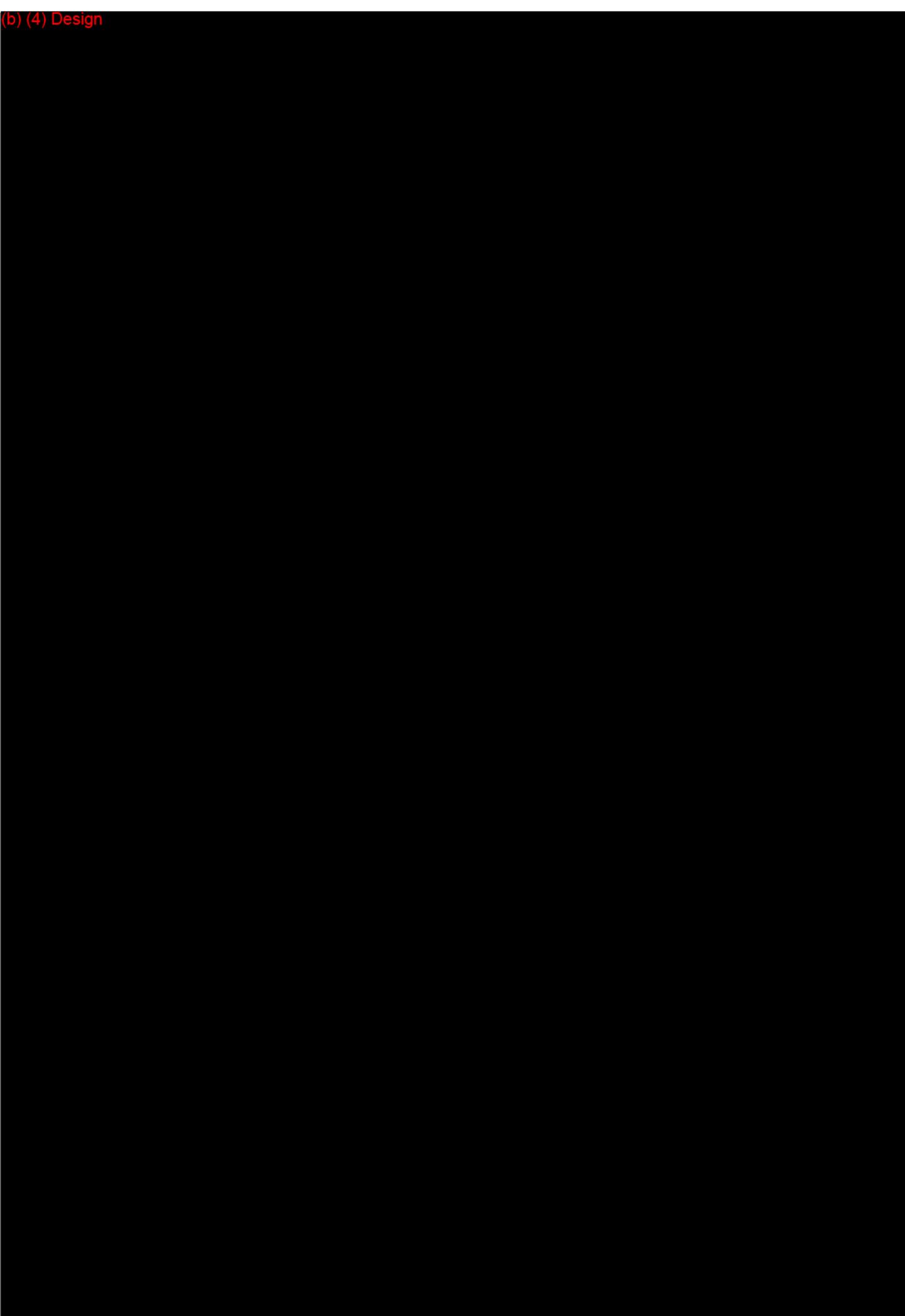


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(b) (4) Design



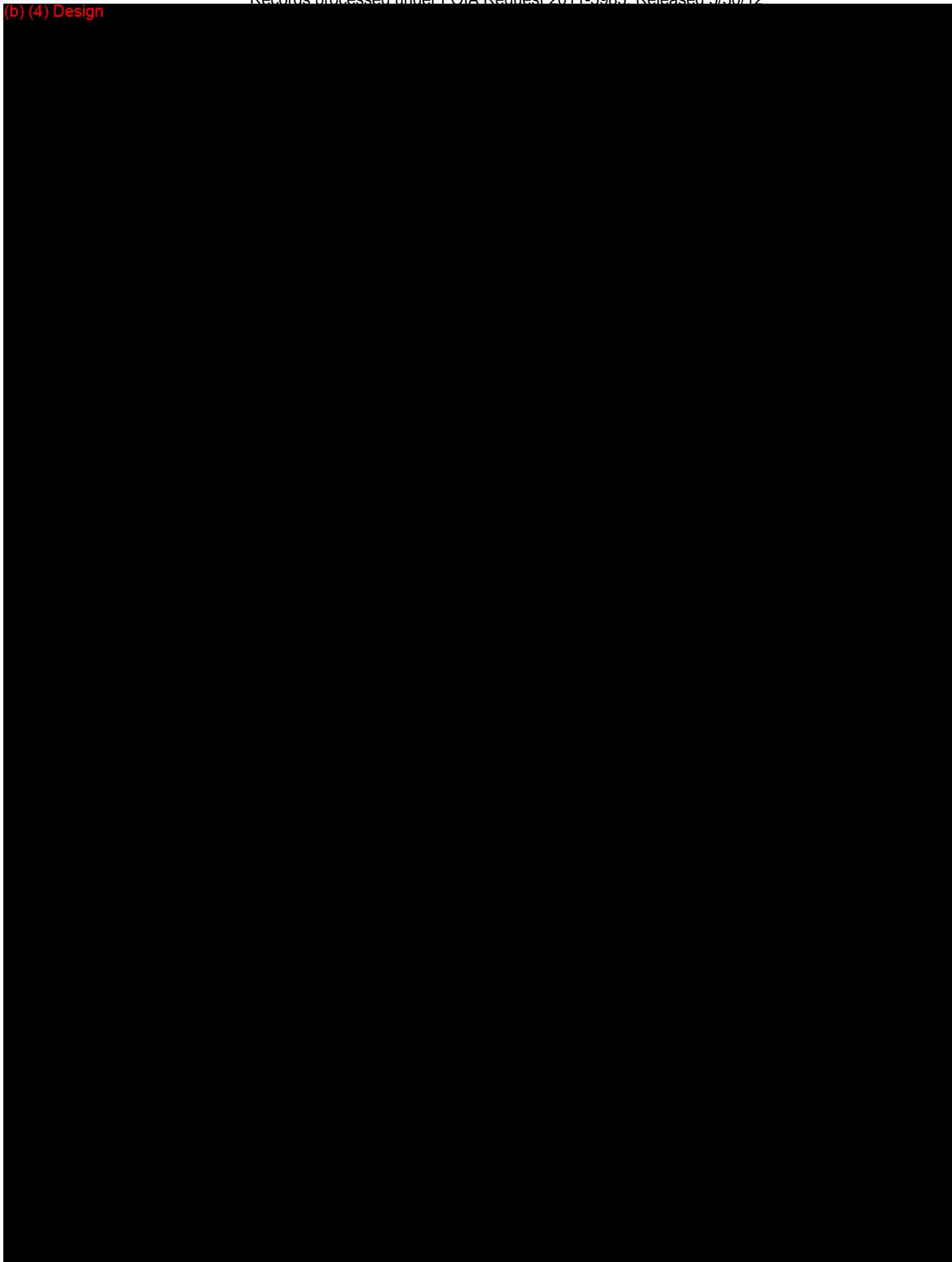


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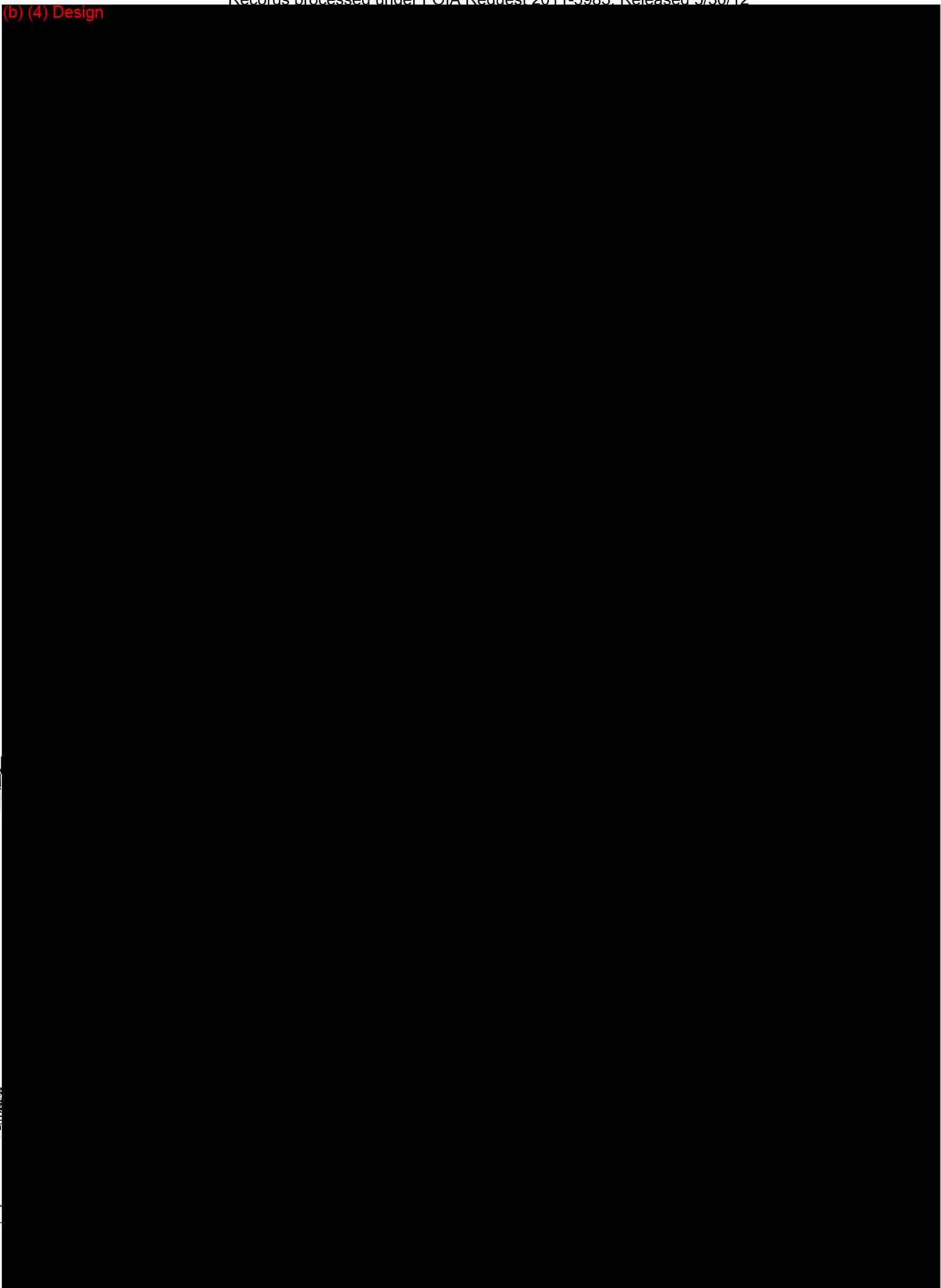
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-140

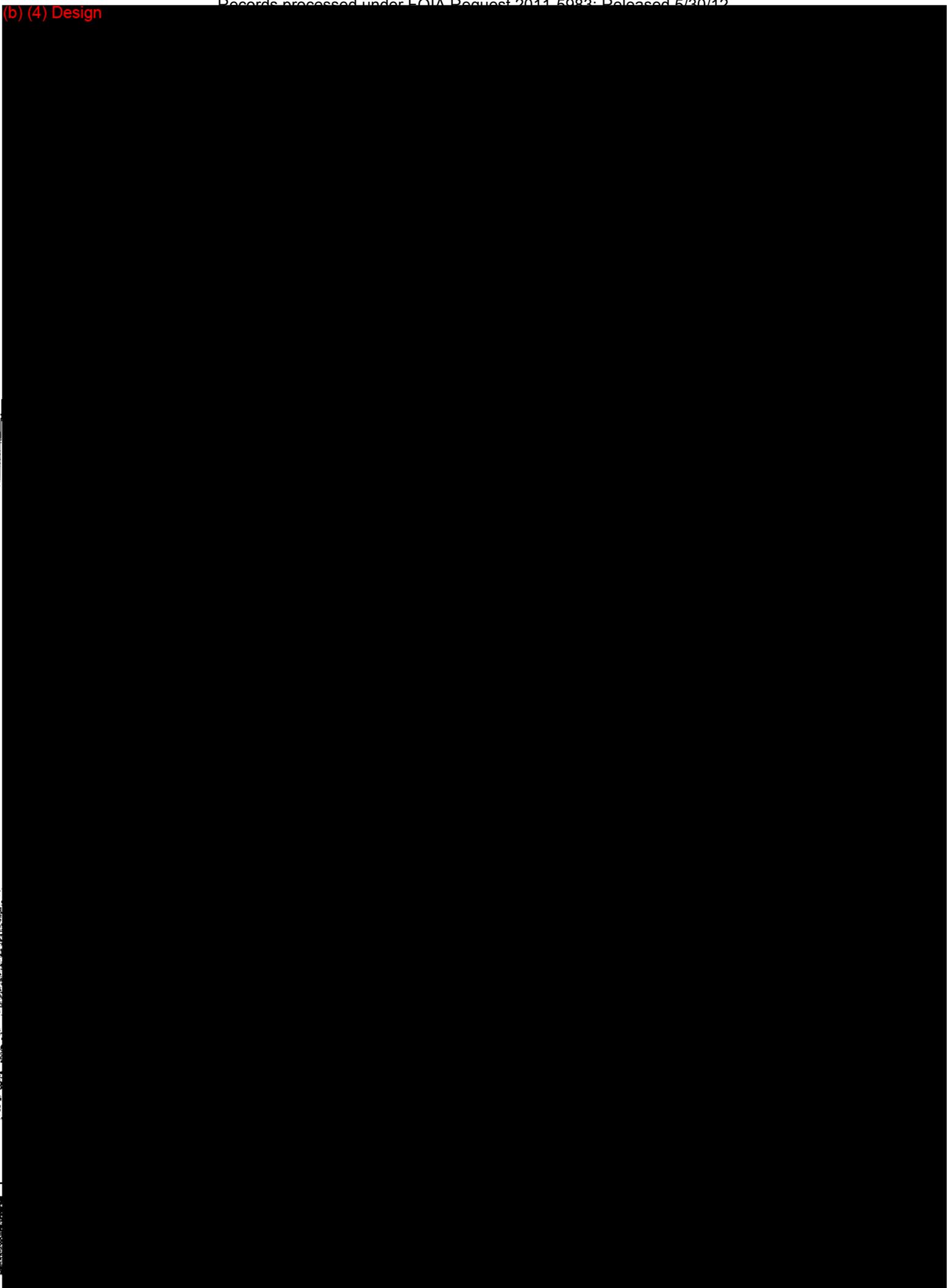
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(b) (4) Design

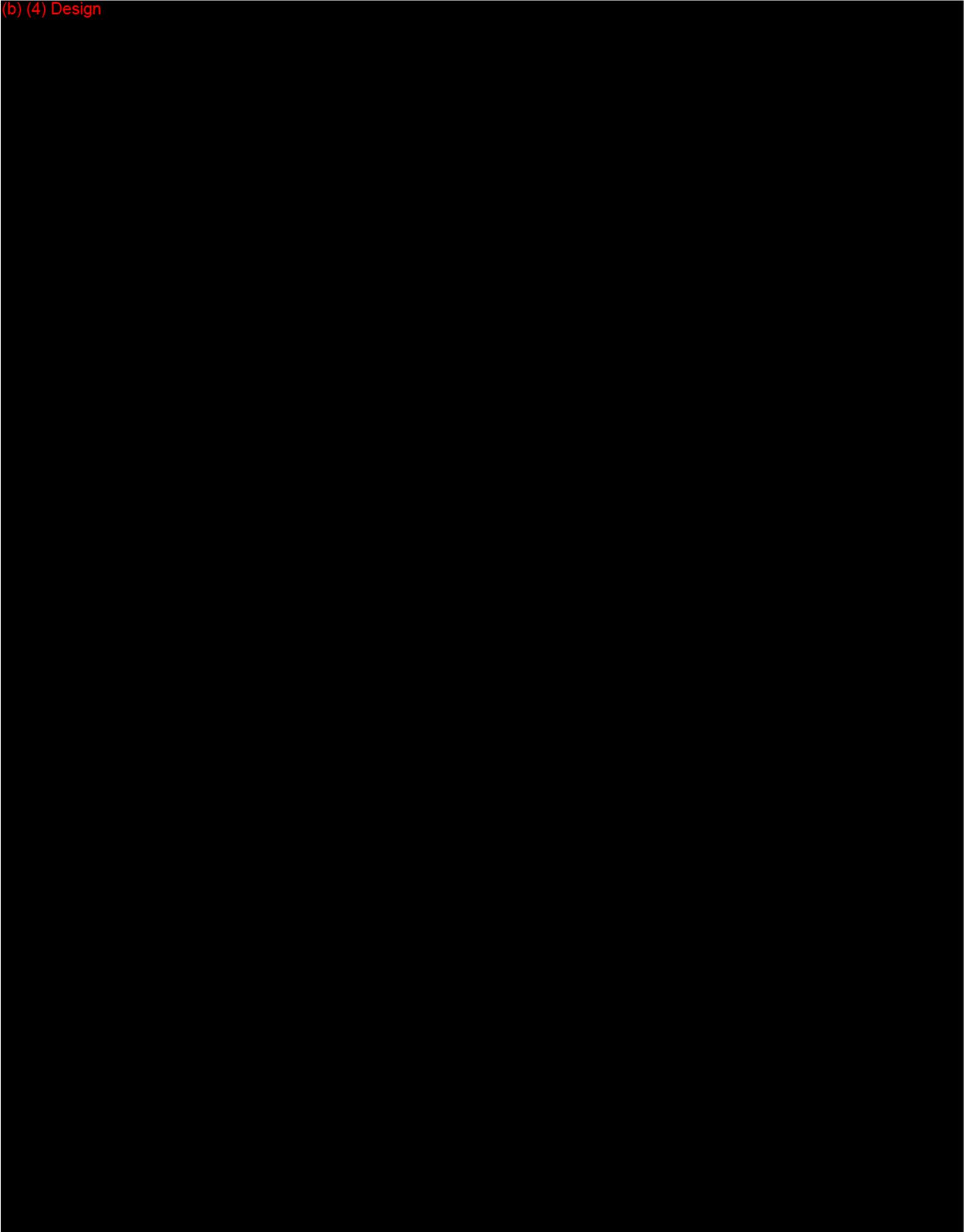


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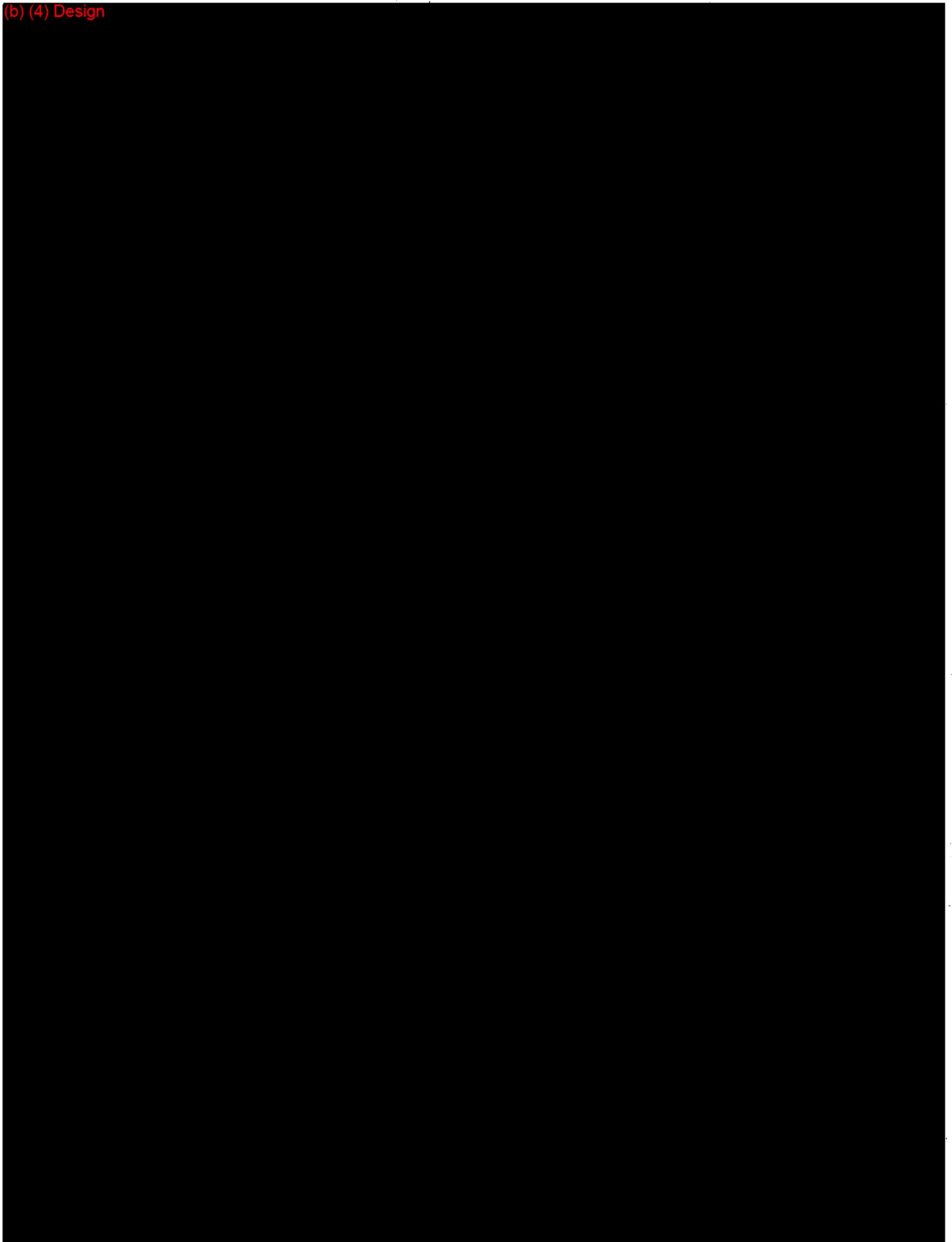


SCR[®] Femoral Component

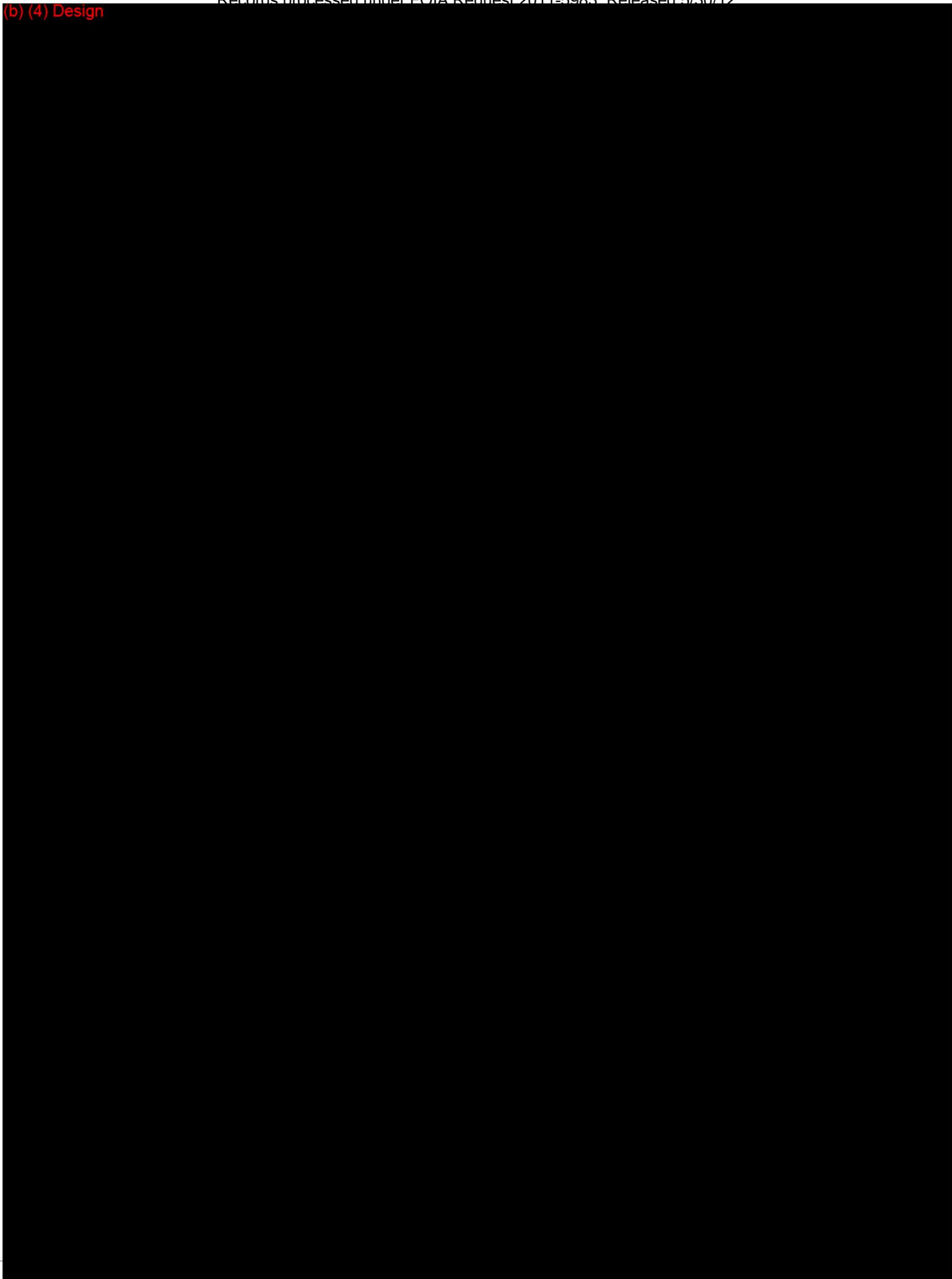
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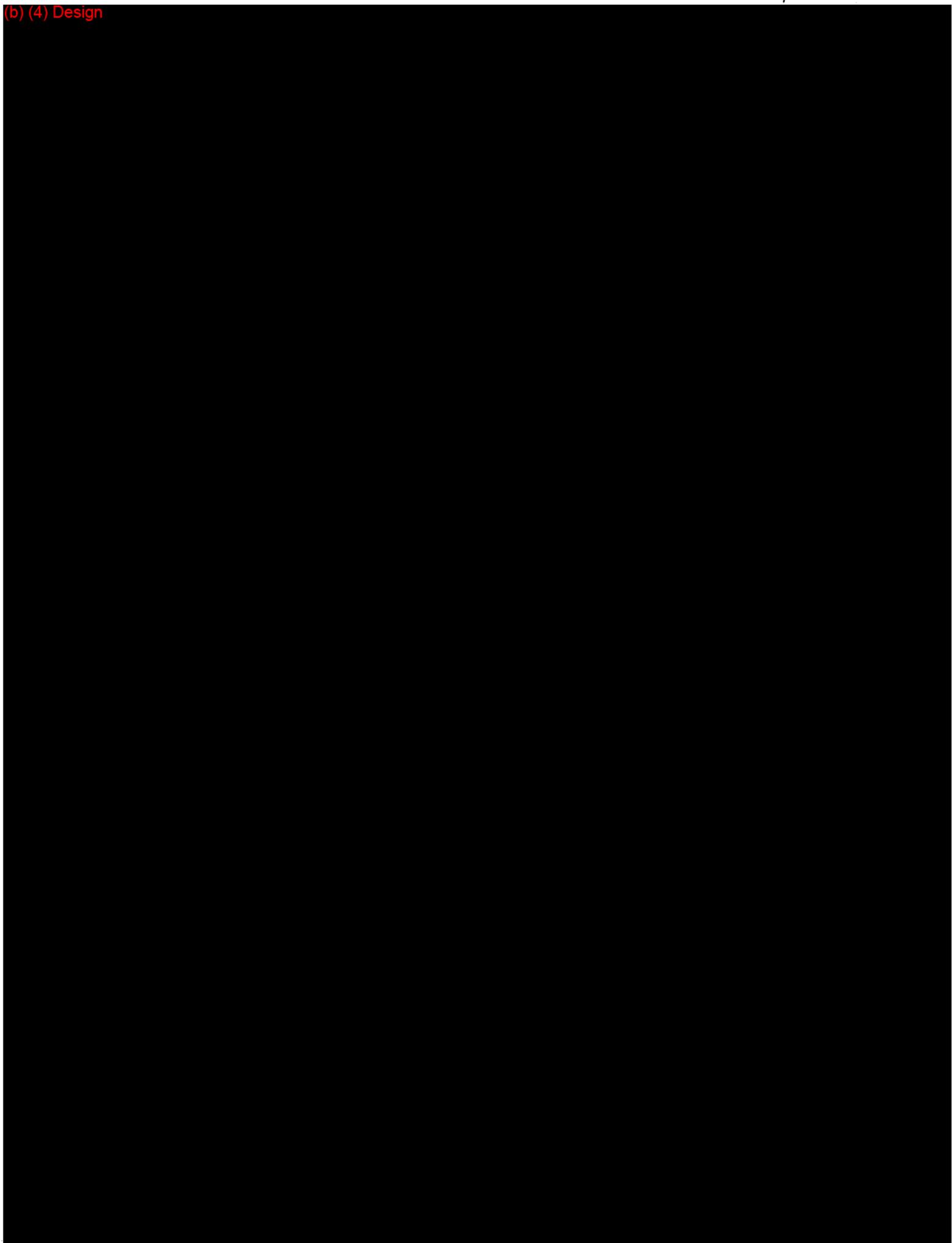
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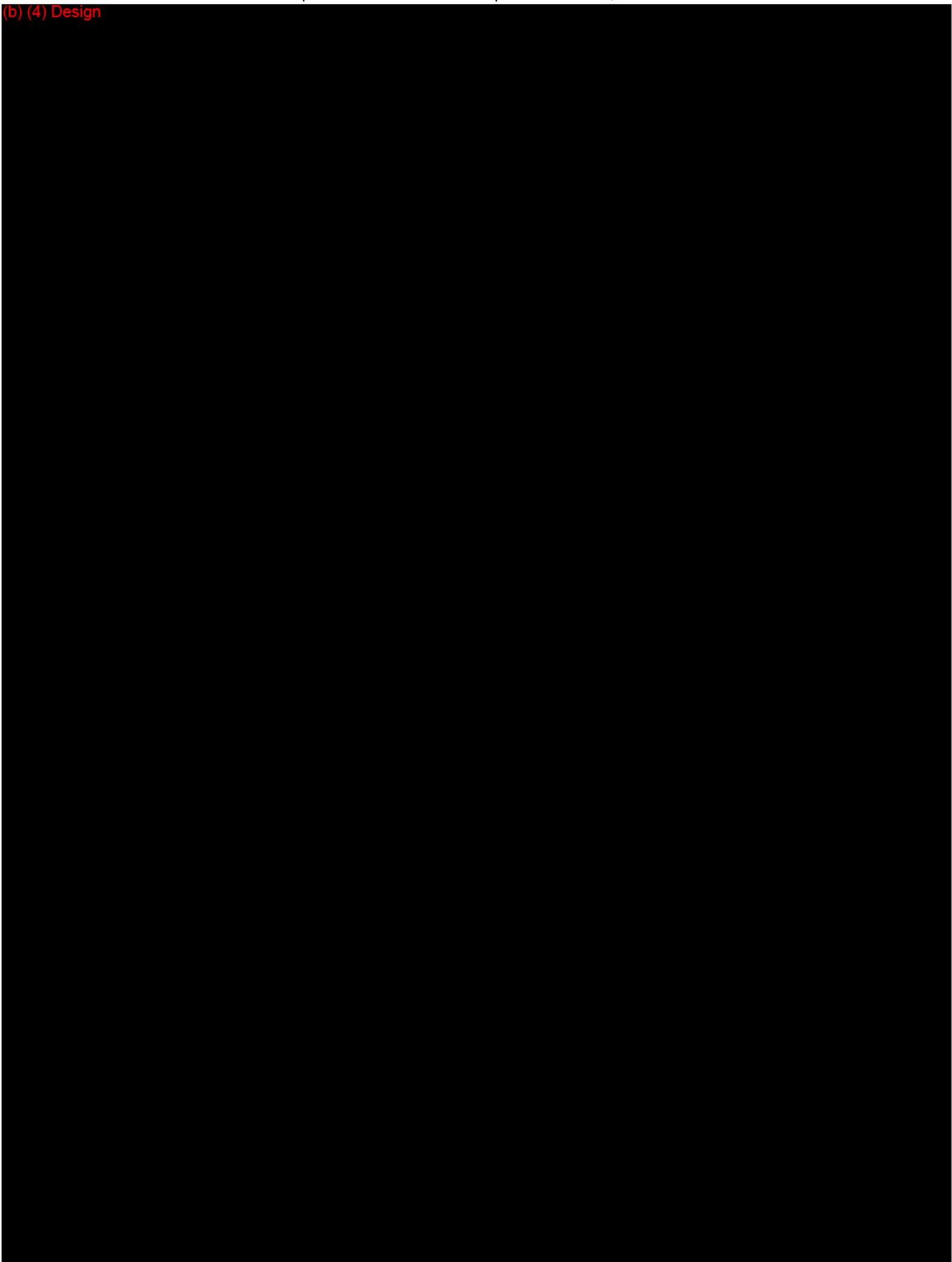
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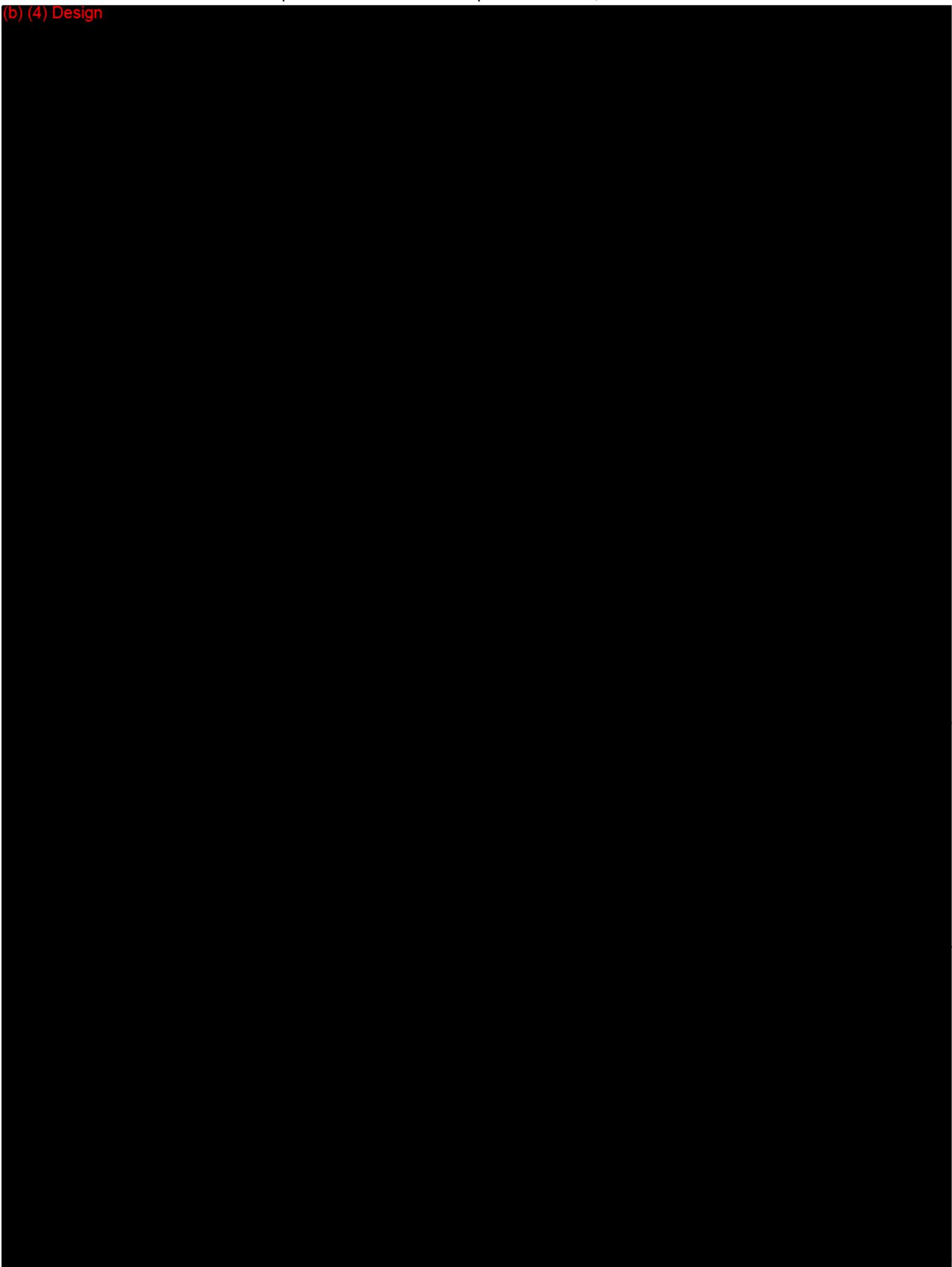
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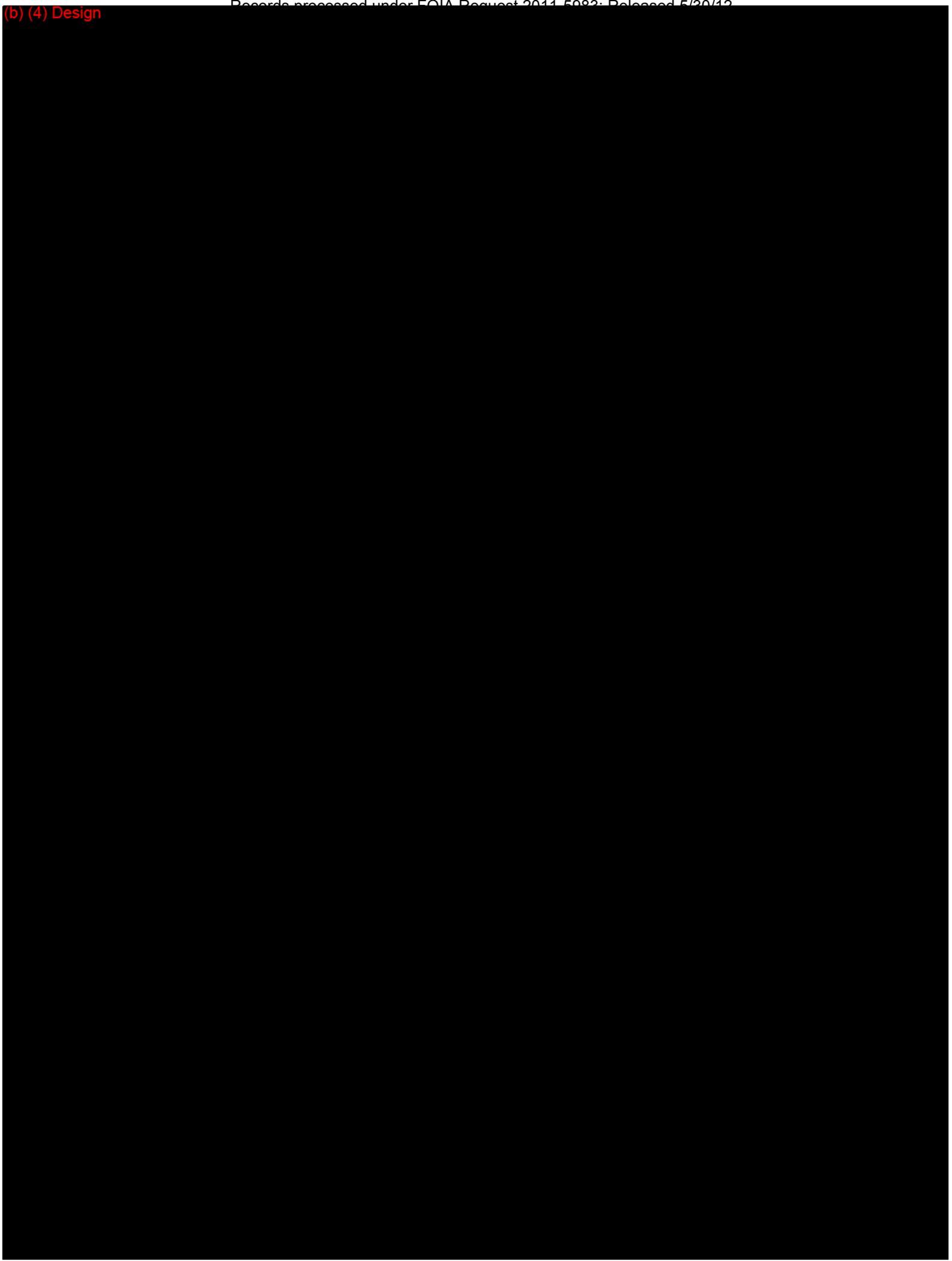
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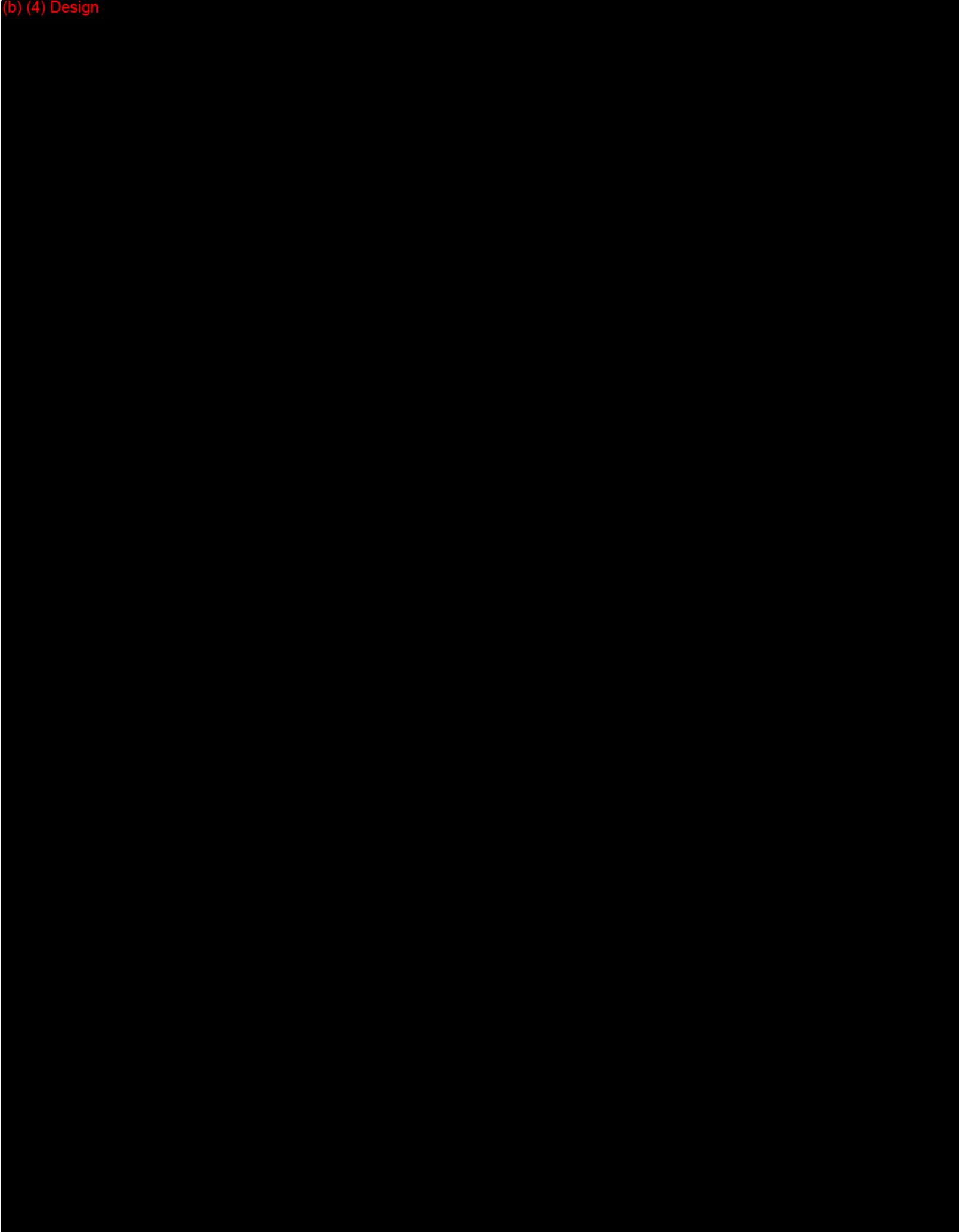
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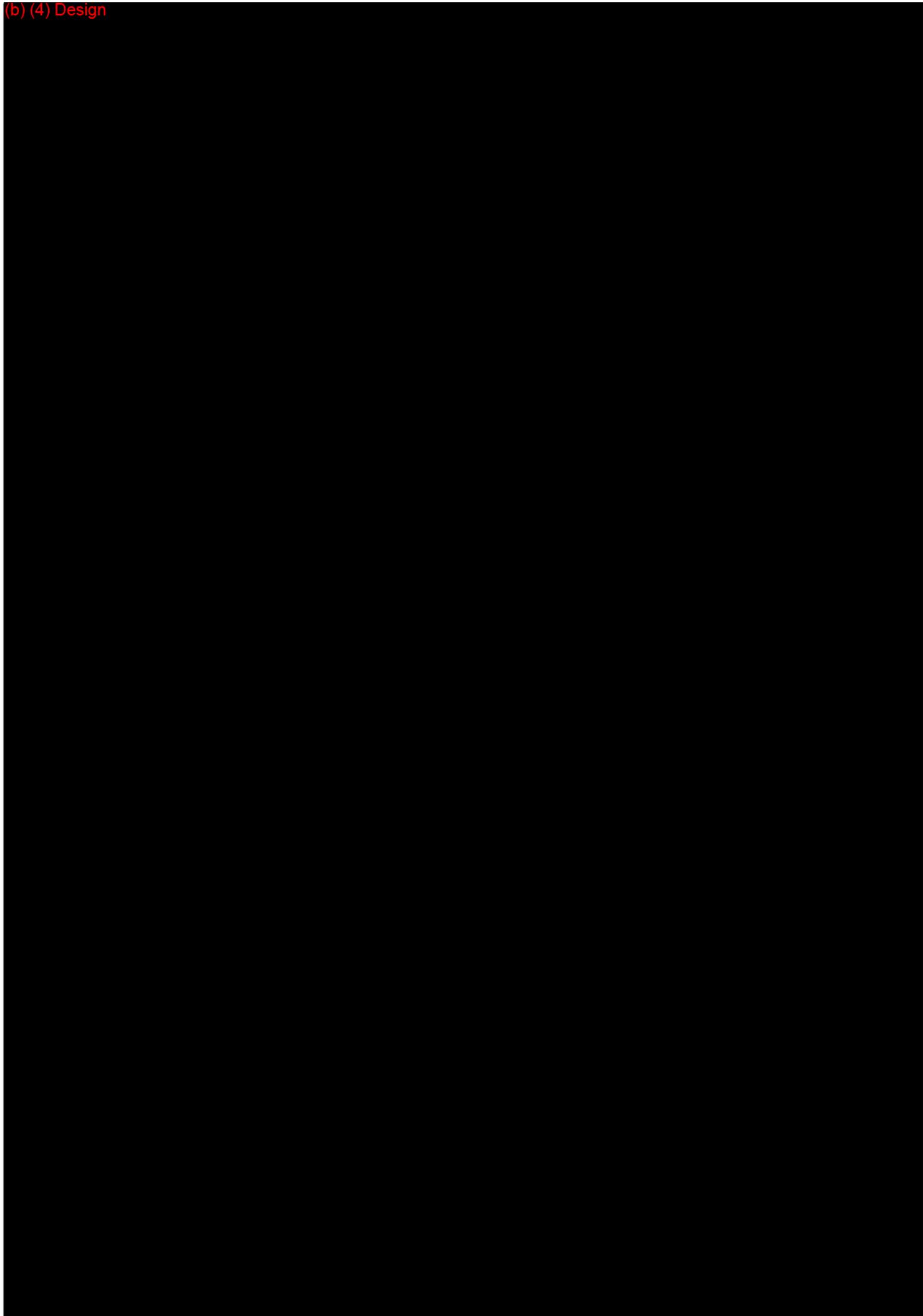
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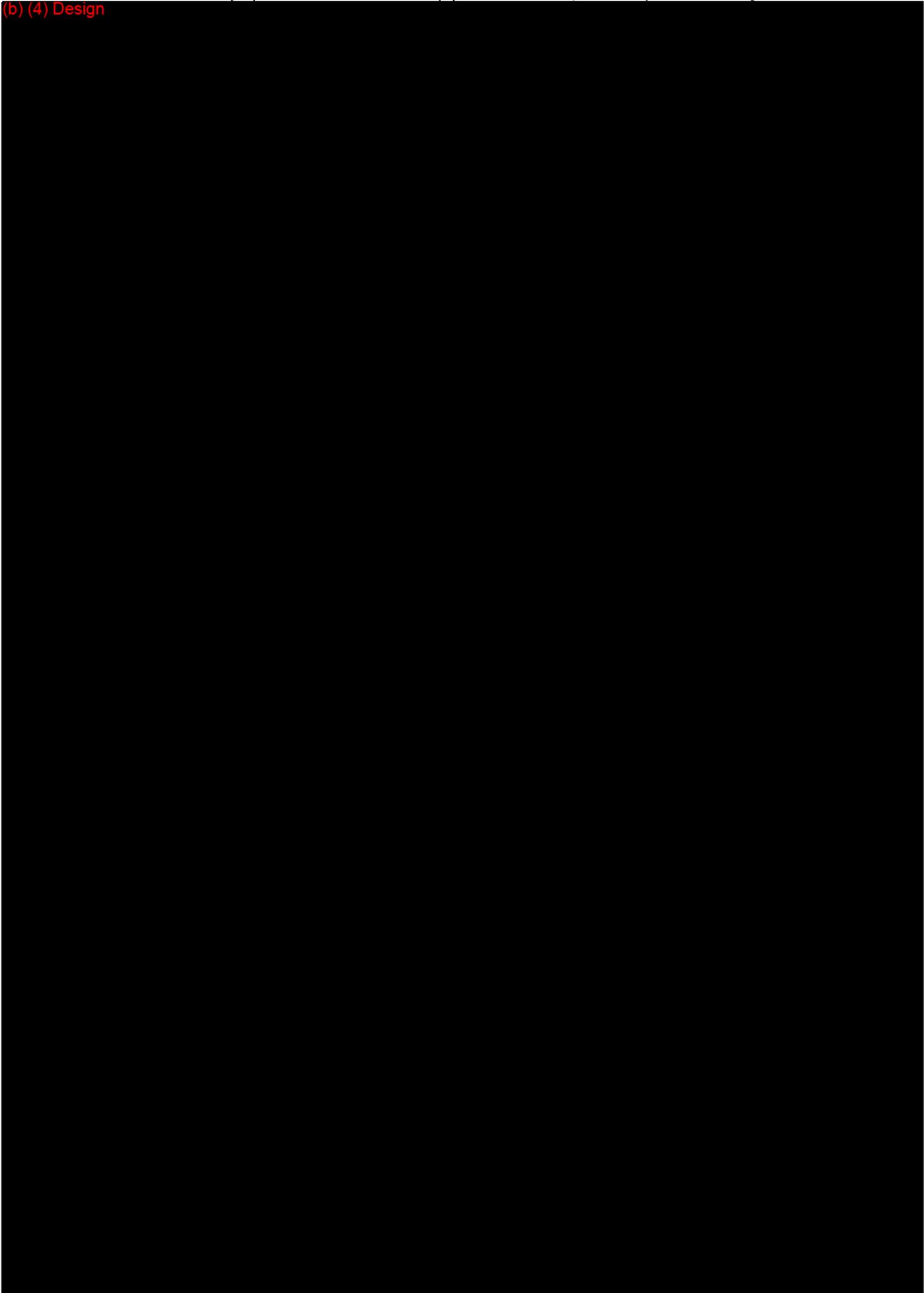
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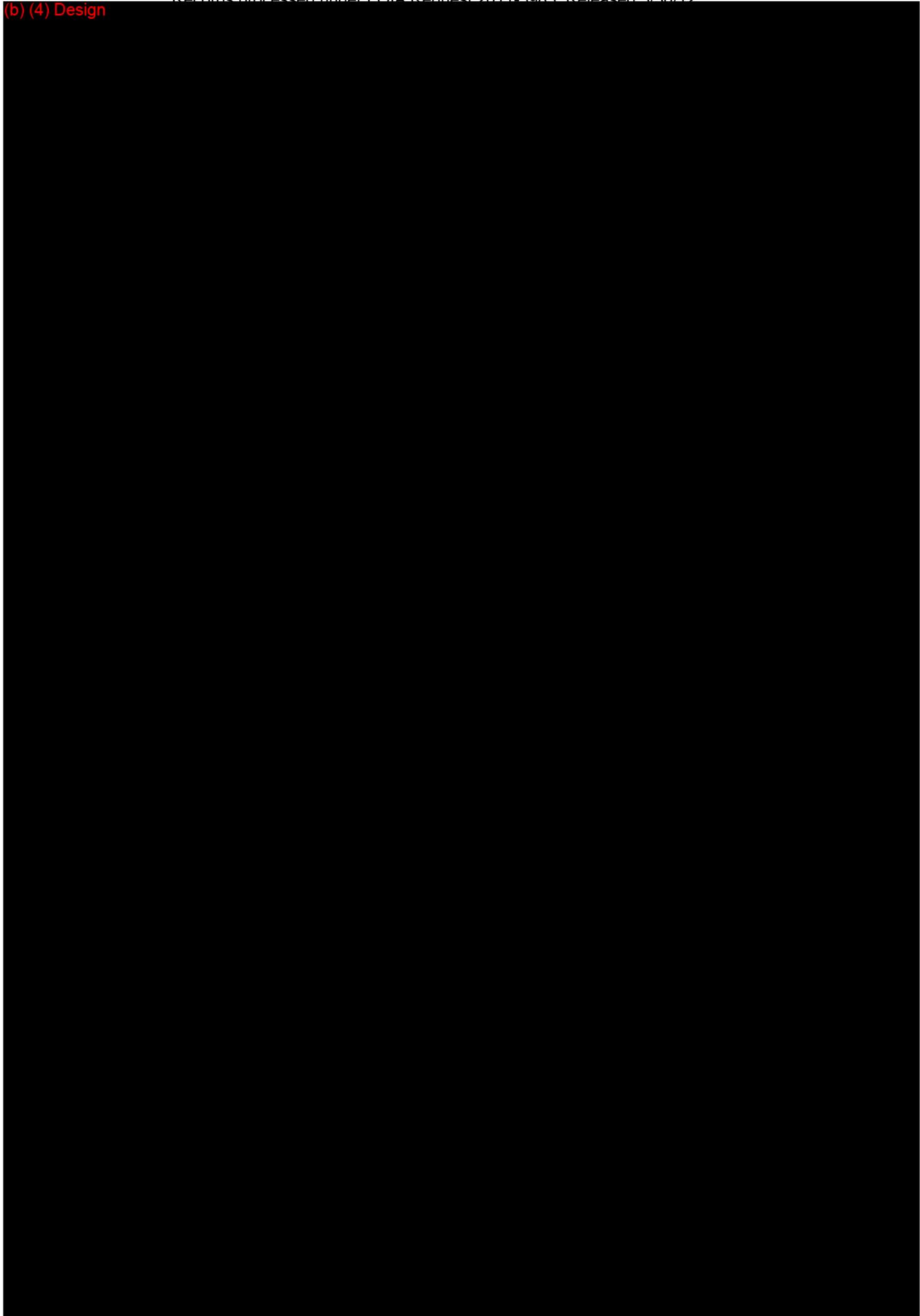
SCR[®] Modular Tibial Tray

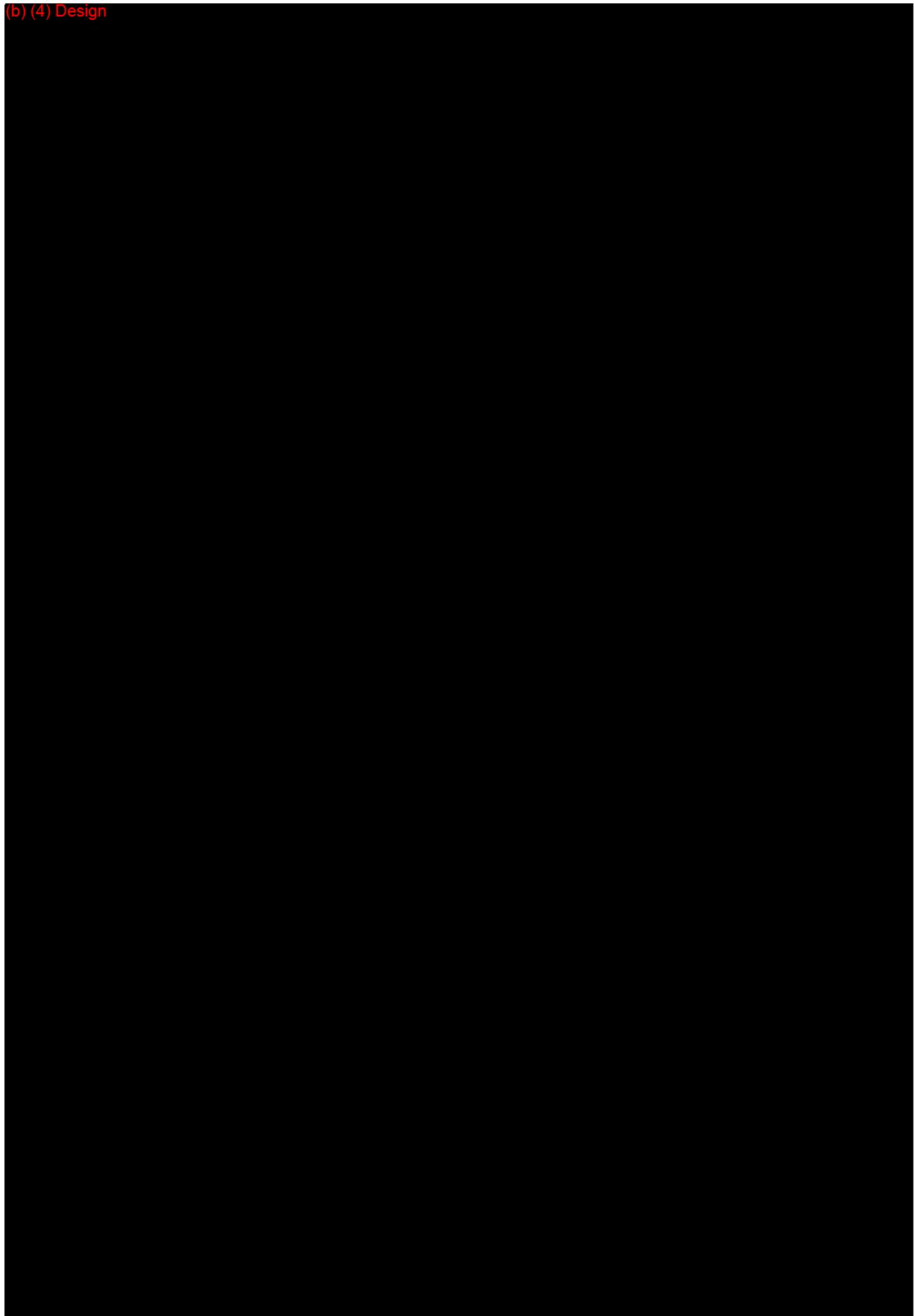


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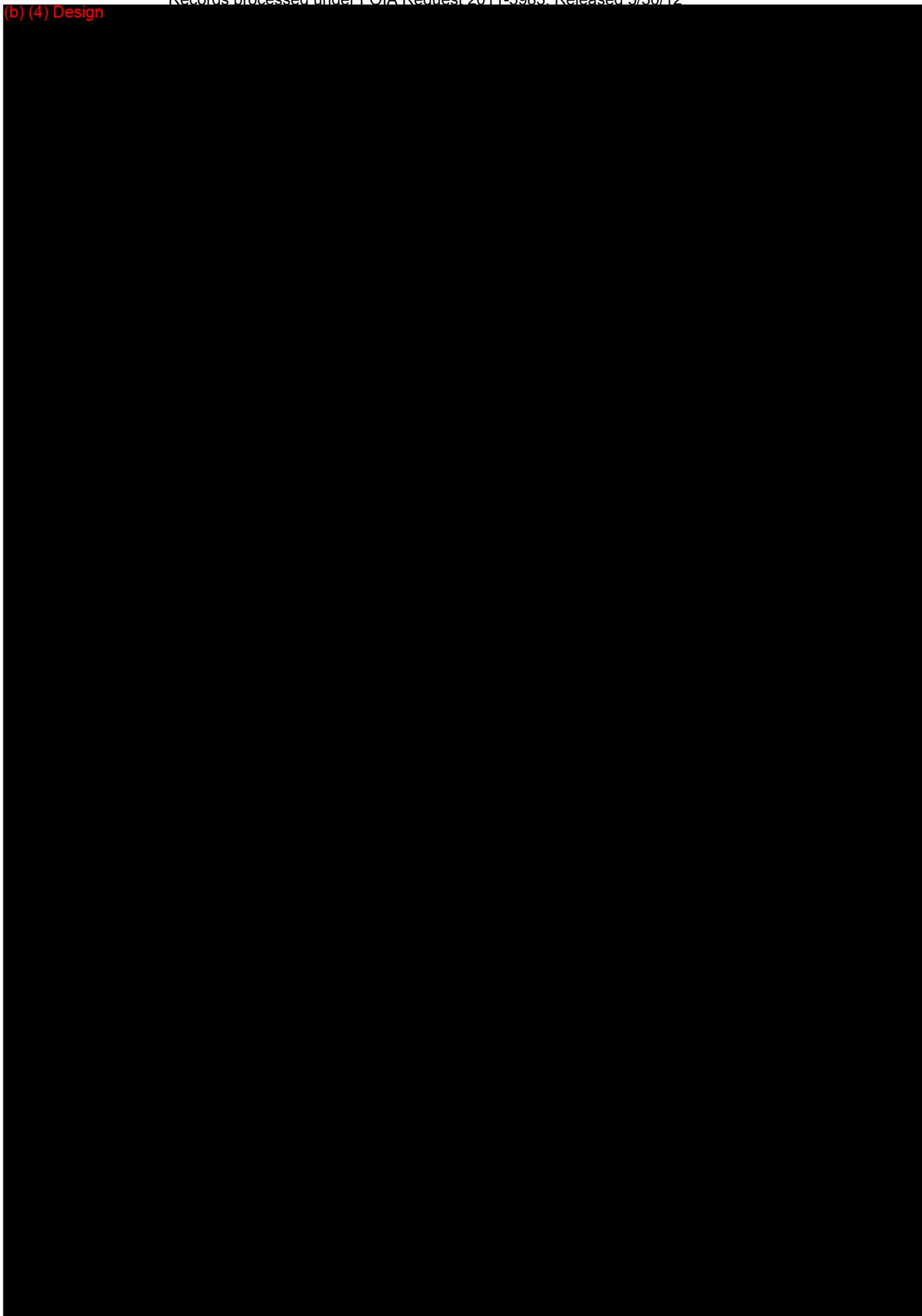


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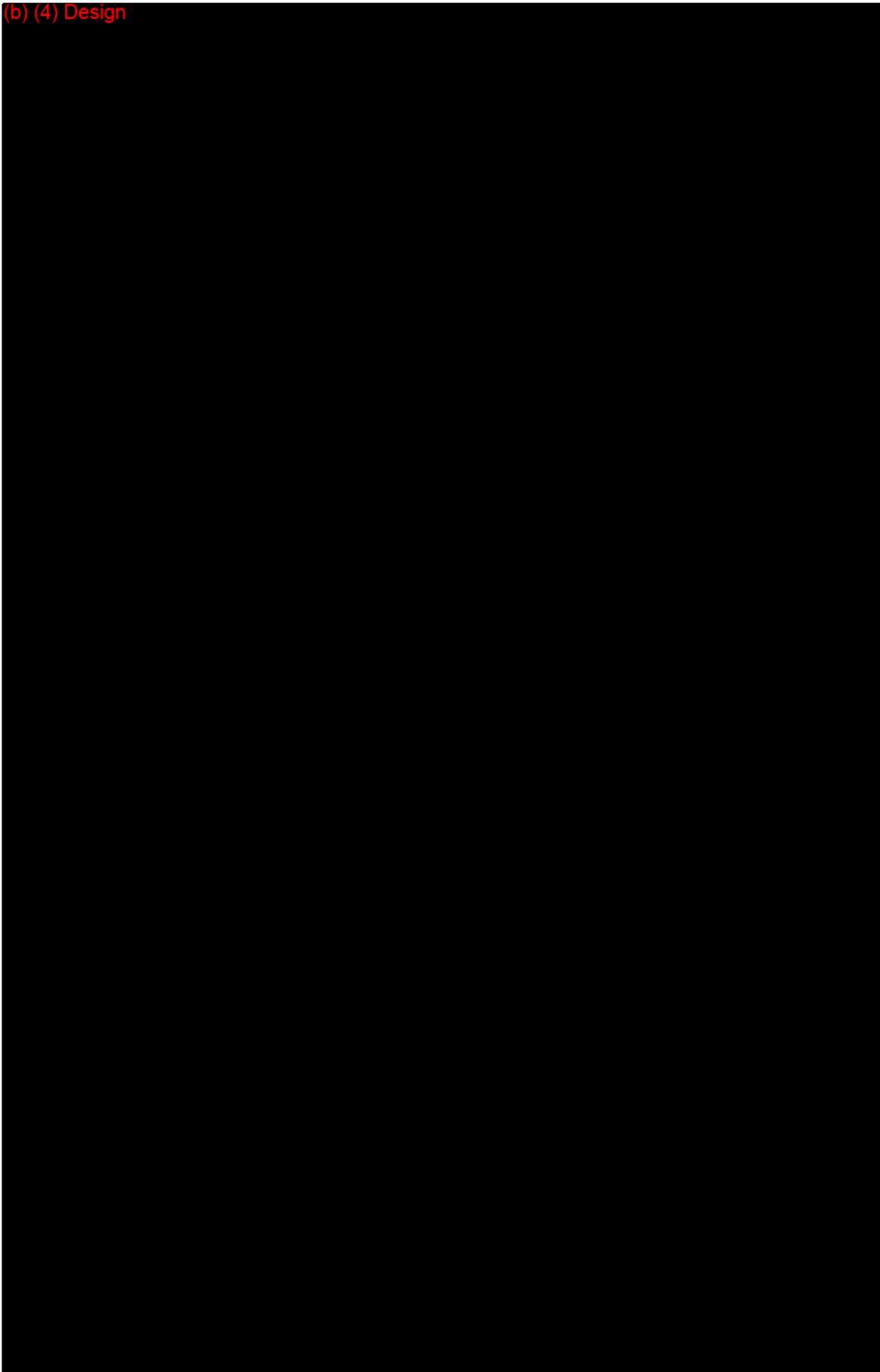


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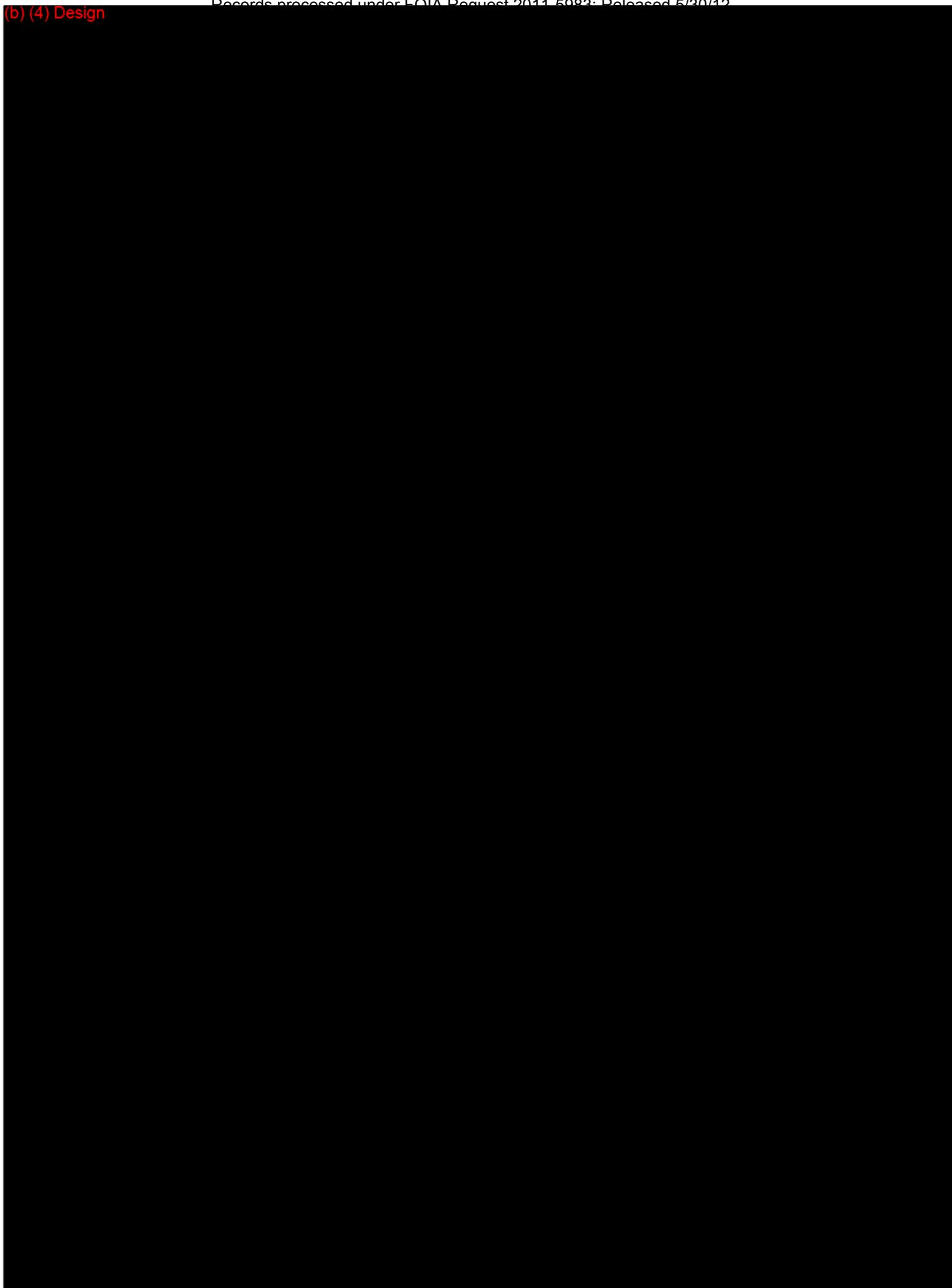
Page 32

CONFIDENTIAL

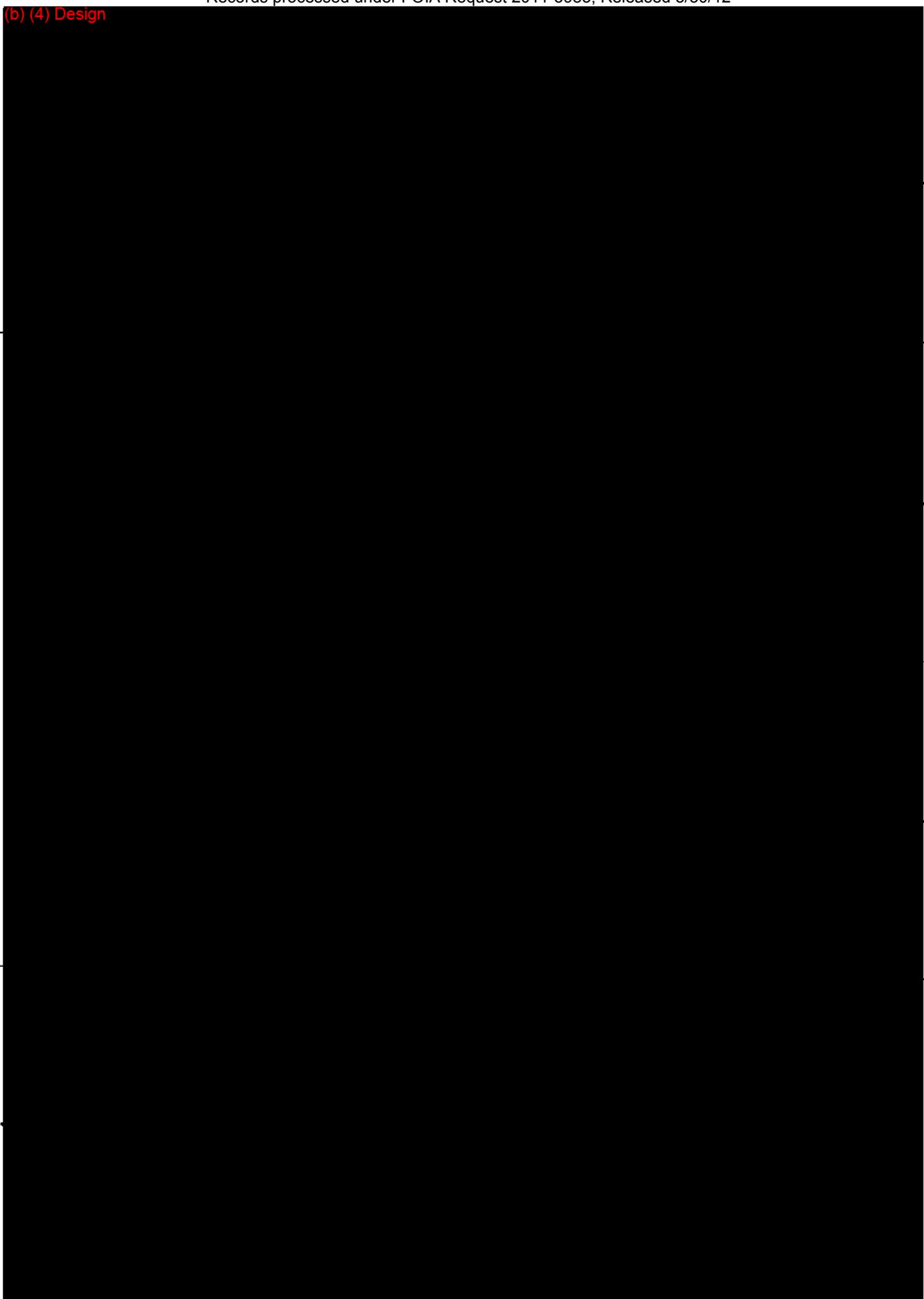
159

SCR[®] Tibial Bearing Insert

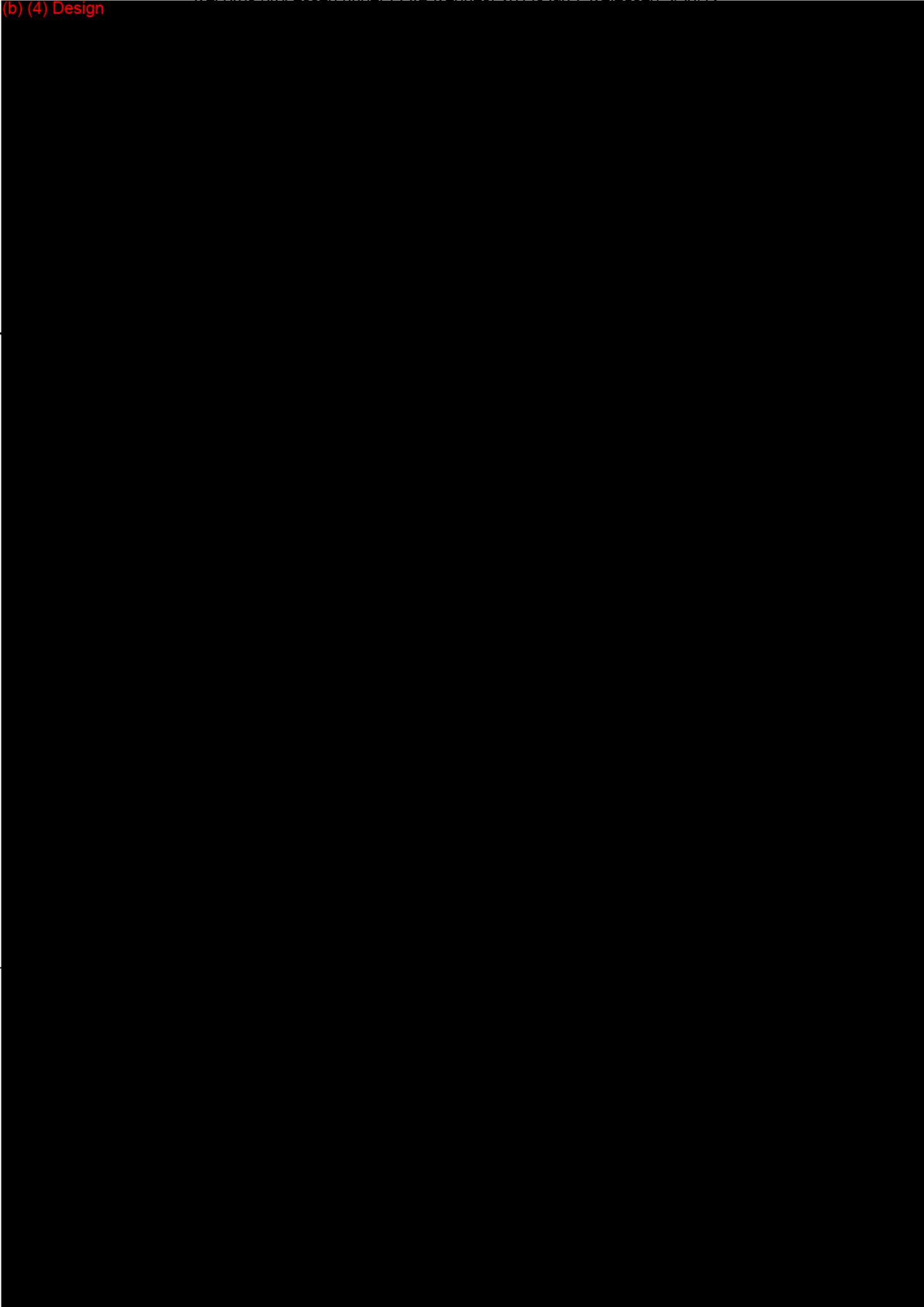
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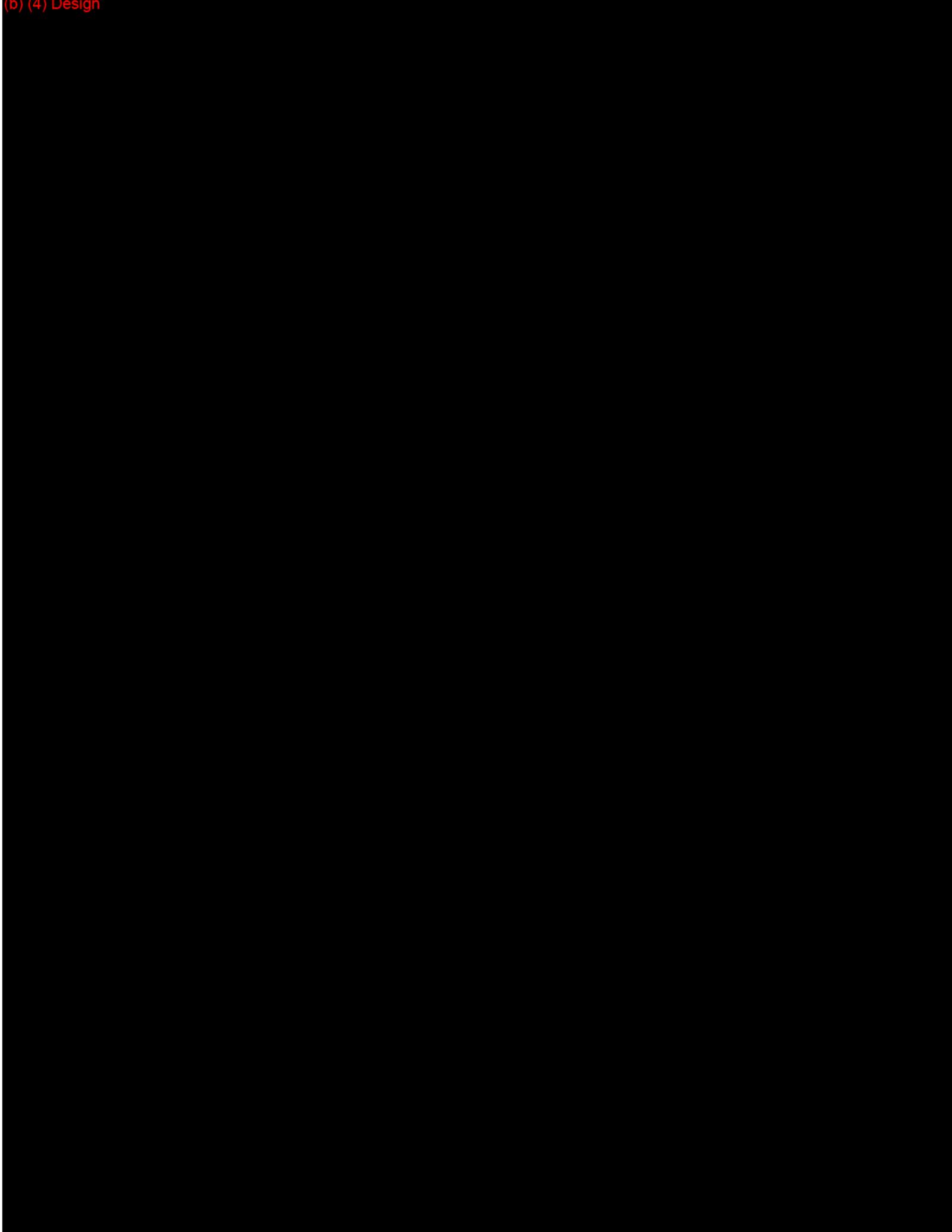


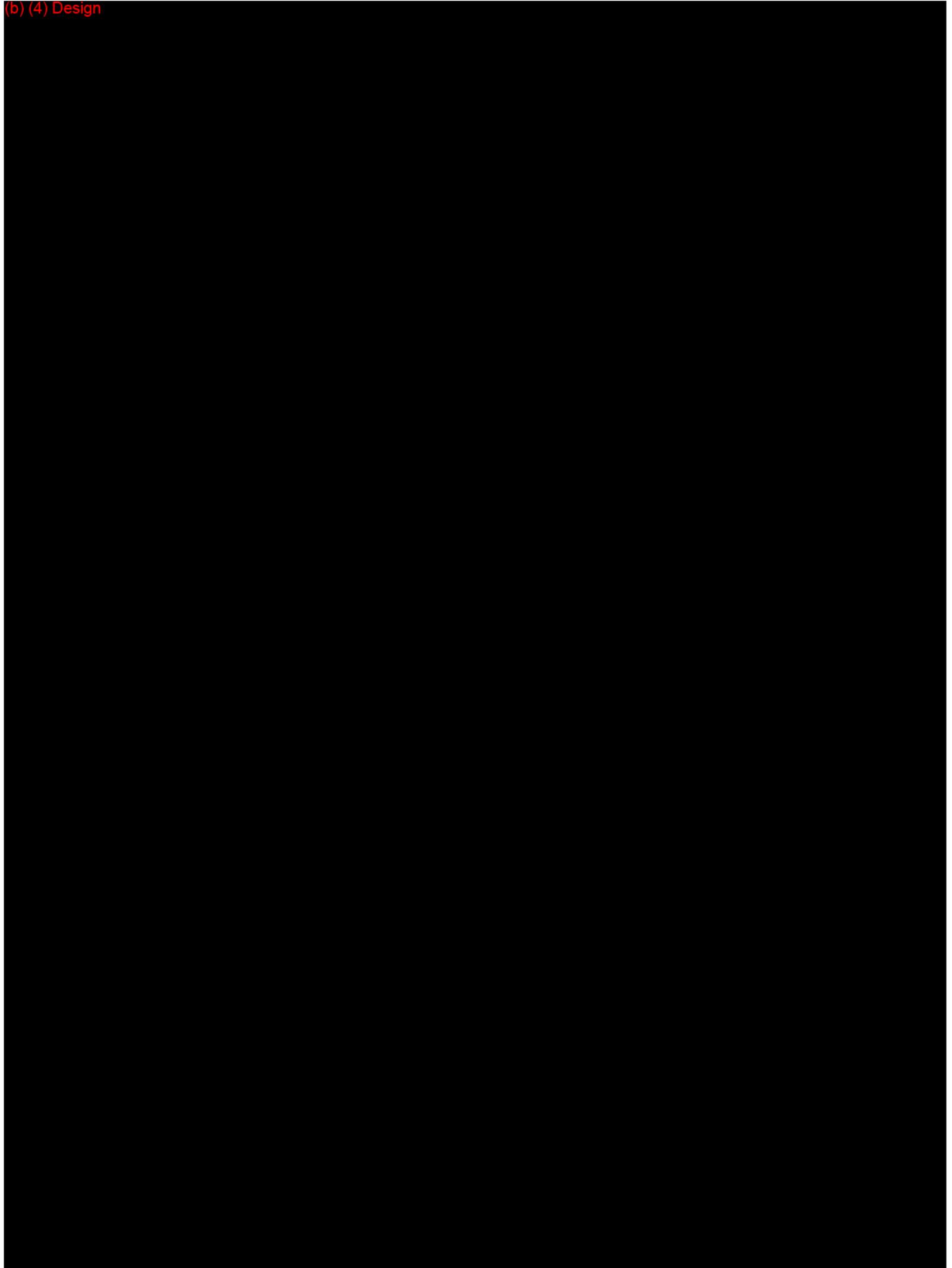
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(b) (4) Design





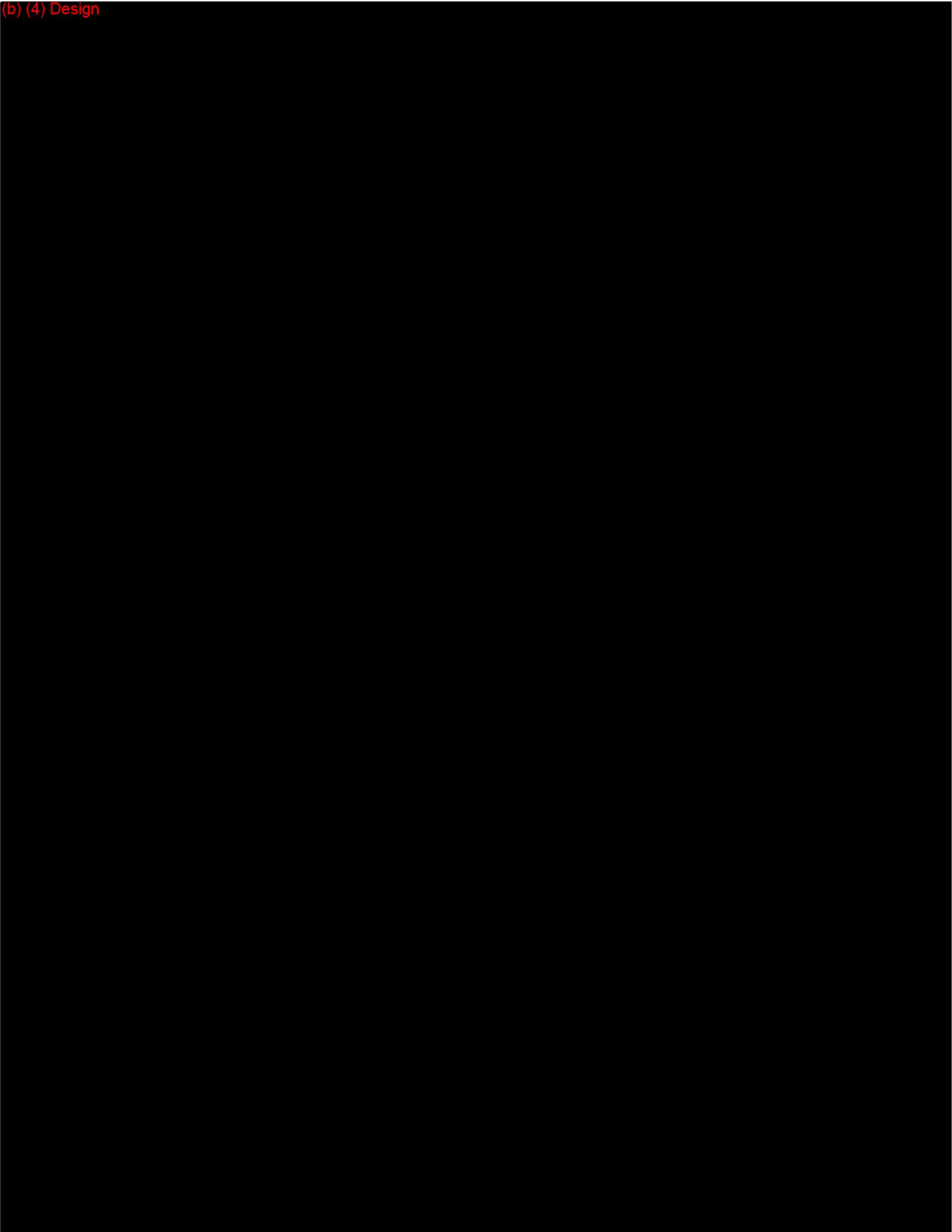


UNIX™ Components

166

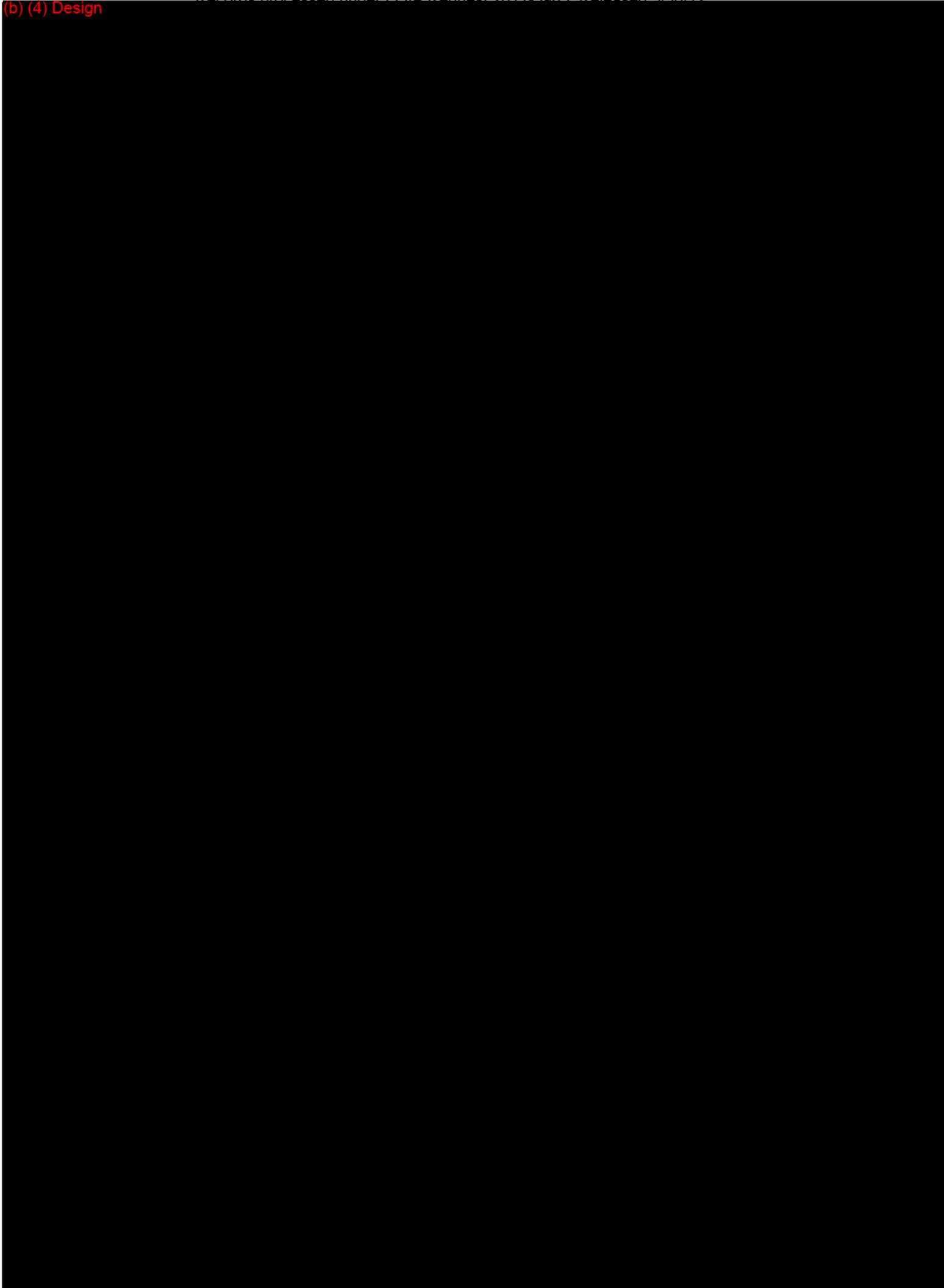
UNIX™ Femoral Component

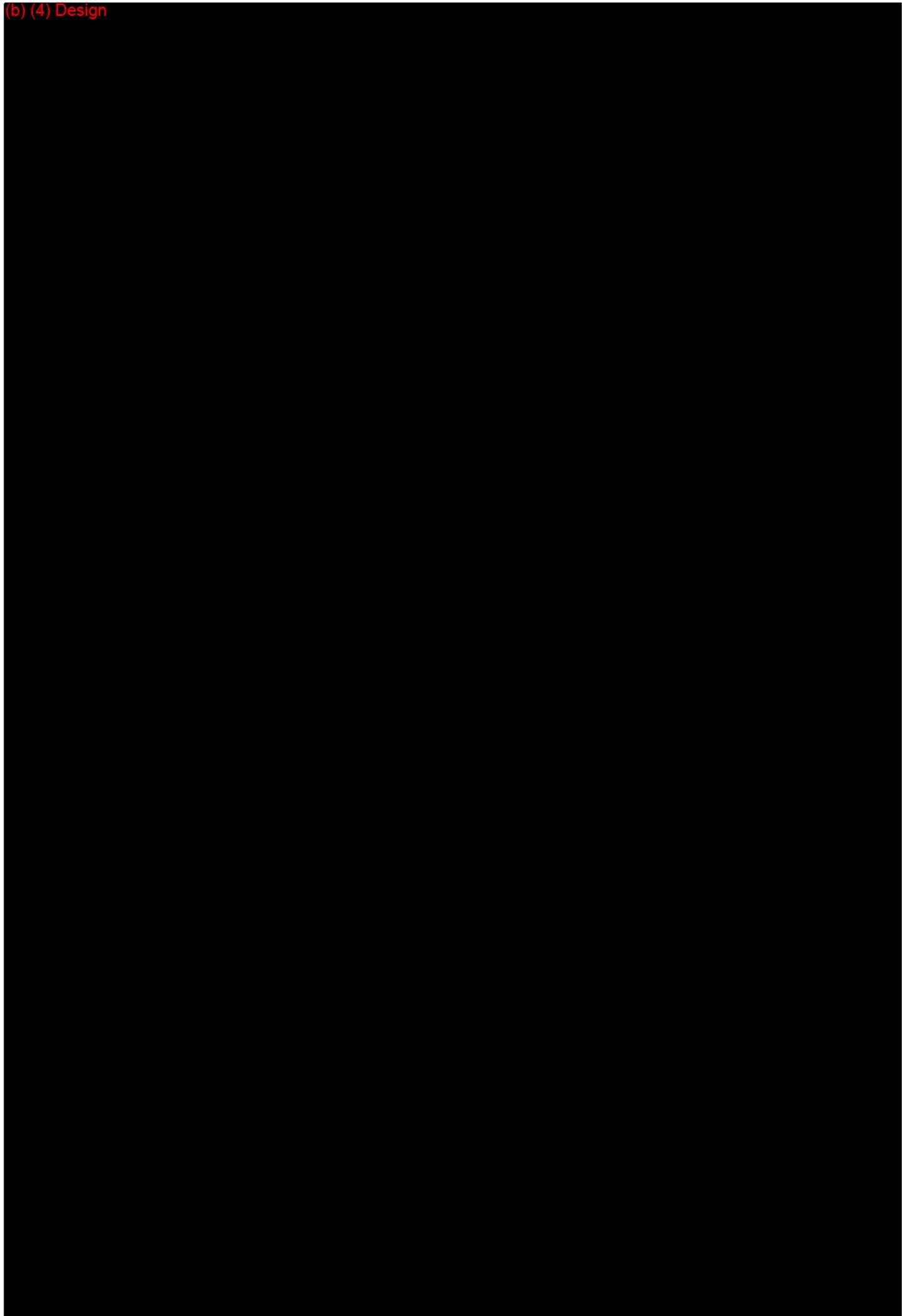
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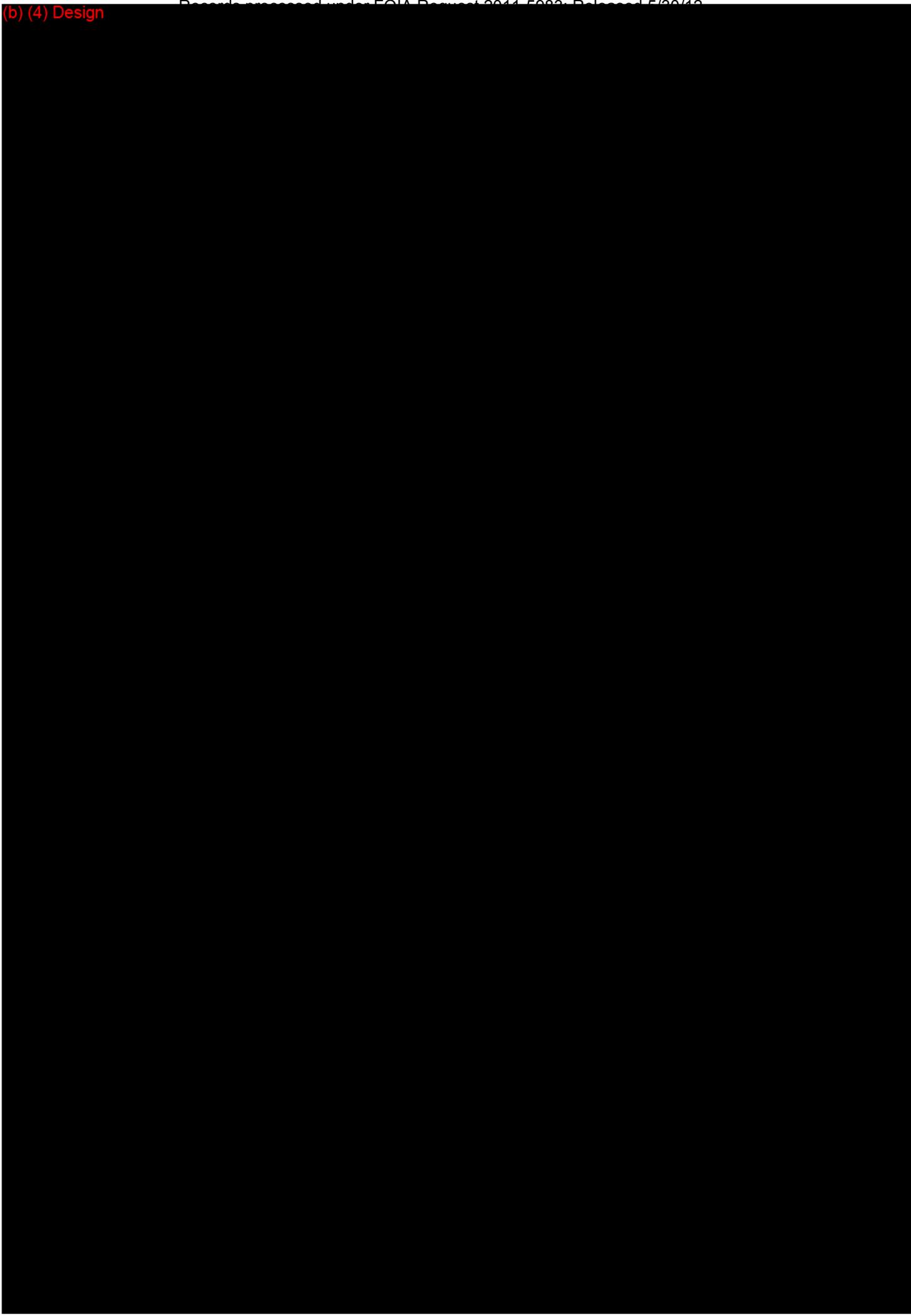
UNIX™ Modular Tibial Tray

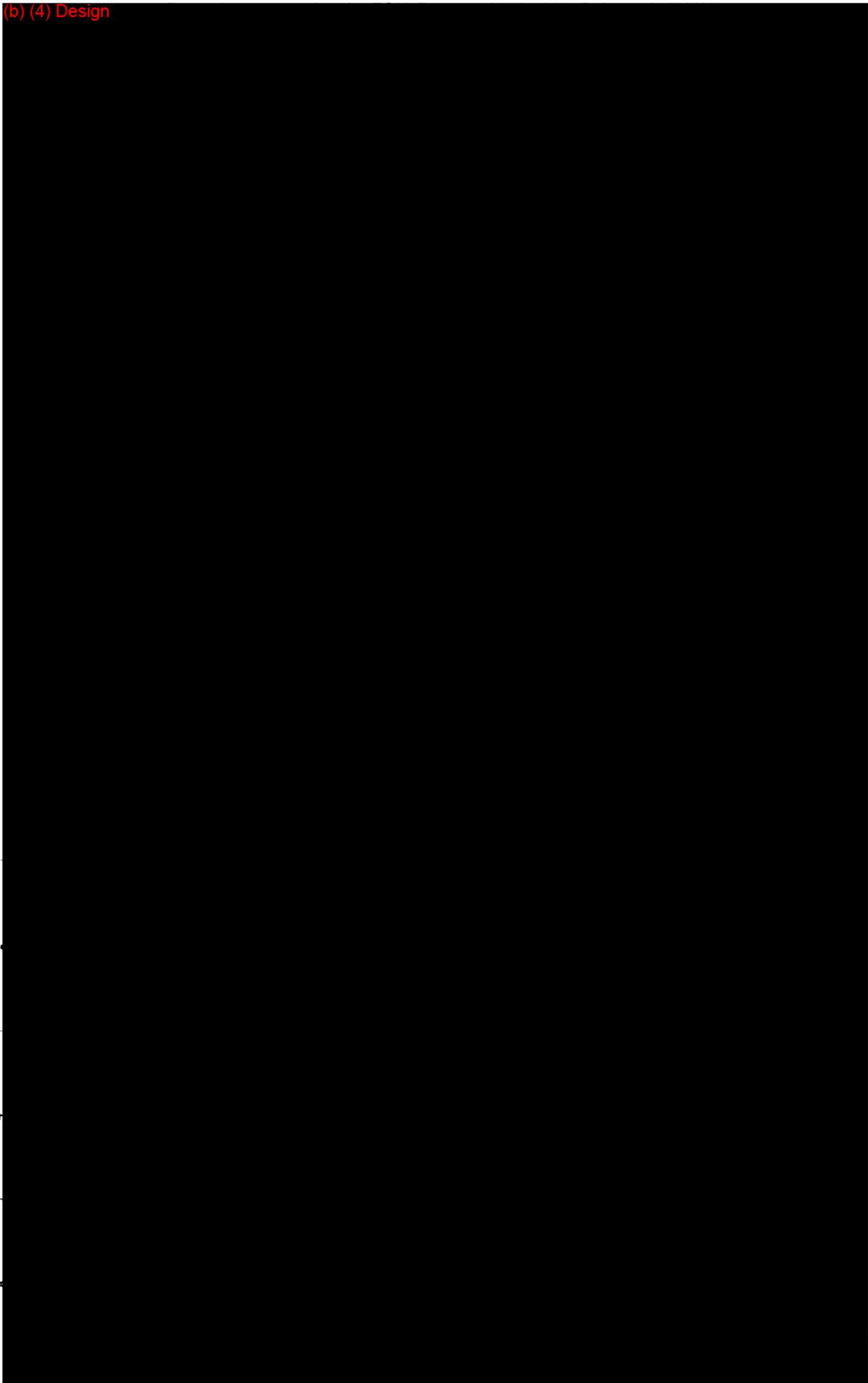
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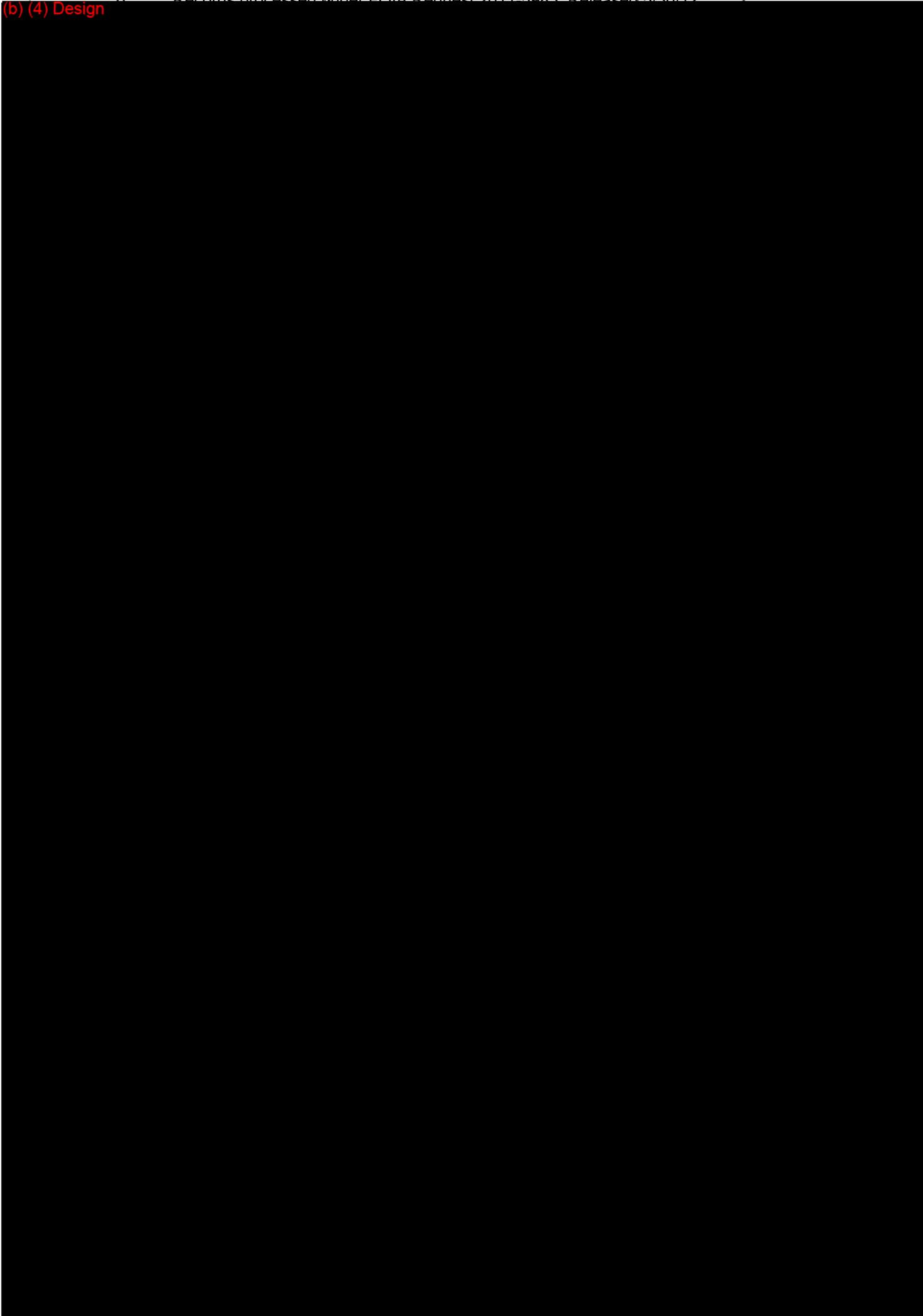
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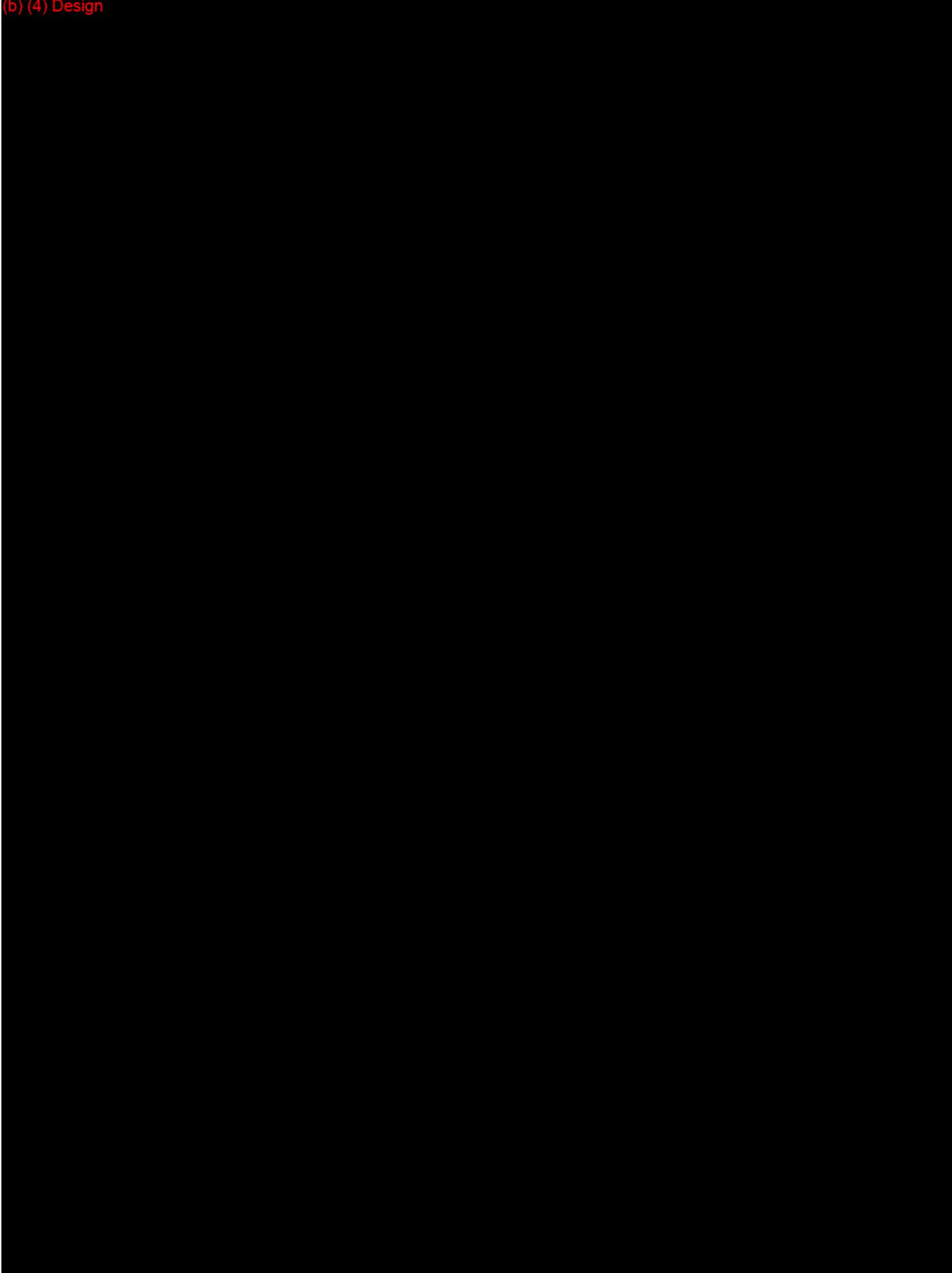


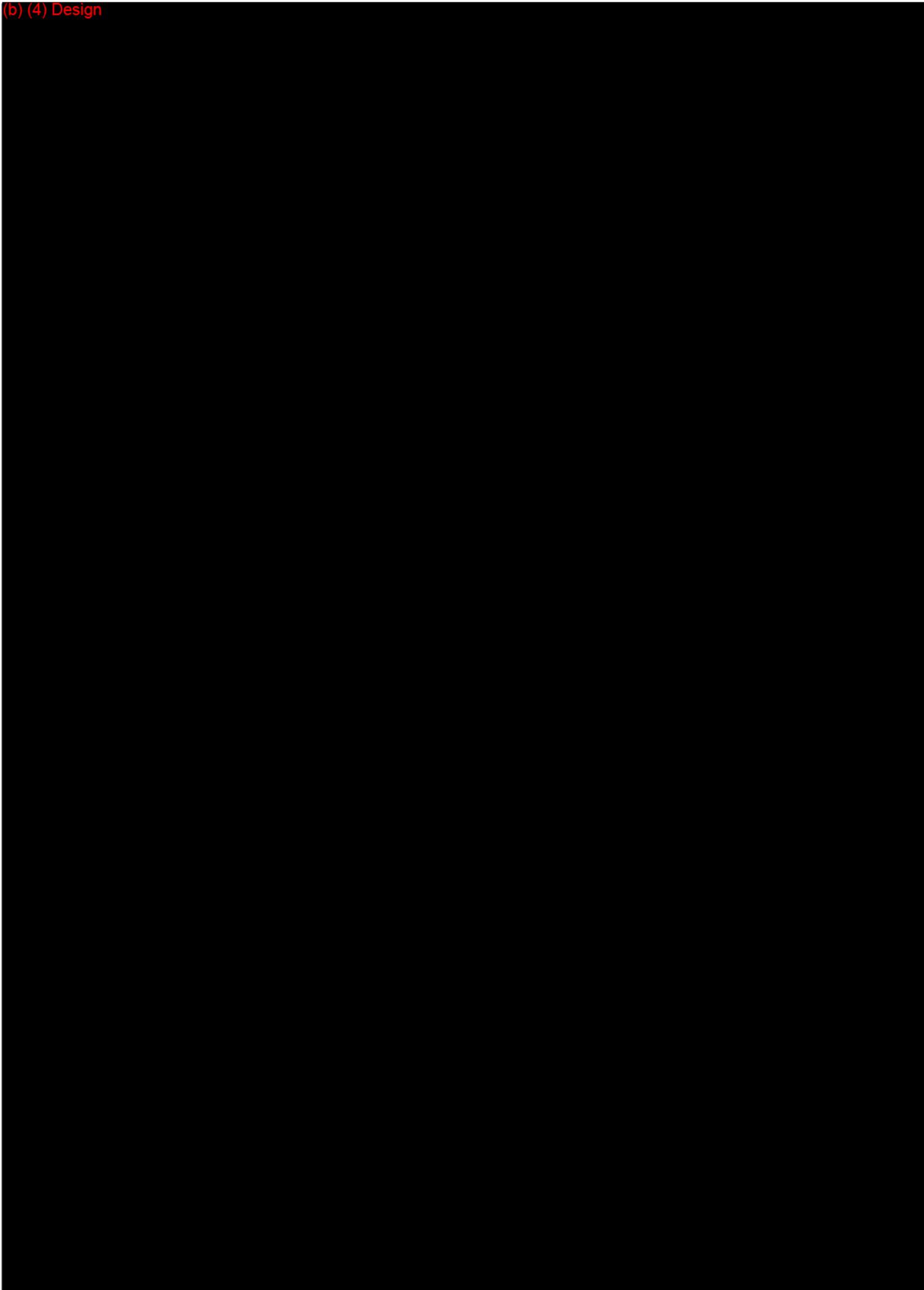
UNIX™ Tibial Insert

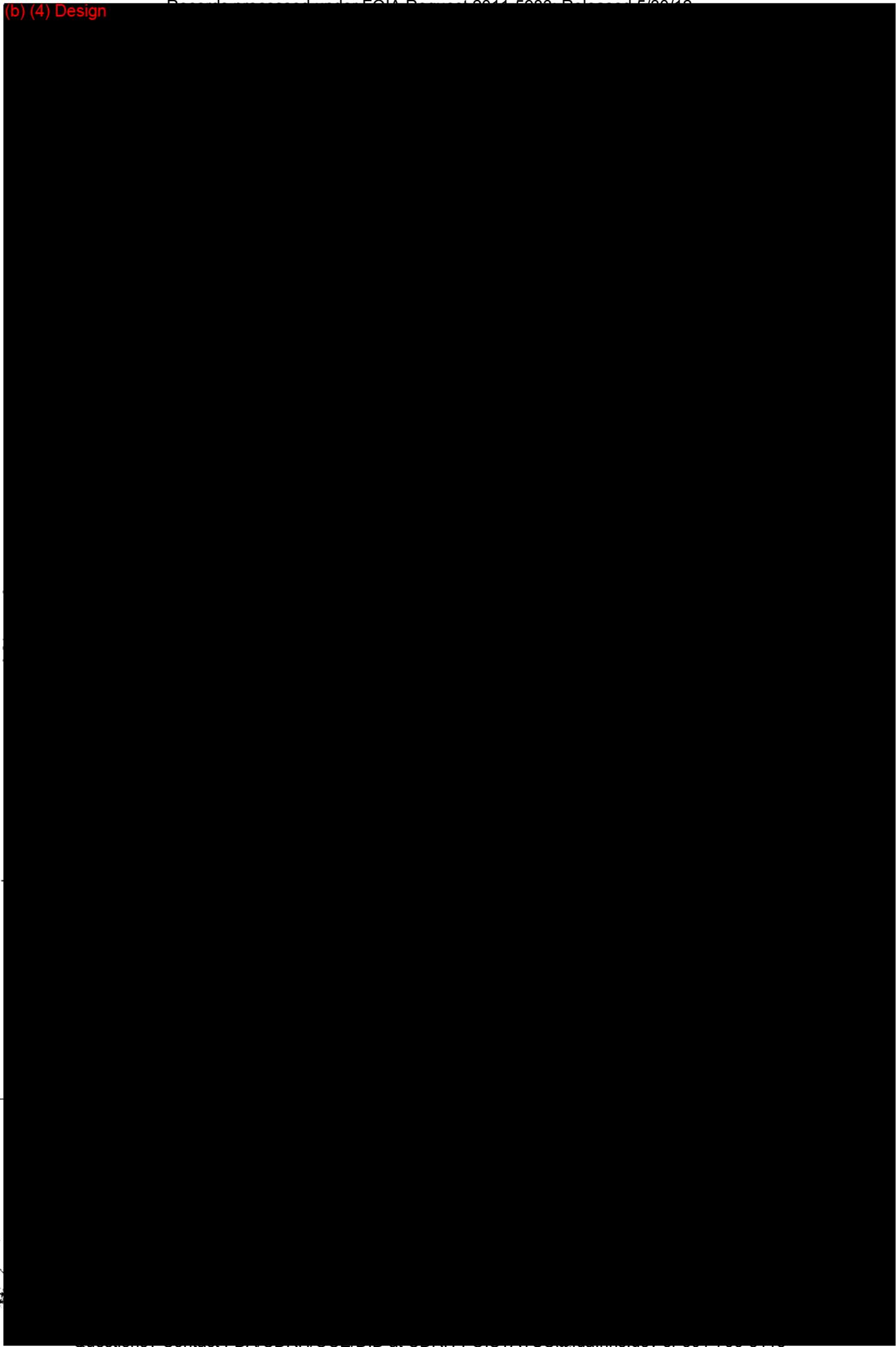
(b) (4) Design



(b) (4) Design







Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX B
PACKAGING INFORMATION

- B-1** Draft Labels
- B-2** Draft Package Insert for Stryker® Compartmental Knee
- B-3** Draft Package Insert for Stryker® Unicompartmental Knees
- B-4** Draft Package Insert for Avon® Patello-Femoral Joint Prosthesis
- B-5** Draft Surgical Technique

Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX B-1
Draft Labels

Draft Label
Unicondylar Femoral Component Sample Label

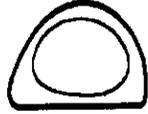
<p>REF 4510 - 002L</p> 	<p>UNIX Uni Knee Femoral Component #2 LEFT</p> <hr/> <p>UNIX Uni Composant Femoral #2 GAUCHE</p> <hr/> <p>UNIX Uni Femurkomponente #2 LINKS</p> <hr/> <p>LOT C1212 SAMPLE 2007 - 01</p>
<p>Howmedica OSTEONICS Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430, USA A Subsidiary of Stryker Corp.</p> <p style="text-align: right; font-size: small;">Authorized Representative in Europe: Stryker France ZAC Sables Green Puygnan Av. de Sables Green 69881 MEY ZIEU Cedex, France.</p>	
<p>REF 4510 - 002L (STERILE) R Cobalt Chrome LOT C1212 SAMPLE</p>	
<p>Unix uni-knee femoralkomponent #2 Vasstre</p>	<p>UNIX Uni Femurkomponent #2 LINKS</p>
<p>Componente femoral unicompartmental Unix d/Joelho N.º 2 Esquerdo</p>	
<p>Unix Uni -poin Reisiluusosa #2 Vasen</p>	
<p>Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.</p>	
<p>2002 - 01 2007 - 01</p> <p style="font-size: x-small;">Made in Ireland</p>	
<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg); text-align: center;"> <p>REF 4510 - 002L</p> <p>LOT C1212 SAMPLE</p> </div> <div style="text-align: center;"> <p>Howmedica OSTEONICS 0086</p> <p>REF 4510 - 002L (STERILE) R LOT C1212 SAMPLE</p> <p>UNIX Uni Knee Femoral Component #2 LEFT Cobalt Chrome</p>  <p>***E0254510002L1A***</p>  <p>***\$C1212SAMPLEAD***</p> </div> </div>	
<p>Warning: Device is intended for cemented use only in USA</p>	

Note: Reference number and description will vary depending on product family

Draft Label
Tibial Insert Sample Label

OSTEONICS
UNIX UNI KNEE
Tibial Bearing Insert

Catalog No. **4540-0210**
#2



· 10mm Thick

N Vac™
Howmedica Osteonics Corp.
Stryker Ireland
Carrigtwohill Industrial Estate
Carrigtwohill, County Cork
Ireland



+H8254540021003



+\$\$8010810CASECASECA3W

Authorized Representative in Europe
Stryker France
ZAC Satolas Green Pusignan
Av de Satolas Green 69881 Meyzieu
Cedex France



UHMWPE

2010-08

STERILE R  **CE0086** 

CAUTION: Federal Law(USA) restricts this device to sale by or on the order of a Physician

Warning: Device is intended for cemented use only in USA

Note: Reference number and description will vary depending on product family

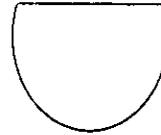
Draft Label
Tibial Component Sample Label

**OSTEONICS
UNIX UNI KNEE**

Catalog No. **4530-0110**

#1

All Polyethylene Tibial Component



· 10mm Thick



Howmedica Osteonics Corp.
Stryker Ireland
Carrigtwohill Industrial Estate
Carrigtwohill, County Cork
Ireland



+H8254530011001



+\$\$8010810CASECASECA1U

Authorized Representative in Europe
Stryker France
ZAC Satolas Green Pusignan
Av de Satolas Green 69881 Meyzieu
Cedex France



UHMWPE

2010-08

STERILE R



CE0086



CAUTION: Federal Law(USA) restricts this device to sale by or on the order of a Physician

Warning: Device is intended for cemented use only in USA

Note: Reference number and description will vary depending on product family

183

Draft Label
Tibial Component Sample Label

REF **6636-2-306**

EIUS® UNI KNEE

Tibial Component

- All Polyethylene
- Left Medial/Right Lateral
- X-Small
- 6mm Thickness



Composant tibial
· Tout · polyethylene · Très Petit · Interne gauche/latéral droit · Épaisseur 6mm

Tibiakomponente
· Aus Polyethylen · Extra Klein · Links medial/Rechts lateral · Dicke 6mm

Componente tibiale
· Tutto in polietilene · Extra Piccolo · Sinistro mediale/destro laterale · Spessore 6mm

Componente tibial
· Polietileno · Extra Pequeño · Medial izquierdo/lateral derecho · 6mm Grosor,

Tibiacomponent
· Geheel en al van polyethyleen · Extra Klein · Links mediaal/rechts lateraal · 6mm Dikte

Tibial komponent
· 100% polyetylen · Extra Liten · Vänster medial/höger lateral · 6mm tjocklek

N Vac

Authorized representative in Europe
RA/QA Manager
STRYKER France
BP 50040-95946 Roissy CDG Cedex
FRANCE
Tel. (33) 1.48.17.50.00




UHMWPE

STERILE R **CE0473** **2008-09**

CAUTION: Federal Law(USA) restricts this device to sale by or on the order of a Physician



+H825663623060J



+\$\$8010908TESTJ6

HOWMEDICA OSTEONICS CORP.
59 Route 17
Allendale, NJ 07401
A subsidiary of Stryker Corp.

Warning: Device is intended for cemented use only in USA

Note: Reference number and description will vary depending on product family

184

Draft Label
 Avon® Femoral Component Sample Label

stryker Howmedica OSTEONICS REF 6430 - 0 - 050	Avon Patello-Femoral Joint Femoral Prosthesis X-Small
	Articul. patello-femorale Avon Prothese Femorale X-Petit
	Avon Patello-Femoralgelenk Femurprothese X-Klein
	LOT E1212 SAMPLE 2009 - 01

stryker Howmedica OSTEONICS	CE 0050		
Howmedica International S.de R.L. Raheen Business Park, Limerick, Ireland.			
REF 6430 - 0 - 050	STERILE R	Vitallium®	LOT E1212 SAMPLE
Avon Patello-lärljed Femurprotese X-Small	Avon patello-femoraal gewricht Femurprothese X-Klein		
Prótese Femoro d/ Articul. Femoro-rotuliana Avon X-Pequeno			
Avon-patellofemoraalnivel Reisiluun Proteesi X-Pieni			
Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital.			
 2004 - 01 Made in IRELAND			 2009 - 01



*+E025643000501 *



+\$E1212SAMPLE 0

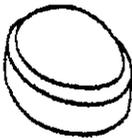
Warning: Device is intended for cemented use only in USA

Note: Reference number and description will vary

185

Draft Label
Patellar Component Sample Label

Howmedica
REF 6642-2-620



Howmedica Osteonics Corp.
Stryker Ireland
Carrigrohilly Industrial Estate
Carrigrohilly, County Cork

Authorized Representative in Europe
Stryker France - ZAC Satolas Green Pusignan
Av de Satolas Green 69881 Meyzieu
Cedex France

DURACON® TOTAL KNEE SYSTEM
SYMMETRIC PATELLA
31mm X 9mm

Système total de genou DURACON®
Rotule symétrique
31mm X 9mm

DURACON® Totalkniesystem
Symmetrische Patella
31mm x 9mm

LOT CASECASECA  2010-06

CE0086
LOT CASECASECA

REF 6642-2-620

ΟΛΙΚΟ ΣΥΣΤ. ΓΟΝΑΤ. DURACON®
ΣΥΜΜΕΤΡΙΚΗ ΕΠΙΓΟΝΑΤΙΔΑ
31mm X 9mm

SISTEMA JOELHO TOTAL DURACON®
RÓTULA SIMÉTRICA
31mm X 9mm

DURACON® TOTALE KNIE-SYSTEEM
SYMMETRISCHE PATELLA
31mm X 9mm

STERILE R Duration® Stabilized UHMWPE

Sist.Ginocchio Totale DURACON®
Rotula simmetrica
31mm X 9mm

DURACON® Sistema Rodilla Total
Patela Simétrica
31mm X 9mm

Duracon® Total Knee-system
Symmetrisk patella
31mm X 9mm

Caution: Federal law in USA restricts this device to sale by or on the order of a physician or hospital

 2005-06





 2010-06

U.S. Pat.
Made in IRELAND



+H825664226200F



+\$\$8010610CASECASECAF%

Warning: Device is intended for cemented use only in USA

Note: Reference number and description will vary depending on product family

186

Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX B-2

Draft Package Insert for Stryker® Compartmental Knee

DRAFT PACKAGE INSERT

STRYKER® COMPARTMENTAL KNEE SYSTEM

Description

The Stryker® Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patello-femoral joint and/or the condyle region(s) of the femoral joint. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and/or unicondylar arthroplasty. The characteristics specific for each component are detailed on the product label.

Materials

Femoral Components	ASTM F-75 cobalt chromium alloy
Modular Tibial Trays	ASTM F-75 cobalt chromium alloy
Tibial Inserts	ASTM F-648, Ultra-high molecular weight polyethylene
Tibial Components	ASTM F-648, Ultra-high molecular weight polyethylene
Patellar Components	ASTM F-648, Ultra-high molecular weight polyethylene

Indications for Use

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartamental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartamental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

Contraindications

1. For patellofemoral arthroplasty, use of these prostheses would be contraindicated in patients with untreated advanced arthritic changes in other compartments of the knee beyond the patello-femoral articulation.
2. Patient has an active or suspected latent infection in or about the knee joint.
3. Patient has a malignancy in the area of the involved knee joint.
4. Patient has a known sensitivity to device materials.
5. Patient's bone stock is compromised by disease and/or infection, or prior implantation which cannot provide adequate support and/or fixation cannot be provided to the prosthesis.
6. Patients with inflammatory arthritis.
7. Patients with major deformity affecting the mechanical axis of the knee or neuromuscular disorders compromising motor control and/or stability.
8. Any mental neuromuscular disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in post-operative care.
9. Skeletal immaturity.
10. Ligamentous instability such that the postoperative stability afforded by the unicompartmental knee prosthesis would be compromised such as multidirectional/ACL instability
11. For unicondylar arthroplasty, untreated damage to the contralateral compartment of the ipsilateral knee
12. For unicondylar arthroplasty, untreated deterioration or destruction of the patello-femoral joint,
13. Severe deformity and/or recurrent subluxation of the knee joint.
14. Obesity. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of fixation of the device or failure of the device itself.
15. Severe tibial bone loss/deformity (ver 15 degrees varus)

Precautions

Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected in normal healthy bone, and the patient should not have unrealistic functional expectations.

Appropriate selection, placement and fixation of the knee components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service. The Patient should be warned about these limitations.

Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched as a result of contact with metal or abrasive objects.

Utilization and Implantation

The appropriate surgical protocol provides additional procedural information.

The recommended trial components are used for size determination, trial reduction and range of motion evaluation. This preserves the integrity of the actual implants and their sterile packaging. Radiographic templates are also available to assist in the preoperative predication of component size.

Warnings

Choose the correct size of implant. Position it and fix into place with bone cement with care.

The alignment of the patello-femoral implants in the knee is important. Care should also be taken to ensure correct alignment of patella implants and correct tensioning of the patellar tendon.

Discard all damaged or mishandled implants.

Never reuse an implant, even though it may appear undamaged.

Polished bearing areas must not come in contact with hard or abrasive surfaces.

Bearing areas must always be clean and free of debris prior to assembly.

Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.

Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Except where noted, Howmedica Osteonics strongly advises against the use of another manufacturer's knee component with any Howmedica Osteonics knee component. Any such use will negate the responsibility of Howmedica Osteonics for the performance of the resulting mixed component implant.

Intentional removal of a knee component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces.

Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

Take to use components from the appropriate system. The Table below lists compatible components. The components from the different unicondylar prostheses cannot be mixed and matched. For example, A EUIS[®] femoral component must be used with an EUIS[®] tibial component and not a SCR tibial component.

	Polyethylene Patellas	EUIS [®] Tibial Components	SCR [®] Tibial Components	UNIX [™] Tibial Component	UNIX [™] Tibial Insert Component
Avon [®] Femoral Components	✓				
EUIS [®] Femoral Components		✓			
SCR [®] Femoral Components			✓		
UNIX [™] Femoral Component				✓	✓
UNIX [™] Tibial Component					✓

✓ = Compatible

Adverse Effects

While the expected life of knee replacement components is difficult to estimate, it is finite.

These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Dislocation of the prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.

Loosening of knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.

Fatigue fracture of knee components, including tibial, femoral and patellar components, has occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.

Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.

Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.

Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.

Metal sensitivity reactions have been reported following joint replacement.

Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.

With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondly, particulate can also be generated by third-body wear.

Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

Sterilization

This knee component has been sterilized by gamma radiation.

The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile.

Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.

Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.

If the package is opened, but the product is not used, the component must not be resterilized and must be discarded or returned to the supplier.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

WARNING: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.

Howmedica Osteonics Inc.
Mahwah, NJ

2005-08
XXX-X-XXX

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Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX B-3

Draft Package Insert for Stryker® Unicompartmental Knees

DRAFT PACKAGE INSERT

STRYKER® UNICOMPARTMENTAL KNEE SYSTEMS

Description

The Stryker®'s Unicompartmental Knee Systems are modular unicompartmental knee prostheses consisting of sterile, single-use components intended for replacement of the femoral condyle regions for either the right or left knee. The system includes femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for unicompartmental arthroplasty. The characteristics specific for each component are detailed on the product label.

Materials

Femoral Components	ASTM F-75 cobalt chromium alloy
Tibial Components	ASTM F-648, Ultra-high molecular weight polyethylene
Modular Tibial Trays	ASTM F-75 cobalt chromium alloy
Tibial Inserts	ASTM F-648, Ultra-high molecular weight polyethylene

Indications for Use

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are sterile, single use only and are intended for implantation with bone cement.

Contraindications

1. Patient has an active or suspected latent infection in or about the knee joint.
2. Patient has a known sensitivity to device materials.
3. Patient's bone stock is compromised by disease and/or infection, or prior implantation which cannot provide adequate support and/or fixation cannot be provided to the prosthesis.
4. Patients with inflammatory arthritis.
5. Patients with major deformity affecting the mechanical axis of the knee or neuromuscular disorders compromising motor control and/or stability.
6. Any mental neuromuscular disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in post-operative care.
7. Skeletal immaturity.

8. Ligamentous instability such that the postoperative stability afforded by the unicompartamental knee prosthesis would be compromised such as multidirectional/ACL instability
9. Untreated damage to the contralateral compartment or the ipsilateral knee not being replaced by a prosthesis.
10. Untreated deterioration or destruction of the patello-femoral joint,
11. Severe deformity and/or recurrent subluxation of the knee joint.
12. Obesity. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of fixation of the device or failure of the device itself.
13. Severe tibial bone loss/deformity (ver 15 degrees varus)

Precautions

Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected in normal healthy bone, and the patient should not have unrealistic functional expectations.

Appropriate selection, placement and fixation of the knee components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service. **The Patient should be warned about these limitations.**

Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched as a result of contact with metal or abrasive objects.

Utilization and Implantation

See the appropriate surgical protocol provides additional procedural information.

The recommended trial components are used for size determination, trial reduction and range of motion evaluation. This preserves the integrity of the actual implants and their sterile packaging. Radiographic templates are also available to assist in the preoperative predication of component size.

Warnings

Choose the correct size of implant. Position it and fix into place with bone cement with care.

Discard all damaged or mishandled implants.

Never reuse an implant, even though it may appear undamaged.

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Polished bearing areas must not come in contact with hard or abrasive surfaces.

Bearing areas must always be clean and free of debris prior to assembly.

Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.

Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Except where noted, Howmedica Osteonics strongly advises against the use of another manufacturer's knee component with any Howmedica Osteonics knee component. Any such use will negate the responsibility of Howmedica Osteonics for the performance of the resulting mixed component implant.

Intentional removal of a knee component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces.

Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

Adverse Effects

While the expected life of knee replacement components is difficult to estimate, it is finite.

These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Dislocation of the prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.

Loosening of knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.

Fatigue fracture of knee components, including tibial, femoral and patellar components, has occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.

Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.

Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal

disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.

Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.

Metal sensitivity reactions have been reported following joint replacement.

Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.

With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondly, particulate can also be generated by third-body wear.

Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

Sterilization

This knee component has been sterilized by gamma radiation.

The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile.

Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.

Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.

If the package is opened, but the product is not used, the component **must not** be resterilized and must be discarded or returned to the supplier.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

WARNING: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.

Howmedica Osteonics Inc.
Mahwah, NJ

2005-08
XXX-X-XXX

Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX B-4

Draft Package Insert for Avon® Patello-Femoral Joint Prosthesis

PROPOSED PACKAGE INSERT

AVON[®] PATELLO-FEMORAL JOINT PROSTHESIS

Description

The Avon[®] Patello-femoral Joint Prosthesis is intended for reconstruction of the patello-femoral joint. The characteristics specific for each component are detailed on the product label.

Materials

Femoral Component ASTM F-75 cobalt chromium alloy

Indications

The Avon[®] Patello-femoral Joint Prosthesis is intended to be used in cemented patello-femoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. These components are single use only and are intended for implantation with bone cement.

Contraindications

1. Use of these prostheses would be contraindicated in patients with untreated advanced arthritic changes in other compartments of the knee beyond the patello-femoral articulation.
2. Patient has an active or suspected latent infection in or about the knee joint.
3. Patient has a malignancy in the area of the involved knee joint.
4. Patient has a known sensitivity to device materials.
5. Patient's bone stock is compromised by disease and/or infection, and adequate support and/or fixation cannot be provided to the prosthesis.
6. Patients with inflammatory arthritis.
7. Patients with major deformity affecting the mechanical axis of the knee or neuromuscular disorders compromising motor control and/or stability.

Precautions

Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device,

or both. The prosthesis will not restore function to the level expected in normal healthy bone, and the patient should not have unrealistic functional expectations.

Appropriate selection, placement and fixation of the knee components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service. The Patient should be warned about these limitations.

Utilization and Implantation

The Howmedica Osteonics surgical protocol provides additional procedural information.

Warnings

Choose the correct size of implant. Position it and fix into place with bone cement with care.

The alignment of the patello-femoral implants in the knee is important. Care should also be taken to ensure correct alignment of patella implants and correct tensioning of the patellar tendon.

Discard all damaged or mishandled implants.

Never reuse an implant, even though it may appear undamaged.

Polished bearing areas must not come in contact with hard or abrasive surfaces.

Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.

Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Except where noted, Howmedica Osteonics strongly advises against the use of another manufacturer's knee component with any Howmedica Osteonics knee component. Any such use will negate the responsibility of Howmedica Osteonics for the performance of the resulting mixed component implant.

Intentional removal of a knee component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces.

Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**

Adverse Effects

While the expected life of knee replacement components is difficult to estimate, it is finite.

These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Dislocation of the femoral or patellar prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.

Loosening of knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.

Fatigue fracture of knee components, including tibial, femoral and patellar components, has occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.

Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.

Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.

Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.

Metal sensitivity reactions have been reported following joint replacement.

Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.

With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondarily, particulate can also be generated by third-body wear.

Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

Sterilization

This knee component has been sterilized by gamma radiation.

The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile.

Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.

Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.

If the package is opened, but the product is not used, the component **must not** be resterilized and must be discarded or returned to the supplier.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

WARNING: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.

Howmedica International S. de R.L.

Raheen Business Park
Limerick, Ireland

2005-07
XXX-X-XXX

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Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX B-5
Draft Surgical Technique

DRAFT SURGICAL TECHNIQUE

STRYKER® COMPARTMENTAL KNEE SYSTEM

Description

The Stryker® Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and/or unicondylar arthroplasty. The characteristics specific for each component are detailed on the product label.

Indications for Use

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartamental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartamental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

Warning: This Device Is Intended For Cemented Use Only.

Caution: Federal Law (U.S.A.) Restricts this device to sale by or on the order of a Licensed Physician

Howmedica Osteonics Inc.
Mahwah, NJ

2005-08
XXX-X-XXX

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Take to use components from the appropriate system. The Table below lists compatible components. The components from the different unicondylar prostheses cannot be mixed and matched. For example, A EUIS[®] femoral component must be used with an EUIS[®] tibial component and not a SCR tibial component.

Compatibility Chart of Components

	Polyethylene Patellas	EUIS [®] Tibial Components	SCR [®] Tibial Components	UNIX [™] Tibial Component	UNIX [™] Tibial Insert Component
Avon [®] Femoral Components	✓				
EUIS [®] Femoral Components		✓			
SCR [®] Femoral Components			✓		
UNIX [™] Femoral Component				✓	✓
UNIX [™] Tibial Component					✓

✓ = Compatible

Pre-operative planning / Incision

Appropriate preoperative radiographs should be used to establish the arthritic condition of the knee. These might include anterior/posterior, lateral, and skyline (Merchant or tangential) views. Long-leg standing films can also be used for determination of the mechanical axis. Diagnostic arthroscopy of the opposite compartment and patello-femoral joint is optional as a pre-operative assessment.

Skin incision should be planning according to the possible compartments that will require treatment. Compartments can be considered independently when considering treatment options. Indications, contraindications, warnings and precautions for treatment of affected compartments for each of the unicompartmental prosthesis should be used for guidance (See the IFU packaged with prosthesis being implanted for additional information).

Intra-operative diagnosis

After exposure has been achieved, a visual inspection of all compartments should be performed. This inspection is used to compare to preoperative planning and confirm the compartment or compartments, which will require treatment. All indications and contraindications and typical patient selection criteria for planned procedures should still apply (See IFU packaged with the prosthesis for additional information).

Protocol, treating one or more compartment

When considering treating multiple compartments with multiple prostheses, it should be noted that device instrumentation, sizing and alignment are to be considered independently, regardless of the order or type by which the prostheses are implanted. If it is determined that more than one compartment requires treatment, the surgeon should

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follow the protocol for implantation of the first prosthesis to completion. (See attached individual protocols for each prosthesis.) Then, the surgeon should then proceed in treating the other affected compartment(s).

For example, if medial tibio-femoral disease and patello-femoral disease were present in the same compartment. A physician could proceed with treatment by implanting a unicondylar implant, according to the surgical protocol for that prosthesis without consideration of the patello-femoral compartment.

Upon completion of the unicondylar procedure the surgeon would continue with the patello-femoral joint replacement according to the protocol for that prosthesis. It is the surgeon's discretion to the order in which the individual compartments are treated.

Intra-Operative Assessment

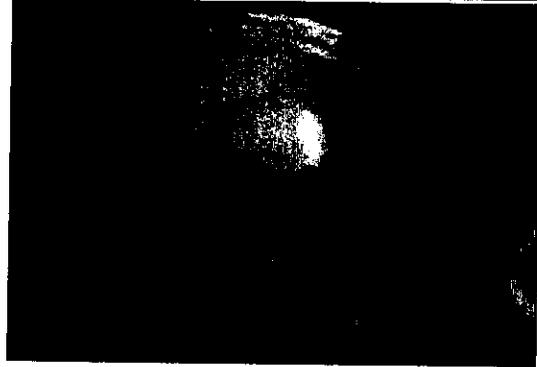
The anterior resection must be above the level of the anterior tidemark to prevent impingement. Check alignment to ensure the tip of the prosthesis is aligned with the anterior wear pattern or tidemark. Also, check the region of the intercondylar notch to be sure impingement has not occurred and there is clearance between the components. Do a final check by bringing the leg into extension and evaluating the extension alignment.

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Surgical Technique for patellofemoral arthroplasty using the Avon[®] PFJ Prosthesis

The patient is prepared for total knee replacement surgery. A leg holder allows support of the leg for easy adjustment. A tourniquet is generally used. A medial parapatellar incision is preferred.

1



The incision is made with the knee flexed to 90 degrees. It should be extended to the tibial tubercle and the capsule incised on the medial side. Care should be taken not to damage the medial meniscus during division of the synovium. The lateral flap should be released to enable the fat pad and the patella to be everted. Be careful to avoid damage to the anterior meniscal and cruciate structures.

2



The patella is everted laterally to expose the anterior aspect of the knee joint. The synovium around the edge of the patella is incised to define the edges. Release of the lateral retinaculum from the lateral margin of the patella and osteophyte is always required. (A peri-patella release).

3



A notchplasty may be required to remove notch osteophytes, confirming the integrity of the cruciate ligaments.

The index finger is inserted into the notch to ensure a smooth arch and adequate space for the cruciate ligaments.

The anterior aspect of the femur should be exposed by incision of the anterior synovium of the supra patella pouch.

4

The flaps are elevated to get a good view of the anterior cortex of the femur.

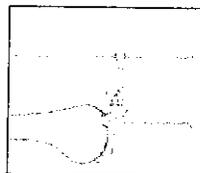
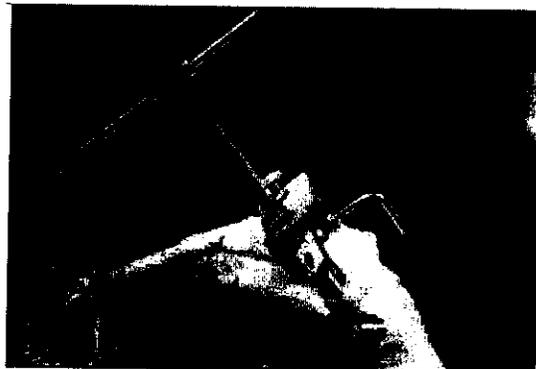


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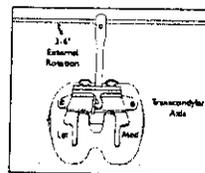
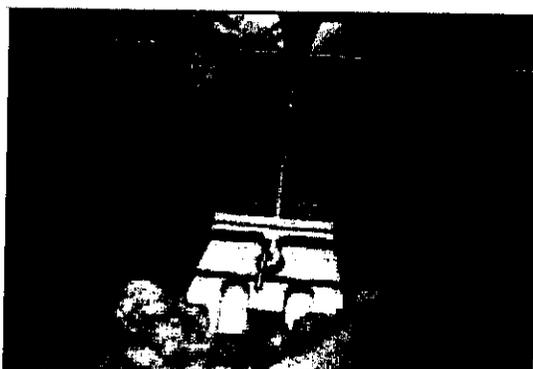
5

Place the anterior cutting guide onto the femoral condyles so that the flat surface is parallel to the anterior cortex of the femur. This is facilitated by the saddle of the guide which is placed in the notch of the femur. The two inferior skids provide a reference for placement against the posterior aspect of the condyles, although this cannot be easily seen with the limited incision that is generally used.



6

The extra medullary femoral alignment guide rod and tower are designed to assist in obtaining accurate alignment. This should be in line with the anterior cortex of the femur in the lateral sagittal plane. A 1/8" diameter hole is drilled into the intramedullary canal through the central drill guide of the cutting block and the intramedullary rod inserted.



7

Final positioning of the femoral cutting block is confirmed with respect to rotation.

Attention should be made to ensuring that there is 3-6° of external rotation of the block on the femur. Internal rotation may lead to mal-tracking and overload and should be avoided. When satisfactory alignment has been achieved the position of the block is fixed with two 1/8" diameter pins. The lateral pin should be inserted first to minimize internal rotation of the block. The extra medullary tower is now unscrewed.



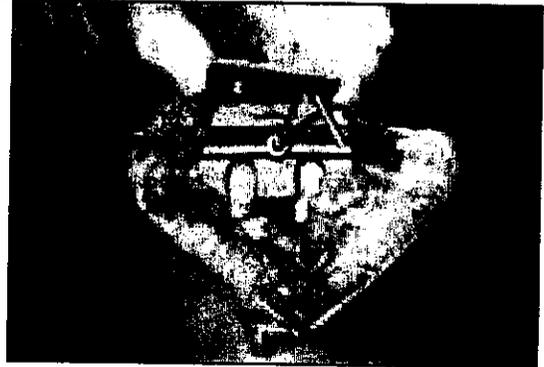
8

The height of the trochlea is assessed using the anterior reference indicator which measures the exit point of the anterior resection using the superior surface of the cutting block. The cut should pass just beneath the deepest part of the groove, exiting parallel to the anterior cortex.

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If the zero position of the cutting guide produces a resection which removes too much bone, then the 2mm, 4mm or 6mm plates may be added to raise the level of the cut so that notching of the anterior femoral cortex does not occur. If in doubt, always use a thicker cutting plate to remove the minimum amount of bone; more can be removed later if required.

9



Once a satisfactory resection of the anterior trochlea has been achieved, place the Trial Template onto the cut bone surface. Sizing is correct when a gap of 2mm is present between the template and the anterior part of the intercondylar notch. This will allow a thin bridge of intact articular cartilage between the intercondylar notch and the posterior edge of the prosthesis.

10

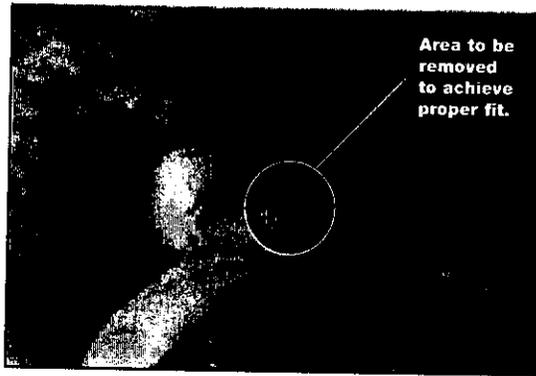


The articular cartilage at the edge of the template is marked with a pen.

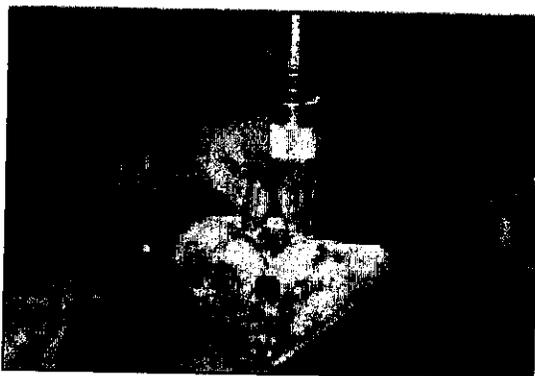
The articular cartilage underlying the area of the template is removed so that the prosthesis can be inset close to the articular edge. This can be lifted off the sub-condylar bone using an osteotome held in both hands and moved vertically across the surface. The osteotome is used to complete the removal at the tip of the prosthesis.

11





12 The bone is then shaped to provide a smooth transition between the anterior surface of the femur and the curved part of the condyles. This is easily done with the edge of the oscillating saw, osteotome or a bur. The fit is checked with the template. Once a perfect fit has been achieved the femoral template is punched into position and secured using four pins.



13 The four guide holes in the template are drilled with the 4.5mm drill to accommodate the fixation studs of the implant. The template is then removed and the trial prosthesis impacted into position to provide a correct fit. The inferior stud is inserted first. The prosthesis is punched into position in the line of the long axis of the femur. The position of the impactor is then increased to 30°, then to 70° and finally to 90° with the second flat surface of the punch.

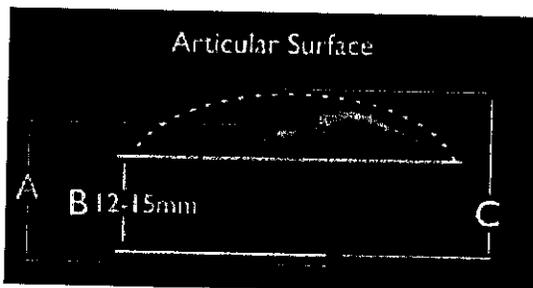


The Patella.

14a

The soft tissue attachments at the periphery of the patella are incised to expose the insertions of the quadriceps and patella tendons. The lateral patello-femoral ligament is incised and released close to the femur **avoiding the**

geniculate arteries. An important release of the lateral retinaculum is performed on the lateral margin of the patella from the proximal quadriceps tendon down to the distal patella tendon. Sufficient release should be performed so that the patella moves freely both medially and laterally. (A sub periosteal Peri-patella release).



14b

The height of the patella is measured with the calipers. (*Measurement A, Step 14b*). Allowance is made for the patella wear. The patella cutting guide is positioned so that after allowing for the worn bone and cartilage, between 6mm and 11mm of the patella is removed. This is equivalent to the thickness of the prosthesis and when the prosthesis is implanted should correct restoration of patellar height. A minimum of 12mm of patella bone should always be left after the resection.

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An oscillating saw is used to make the cut and the residual bone thickness checked with the calipers (*Measurement B, Step 14b*). Apply and centralize the Patella Drill Template and drill the three peg holes. The appropriate patella trial is inserted (small, medium, large) and the restored height is checked (*Measurement C, Step 14b*). **The thickness of the patella prostheses are: Small 9mm, Medium 9.5mm and Large 10mm.**

15a



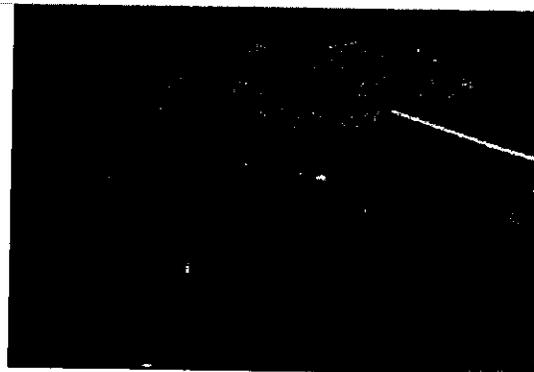
15b



The patella is reduced and the tracking checked to assess stability of the patella in the femoral groove while the knee is flexed through 120 degrees. The medial facet of the patella should be in contact with the femur throughout the range of movement. The 'rule of no thumb' is applied by ensuring that tracking is stable without pressure from the thumb. If tracking is not perfect, further release of the retinaculum from the edge of the patella should be performed. The stitch test helps to judge the patella tracking.

16

If there is persistent mal-alignment of the patella, then it may be necessary to consider bony or soft tissue realignment using the Roux or Elmslie techniques. If this is felt to be inadvisable, then the surgeon should proceed to a total joint replacement which will allow correction of tibial rotation.



Once satisfactory tracking has been confirmed, bone cement is applied to the cut anterior femoral surface and the patella, using a cement gun (with an oblique cut to the nozzle) to pressurize the cement.

The Femoral Impactor and Patella Clamp are used to seat the femoral and patellar prostheses. A final check of satisfactory patella tracking is made

17

and the wound is closed in the usual way.

Ensure there is no edge impingement of the medial border of the patella on the femoral condyle at 120° flexion. The flat odd facet of the button should present a smooth surface at this point.



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To Facilitate Accurate Patella Tracking

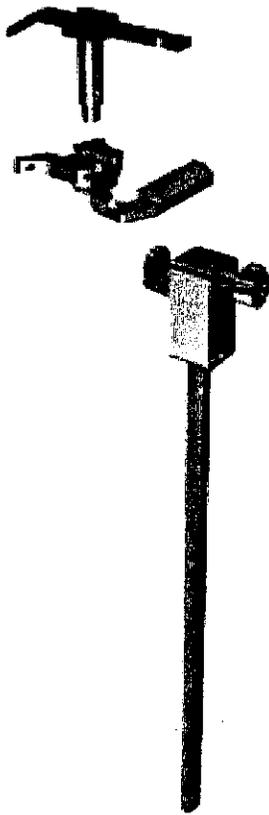
1. Femoral component positioned in slight external rotation (maximum 6°)
2. Femoral component positioned slightly lateral (1-2mm) to the intercondylar mid-line.
3. Anterior cut parallel to the anterior femoral cortex to avoid elevating the trochlear.
4. Release the patello-femoral fold close to the femur.
5. Lateral retinaculum dissected off the lateral osteophyte of the patella to release the lateral retinacular contracture. (A sub periosteal Peri-patella release).
6. Patella measured prior to resection to achieve approximate reconstruction of the original patella thickness.
7. Patella jig positioned so patella resection is symmetrical.
8. Residual patella bone thickness of 12-15mm to reduce the potential for overstuffing of the joint.
9. At full extension, flip the replaced patella at 90° to the trochlear. The retinaculum should be loose enough to allow the edge of the patella to reach medial to the mid-line of the trochlear groove. (Flip test).
10. Shape of the trochlea allows unconstrained movement in extension. The patella is then captured by the groove as the knee flexes to 90°.
11. The patella dome has a 3mm medial offset.
12. The medial patella facet should remain in contact with the medial trochlear and femoral condyle throughout the full range of motion. The patella odd facet will bear against the medial femoral condyle in deep flexion (over 110°). There should be no impingement as-the patella rotates internally at 120° and flexion.
13. If any tendency is observed for the medial facet to lift from the femoral trochlear, then a further release of the lateral retinaculum from the border of the patella should be performed. A mid lateral release is avoided to prevent damage to the lateral retinacular vessels and soft tissue hematoma. (This considerably slows recovery).
14. If tracking is not perfect, then a single stitch can be applied to the mid-point of the retinaculum and the tracking reassessed. This simulates wound closure. (Stitch test).
15. If lateral mal-alignment persists then consider tibial tubercular repositioning or revert to a total knee placement.

Surgical Technique for femorotibial arthroplasty using the
EUIS[®] Unicompartmental Knee System



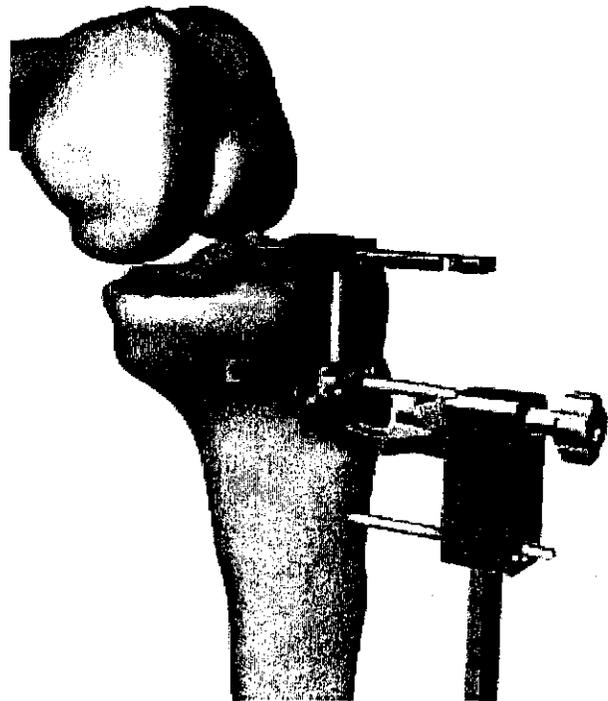
**TIBIAL INSTRUMENT ASSEMBLY/
TIBIAL ALIGNMENT**

1. Tibial Instrument Assembly



- a) Assemble the Ankle Clamp, Tibial Alignment Rod, appropriate Tibial Alignment Guide, and Stylus as shown.

2. Tibial Alignment

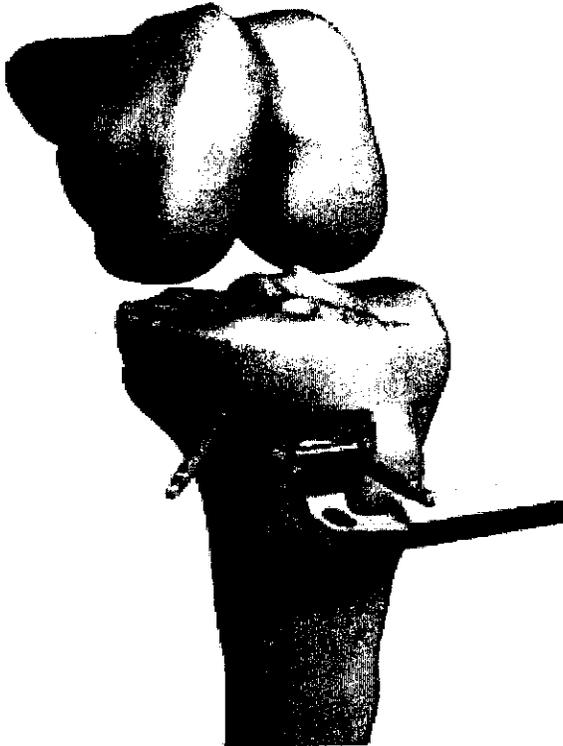


- a) With the knee flexed, place the Ankle Clamp around the distal tibia just above the malleoli. Place the stylus in the lowest point on the affected side of the tibial plateau.
- b) The Tibial Alignment Rod should be in line with the anatomic axis in the frontal plane and parallel to the anatomic axis in the sagittal plane. A five degree posterior slope is built into the Tibial Alignment Guide.
- c) An optional 1/8" (3.2mm) pin may be placed percutaneously into the anterior tibia through the Alignment Rod just below the locking knob to help stabilize the extramedullary guide while fine adjustments are made in its alignment.

TIBIAL ALIGNMENT/TIBIAL RESECTION

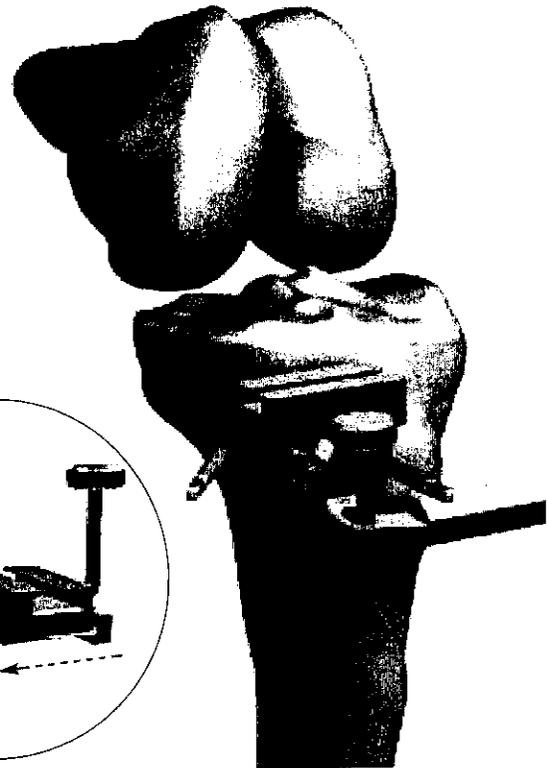
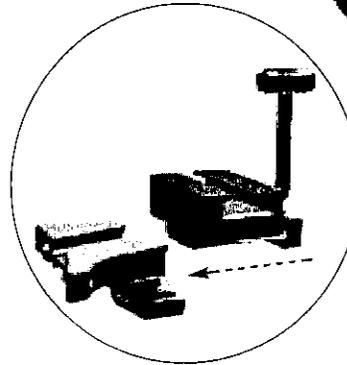


3. Tibial Alignment Guide



- a) Use 1/8" (3.2mm) pins to secure the Tibial Alignment Guide to the proximal tibia through the lower set of straight holes and through the angled hole furthest from the extensor mechanism.
- b) Remove the Ankle Clamp, Tibial Alignment Rod and Tibial Stylus.

4. Tibial Resection Level

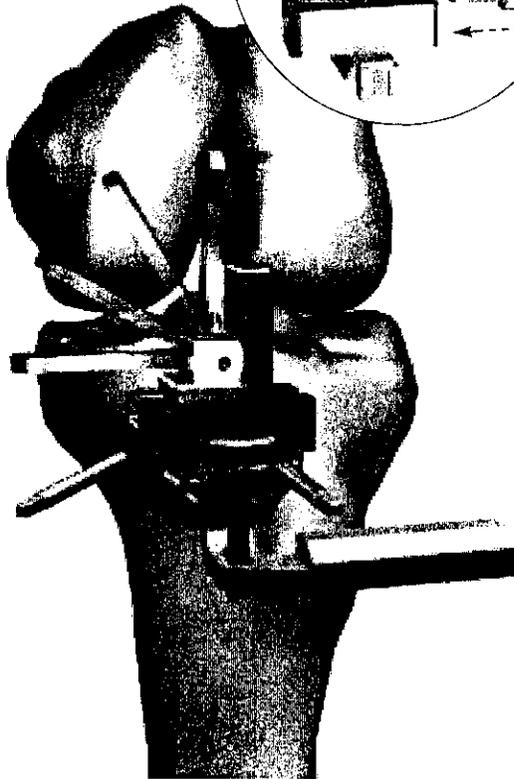


- a) The goal of the tibial resection is to create a space which will accept the thinnest component necessary.
- b) The Tibial Cutting Guides are designed to create a 2, 4, 6 or 8mm resection from the tip of the stylus. Slide the desired thickness Tibial Cutting Guide into the Tibial Alignment Guide. Secure the Cutting Guide by sliding the Retaining Pin through the triangular bracket on the anterior aspect of the Cutting Guide and into the slot in the Tibial Alignment Guide.



TIBIAL SAGITTAL CUT/TRANSVERSE CUT

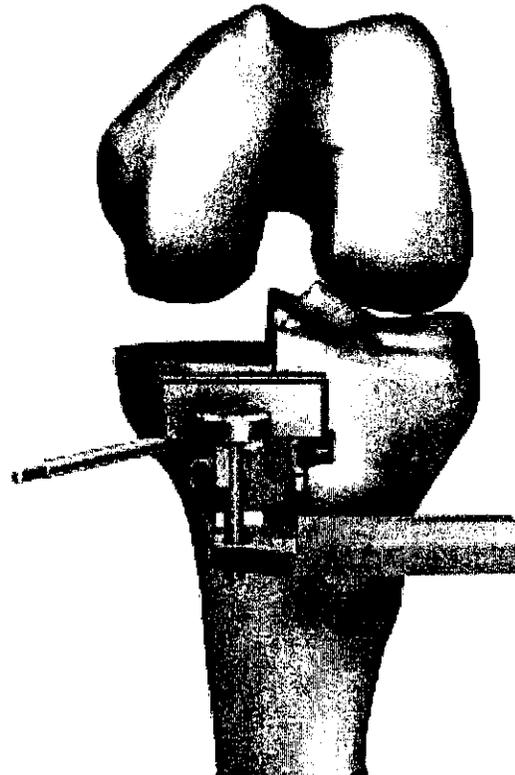
5. Tibial Sagittal Cut



- a) Slide the Sagittal Cutting Guide into the Tibial Cutting Guide. Position the Guide to create a resection near the attachment of the anterior cruciate ligament. Lock the Guide into place and use a reciprocating saw against the rounded surface to make the sagittal wall cut to the level of the Tibial Cutting Guide.

Note: Be cautious when making the sagittal wall cut and use retractors to protect surrounding soft tissue and ligamentous structures.

6. Tibial Transverse Cut

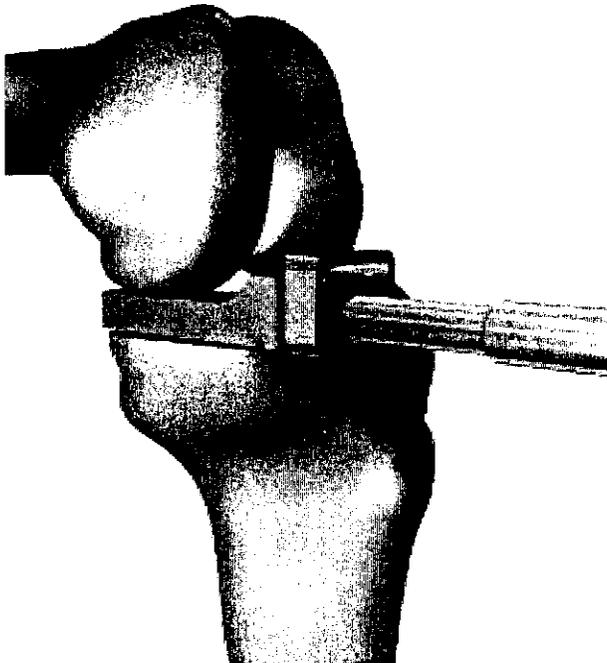


- a) Remove the Sagittal Cutting Guide.
- b) Use an oscillating saw to make the transverse tibial resection while being careful not to cut beyond the sagittal wall. The reciprocating saw blade may be left in the cut to assist as a stop for the tranverse cut.
- c) Remove the Tibial Cutting Guide, leaving the Tibial Alignment Guide in place.

JOINT SPACE ASSESSMENT/ FEMORAL SIZING

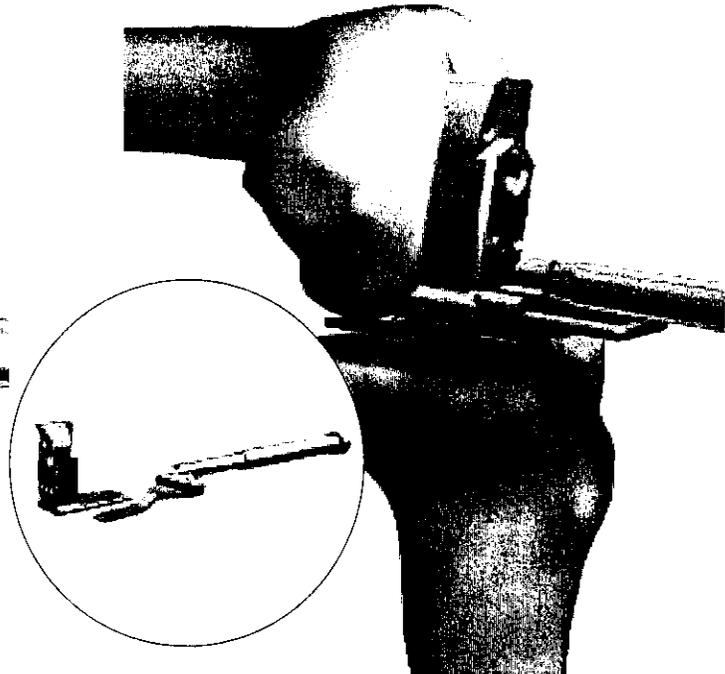


7. Joint Space Assessment



- a) With the knee flexed 90° insert the appropriate Tensing Positioner into the joint space. Tensing Positioners are available in 4 sizes – 8, 9, 10 and 12mm, which correspond to tibial component thickness. Take the knee through a full range of motion with the Tensing Positioner in place to assess:
 - i) Flexion and extension gaps
 - ii) Estimated amount of correction
 - iii) Soft tissue balance.
- b) Once the appropriate Tensing Positioner is identified, remove it from the joint space and set it aside.

8. Femoral Sizing

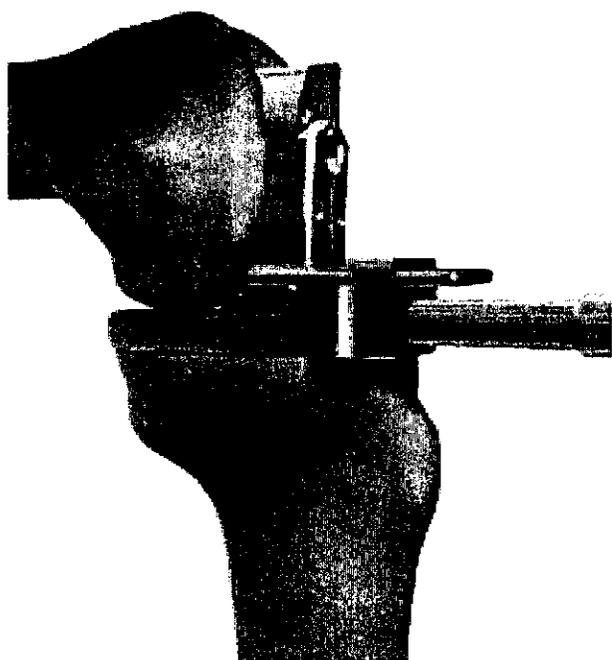


- a) Based on the pre-operative assessment, select the appropriate Femoral Cutting Guide and assemble it to the Femoral Sizing Handle.
- b) With the knee flexed to 90°, insert the assembly into the joint space. The tongue of the Sizing Handle should be against the posterior condyle and the contoured surface of the Femoral Cutting Guide should be against the distal femur. The proper size femoral component is determined when:
 - i) The Femoral Sizing Handle is parallel to the femoral shaft; and
 - ii) The anterior aspect of the Femoral Cutting Guide is at the tidemark; and
 - iii) Sufficient medio-lateral coverage is achieved.



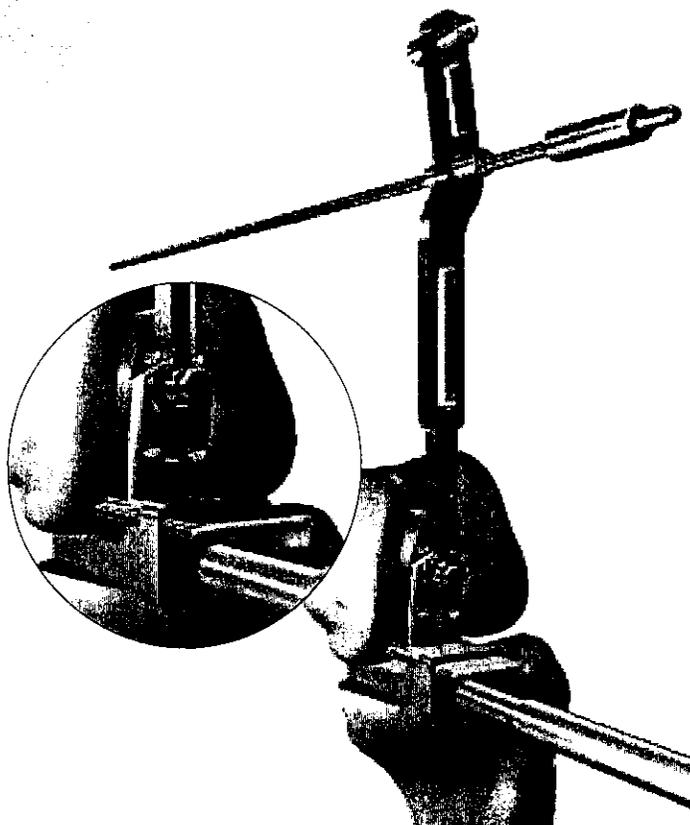
FEMORAL ALIGNMENT

9. Femoral Alignment



- a) Slide the selected Femoral Cutting Guide into the Tensing Positioner previously chosen. Assemble the Distal Femoral Alignment Guide to the Femoral Cutting Guide as shown. Place the assembly into the joint space and pass a long Alignment Rod through the Distal Femoral Alignment Guide. The Femoral Cutting Guide is properly aligned when the following conditions are met:
- i) The knee is flexed to 90° and the anterior aspect of the Femoral Cutting Guide is at the tidemark. This establishes proper flexion/extension position.
 - ii) The Alignment Rod references the femoral head, and is parallel to the femoral axis. This provides alignment with the mechanical axis and varus/valgus position.

10. Distal Alignment Guide

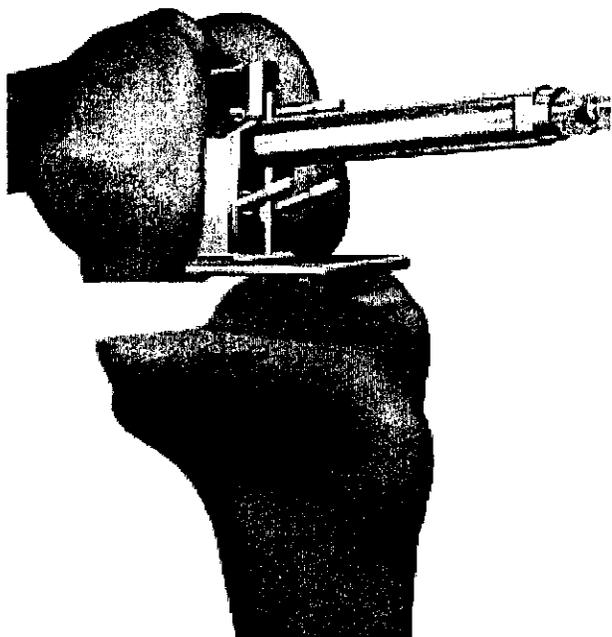


- iii) Sufficient medio-lateral coverage is achieved. The Femoral Cutting Guide profile matches the corresponding implant.
- b) By referencing the flat tibial cut while tensing the joint, the Tensing Positioner provides parallelism between the transverse tibial and posterior femoral resections. The Positioner also sets the A-P position of the component relative to the posterior condyle to create a 6mm posterior femoral resection.
- c) Once properly aligned, pin the Cutting Guide. Note that the two X-holes on the inferior aspect of the Cutting Guide angle downward.

POSTERIOR FEMORAL RESECTION & PEG PREPARATION/FIN PREPARATION



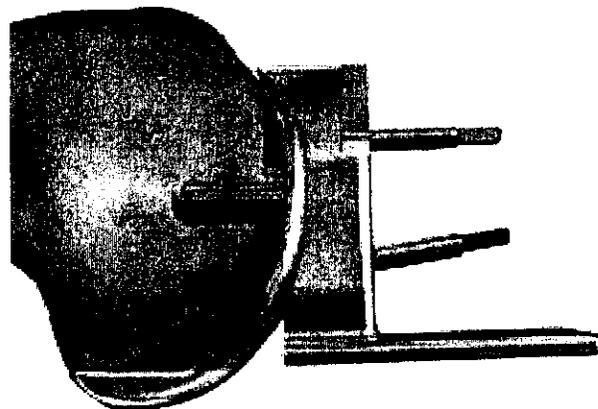
11. Posterior Femoral Resection and Peg Preparation



- a) Remove the Femoral Tensing Positioner and the Distal Femoral Alignment Guide. Advance the 1/8" Femoral Drill through the smaller drill hole on the fin until it stops.
- b) Prepare for the femoral peg using the large Femoral Peg Drill with Stop.
- c) Resect the posterior condyle by cutting along the bottom surface of the Femoral Cutting Guide, taking care to protect surrounding soft tissue. The resulting femoral resection is 6mm for all sizes.

Note: The femoral peg drill may be left in the cutting guide (as shown) for added stability while making the posterior resection.

12. Fin Preparation



- a) Use an oscillating saw to prepare the fin slot so that it matches the geometry of the component. This is facilitated by inspecting the sagittal view of the femoral trial to estimate the proper depth of the fin slot preparation.

Note: The fin runs the entire length of the component and varies in depth.



FLEXION/ EXTENSION GAP CHECK/ BUR TEMPLATE PLACEMENT

13. Flexion/Extension Gap Check



- a) An optional flexion/extension gap check may be performed using the Flexion/Extension Alignment Blocks which represent the tibial implant in extension and the sum of the tibial and femoral component thicknesses in flexion.
- b) To assess the tension and alignment of the knee in extension, bring the leg into extension and insert the "extension" side of the Block into the joint space. Long alignment rods may be placed through the Block in both the superior and inferior directions to assess mechanical alignment. Tension and alignment of the knee in flexion may also be examined by taking the knee to 90° and inserting the "flexion" side of the block.

14. Bur Template Placement

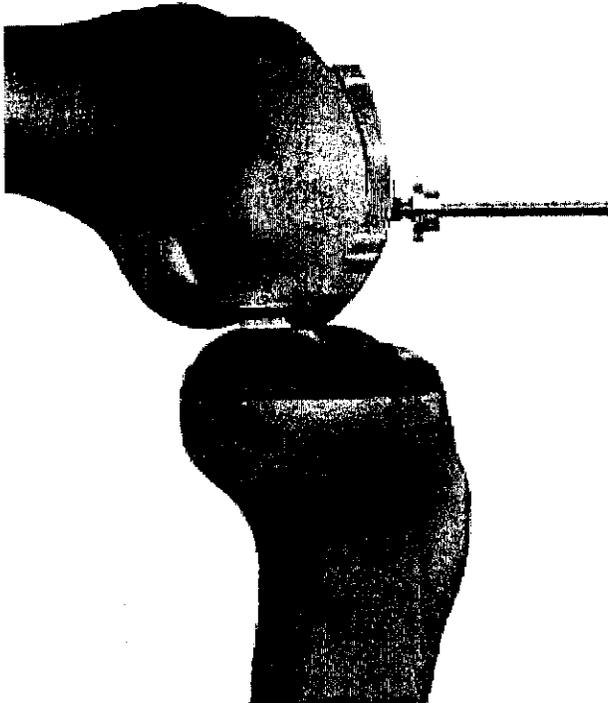


- a) Remove the Tibial Alignment Guide.
- b) Select the proper Femoral Bur Template. Place the Template onto the distal femur, referencing the posterior resection, fin slot and 1/8" peg hole.
- c) Using the Femoral Component Impactor, gently tap the template into place. The template is in the proper position when the posterior plate is flush against the posterior resection. Optional Pin holes on the Femoral Bur Template can be used for additional fixation.

DISTAL FEMORAL BURRING/ FEMORAL TRIALING AND FINAL FIT

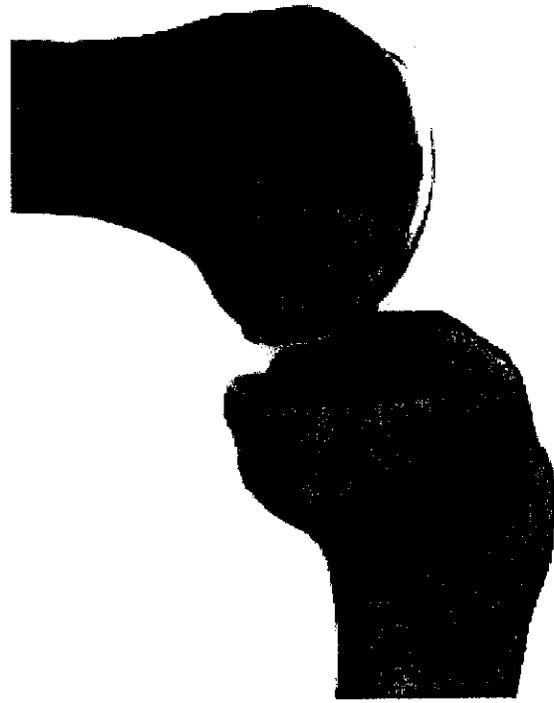


15. Distal Femoral Burring



- a) Operate the EIUS™ system bur within the guide channel of the Femoral Bur Template. This prepares the distal femur to accept the profile of the femoral component. Proper depth is achieved when the bur stop is flush against the polished surface of the bur template.
- b) Remove the femoral bur template from the femur. Complete the preparation by removing the middle strip of bone using a rongeur or bur.

16. Femoral Trialing and Final Fit

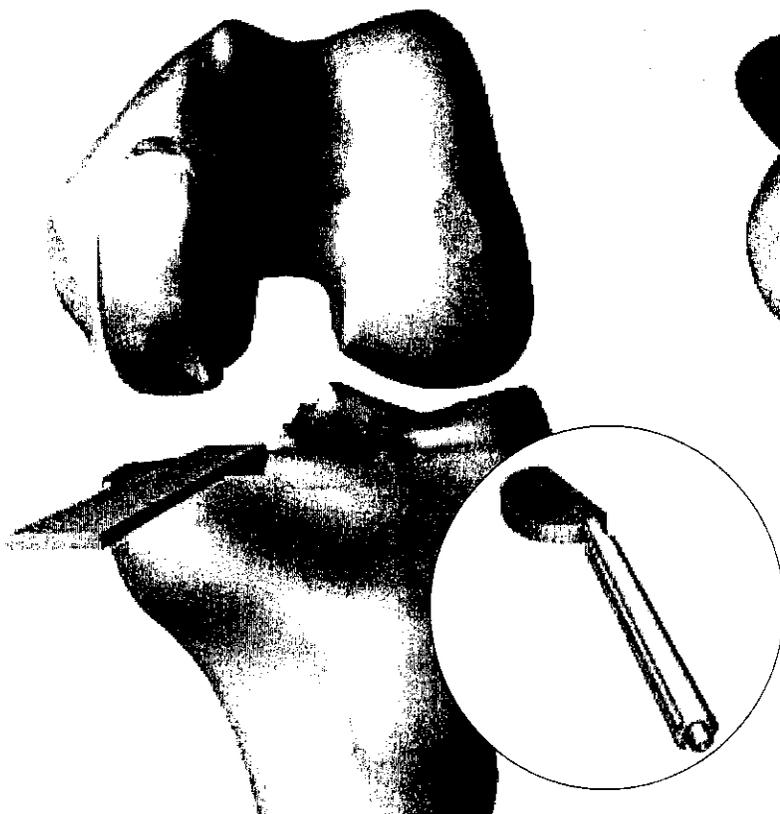


- a) Place the trial component on the femur. Using the Femoral Component Impactor, tap the Femoral Trial until the trial sits fully into the prepared distal femur.



TIBIAL SIZING/TRIAL REDUCTION

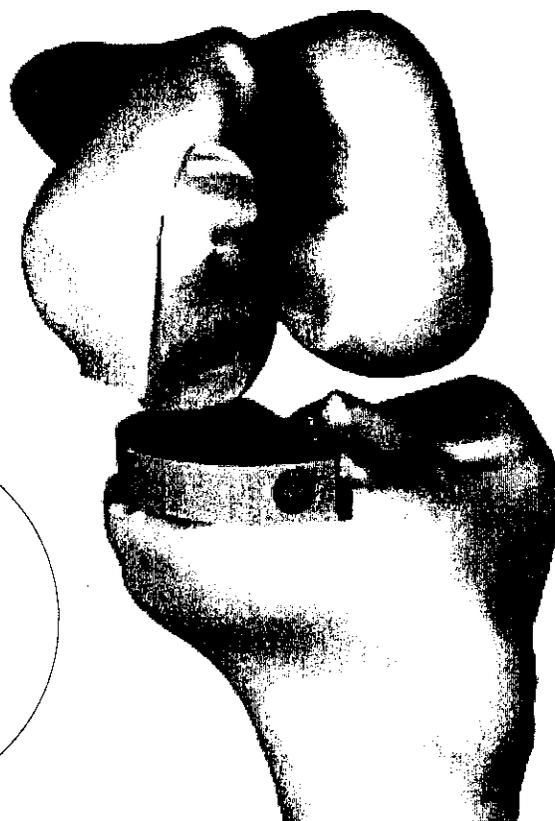
17. Tibial Sizing



- a) Place the Tibial Sizing Guide along the sagittal cut, hooking it over the posterior edge of the tibial resection, note the size indicated.
- b) Connect the appropriate size keel-less Tibial Trial to the Quick Connect Handle. Place the Tibial Trial on the tibial resection and assess for correct fit. If the margins of the trial extend past the cortical rim, the sagittal cut can be advanced in order to eliminate the overhang.

Note: Size interchangeability between the femoral and tibial components is limited to one up/one down.

18. Trial Reduction

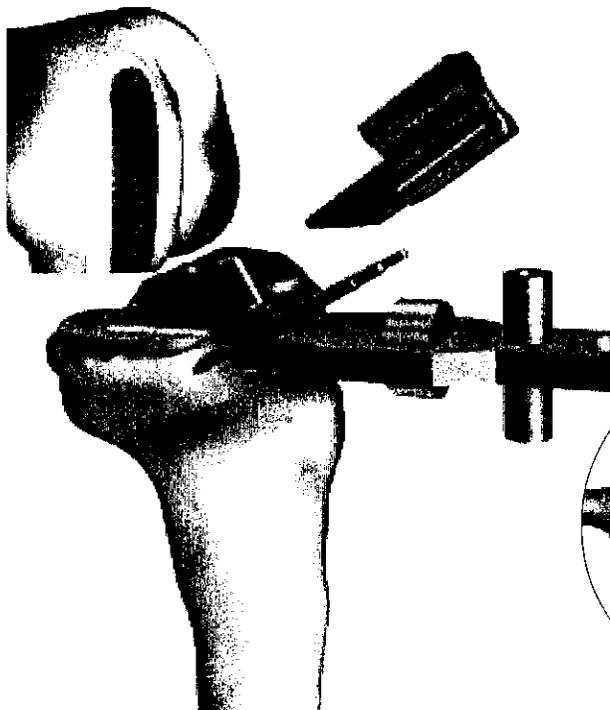


- a) With the femoral trial and tibial trial in place, take the knee through full ROM. In this way, a check is made to ensure that the components are well centered and that there is no component displacement. The tibial component should be stable and should not lift off or move in the sagittal plane during ROM testing.
- b) Care should be taken to ensure that there is slight under correction of the overall alignment. Ligamentous tension should be well balanced.

TIBIAL KEEL PREPARATION



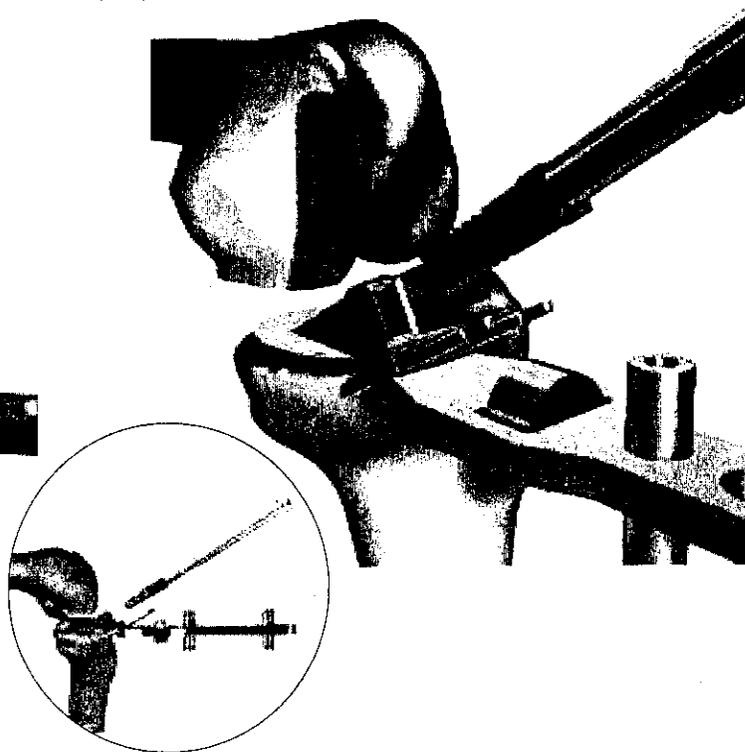
19. Tibial Keel Preparation



- a) Attach the Alignment Handle to the appropriate Tibial Punch Guide and position on the prepared tibia.
- b) Use the Tibial Impactor on the top rounded edge of the Punch Guide to advance the spikes into the tibia and seat the Guide flush on the tibia. If additional fixation is required, 1/8" headless pins may be drilled into the tibia through the angled anterior holes just above the Alignment Handle.

Note: A long Alignment Rod can be passed through the Alignment Handle distally as an additional tibial placement check.

20. Tibial Keel Preparation (continued)

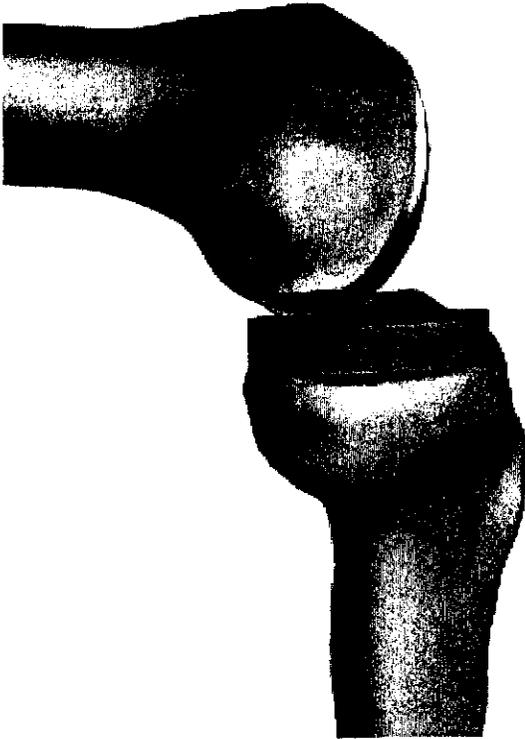


- c) Place the appropriate Tibial Drill Bushing into the slot of the Punch Guide. Pass the Tibial Keel Drill with Stop through each hole of the Drill Bushing.
- d) Remove the Drill Bushing and impact the appropriate Tibial Punch into the same slot in the Punch Guide until it hits the stop.



FINAL IMPLANTATION

21. Final Implantation



- a) Placement of the final implants is facilitated by cementing the tibial component first.
- b) When cementing each component, apply cement to the keel and peg preparations as well as the components. Impactors are provided for both the tibia and femur.
- c) A curette or bent nerve hook may be used to clear out any excess cement paying particular attention to the posterior region of the implant and margins of the tibial eminence.

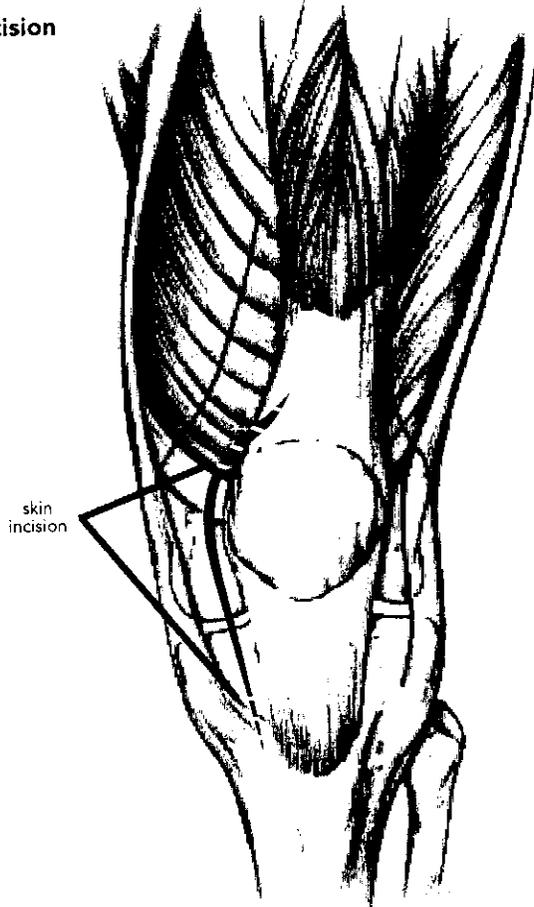
Note: If sclerotic bone is present, a drill or bur may be used to perforate the bone to improve cement penetration.

Note: Placing a sterile gauze or similar cloth in the posterior joint capsule prior to implantation and slowly removing the cloth after implantation may drag excess cement out of the joint. A dental mirror may also be useful in cement removal.

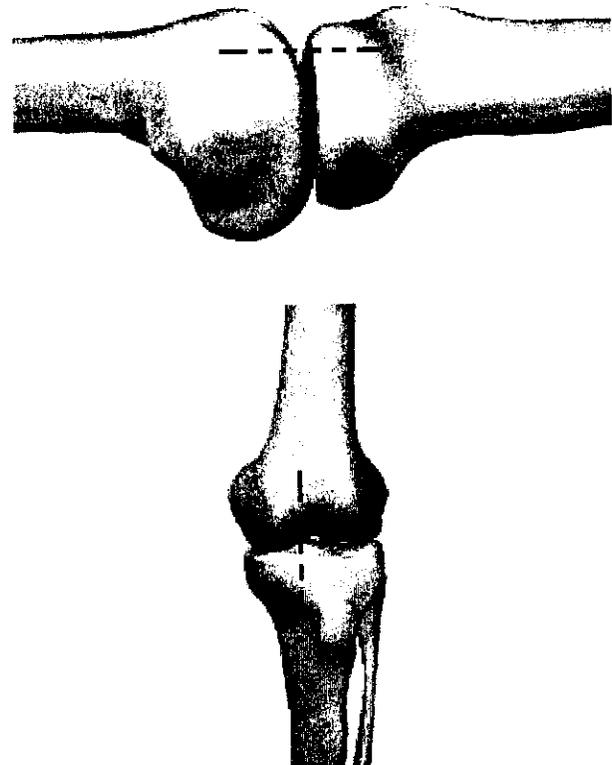


PREPARATION/INCISION

Incision



Anatomical Landmarks



The skin incision should be approximately 1cm medial to the patella. Continue with an arched incision distally to the medial boundary of the patella tendon attachment. Following the skin incision, a medial capsular incision is made (as indicated by the red dotted lines). Expose the patella border and resect osteophytes. To improve visualization, resect the anterior menisci and the infrapatellar fat body until the intercondylar eminence is exposed.

- a) Before starting to prepare for the tibial resection extend the leg fully and mark on the femur with a pen the most anterior wear point between the femur and tibia. This point will be referred to as the tide mark, and represents the anterior boundary of the femoral component.
- b) Also mark the antero medial (or antero lateral) contact area of the femur or tibia in order to assist in defining the position of the tibial sagittal cut.
- c) Prior to the start of the procedure the center of the femoral head may be identified by placing an EKG lead over the femoral pulse just below the inguinal ligament to estimate the center of rotation of the hip. This lead can then be palpated through the drapes and used to assess alignment.

Surgical Technique for femorotibial arthroplasty using the SCR® Unicompartmental Knee System

INTRODUCTION

The SCR™ Single Compartment Replacement Knee represents the culmination of a collaborative effort among Osteonics, Vincent Eilers, M.D. and Donald Armstrong, O.P.A.-C. of the St. Anthony Orthopaedic Clinic, St. Paul, Minnesota. The SCR Unicompartmental System, an evolutionary concept, was developed to address degenerative joint disease with anatomically-designed medial and lateral components.

Pre-operative Planning and X-ray Evaluation

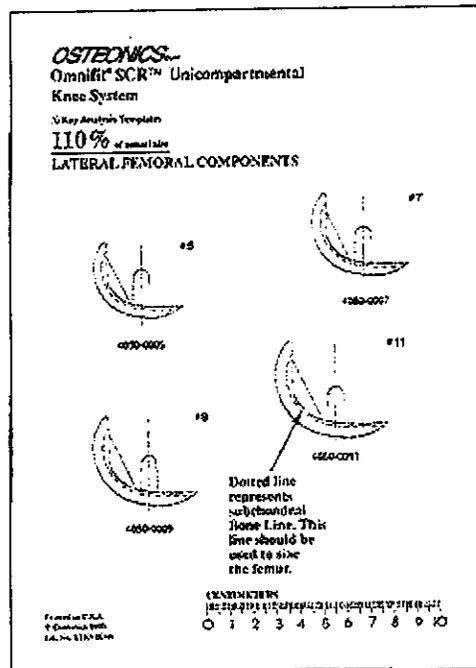
Pre-operative planning will aid in the selection of the most favorable implant style and size for the patient's knee pathology. Optimal implant fit and instrument selection can be more closely evaluated with the use of pre-operative X-ray analysis. Determination of the probable implant style and size with associated instrument options, will facilitate operating room preparation and assure availability of an appropriate size and style selection. Final implant size selection, however, is made in the operating room.

Tip: Osteophytes and degenerative changes should be noted in particular.

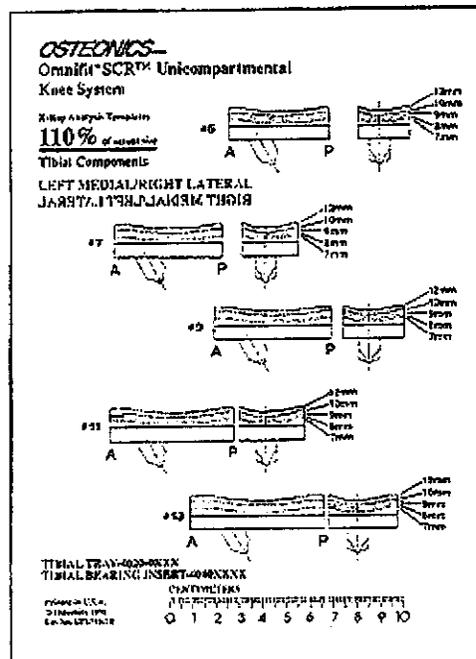
It is Osteonics' recommendation that a full set of appropriate X-rays on each patient and a pre-operative X-ray evaluation and analysis be performed.

Tip: 6 FT A/P Standing, Bent Knee Standing, Cross Table Lateral and Sunrise view X-rays are recommended.

Osteonics provides X-RAY MAGNIFICATION MARKERS and SCR OMNIFIT Knee templates, sized 110% of actual prosthetic and instrument size to estimate instrument acceptance and prosthetic size and style.



X-ray Template: LTEMK 8B



X-ray Template: LTEMK 7B

225



OSTEONICS^{corp}
OMNIFIT[®] SCR[™] Unicompartmental Knee
 X-Ray Analysis Templates
110% of actual size
 A-P and M-L Silhouettes

MEDIAL FEMORAL COMPONENTS

Right

#5
 4010-005R J200-010A

#7
 4010-007R J700-010A

#9
 4010-009R J800-010A

#11
 4010-011R J1100-010A

Dotted line represents subchondral bone line. This line should be used to size the femur.

CENTIMETERS
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X-ray Template: LTEMK 9B

GENERAL INFORMATION

Incisions and Soft Tissue Releases

Medial Approach

A standard anterior midline incision is utilized (Fig. 1). Any previous incision should be used or incorporated if the risk of skin sloughing is present.

The knee capsule is generally entered through a medial parapatellar approach approximately 1 cm from the medial border of the patella (Fig. 2).

The quadriceps tendon is incised longitudinally to allow adequate patellar eversion and sufficient knee flexion (Fig. 3).

Tip: Lateral Release- Prior to dislocation of the patella, assessment of the patellofemoral joint might indicate the need for lateral retinacular release. This is recommended if there is any significant patellofemoral involvement or tightness of the lateral retinaculum. A lateral retinacular release can be carried out either through the interior transsynovial approach or an exterior release, which may be achieved by exposing the lateral retinaculum through the prepatellar bursal space, and using cutting electrocautery for a longitudinal release. In this manner, the superior genicular artery can usually be protected and preserved, carefully coagulating any other bleeding points. The release should extend from the myofascial junction proximally and to the level of the tibial tubercle distally.

Tip: Southern Approach- Although less traditional, the Quadriceps Sparing or "Southern Approach" may be utilized. The authors have found this to provide adequate exposure and earlier quadriceps rehabilitation for the patient.

The patella is everted laterally.

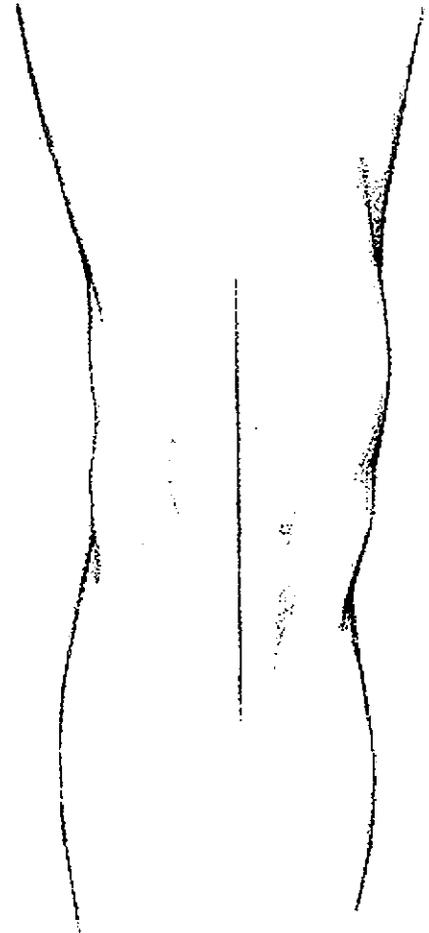


Figure 1

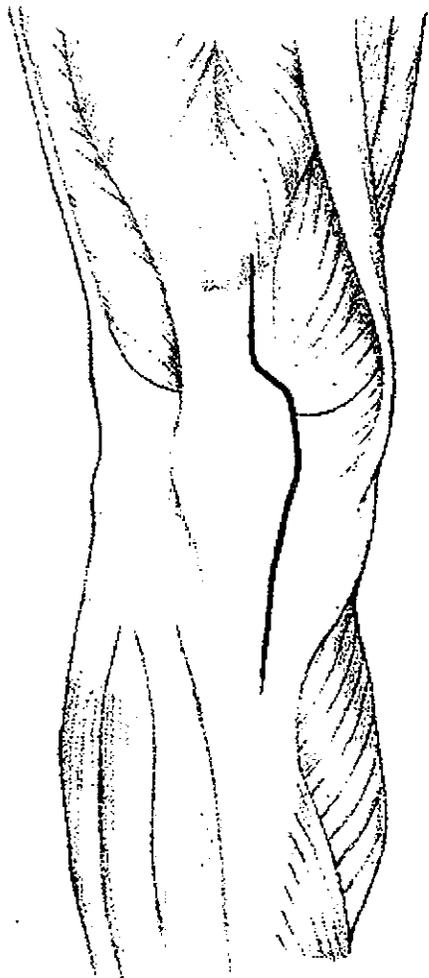


Figure 2

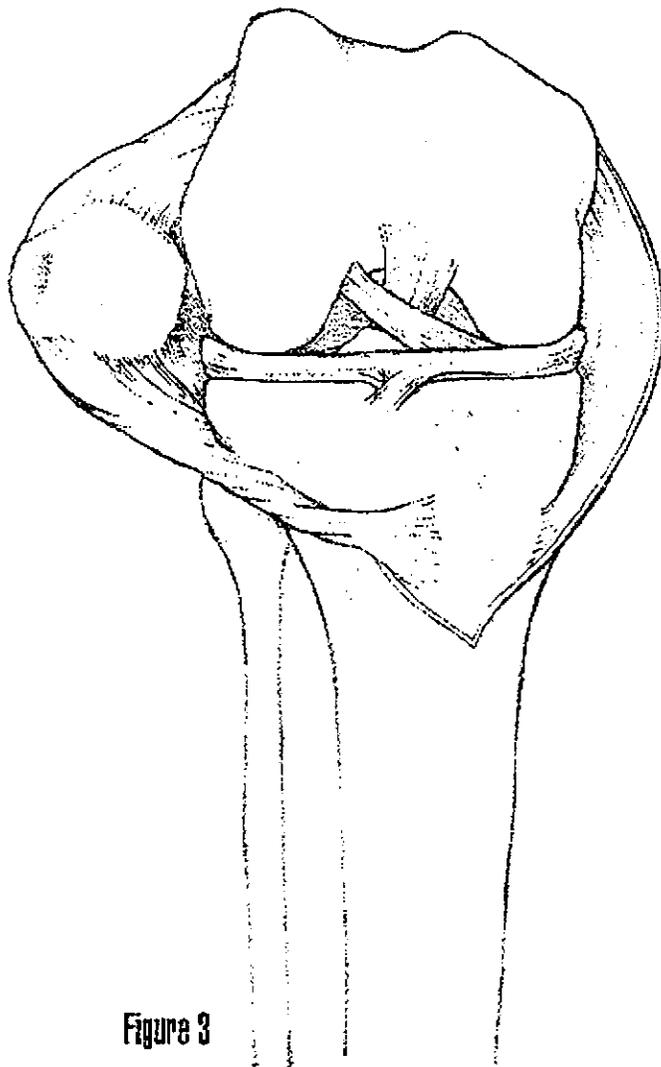


Figure 3

Intra Articular Technique

A special effort should be made to remove all periarticular osteophytes. *The most important areas are those under the collateral ligaments* on both the femoral and tibial sides.

Tip: A Lempert Rongeur works well.

The intercondylar notch area should be remodeled by removal of any central osteophytes.

Check for the presence of an anterior tibial boss osteophyte. This osteophyte is present just anterior to the anterior cruciate ligament origin.

The knee is then extended and stressed into a corrected position. The knee should correct to at least neutral to 7° of valgus, but preferably into 3° to 5° of valgus. If this is not easily obtained, re-evaluate for periarticular osteophytes.

Standard soft tissue releases may also be necessary in severe malalignment situations.

Tip: Overcorrection beyond the recommended alignment is to be avoided. Inability to achieve proper alignment will overload the unaffected compartment increasing the risk of arthroplasty failure or degenerative changes to the unaffected side.

Medial Femoral Preparation

Extend the knee and identify the most anterior area of tibial contact on the anterior femoral condyle.

Highlight the anterior tidemark with methylene blue.

The 3/4" curved gouge is selected and a 3mm groove is cut into the residual femoral articular cartilage and bone at the level of the anterior tide mark (Fig. 4).

Bend the knee to 90°.

Use a small oscillating blade to shave or plane away the degenerative cartilage and subchondral bone in the anterior tidemark area. This preshaping of the femoral condyle is critical and should be continued until close approximation of the arc of the selected femoral resection guide is achieved (Fig. 5).

Note: For proper placement and alignment to be achieved all lig and femoral components must extend to the limits of the anterior tidemark.

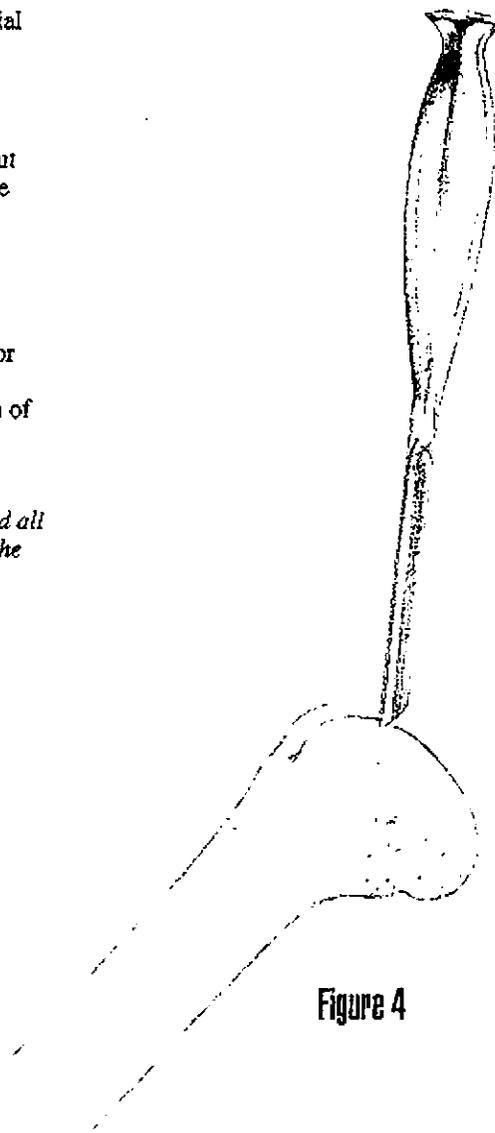


Figure 4

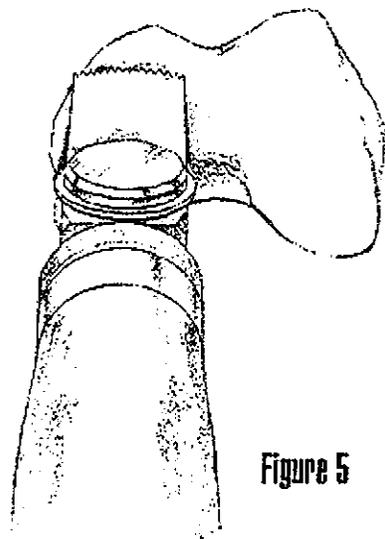


Figure 5

Sizing of the Femoral Condyle

Slide the Femoral Reference Axis Bar onto the flexed knee directly atop the patellofemoral groove and under the quadriceps keeping the instrument parallel to the long axis of the femur. The flanges will sit flush on the femur and will be tucked up under the muscle (Fig.6).

Mark the distal femoral condylar axis with methylene blue. Placing two midline points and connecting them will assist in determining this axis (Fig. 7).

Select the pre-operatively determined femoral drill/resection guide.

This guide serves two purposes:

- To size the femoral condyle
- To partially prepare the condyle to accept the femoral component

Place the femoral drill/resection guide along the distal femoral condylar axis with the anterior tip of the guide in the previously shaped anterior tide mark area.

The proper size and placement of the femoral drill/resection guide has been determined when:

1. The drill resection guide is centered along the divergent axis of the condyle.
2. The posterior foot rests on the posterior condyle.
3. The anterior tip sits within the tidemark area.
4. The instrument handle is oriented 90° to the femoral reference axis bar.

Tip: When the femoral drill/resection guide is properly aligned along the condylar axis, the edge of the femoral guide should be in parallel alignment with the peripheral articular border of the femoral condyle.

Note: If the size of the femoral condyle appears to fall between two sizes, the smaller size should be chosen.

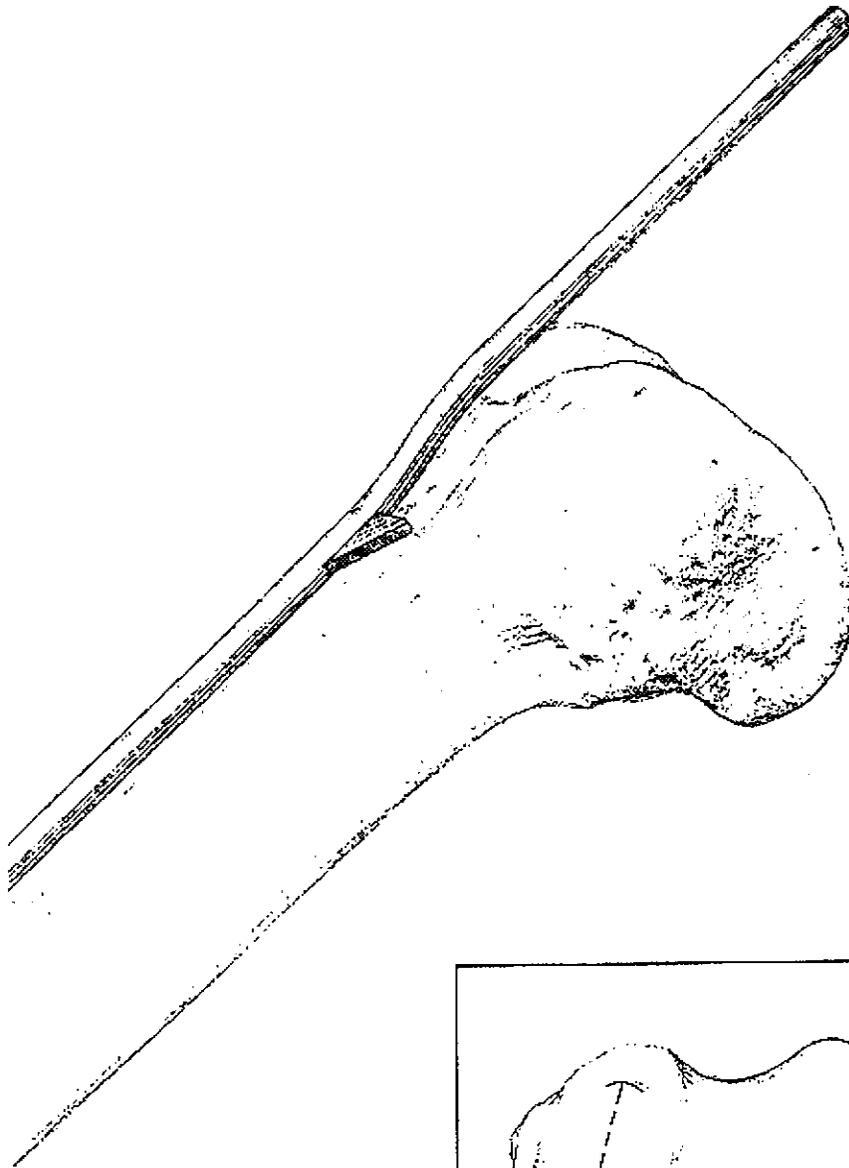


Figure 6

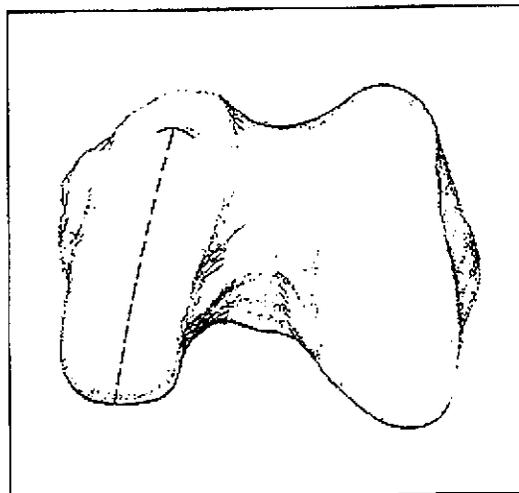


Figure 7

Drilling and Resection of the Femoral Condyle

Medial Compartment Replacement

Make certain the femoral reference axis bar is in position.

Reposition the properly sized medial femoral drill/resection guide as outlined above after proper size determination.

Drill the small anterior hole using the 1/8" drill bit (Fig. 8).

Tap a headed 1/8" fixation pin into the hole to secure fixation.

Making certain alignment has been maintained, drill the middle hole and follow with pin placement (Fig. 9)

The most posteriorly located hole is drilled to mark the area that must be prepared for the implant keel.

Use the 1/4" drill bit with stop to prepare the peg holes. Particular care should be taken in introducing and keeping the drill bit in neutral alignment in the guide to minimize friction against the metal (Fig. 10).

Tip: After drilling the anterior peg hole, a 1/4" femoral drill plug may be inserted to increase the stability of the femoral resection guide. This is especially necessary when encountering with soft bone.

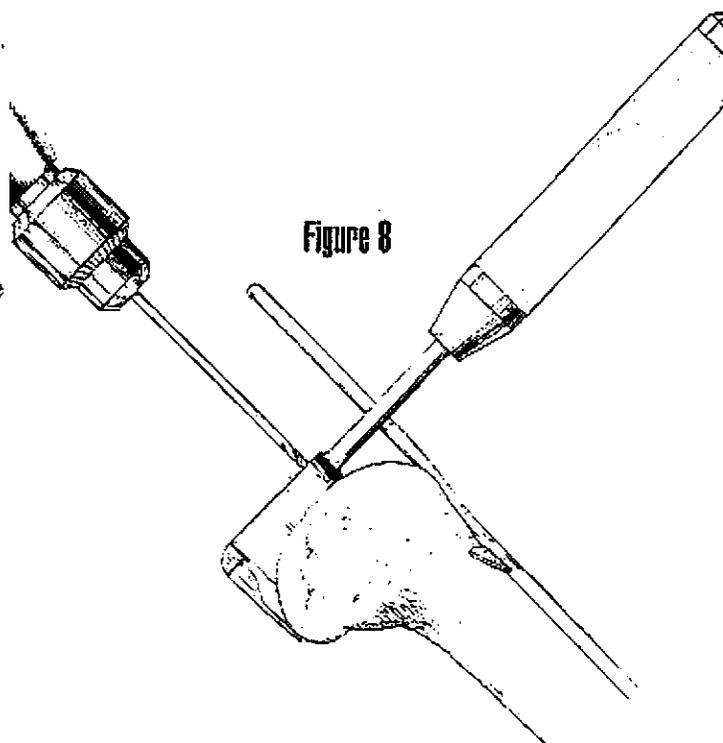


Figure 8

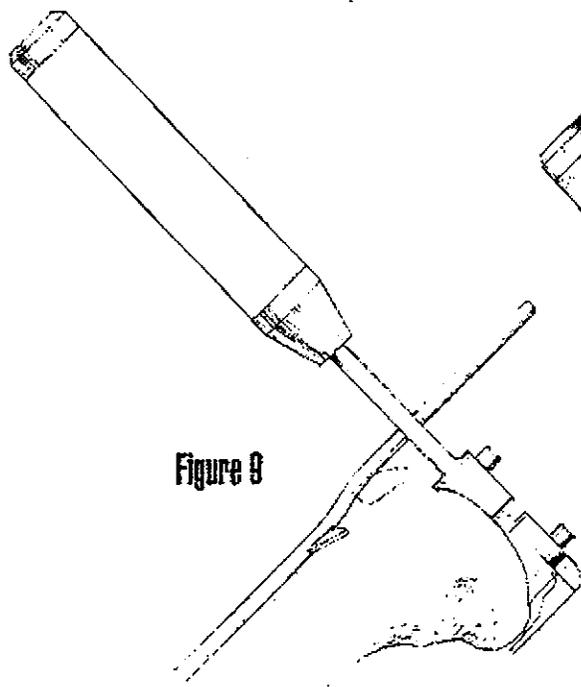


Figure 9

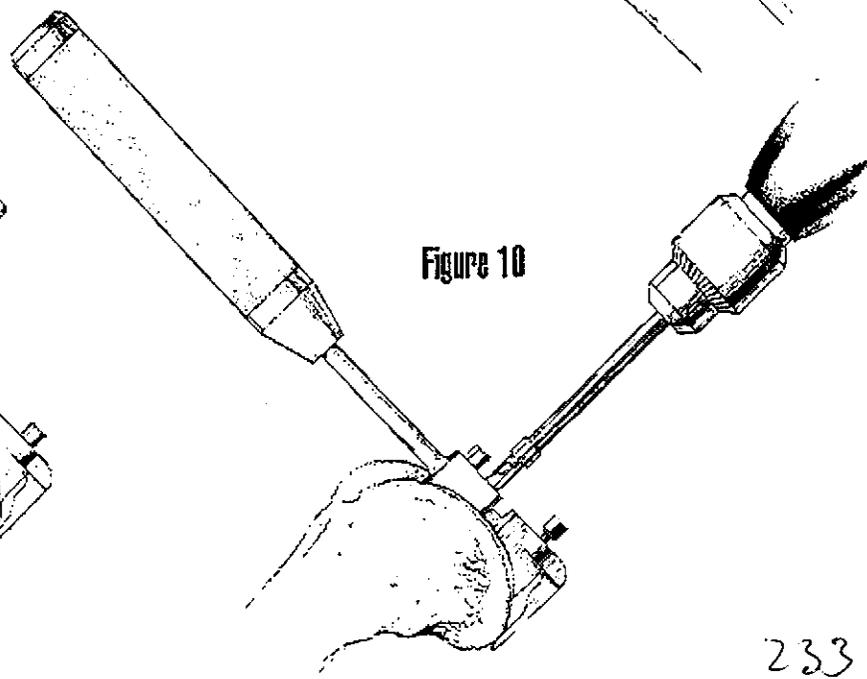


Figure 10

Using a .025" thick blade through the side of the resection guide slot, resect the posterior femoral condyle (Fig. 11).

Tip: If the bone is hard and sclerotic, advance the blade slowly to avoid blade deflection. Several passes may be necessary.

Remove the drill/resection guide.

Using the oscillating blade connect the posterior 1/8" drill hole with the posterior slot made by the 1/8" drill. The width of the slot should correspond to the width of the posterior 1/8" drill hole (Fig. 12).

Use an angled 000 curette to remove the remaining bone. This narrow angled slot will accommodate the posterior fin of the femoral component.

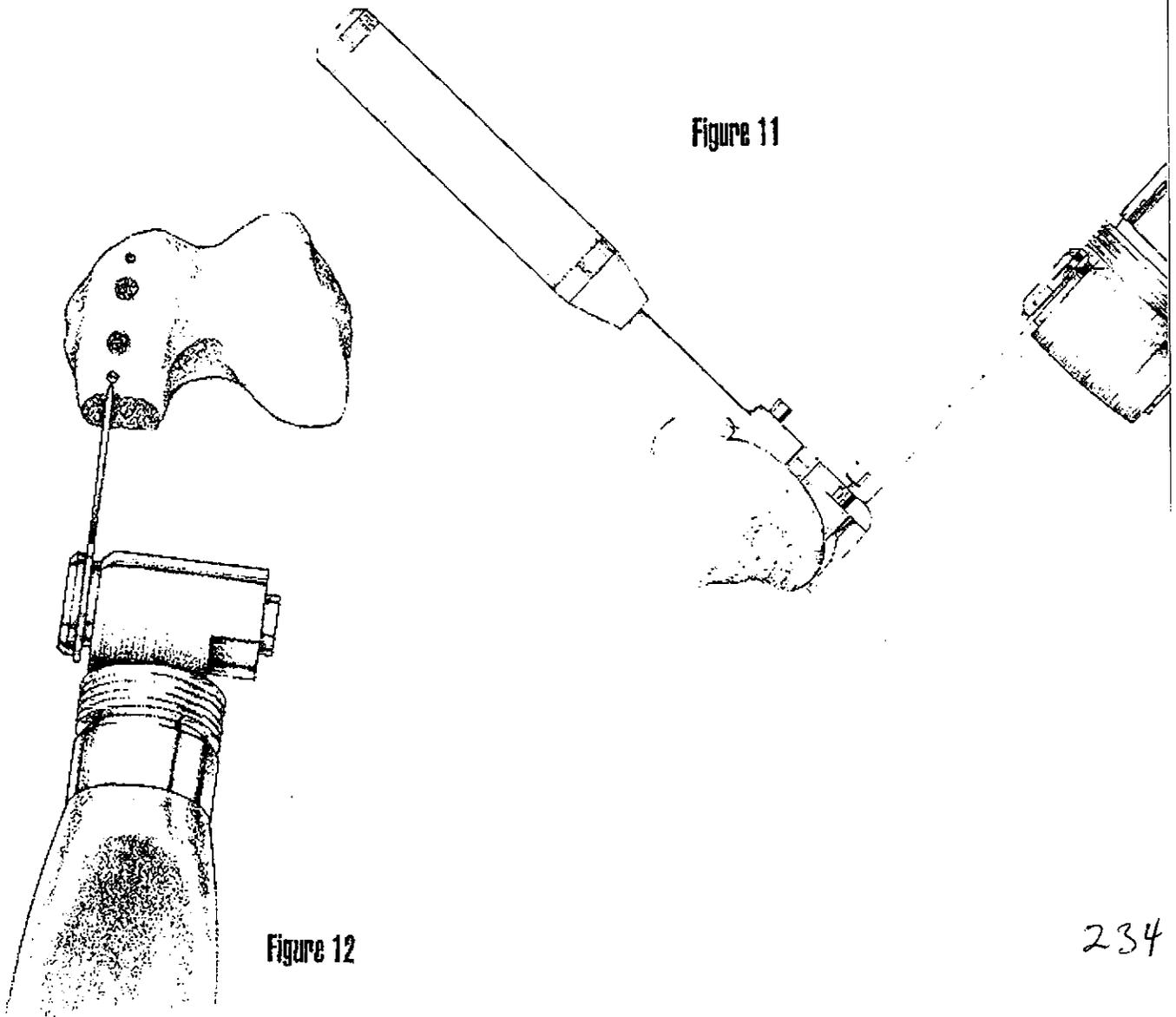


Figure 11

Figure 12

Contouring of the Femoral Condyle

Select the appropriately sized Femoral Contour rail. The size should be the same as the femoral drill/resection guide just used.

Tap the Contour Rail into the two 1/4" drill holes for the medial preparation (Fig. 13).

Make sure the rail is inserted with proper anterior and posterior orientation and is flush on the condylar surface.

Assemble the Femoral Contour Burr to a high-speed drill (approximately 1200 RPM) and make sure the drill is placed in the forward mode.

Straddle the burr bushing on the rail (Fig. 14).

Keeping the burr perpendicular to the rail using a light buffing action, move the burr from posterior to anterior over the femoral condyle with several passes until the bushing is flush on the rail. Due to the natural slope of the medial condyle, the majority of bone being removed will be on the medial side of the medial condyle. Remove the contouring rail.

Note: Care should be taken to control the burr and not allow it to ride off the contouring rail. This may damage the articular cartilage in the patellofemoral area.

Remove the contouring rail.

The remaining rib of bone in the center of the condyle and in the anterior margin in the tidemark area should be planed off with the oscillating saw since these areas are not accessible with the burr.

Further planing and shaping can be accomplished with the Bone File.

If additional bone removal is deemed necessary, the contouring procedure may be repeated.

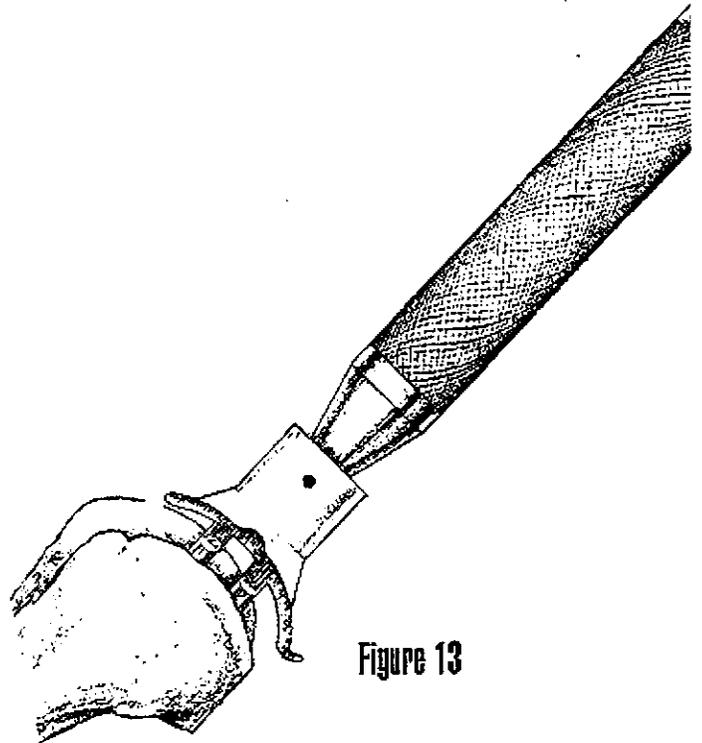


Figure 13

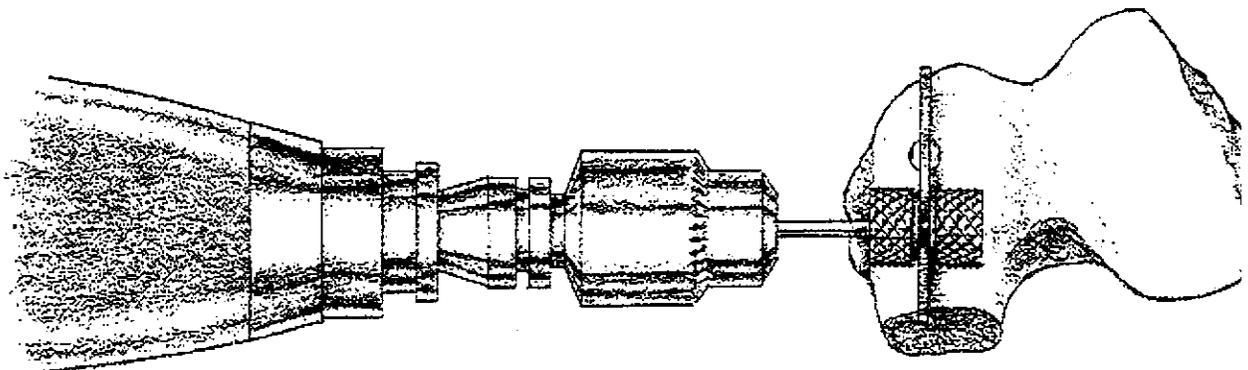


Figure 14

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Tibial Preparation

Determination of the Tibial Resection Level

Vertical Plane

Place the knee in 90 degrees of flexion.

Put the appropriately sized 7mm thick Tibial Bearing Insert Trial at a right angle to the top of the tibial plateau with the dished out portion of the bearing insert trial against the Trial Femoral Component. A headed fixation pin can be passed through the slot in the Bearing Insert Trial into the hole in the femoral trial to hold it in place.

Align the outer-most point of the curved edge of the Bearing Insert Trial to the outer-most point of the cortical margin of the tibial plateau.

Using the intercondylar edge of the Tibial Bearing Insert Trial as a guide, draw a methylene blue line from anterior to posterior on the intercondylar surface of the tibial plateau. This line will identify the intercondylar edge and the vertical resection boundary (Fig. 16).

Note: Because of the tibial plateau anatomy and the desire to place the edge of the component against bone and on the cortical rim, the vertical resection line is angled slightly into the affected compartment (posterior-medial in a medial compartment replacement) and is NOT directly anterior to posterior (Fig. 17).

Figure 16

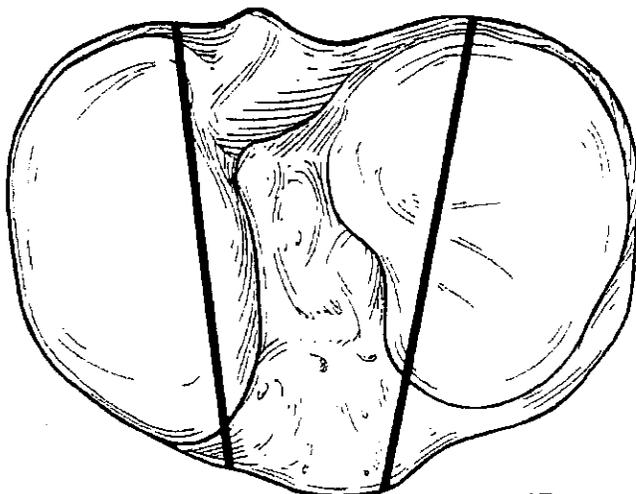
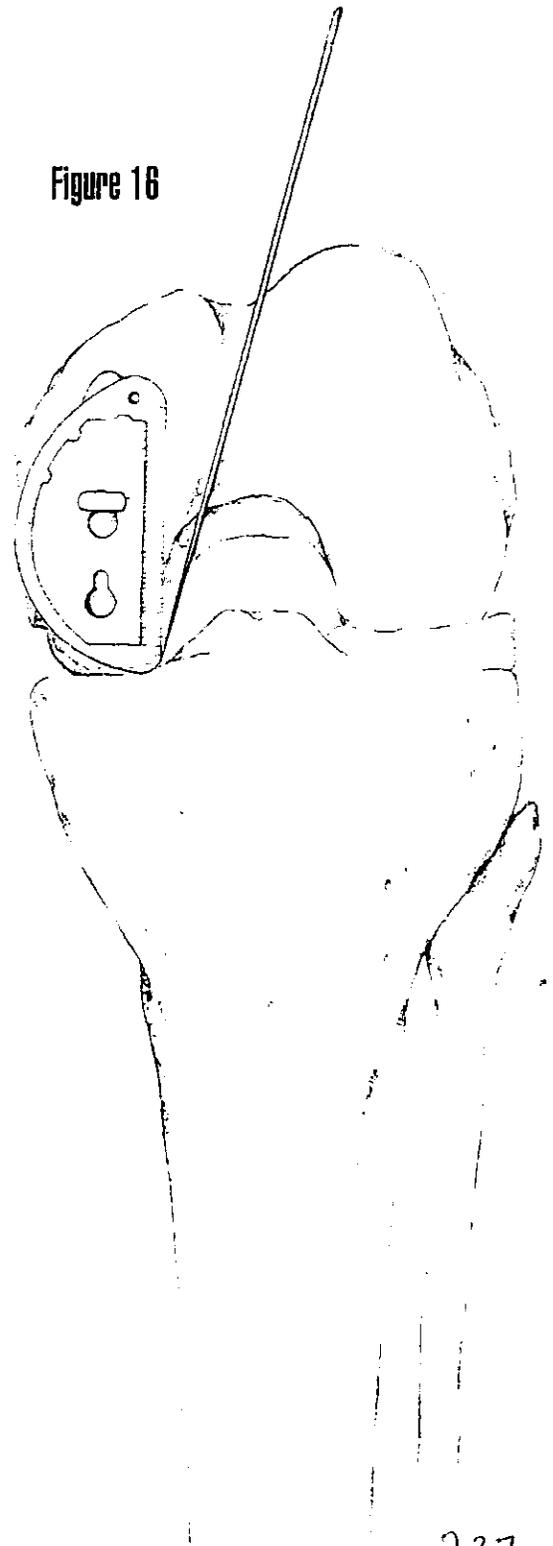


Figure 17

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Horizontal Plane

Attach the Tibial Resection Guide for the appropriate compartment into place on the Tibial Alignment Guide and secure the two pieces by tightening the set screw.

The Tibial Alignment Guide has 3 adjustments:

- Vertical Adjustment for different length tibiae
- A/P Adjustment to control flexion/extension, and/or posterior sloping of the tibial resection, and
- M/L Adjustment to control varus/valgus alignment of the proximal tibial resection.

The spring loaded ankle clamp stabilizes and allows positioning of the distal portion of the instrument so that the center of the ankle can be cradled by the "V" shaped portion of the instrument.

Position the rod portion of the Tibial Alignment Guide parallel to the long axis of the tibia in the sagittal plane. Particular attention should be paid to the proximal one-third of the tibia. Alignment malposition may cause inappropriate anterior/posterior slope of the resection plane.

Coronal alignment can be assisted by placing the shaft in line with the center of the talus.

Rotational alignment can be assisted by passing a 1/8" drill bit through the appropriate hole at the bottom of the instrument. The drill bit should parallel to the intermalleolar axis.

Assemble the Tibial Resection Stylus to the Resection Guide by placing it into the hole located on the cutting surface of the resection guide.

The level of tibial resection is determined by locating the point of the stylus on the lowest spot on the tibial *articular* surface. With the stylus fully seated in the resection guide the plane of resection will be 2 mm *below* the stylus tip (Figs. 18 & 19).

When the level has been established, the thumbscrew which controls vertical length adjustment of the Tibial Alignment Guide is secured.

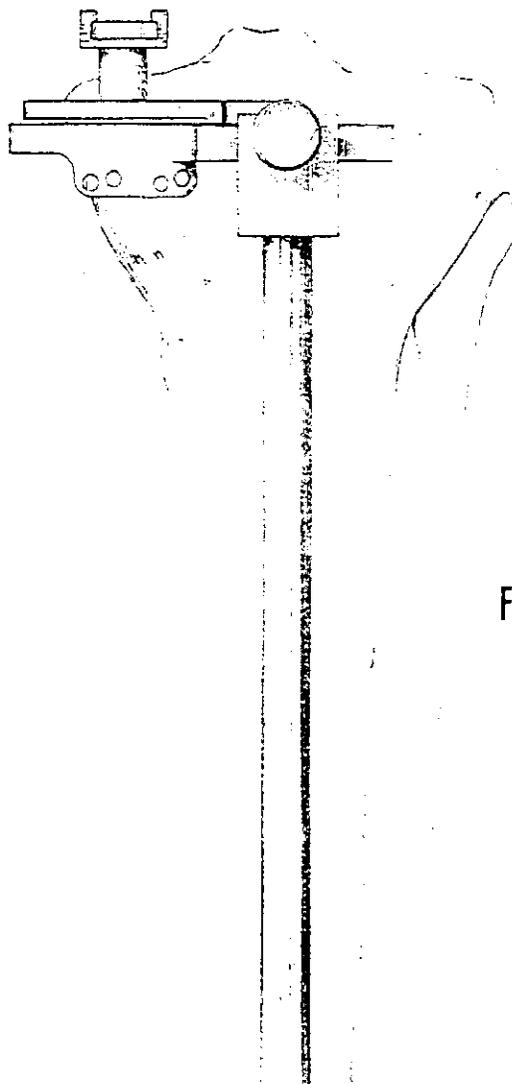


Figure 18

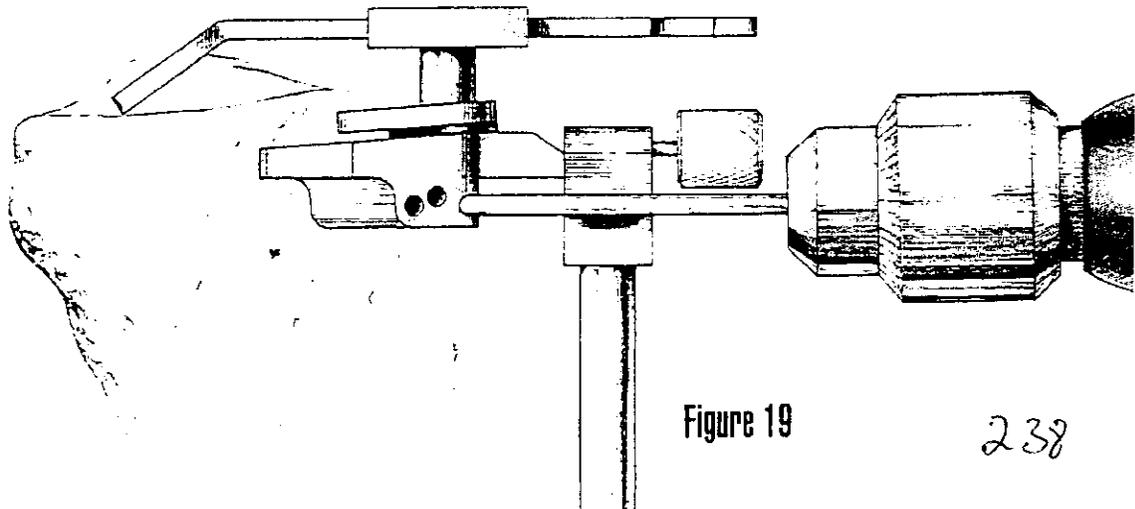


Figure 19

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Resection Guide Fixation

OPTION:

Drill the 1/8" hole closest to the center of the knee at the level marked as "0". After drilling place a Fixation Pin.

Remove the Stylus.

Keep the Tibial Alignment Guide and the Resection Guide in place.

OR-

Drill two 1/8" holes through the holes marked "0". After each drilling procedure place a Fixation Pin (Fig. 20).

Remove the Stylus.

The Tibial Alignment Guide can now be removed by loosening the set screw, leaving only the Resection Guide in place.

Tip: Check the intended level of resection by passing the saw blade through the slot and gauging the depth and slope.

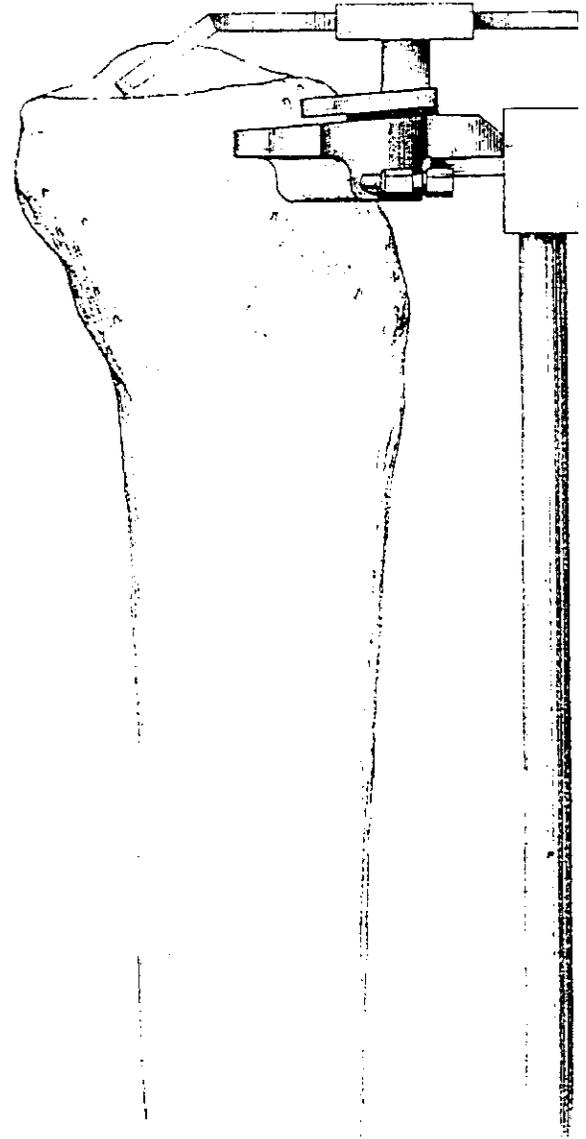


Figure 20

Tibial Resection

After introducing the oscillating saw blade from the open side into the slotted resection guide make the horizontal resection. The horizontal cut should not undermine the intercondylar area of the tibial plateau (Fig. 21).

Note: With the resection guide aligned per the instructions listed above the slope of the horizontal resection is 4° posterior.

With the reciprocating saw blade (Catalog# 3127-0025), the vertical cut is performed along the methylene blue line in the intercondylar notch area (Fig. 22).

Remove the bone wedge.

Resect the remaining posterior horn of the meniscus and all posterior osteophytes. File smooth if required.

Tip: When using the oscillating saw, care should be taken not to undermine the tibial spine. Equally important is control of the reciprocating saw so as not to notch the tibial plateau.

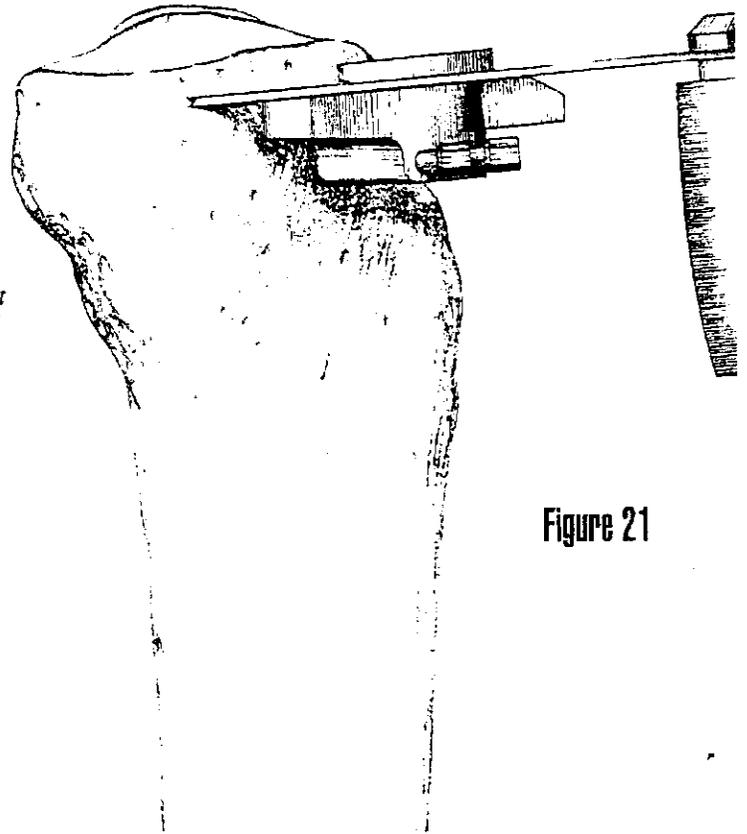


Figure 21

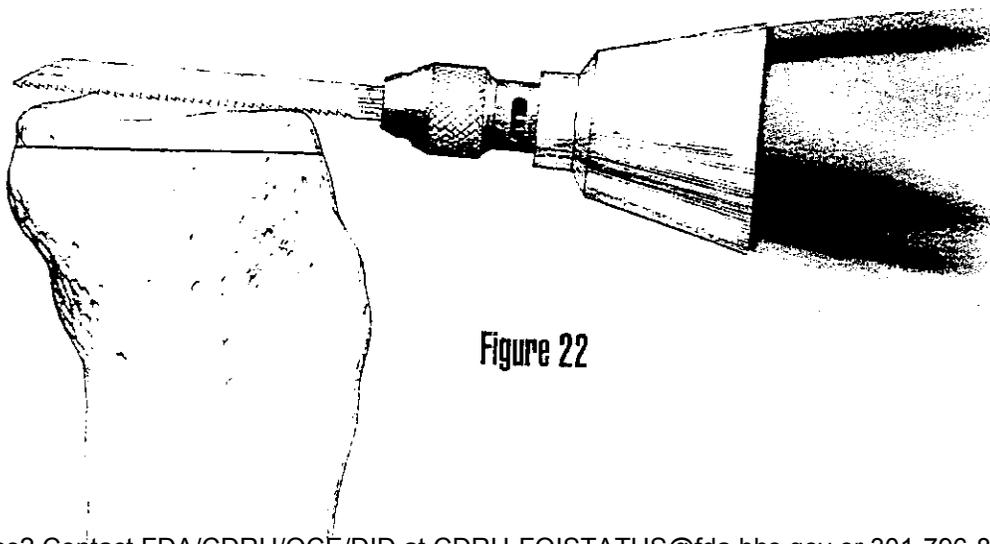


Figure 22

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Tibial Implant Selection and Assessment

Select the appropriate tibial baseplate. The size selected should most closely approximate the exact anterior-posterior depth of the plateau. Slight overhang posteriorly is preferable to undersizing.

Assess tibial coverage and surface preparation. The curved edge of the baseplate should align with the curved anatomy of the tibia. The straight edge of the baseplate should abut the vertical wall of the intercondylar resection. Any overhang of the curved surface of the baseplate can be corrected by using the Flat Square file on the vertical cut. Minor elevations on the horizontal resections can be planed as well.

Select and lock into place the 7 mm Tibial Bearing Insert Trial for the previously selected Tibial Baseplate (Tibial Trial Assembly) (Fig. 23).



Figure 23

With the knee at 90° of flexion, gently distract the knee, the Tibial Trial Assembly should be easy to insert.

With the tibial trial assembly in place and positioned properly, the contour of the tibial plateau on the intercondylar side will be of equal height. The prosthesis should not sit higher than the vertical resection anteriorly. The natural slope and contour of the tibial plateau should be reproduced and the joint line reestablished.

Place the knee through its arc of motion and evaluate for ligament stability. There should be no flexion contractures, and the range of motion should be from full extension to 120° of flexion. A tension-free range of motion is the goal.

Increase the Tibial Bearing Insert Trial thickness to achieve proper ligament tension and axial alignment.

When satisfactory placement of the Tibial Trial Assembly is achieved, a mark should be made on the anterior tibia corresponding to the scribing mark on the baseplate. This mark will serve as a reference point for subsequent placement of the baseplate (Fig. 24).

Tips: If the tibial trial assembly rocks in flexion, resection of the tibial plateau may be insufficient. Additional tibial resection can be performed by applying the resection guide on the previously placed 1/8" pins at the "+1" level or with judicious use of a bone file.

Posterior femoral condylar overhang impingement is another cause of rocking. Resect the overhang with the knee hyperflexed and gently distracted.

With satisfactory tibial resection and trial reduction detach the trial baseplate from the tibial bearing insert.

Attach the Baseplate to the Trial Baseplate Handle/Drill Guide.

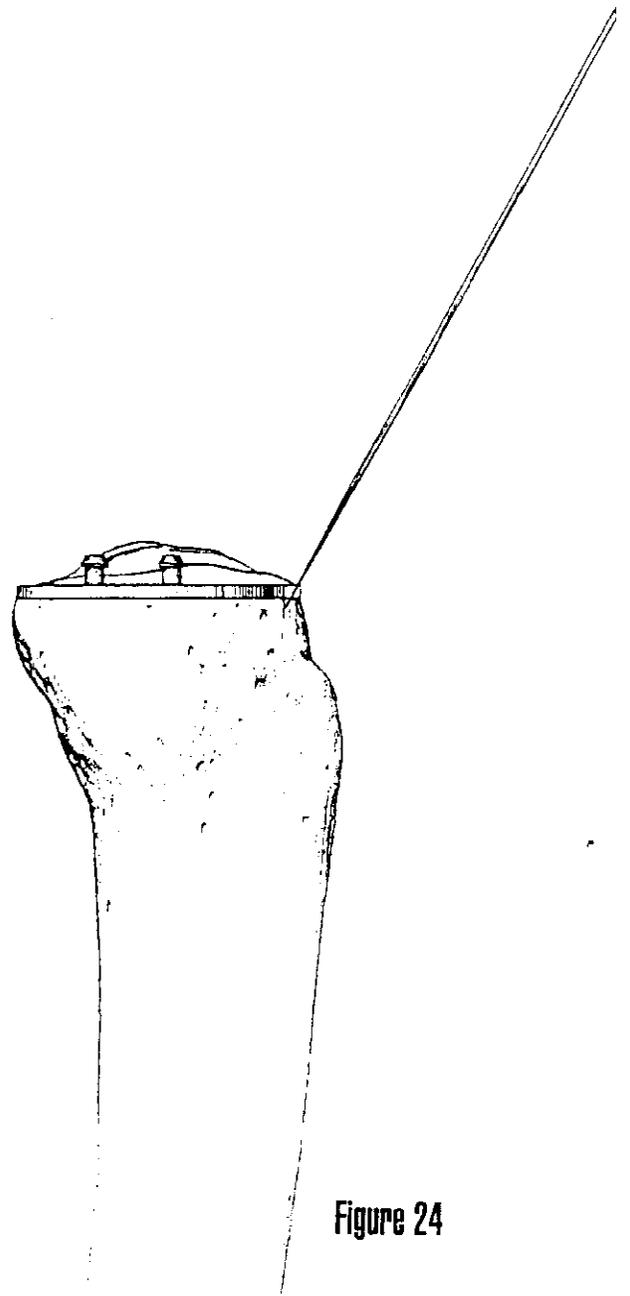


Figure 24

Tibial Keel Preparation

Seat the trial baseplate in the same manner as when sizing the resected tibial plateau.

Align the scribe mark with the previously made mark on the anterior tibia.

The 1/8" drill bit with stop is used to make a drill hole through the guide in the tibial baseplate assembly. Care should be taken to prevent drill guide migration during the drilling procedure, as this will compromise accurate alignment of the tibial tray component (Fig. 25).

Disassemble the Baseplate Handle from the Tibial Baseplate.

Place the Tibial Baseplate on the tibia in the previously determined position.

Place the tip of the Tibial Post Punch into the 1/8" drill hole (Fig. 26).

Gently TAP the Tibial Post Punch through the Tibial Baseplate. Care should be taken to maintain proper positioning of the baseplate as the punch is impacted into the 1/8" drill.

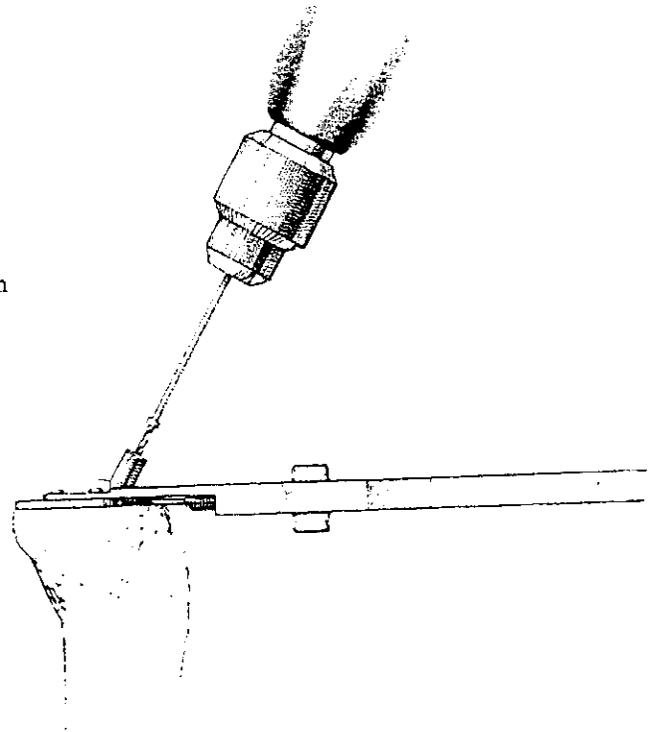
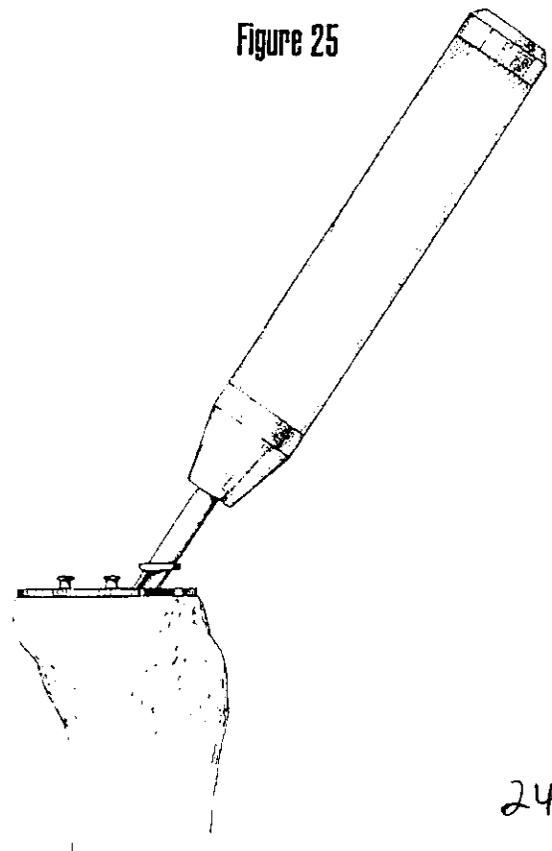


Figure 25



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Implantation of Components

Prepare the bone surfaces for cementing per surgeon's individual protocol. A clean and blood-free surface is recommended.

Cement in a low viscous state will improve cement interdigitation with trabecular bone.

Tibial Component:

Distract the flexed knee with a bone hook in the notch area.

Tip: It may also be helpful to rotate the tibia (externally-medial compartment/ internally- lateral compartment), as this provides easier access to the tibial plateau.

Place cement on the tibial surface and if desired into the prepared tibial hole. Mark the hole placement.

Attach the Tibial prosthesis to the Tibial Impactor/Extractor (Fig. 27).

Position the tibial prosthesis with the post aligned properly in the prepared hole. The tibial keel must engage the hole preparation before impaction of the component.

Using the tibial impactor, *lightly tap* the tibial base plate in place. It is important that the component is visualized to insure that it is completely seated both anteriorly and posteriorly.

Remove all excess cement with a small, angled curette.

OPTION:

The appropriately sized Tibial Bearing Insert TRIAL can be snapped into place before implanting the femoral component if one additional trial reduction is desired

OR-

The appropriately sized UHMWPE Tibial Bearing Insert can be snapped into place facilitating ease of insertion prior to implanting the femoral component.

It is recommended that the UHMWPE Tibial Bearing Insert be implanted before cementing the Femoral Prosthesis in place.

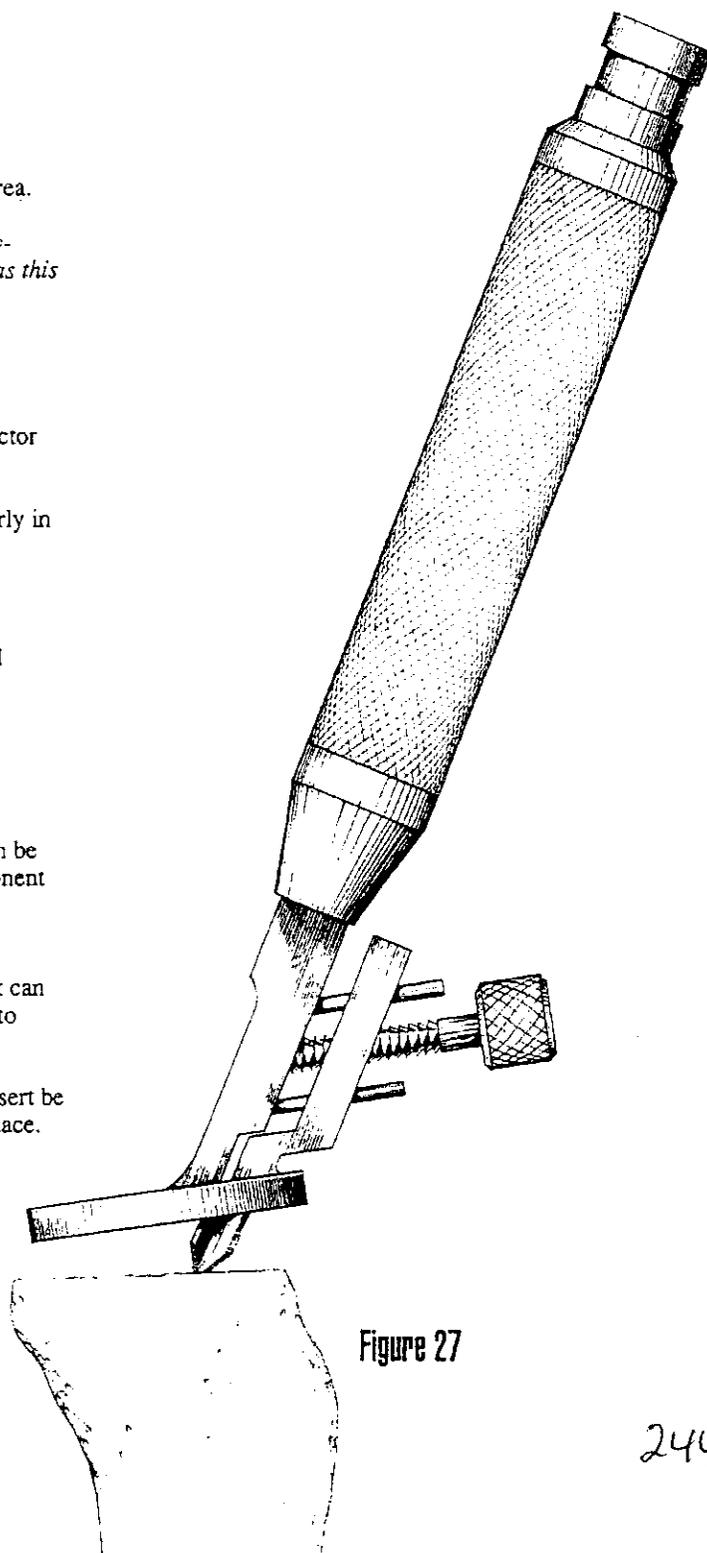


Figure 27

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Bearing Insert

Remove the trial Bearing Insert after final assessment of thickness is made.

Gently distract the knee while flexed at 90° to open the compartment maximally. Remove any cement fragments which may not allow bearing to seat properly.

Place the UHMWPE Bearing Insert into the Tibial Tray Component making sure to direct the posterior tab of the insert under the posterior lip of the tray. It is necessary to keep the posterior lip of the bearing insert locked into the baseplate when seating it properly.

Tap on the anterior surface to lock the Bearing Insert into place.

Check to make sure complete seating has been accomplished.

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Femoral Component:

While maintaining distraction with the knee flexed at 90°, insert the cement into the prepared femoral bed.

Properly align the femoral component so that the post/s and keel will engage the prepared holes in the femur.

Using the femoral component impactor, lightly tap the femoral component in place (Fig. 28).

Remove all excess cement from the femoral side.

Place the knee in full extension to physiologically compress excess cement and cause further cement interdigitation.

Flex the knee again and inspect to insure removal of all excess cement then return the knee to full extension.

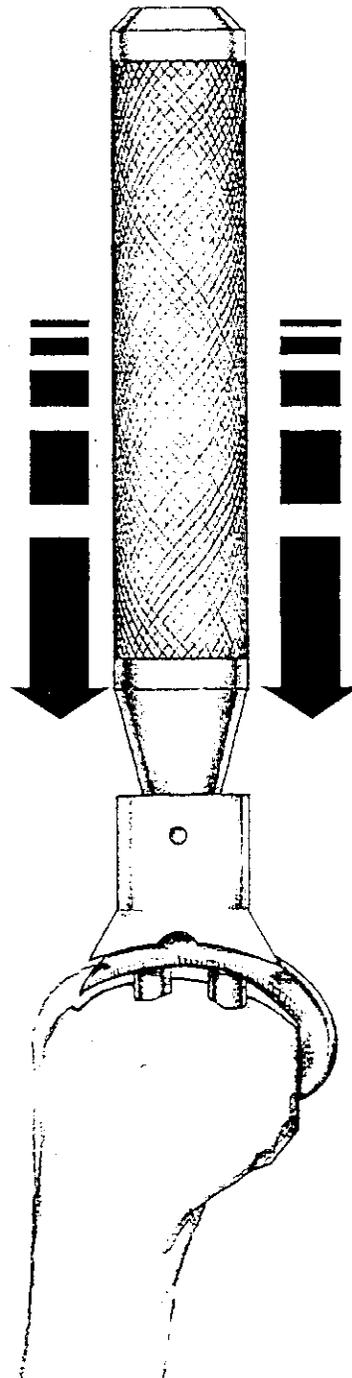
Allow the cement to polymerize before moving the knee again.

Closure

Deflate the tourniquet and achieve hemostasis.

The knee should be thoroughly lavaged. Closed suction drainage is recommended. Close the soft tissues in the normal layered fashion.

Figure 28



Lateral Femoral Preparation

A standard anterior midline incision is utilized. Any previous incision should be used or incorporated if the risk of skin sloughing is present.

If there is any question regarding the condition of the medial compartment, a small arthrotomy may be made on the medial side of the knee prior to exposure through a lateral incision.

Tip: If the medial compartment is significantly involved and a Tricompartamental is indicated, exposure of the knee is easier through the medial approach.

The capsule is entered through a lateral parapatellar approach approximately 1 cm from the lateral border of the patella.

The quadriceps tendon is incised longitudinally to allow adequate patellar eversion and sufficient knee flexion.

The patella is dislocated medially.

Lateral Compartment Replacement

Make certain the femoral reference axis bar is in position and the knee adequately flexed.

Position the properly sized lateral femoral drill/resection guide as outlined above.

Mark the distal femoral condylar alignment with methylene blue. The lateral compartment tidemark is identified in full extension. The anterior edge of the femoral component is oriented toward the lateral portion of the lateral condyle. With the knee flexed, a line is drawn through the center of the lateral femoral condyle. (Fig. 29).

Tip: To check the positioning of the guide a 1/4" drill bit can be inserted in a drill hole. The long axis of the 1/4" drill should be parallel with the femoral reference axis bar and/or the long axis of the femur in the lateral plane.

Drill the small hole anteriorly using the 1/8" drill bit.

Tap a headed 1/8" fixation pin into the hole to secure fixation.

Recheck guide alignment.

Select the side providing the best purchase in bone then drill either of the two (2) posterior holes.

Place a headed 1/8" fixation pin into the prepared hole.

With fixation achieved, drill the 1/8" hole located inside the chamber of the 1/4" drill hole and drill the most posteriorly positioned 1/8" hole located in the center of the resection slot (Fig. 30).

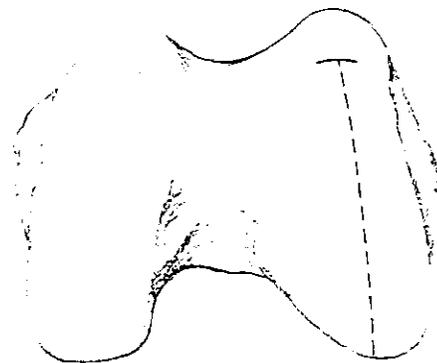


Figure 29

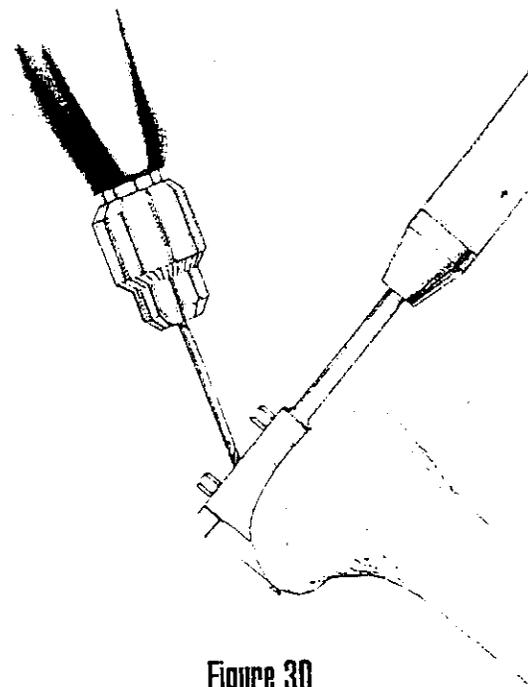


Figure 30

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Use the 1/4" drill bit with stop to prepare the peg hole. Particular care should be taken in introducing and keeping the drill bit in neutral in the guide to minimize friction against the metal (Fig. 31).

Pass an oscillating saw with a blade of .025" thickness through the side of the resection guide slot and resect the posterior femoral condyle.

Tip: If the bone is quite hard and sclerotic, advance the blade slowly to avoid blade deflection. Several passes may be necessary.

Remove the drill/resection guide.

With methylene blue, draw a line from the most posterior 1/8" drill hole to the second midline positioned posterior 1/8" drill hole.

Using the thin oscillating blade cut two slots along the drawn methylene blue lines. The width of the slot should be equal to the 1/8" drill hole.

Use an angled 000 curette to remove the remaining bone. This narrow angled slot will accommodate the posterior fin of the femoral component.

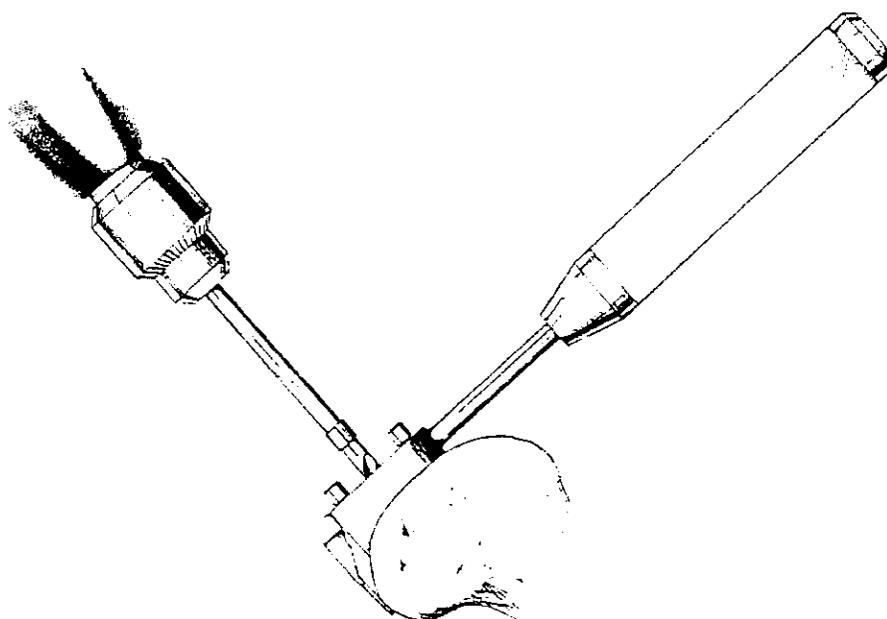


Figure 31

Surgical Technique for femorotibial arthroplasty using the
UNIX™ Unicompartmental Knee System

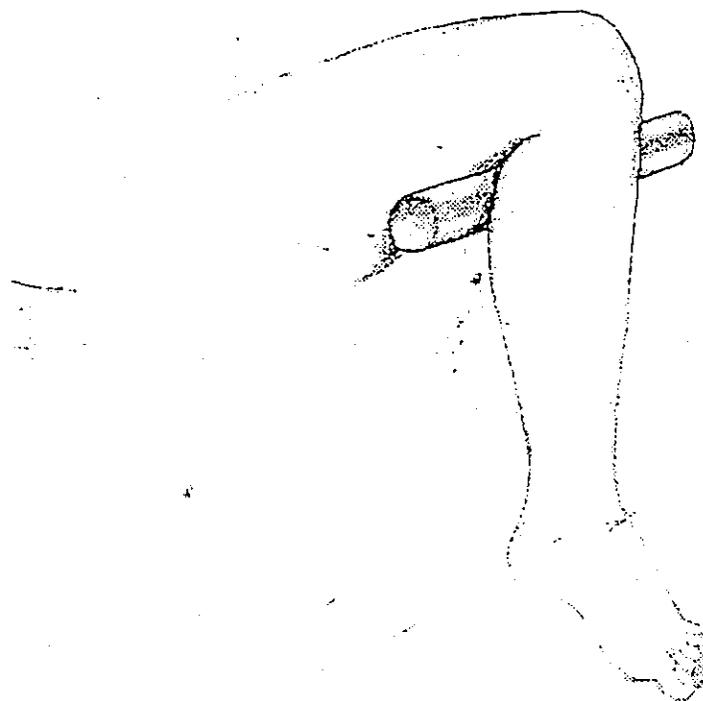
Surgical Technique for femorotibial arthroplasty using the UNIX™ Unicompartmental Knee System

1. Pre-operative planning

Obtain a set of preoperative X-rays including A.P., lateral, skyline and long-standing films to determine the mechanical axis and patient suitability for unicompartmental knee replacement.

Patient positioning

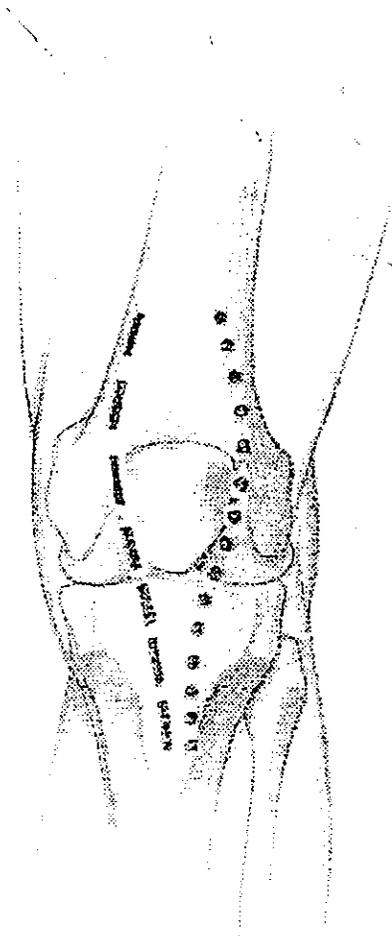
Place the patient in a supine position on the operating table with the foot section of the table removed. The recommended positioning involves placing the knee over a bar as used for meniscus surgery. The bar should be positioned high under the femur to allow the knee to be taken through its full range of movement, including flexion of at least 110 degrees.



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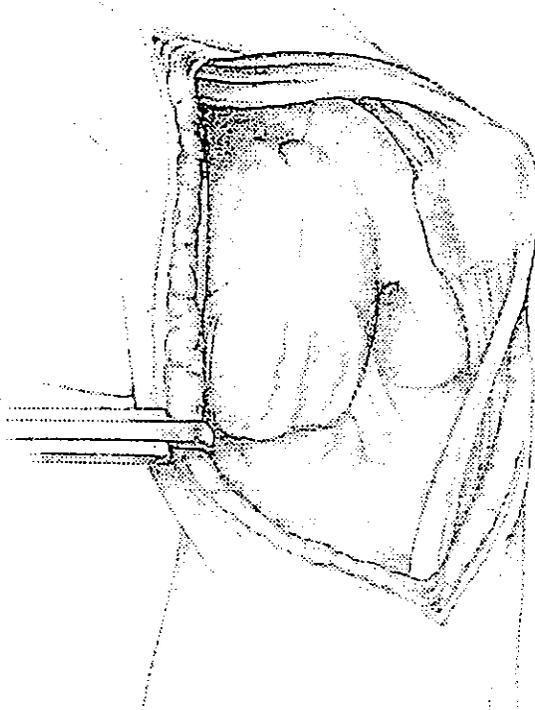
2. Approach and Exposure

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The joint is approached via an anterior paramedian incision, to the left or right of the patella, depending on the compartment to be treated. The curvilinear incision is started approximately 3cm from the base of the patella and continued along the edge of the patella tendon and finished approximately 3 cm to the left or right of the tibial tubercle.

The patella is dislocated and reflected toward the healthy side, and the meniscus is removed. A peritibial release is performed and extended beyond the posterolateral corner. The patellar tendon is held out of the way, taking care not to damage the fat pad.

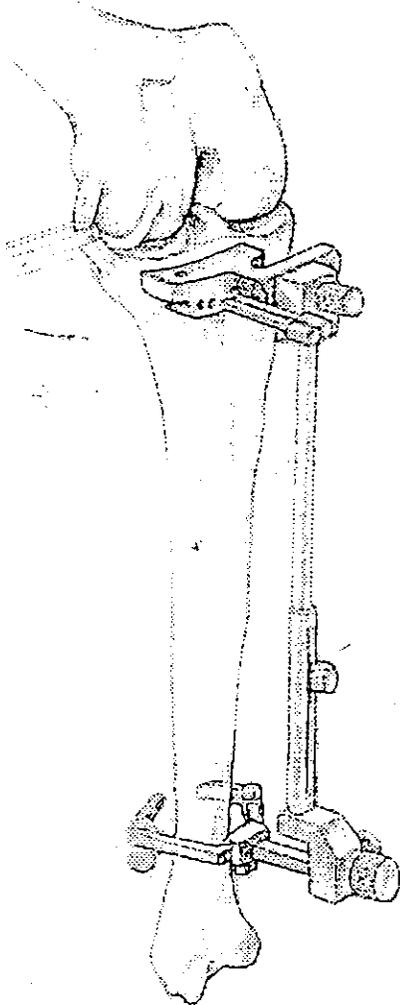
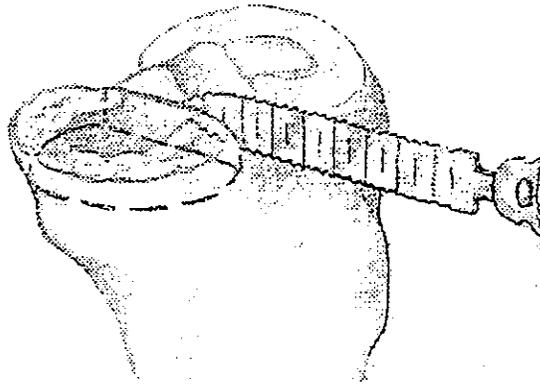


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3. Tibial Resection

Vertical Cut

The midline vertical cut is made flush against the tibial spine. For the Medial compartment the cut is made in a strictly anterior posterior direction and for the Lateral compartment the cut is made in an anterior medial direction. The starting point of the saw cut can be notched at the anterior border using a chisel.



Horizontal Cut

The horizontal cut is made by using the external tibial alignment guide. The resection level is determined by the styluses. The "standard" stylus indicates the level on the affected side, just below the concavity of the of the plateau to minimise loss of bone. The contralateral stylus references the cut to the healthy side and allows for the cut to be made automatically at 8mm from the joint line, preventing resection at too high a level.

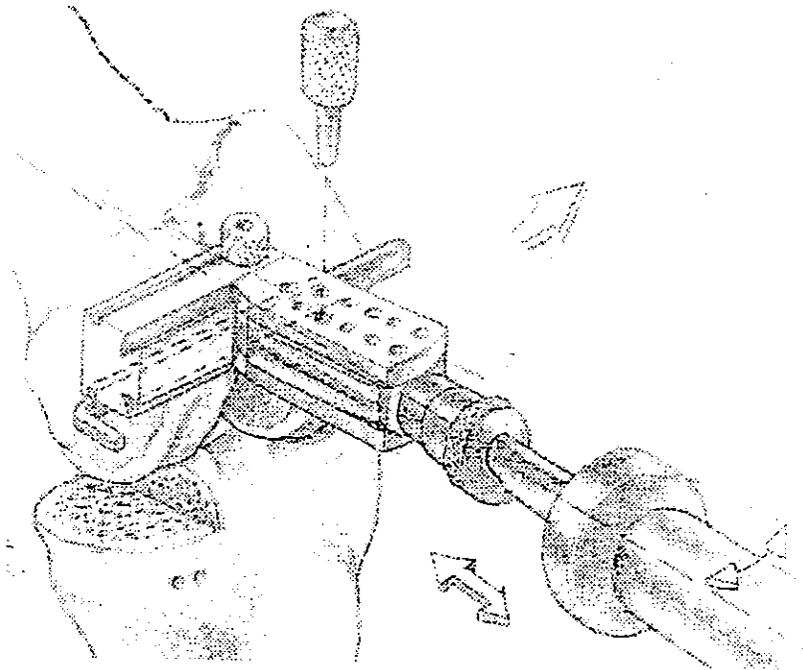
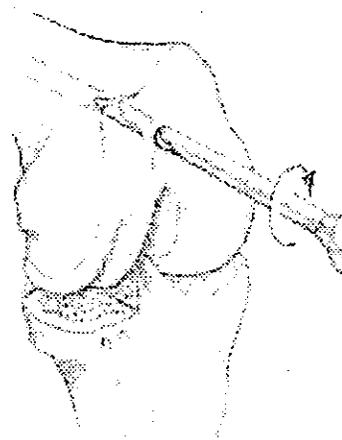
The cutting block is then pinned to the tibia using 2 or 3 headless fixation pins prior to making the horizontal resection. The tibial alignment guide is left in place to give additional stability to the cutting block. The saw cut is kept horizontal in both the coronal and sagittal plane. The cut is made using a sagittal saw (blade approximately 15mm). The cut is made using a sagittal saw (blade approximately 15mm).

4. Distal Femoral Cut

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Positioning the IM guide

The opening for the introduction of the IM rod is situated above the intercondylar notch, just medial to the midline. A 5/16 inch hole is drilled and the rod introduced. The half block for the distal cut is turned outwards or inwards as required for lateral or medial compartment replacement and placed against the affected condyle.



Determining the resection level in the coronal plane

The condylar slide is passed through the lower groove on the distal half block, to the contralateral condyle. This gives the bicondylar line and allows the shaft angle (5, 7, 9, or 11 degrees) to be set by placing a pin in the "cribbage board" on the alignment rod holder.

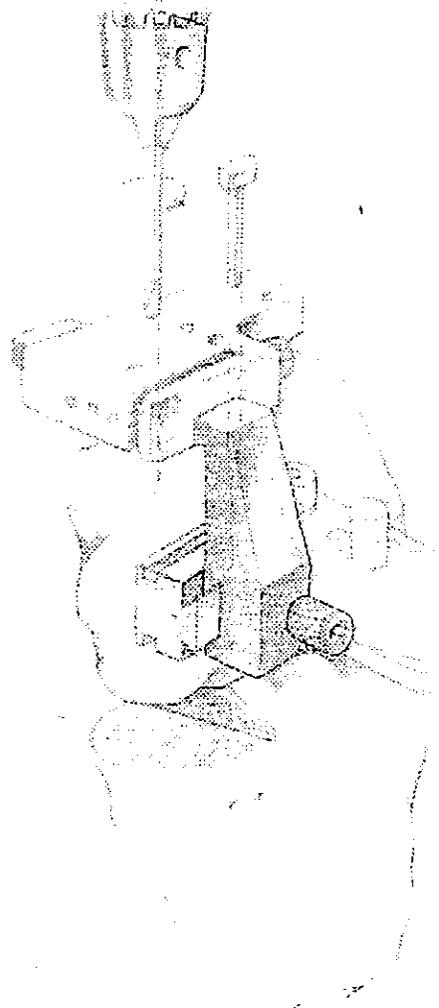
OR

The Valgus angle of the femur may be determined from the pre-operative long leg films and this angle is then set prior to the insertion of the intra-medullary rod. This may require the placement of the half block 1 to 2 mm away from the affected site to allow for bone loss.

Application of the distal cutting guide/ Distal Femoral Cut

The femoral cutting guide holder is slotted onto the dovetail on the distal half block. Then the cutting guide is attached to the holder to the 4 mm mark. This will give an appropriate distal femoral resection in most cases, accommodating the femoral component and allowing for condylar wear, without removing too much bone stock. The cutting guide is then fixed to the anterior femur with 4 headless pins.

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Removal of the intramedullary rod and assembly must be performed as follows;

1. Remove the screw connecting the distal half block to the IM rod
2. Remove the pin from the cribbage board and withdraw the IM rod
3. Remove the half block and the cutting guide holder

The cutting guide is then lowered vertically to be seated flush onto the condyle. The Blade Runner may be used to assess the level of resection prior to making this cut. The distal cut is then made taking care to bias the blade towards the bone. Care must also be taken to ensure that the blade is not deflected by hard bone.

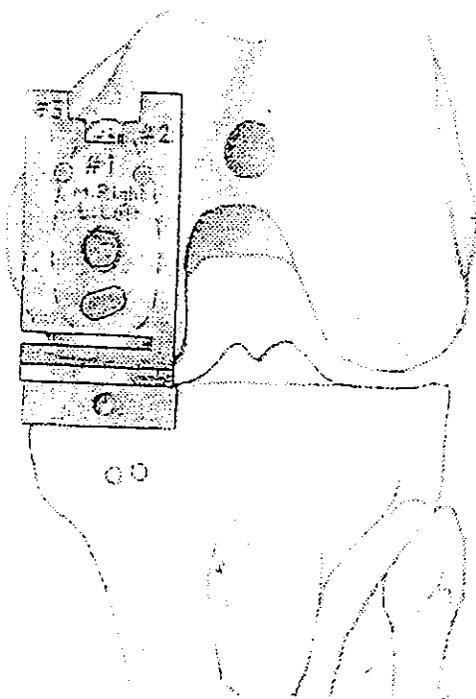
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5. Posterior Resection

Application of Posterior Cutting Block

The posterior cutting block is placed flush onto the distal cut surface. With the knee in 90 degree flexion the tibial spacer is slipped under the sole plate of the cutting block. The thickness of the spacer and sole plate is 8mm, which corresponds to the minimum thickness of the tibial component. The block is seated directly on the tibial cut surface, ensuring automatic positioning of the cutting instruments.

If it is not possible to place this construct into the joint space it is necessary to recur the tibia to avoid tightness in flexion.



Attaching the cutting block and posterior cut

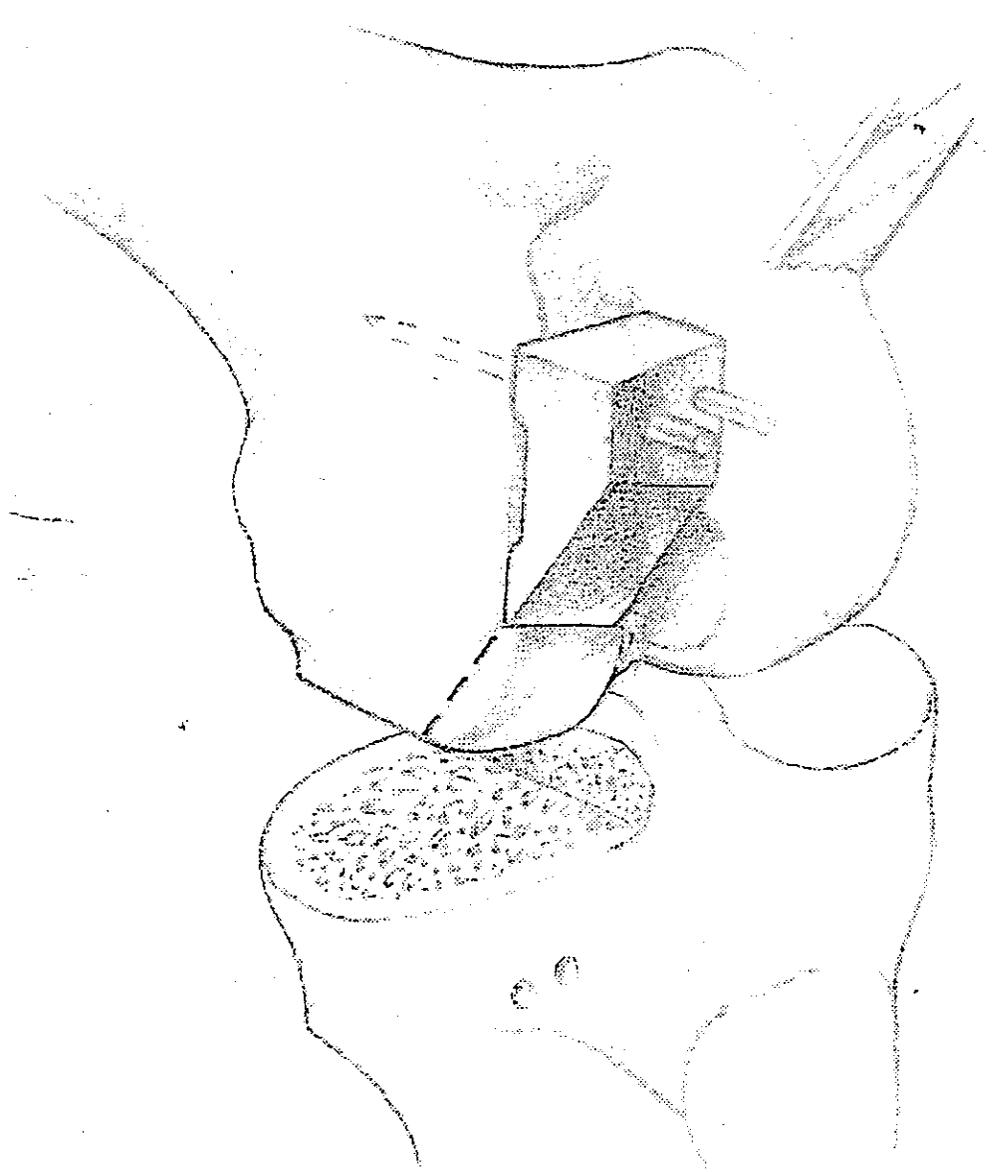
Two headless pins are inserted through the upper part of the block, after ensuring that the block is in full contact with the underlying bone. A third pin is inserted through the lower part of the block. The cut is made with an oscillating saw, 10 mm blade. Care is taken to ensure the blade is biased toward the bone, as described above for the distal cut.

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6. Chamfer Cut

The posterior cutting block is removed leaving behind the 2 headless fixation pins in the upper part, which allows for the automatic positioning of the chamfering block over these pins. The pins are hammered flush. Each component has its own chamfering block which also comes in a Right and Left version.

The chamfer cut is made with an oscillating saw (15mm blade) placed on the cutting block, with the block pressed firmly against the distal surface by an assistant. The assymetrical block will determine the angulation of the femoral lock.



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7. Implant positioning tests

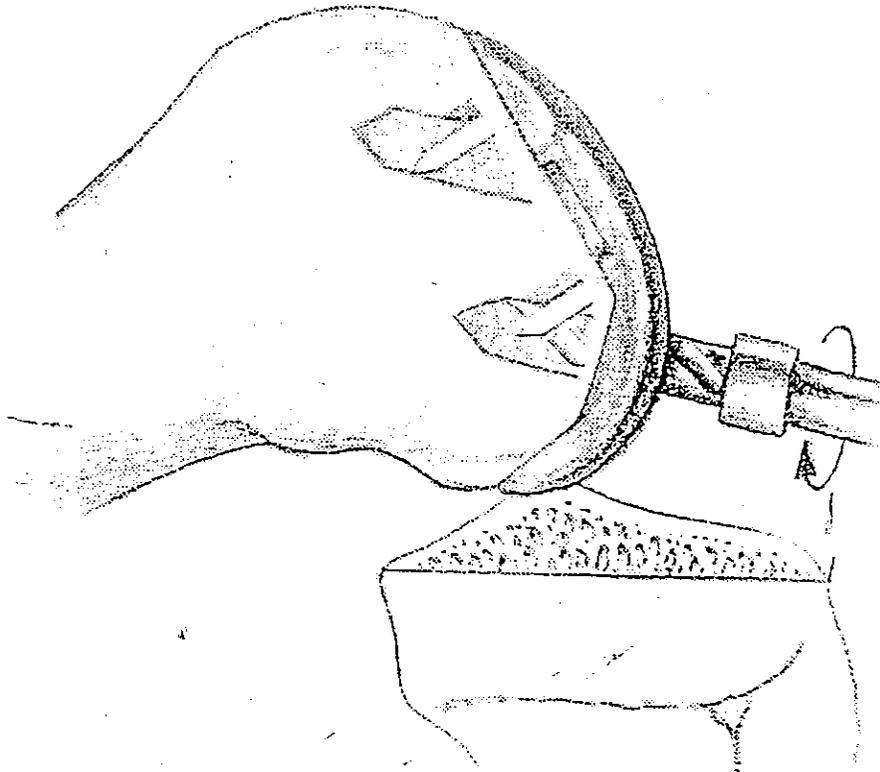
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Joint debridement

After the various cuts have been made, any remaining steps towards joint debridement such as meniscal remnants, further osteophytes, or loose bodies should be performed to prevent impingement.

Insertion of femoral trial

The femoral trial of the chosen size is impacted along the midline of the condyle. A femoral impactor is used held at an angle of 10-15 degrees to the axis of the femur. Avoid upward impaction as this may lead to subsequent posterior tilting of the implant. At this stage, the femoral trial is held in place by its splks, and the oblique holes are all drilled using a 1/4 inch drill with stop.



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Checking self stabilization

A tibial trial is inserted and the knee is taken through its full range of movement. This ensures that the components are well centred, that there is no angular displacement, and that the tibial component is stable.

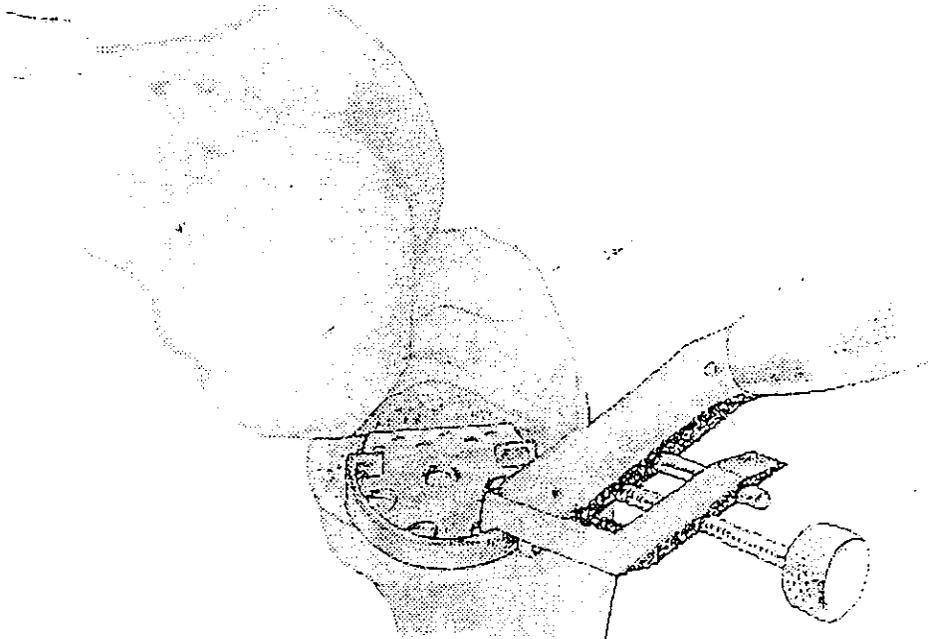
A trial tibial component is selected and placed into position, the placement of the tibial trial will require modest force to overcome joint tension, the knee is taken through a full range of motion. The tibial trial should seat flush with the tibial spine medially and the curved portion of the trial should seat on cortical bone.

Following a successful trial reduction the position of the anterior margin of the tibial trial is then marked on the tibial spine with the diathermy and the femoral peg holes are drilled using a 1/4 inch drill with stop.

8 Insertion of the Tibial Tray

The definitive tibial component is selected, the tibial tray is loaded onto the tibial tray holder with the jaws locked onto the anterior third of the tray. The tray tab is impacted into the slot under the tibial spine made when the horizontal cut with the anterior margin aligned with the scribe mark on the tibial spine. A posterior tibial impactor may be used to complete the impaction of the implant.

A long 3mm drill is used to drill holes through the anterior and lateral holes in the baseplate. 6.5 mm cancellous bone screws are used to gain good bone purchase in the cancellous bone. It is preferable to have the 2 lateral screws gain purchase in the metaphyseal cortex. It may not be possible to gain access to the posterior hole due to joint tension.



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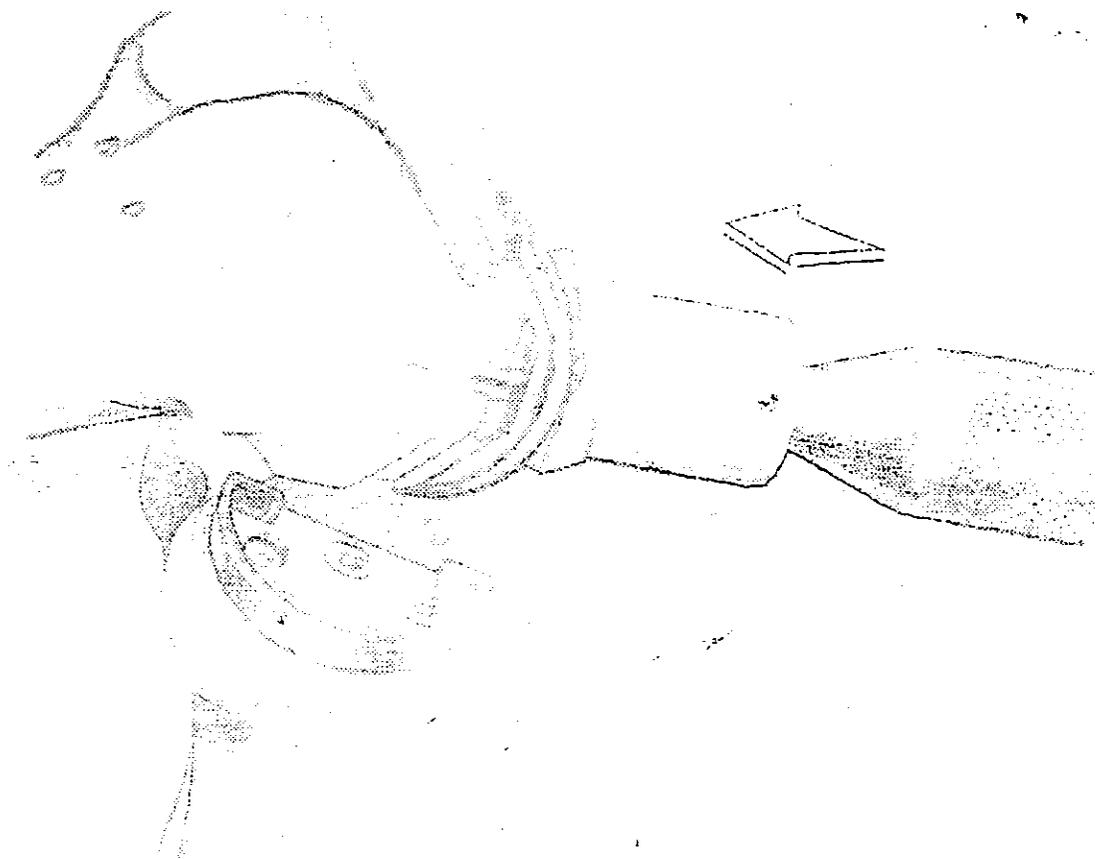
9 Impaction of the Femoral component and Tibial Bearing

For a cemented implant the cement is prepared in the usual way and an impactor is used to drive the femoral component home. The direction of impaction is important, to guard against implant malposition,

The oblique posts on the component should be inserted by hand over the first few millimeters, followed by almost horizontal impaction at an angle of 15-20 degrees to the shaft axis. The component should readily engage the oblique holes and finish up flush with the distal cut surface before contacting the chamfer and the posterior surface.

The polyethylene insert is placed by hand against the posterior corner of the tray and then punched in anteriorly using the insert impactor. Care must be taken to ensure that the edge of the tray is clear, especially along its straight medial part where bone from the tibial spine may overhang if the initial bone cut was not strictly vertical. A final check should be made to ensure that no soft tissue is trapped in the posterior part of the tray.

DRAFT

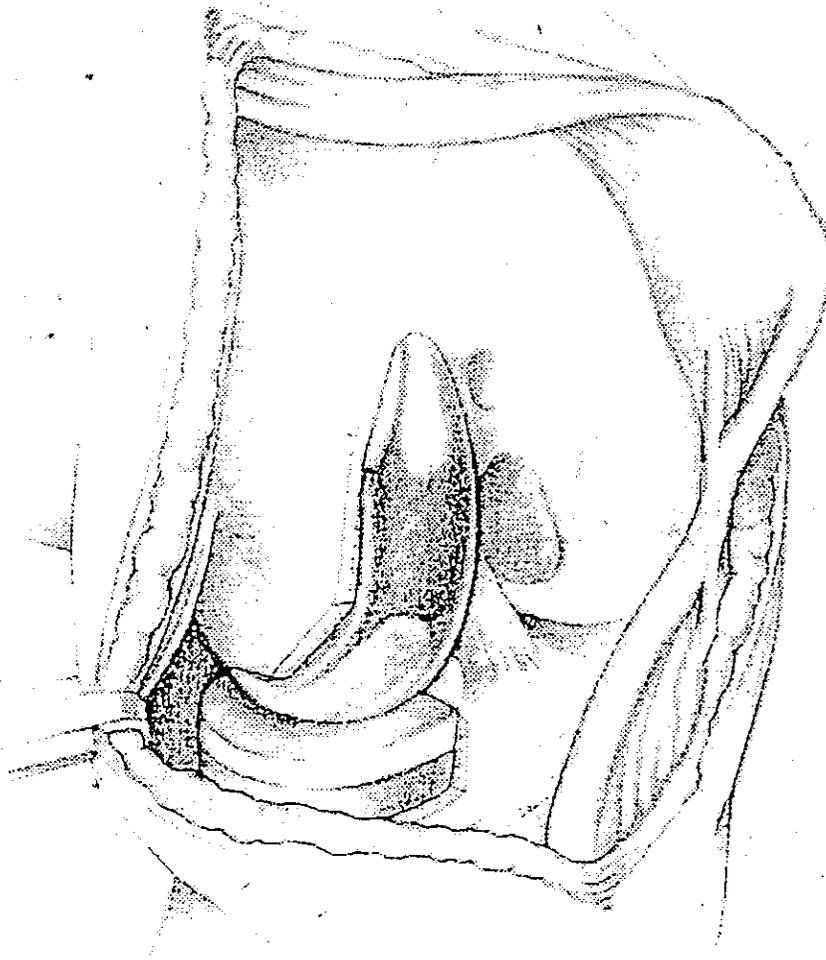


10. Patella

DRAFT

The anterior part of the femoral component is tapered to prevent patellar impingement, however a routine facetectomy is recommended and a full range of movement performed prior to closure to check for impingement.

In the medial component the retinaculum and Vastus are sutured, however in a lateral replacement the retinaculum is not sutured. The joint is closed with a few sutures in the synovial membrane and the fat pad.



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Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX C
TEST REPORT

325 Corporate Blvd
Mahwah, NJ 07430
t: 201 831 5059 f: 201 831 4059
jerry.dalessio@stryker.com



Orthopaedics

Memo

To: (b) (4)

From: (b) (4)

Date: (b) (4)

Re: (b) (4)
(b) (4)

- (b) (4)
- o Potential Risk: (b) (4)

- o Reduction or elimination of Risk: (b) (4)

(b) (4)

- (b) (4)
 - o Potential Risk: (b) (4)
 - o Reduction or elimination of Risk: (b) (4)

- (b) (4)
 - o Potential Risk: (b) (4)

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- Reduction or elimination of Risk: (b) (4)
no [redacted]

- (b) (4)
 - Potential Risk: [redacted] (b)
 - Reduction or elimination of Risk: (b) (4)

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Appendix A.

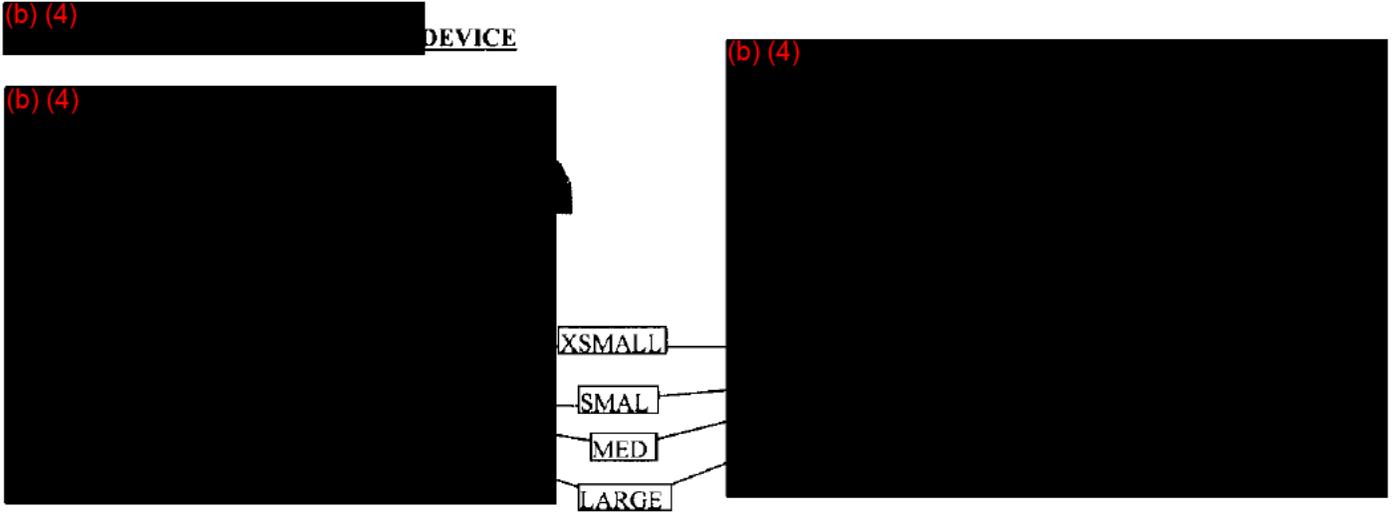
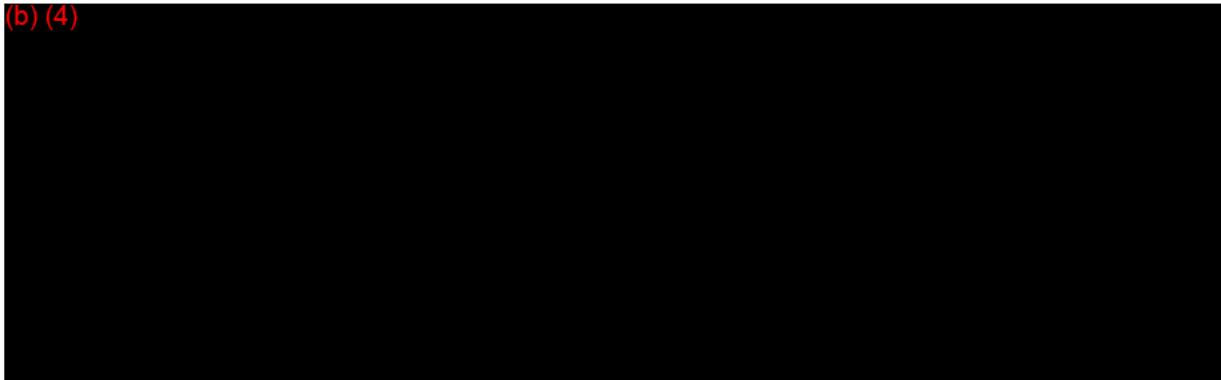
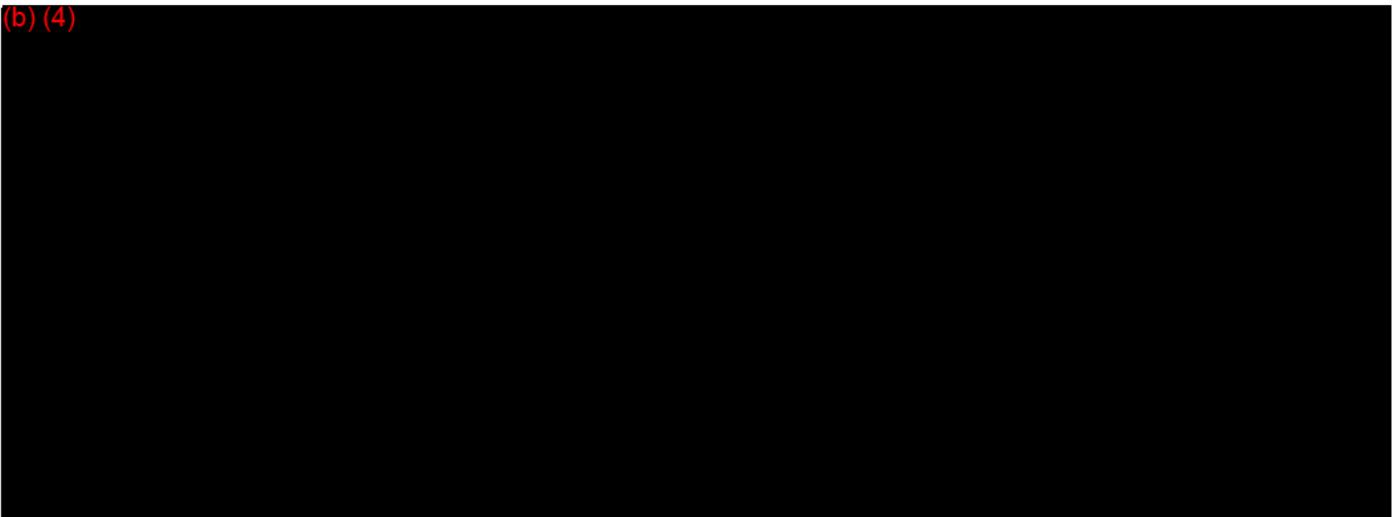


Figure 1. (b) (4)



UNICOMPARTMENTAL FEMORAL COMPONENTS



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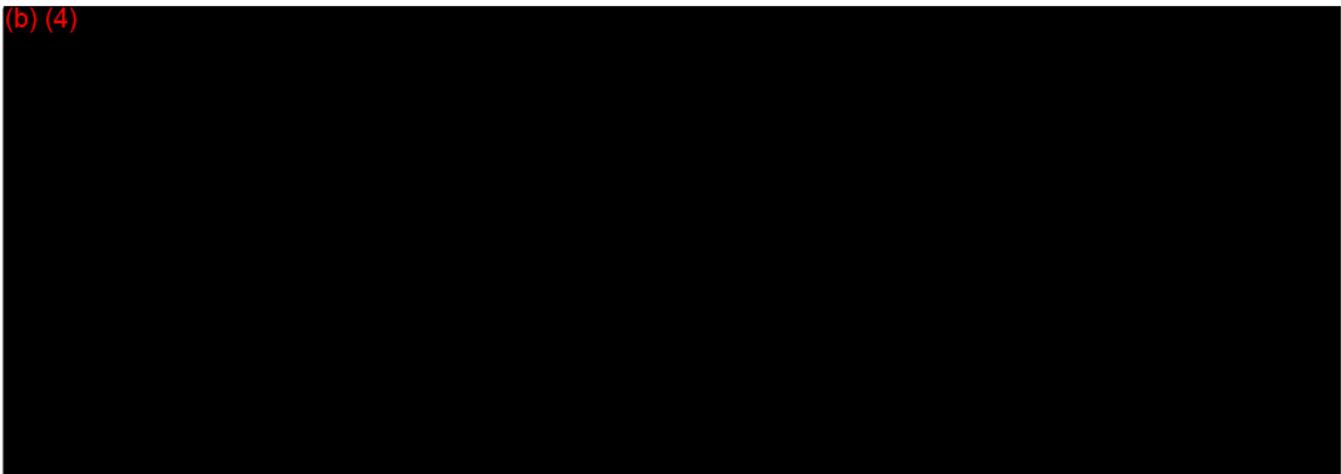
264



Figure 2. (b) (4)

Table 1. Sizes for Unicompartmental components

COMPUTER ASSISTED DESIGN (CAD) LAYOUTS FOR IMPINGEMENT



¹ Hitt K, Shurman JR 2nd, Greene K, McCarthy J, Moskal J, Hoeman T, Mont MA. Anthropometric measurements of the human knee: correlation to the sizing of current knee arthroplasty systems. J Bone Joint Surg Am. 2003;85-A Suppl 4:115-22

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(b) (4)

(b) (4)

(b) (4)

(b) (4)

Figure 4. Size 8

(b) (4)

(b) (4)

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(b) (4)

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(b) (4)

A very large black rectangular redaction box covering the majority of the page's content.

Figure 5. (b) (4)

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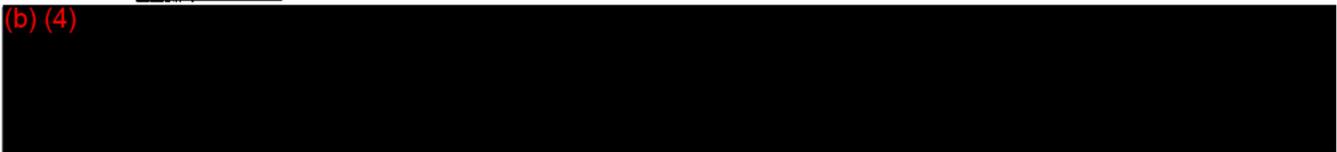
CADAVER EVALUATIONS

(b) (4)

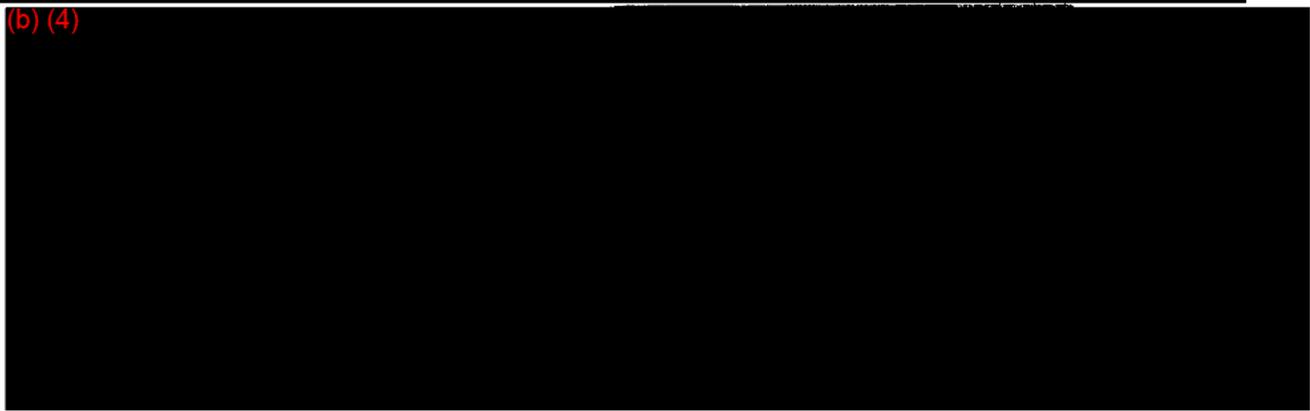
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Specimen 1

(b) (4)

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(b) (4)

A large rectangular black redaction box covering the second specimen section.

Specimen 2

(b) (4)

A rectangular black redaction box covering the third specimen section.

(b) (4)

A rectangular black redaction box covering a section below the specimen headers.

Figure 8. (b) (4)

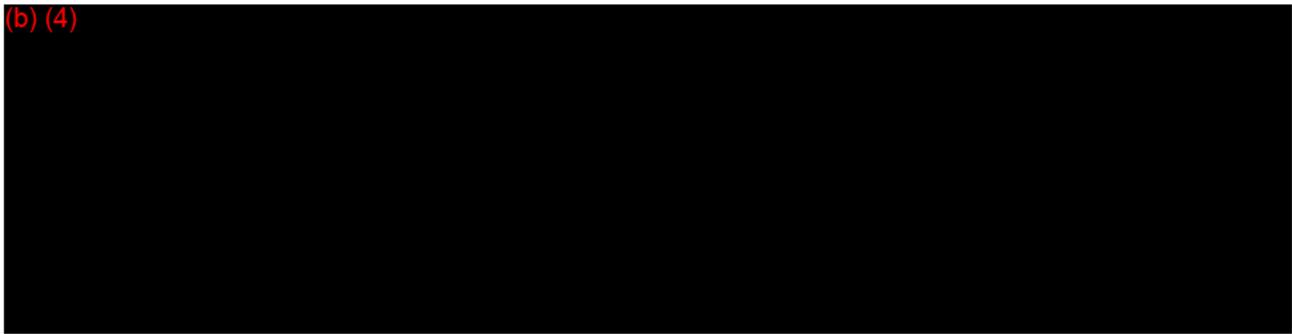
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Summary

(b) (4)



(b) (4)

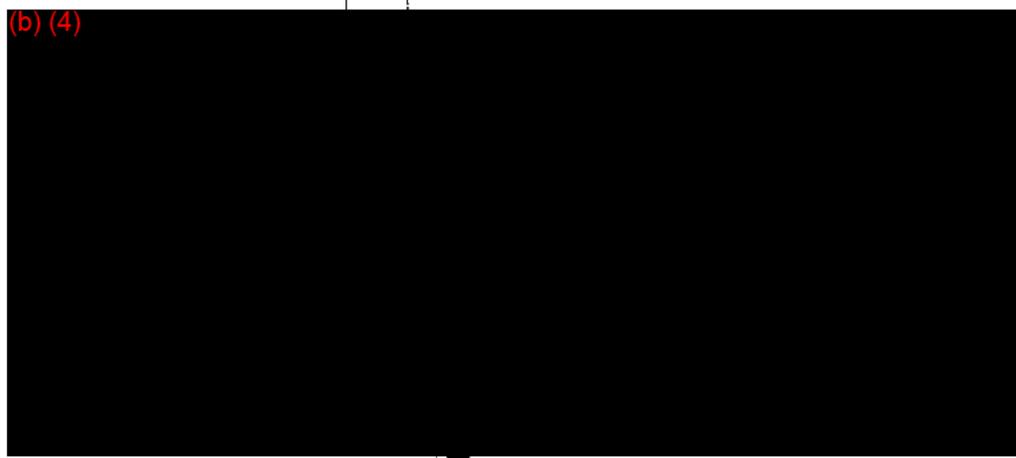
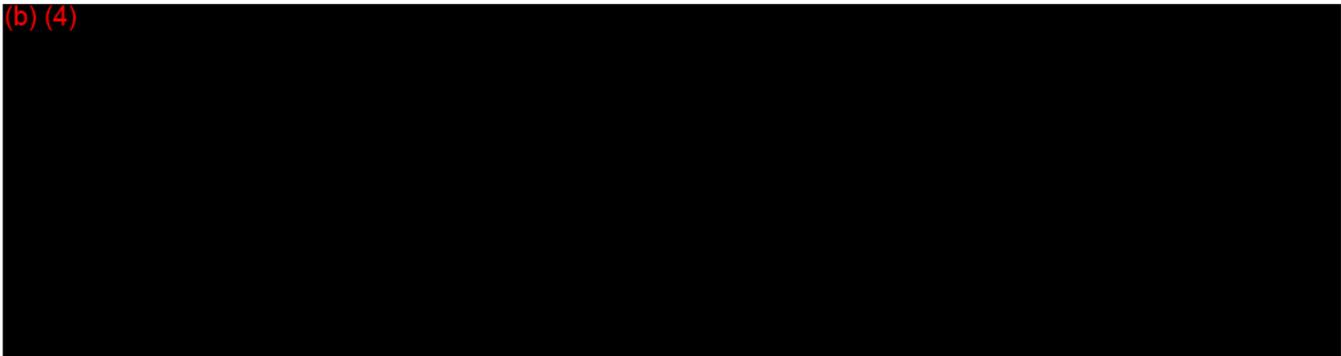


Figure 9. (b) (4)



(b) (4)



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Stryker[®] Compartmental Knee

Traditional 510(k)

APPENDIX D
PREDICATE DEVICE INFORMATION

- Smith & Nephew Hybrid Knee Femoral Components (K042896)
- Avon[®] Patello-femoral Joint Prosthesis (K010100, K020841 & K041160)
- EIUS[®] Unicompartmental Knee System (K992287 & K033769)
- SCR[®] Unicompartmental Knee Prosthesis (K896856 & K911373)
- UNIX[™] Unicompartmental Knee System (K923011)
- PCA[®] Unicompartmental Knee Prosthesis System (K831143)

Stryker® Compartmental Knee

Traditional 510(k)

Smith & Nephew Hybrid Knee Femoral Components

(K042896)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 12 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim P. Kelly
Project Manager
Clinical and Regulatory Affairs
Smith & Nephew, Inc., Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K042896

Trade/Device Name: Hybrid Knee Femoral Components

Regulation Number: 21 CFR 888.3530

Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented
prosthesis

Regulatory Class: II

Product Code: NPJ

Dated: October 19, 2004

Received: October 20, 2004

Dear Ms. Kelly:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

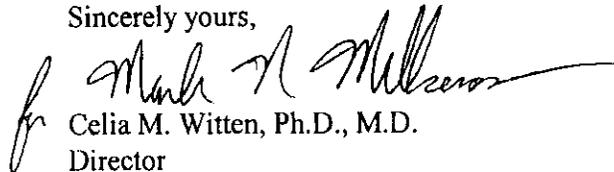
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Page 2 – Mrs. Kelly

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K042896

Device Name: Hybrid Knee Femoral Components

Indications for Use:

The Hybrid Knee Femoral Components are intended to be used for those patients whereby conditions exist that can not be solely addressed by a device that treats a single compartment (i.e. unicompartmental or patellofemoral prosthesis) of the knee.

Indications include:

- post-traumatic arthritis;
- degenerative arthritis; and
- failed osteotomies, hemiarthroplasties; and unicompartmental replacement

These indications will be used for the Hybrid Knee Femoral Components, whereby the medial condyle and patellofemoral regions have been affected by one or more of these conditions.

The Hybrid Knee Femoral Components are single use only and are intended for implantation only with bone cement

Prescription	X	AND/OR	Over-The-Counter
Use	_____		Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Miller

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K042896

K042896

Summary of Safety and Effectiveness

JAN 12 2005

Smith & Nephew, Inc.

Smith & Nephew Hybrid Knee Femoral Components

Contact Person and Address

Kim Kelly, Project Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc., Orthopaedic Division
1450 East Brooks Road
Memphis, TN 38116
(901) 399-6566

Device Description

The **Smith & Nephew Hybrid Knee Femoral Components** are designed for use with tibial components of the Genesis I Unicdylar Knee System and patellar components of the Genesis II Total Knee System. The components are used to replace the medial condyle and patellofemoral regions of a femoral knee joint.

Device Classification Name

Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis,
21 CFR 888.3530

Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis, 21 CFR
888.3540

Indications for Use

The **Hybrid Knee Femoral Components** are intended to be used for those patients whereby conditions exist that can not be solely addressed by a device that treats a single compartment (i.e. unicdylar or patellofemoral prosthesis) of the knee.

Indications include:

- post-traumatic arthritis;
- degenerative arthritis; and
- failed osteotomies, hemiarthroplasties; and unicompartmental replacement

These indications will be used for the Hybrid Knee Femoral Components, whereby the medial condyle and patellofemoral regions have been affected by one or more of these conditions.

The Hybrid Knee Femoral Components are single use only and are intended for implantation only with bone cement.

page 1 of 2

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Mechanical and Clinical Data

A review of the mechanical test data indicated that the **Smith & Nephew Hybrid Knee Femoral Components** are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information

The substantial equivalence of the **Smith & Nephew Hybrid Knee Femoral Components** is substantiated by its similarities in design features, overall indications, and material composition as existing components of the Genesis I Unicdylar Knee System and Genesis II Total Knee Systems distributed by Smith & Nephew, Inc., as well as other commercially available patellofemoral joint prostheses.

page 2 of 2

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Stryker® Compartmental Knee

Traditional 510(k)

Avon® PFJ Prosthesis
(K010100, K020841 and K041160)

Avon™ Patello-femoral Joint Prosthesis

510(k) Premarket Notification

Indications for Use

510(k) Number (if known): K010100

Device Name: Avon™ Patello-femoral Joint Prosthesis

Indications for Use: The Avon™ Patello-femoral Joint Prosthesis is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Avon™ Patello-femoral Joint Prosthesis is intended for use with bone cement only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 3/12
(Per 21 CFR 801.106)

OR

Over-The-Counter Use 1/0

for Mark A. Milkinson (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010100

Avon™ Patello-femoral Joint Prosthesis

510(k) Premarket Notification

510(k) Summary

Device: Avon™ Patello-femoral Joint Prosthesis

The Avon™ Patello-femoral Joint Prosthesis is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Avon™ Patello-femoral Joint Prosthesis is intended for use with bone cement only.

The Avon™ Patello-femoral Joint Prosthesis consists of a distal femoral component fabricated from a cobalt-chromium-molybdenum alloy. This component is intended to be used to resurface the intercondylar groove on the anterior aspect of the distal femur, and is intended to articulate with the all-plastic patellar component of the Kinemax® Plus Total Knee System.

The distal femoral component is a symmetrically designed component available in three sizes (small, medium and large). The design of the Avon™ Patello-femoral Joint Prosthesis closely replicates the anatomic features of the patellar groove on the femur. The design of the polished concave gliding anterior surface of the prosthesis is identical to the proximal anterior surface of the articulating geometry of the Kinemax® Plus Total Knee System femoral component. The patellar groove of the Avon™ Patello-femoral Joint Prosthesis starts at the cruciate cutout – the length of this groove is identical to that for the Kinemax® Plus femoral component. The posterior surface of the distal femoral component employs four fixation pegs for additional stability of the prosthesis when cemented into the femur. Three pegs are parallel, while one is angled relative to the other three. The posterior surface of the femoral component employs a grit blasted roughened surface to facilitate interdigitation with bone cement.

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Avon™ Patello-femoral Joint Prosthesis

510(k) Premarket Notification

510(k) Summary

Avon™ Patello-femoral Replacement

Page 2

The Avon™ Patello-femoral Joint Prosthesis is substantially equivalent to other legally marketed devices. These products are listed below:

1. Intermedics Orthopedics, Inc.- Patello-femoral Joint Replacement (K962190)
2. Smith and Nephew Richards, Inc.- Bechtol Patello-femoral Joint Replacement (Preamendment Status)
3. Walter Abendschein, M.D. – Unicompartmental PatelloFemoral Prosthesis System (K000827)
4. Howmedica Inc. – Kinemax® Plus Femoral Component (K910500)

For information contact: Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17 South
Allendale, NJ 07401
(201) 760-4359

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APR 11 2002

Special 510(k) Notification - Design Modification to the Kinemax® Patellar Component

Confidential

K020841 page 1 of 2

Special 510(k) Summary - Device Modification
for the
Kinemax® All Polyethylene Patellar Component
to be marketed as
the Avon™ Patellar Component

Proprietary Name: Avon™ Patellar Component

Common Name: All Polyethylene Patellar Component

Classification Name and Reference: 21 CFR 888.3540
Knee Joint Patellofemoral Polymer/Metal Semi-
Constrained Cemented Prosthesis

Proposed Regulatory Class: Class II

Device Product Code: OR (87) KRR

The Avon™ Patello-femoral Joint Replacement (found substantially equivalent in K010100) is intended to be used with the legally marketed Kinemax® Plus All Polyethylene Patellar Component in cemented replacement of the patello-femoral joint in patients with degenerative arthritis of the distal femur and patella, patients with a history of patellar dislocation or fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release).

It is the intention of Howmedica Osteonics Corp. to modify the Kinemax® Plus All Polyethylene Patellar Component. The modified device will be marketed as the Avon™ Patellar Component. This all polyethylene patellar component will be used to articulate with the cobalt-chromium alloy femoral component of the Avon™ Patello-femoral Joint Replacement.

The subject Avon™ Patellar Component is identical in design features with the exception of the following: a blend radius has been added on the articular surface of the patella in order to reduce the potential for impingement of the patellar component on the bone.

No other changes have been made to the design of the patellar component. The Avon™

Special 510(k) Notification - Design Modification to the Kinemax® Patellar Component

Confidential

pag 2 of 2

Patellar Component will be available for use with bone cement in patello-femoral replacement surgery.

Design controls were utilized to identify the risks associated with the modified device. Testing was presented to address these risks. A Declaration of Conformity was included.

For Information contact:

Margaret F. Crowe, Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-2584
(201) 934-4359
Fax: (201) 760-8435

Indications for Use

page 1 of 1

510(k) Number (if known): K020841

Device Name: Avon™ Patellar Component

Indications for Use:

The subject Avon™ Patellar Component is intended to be used with the Avon™ Patello-Femoral Joint Replacement in replacement of the patello-femoral joint. The subject Avon™ patellar component is a modification of the Kinemax® All Polyethylene Patellar Component. The Avon™ Patellar Component has been modified to include the addition of a blend radius on the medial aspect of the patella. This blend is designed to reduce the contact stress of the patella on the patello-femoral component. The rest of the design features of the Avon patellar component are identical to that of the previous released Kinemax® All Polyethylene Patellar Component.

The Avon™ Patello-femoral Joint Prosthesis is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Avon™ Patellar Component and the Avon™ Patello-femoral Joint Prosthesis are intended for use with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes OR Over-The-Counter Use No
(Per 21 CFR 801.109)

for Mark N. Miller (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020841

K041160 - Page 1 of 2

MAY 27 2004

Line Extension to Avon™ Patello-femoral Replacement System

Special 510(k) Premarket Notification

Special 510(k) Summary

Proprietary Name: Avon™ Extra-small Patello-femoral Replacement

Common Name: Patello-femoral Replacement

Classification Name and Reference: 21 CFR 888.3540
Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis

Proposed Regulatory Class: Class II

Device Product Code: OR (87) KRR

Predicate Proprietary Name: Avon™ Small Patello-femoral Replacement

Predicate Regulatory Class: 21 CFR 888.3540
Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis

Predicate Product Code: OR (87) KRR

For Information contact: Margaret F. Crowe
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430
Phone: (201) 831-5580
Fax: (201) 831-6038

Description/Technological Comparison

The Avon™ Patello-femoral Joint Prosthesis (cleared for marketing in K010100 and K020841)

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K041160 - Page 2 of 2

Line Extension to Avon™ Patello-femoral Replacement System

Special 510(k) Premarket Notification

is intended to be used in the replacement of the patellofemoral joint in patients with degenerative arthritis of the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. The current system consists of cobalt-chromium femoral components available in three sizes (small, medium, and large), and all-polyethylene components available in three sizes (small, medium, and large). These components are intended to be implanted using bone cement.

It is the intention of Stryker Howmedica Osteonics to introduce an extra-small Avon™ Patello-femoral replacement component. The extra-small Avon™ femoral component differs from the previously released small Avon™ femoral component in the following ways:

1. The width of the patellar flange is reduced by 3mm (small 46.5mm; extra-small: 43.5mm)
2. The intra-condylar distal flange height is reduced by 1.5mm (small 19.5; extra-small 18.0mm)

This component is also intended to be implanted using bone cement.

Intended Use

The Avon™ Extra-Small Patello-femoral Replacement component is a single-use device intended for replacement of the femoral side of the patello-femoral joint.

The Avon™ Patello-femoral Joint Replacement is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

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Stryker® Compartmental Knee

Traditional 510(k)

EIUS® Unicompartmental Knee System
(K992287 & K033769)

K033769

Line Extension to the EIUS® Unicompartmental Knee System

Special 510(k) Premarket Notification

FEB 13 2004 **Special 510(k) Summary of Safety and Effectiveness:
Line Extension to the EIUS® Unicompartmental Knee System**

Proprietary Name: EIUS® Unicompartmental Knee System
Common Name: Unicompartmental Kneec System
Proposed Regulatory Class: Class II
Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented,
Metal Polymer, 21 CFR 888.3520

Device Product Code: 87 HSX
For Information contact: Denise Duchene
Sr. Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Dr.
Mahwah, NJ 07430
Telephone: (201) 831-5612
Fax: (201) 831-6038
Email: dduchene@howost.com

Date Summary Prepared: November 12, 2003

Predicate Device Identification

The EIUS® Unicompartmental Knee System consists of various sizes of femoral components and tibial components and the Scorpio Total Knee System consists of various femoral, tibial and patellar components. The EIUS Unicompartmental Kneec System additional tibial components are equivalent to the currently marketed EIUS tibial components with the exception of the thickness, cement recess and material. The material is equivalent to the currently marketed Scorpio Knee System tibial inserts; whereas the cement recess without a keel is equivalent to the UNIX Unicompartmental Knee and the Biomet Repicci Unicompartmental All Polyethylene Tibia component (also available without a keel). The EIUS Unicompartmental Knee System was determined substantially equivalent under K992287, the UNIX Unicompartmental Kneec was determined substantially equivalent under K923011, the Biomet component was cleared under K980665, and the Scorpio Total Kneec Tibial Insert components were determined substantially equivalent under K962152.

Description of Device Modification

This submission is intended to address a line extension to the EIUS® Unicompartmental Knee System. The line extension includes additional tibial components, 8mm, 9mm, 10mm, and 12mm components without a keel and 6mm components with and without a keel. Also, some changes were made to the cement recess of the tibial component to ensure adequate thickness under the femoral condyle. Finally, the material will change from the current polyethylene material to the polyethylene material used in the Scorpio Knee System. The new components will be used for resurfacing of either the medial or lateral proximal tibia.

page 1 of 2

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Line Extension to the EIUS® Unicompartmental Knee System

2033749

Special 510(k) Premarket Notification

Intended Use:

The EIUS® Unicompartmental Knee System is intended for use in unicompartmental knee arthroplasty. It is intended to be used for patients with moderately disabling joint disease of the knee resulting from painful osteoarthritis or traumatic arthritis; revision of previous unsuccessful unicompartmental knee replacement or other procedurc, or as an alternative to tibial osteotomy in patients with unicompartmental ostcoarthritis.

Statement of Technological Comparison:

The subject components share the same intended use and basic design concept as that of the predicate devices. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.

page 2 of 2

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Indications for Use

510(k) Number (if known): K033769

Device Name: EIUS® Unicompartmental Knee System – Tibial Components

Indications For Use:

The EIUS® Knee System components are for use in Unicompartmental knee arthroplasty as a result of:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis

These components are single use only and are intended for implantation with bone cement.

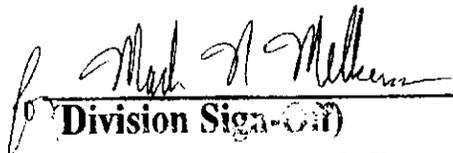
Prescription Use X
(Part 21 CFR 801 Subpart D)

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 General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K033769

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12992287

NOV 16 1999

First Step Unicompartmental Knee System

510(k) Summary

510(k) Summary

Device: First Step Unicompartmental Knee

Common Name: Unicompartmental Knee System

Classification Name: Knee joint femorotibial metal/ polymer non-constrained cemented prosthesis 21 CFR §.888.3520

Regulatory Class: Class II

Product Code: 87 HSX

For Information contact: Karen Ariemma, Regulatory Affairs Specialist
 Howmedica Osteonics Corp.
 59 Route 17
 Allendale, NJ 07401-1677
 (201) 760-8187
 Fax: (201) 934-4368

This device consists of a distal femoral resurfacing component and a proximal tibial resurfacing component. It is intended to be used to replace the medial or lateral compartments of the knee joint, specifically the femorotibial joint damaged as a result of inflammatory and non-inflammatory joint disease or trauma. These components are intended for cemented use only. The femoral component is manufactured from a cobalt-chromium alloy, which conforms to ASTM F-75. The tibial component is manufactured from ultra-high molecular weight polyethylene, which conforms to ASTM F-648.

The substantial equivalence of this device is based on equivalence in intended use, materials, design and operational principles to other predicate devices indicated for unicompartmental knee surgery. These devices include Howmedica Osteonics Corp.'s Duracon Unicompartmental Knee and SCR Uni Knee Systems.

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510(k) Number (if known): K 992287

Device Name: Howmedica Osteonics® First Step Unicompartmental Knee System

The First Step Unicompartmental Knee System consists of a distal femoral resurfacing component and a proximal tibial resurfacing component. The subject components of the First Step Unicompartmental Knee System are single use devices which are sold sterile. The First Step Unicompartmental Knee System is intended for cemented use only.

The specific indications and contraindications of the First Step Unicompartmental Knee System are stated in the following sections.

Indications

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.
- Revision of previous unsuccessful unicompartmental knee replacement or other procedure.
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

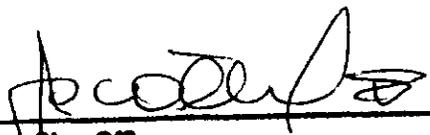
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K 992287

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Stryker® Compartmental Knee

Traditional 510(k)

SCR® Unicompartmental Knee Prosthesis
(Cleared under the name of MOD-ML Unicompartmental Knee Prosthesis)
(K896856 & K911373)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 6 1990

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: K896856
MOD-ML Unicompartmental
Knee Prosthesis

Regulatory Class: II
Dated: December 4, 1989
Received: December 5, 1989

Ms. Pat Kramer
Director, Regulatory Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

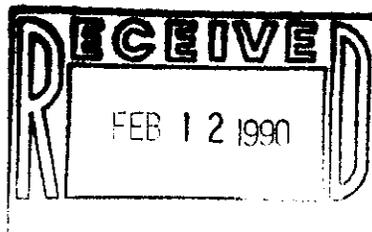
Dear Ms. Kramer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.
3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

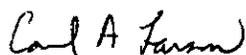


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Page 2 - Ms. Pat Kramer

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

295



OSTEONICS Reconstructive Products Division

Via Federal Express

December 4, 1989

Center for Devices and Radiological Health
510(k) Document Mail Center
HFZ-401
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

Attention: Division of Surgical and Rehabilitation Devices

Re: 510(k) Premarket Notification; MOD-ML Unicompartmental Knee Prosthesis

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this Premarket Notification is being submitted at least 90 days prior to the date when Osteonics Corporation proposes to introduce into interstate commerce, for commercial distribution, a knee implant device.

The following information is being submitted in conformance with 21 CFR §807.87:

- [a] **DEVICE NAME:** Unicompartmental Knee Prosthesis
- TRADE OR PROPRIETARY NAME:** MOD-ML Unicompartmental Knee Prosthesis
- COMMON OR USUAL NAME:** Hemi-Knee Prosthesis
- CLASSIFICATION NAME AND CODE:** Prosthesis, Knee, Femorotibial, Metal/
Polymer, Nonconstrained, Cemented
(87 HSX)

[b] **ESTABLISHMENT REGISTRATION NUMBER:** 2243265

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Continued . . .

59 Route 17, Allendale, NJ 07401-1677 • (201) 825-4900
Telex No. 881553-OSTEONICS

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510(k) Document Mail Center
Premarket Notification Submission
Re: MOD-ML Unicompartmental Knee Prosthesis
December 4, 1989
Page 2 - Continued

- [c] Pursuant to Section 513 of the Federal Food, Drug and Cosmetic Act, as amended, knee implants of this type were placed in Class II. This classification is published at 21 CFR §888.3520.
- [d] No performance standards applicable to the device have been promulgated by the Food and Drug Administration (FDA).

Certain voluntary standards apply to the MOD-ML Unicompartmental Knee Prosthesis. Among these are:

1. The American Society for Testing and Materials (ASTM) Standard Number F-75-82, entitled "Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications."
 2. The ASTM Standard Number F-648-84, entitled "Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants".
- [e] Copies of the proposed labeling (draft) for the device are provided in Section II. Promotional literature for this device will not be printed until substantial equivalence to predicate devices is determined by the FDA.
 - [f] The MOD-ML Unicompartmental Knee Prosthesis is intended for cemented fixation upon the prepared femoral condyle and tibial plateau. This device will be available in both medial and lateral configurations in order to address replacement of either compartment of the knee. The tibial component will consist of a tibial tray and modular tibial inserts to address variations in available bone stock at the operative compartment. The MOD-ML Unicompartmental Knee Prosthesis is substantially equivalent in terms of safety and effectiveness to a number of predicate devices as follows:
 1. M.C.R. Knee Prosthesis; Osteonics Corp.
 2. Synatomic™ Unicondylar Knee Components with Porocoat®; DePuy
 3. P.C.A.™ Unicompartmental Knee System; Howmedica
 4. The Robert Brigham Uni-Condylar Knee; Johnson & Johnson Products, Inc.
 5. Miller-Galante Unicompartmental Knee System; Zimmer

Continued . . .

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510(k) Document Mail Center
Premarket Notification Submission
Re: MOD-ML Unicompartmental Knee Prosthesis
December 4, 1989
Page 3 - Continued

A comparison of the MOD-ML Unicompartmental Knee Prosthesis to the above predicate Osteonics® and competitive products is included in Section III of this Premarket Notification.

The following information is submitted in support of the equivalency of the MOD-ML Unicompartmental Knee Prosthesis to currently marketed devices. The data are organized as follows:

- * Device Description (see Section I)
- * Draft Labeling (see Section II)
- * Rationale for Substantial Equivalence (see Section III)
- * Appendices

To provide the FDA with complete knowledge of the material composition manufacturing methods and relevant testing methods utilized to ensure that the safety and quality standards of this device are in keeping with Good Manufacturing Practices, specific data are submitted in Sections I, III and Appendix A that sufficiently describe these processes. Please note, specific pages are confidential and so marked.

NOTICE: This submission contains methods, data, and analysis of these data which Osteonics Corporation considers "Trade Secret" and commercial privileged and confidential to Osteonics Corporation. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with the Freedom of Information (FOI) Act. A separate copy of this application is being provided for the purposes of public disclosure in accordance with FOI and contains the omittance of trade secret, commercial privileged and confidential information. This special copy is marked "FOR FOI PURPOSES ONLY".

Osteonics Corporation requests that FDA hold as confidential their intention to market their MOD-ML Unicompartmental Knee Prosthesis. We consider the intent to market this device to be confidential commercial information and, therefore, exempt from public disclosure, pursuant to the requirements of 21 CFR §807.95(b). To the best of our knowledge, neither we nor anyone else has disclosed through advertising or any other manner our intent to market this device in the United

Continued . . .

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510(k) Document Mail Center
Premarket Notification Submission
Re: MOD-ML Unicompartmental Knee Prosthesis
December 4, 1989
Page 4 - Continued

States to any individuals, including scientists, market analysts, exporters, or other individuals, except employees, paid consultants, or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy.

We will immediately notify FDA if we disclose the intent to market this device to anyone except employees of, or paid consultants to, this firm or individuals in advertising or law firms pursuant to commercial arrangements with appropriate safeguards for secrecy. We understand that the submission to the government of false information is prohibited by Title 18 of the United States Code (USC), Part 1001 and Title 21 of the USC, Part 331(q).

If there are any questions, or if further information is needed, please contact the undersigned at (201) 825-4900.

Sincerely,



Pat Kramer
Director, Regulatory Affairs
Osteonics Corp.

Enclosures: 510(k) Premarket Notification Application (submitted in duplicate)
510(k) Premarket Notification Application marked: **FOR FOI PURPOSES ONLY**
Sections I through III and Appendices, as noted above

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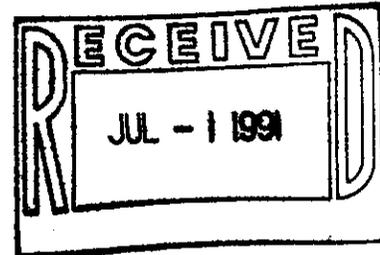
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 26 1991

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Ms. Pat Kramer
Director, Regulatory Affairs
Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677



Re: K911373
Osteonics® Ion Implanted MOD-ML
Uni Knee Femoral Components
Regulatory Class: II
Dated: March 27, 1991
Received: March 28, 1991

Dear Ms. Kramer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.
3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemptions (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

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Page 2 - Ms. Pat Kramer

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Carl A. Layson, Ph.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Stryker® Compartmental Knee

Traditional 510(k)

UNIX™ Unicompartmental Knee System
(K923011)



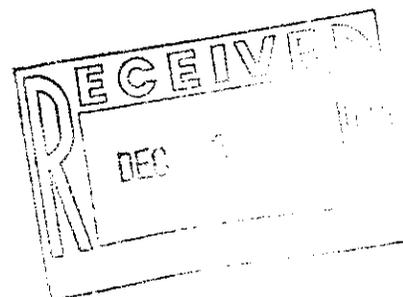
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 30 1993

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Robert A. Koch, J.D.
Manager, Regulatory/Legal Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677



Re: K923011
Osteonics® UNIX Unicompartmental
Knee System
Regulatory Class: II
Dated: March 2, 1993
Received: March 2, 1993

Dear Dr. Koch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.
3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

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Page 2 - Robert A. Koch, J.D.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

J. Clark for MAS for PRE
Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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OSTEONICS

Via Federal Express

June 19, 1992

Center for Devices and Radiological Health
510(k) Document Mail Center
HFZ-401
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

Attention: Division of Surgical and Rehabilitation Devices

Re: 510(k) Premarket Notification; Osteonics® UNIX Unicompartmental Knee System

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this Premarket Notification is being submitted at least 90 days prior to the date when Osteonics Corporation proposes to introduce into interstate commerce, for commercial distribution, a unicompartmental knee implant device.

The following information is being submitted in conformance with 21 CFR §807.87:

- [a] **DEVICE NAME:** Unicompartmental Knee Prosthesis
- TRADE OR PROPRIETARY NAME:** Osteonics® UNIX Unicompartmental Knee System
- COMMON OR USUAL NAME:** Unicompartmental Knee Prosthesis
- CLASSIFICATION NAME AND CODE:** Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer (87 HRY)
- [b] **ESTABLISHMENT REGISTRATION NUMBER:** 2243265

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Continued...

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A Subsidiary of Stryker Corp.

510(k) Document Mail Center
Premarket Notification Submission
Re: Osteonics® UNIX Unicompartmental Knee System
June 19, 1992
Page 2 - Continued

- [c] Pursuant to Section 513 of the Federal Food, Drug and Cosmetic Act, as amended, knee implants of this type were placed in Class II. This classification is published at 21 CFR §888.3530.
- [d] No performance standards applicable to the device have been promulgated by the Food and Drug Administration (FDA).

Certain voluntary standards apply to the Osteonics® UNIX Unicompartmental Knee System. Among these are:

1. The American Society for Testing and Materials (ASTM) Standard Number F-75-82, entitled "Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications."
 2. The ASTM Standard Number F-648-84, entitled "Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants".
- [e] Copies of the proposed labeling (draft) for the Osteonics® UNIX Unicompartmental Knee System's femoral components and tibial bearing inserts are provided in Section II. Promotional literature for these devices will not be printed until substantial equivalence to predicate devices is determined by the FDA.
 - [f] The modular femoral components and modular tibial bearing inserts of the Osteonics® UNIX Unicompartmental Knee System are manufactured in the United States and marketed in Europe and are therefore addressed in this 510(k) notification. The tibial tray of the Osteonics® UNIX Unicompartmental Knee System is both manufactured and marketed in Europe and is therefore not a subject of this 510(k) notification. The femoral component of the Osteonics® UNIX Unicompartmental Knee System is intended for cemented fixation upon the prepared femoral condyle. This device is available in both right and left configurations and is able to address the replacement of either compartment of the knee. The tibial bearing inserts are modular in order to address variations in available bone stock at the operative compartment. The femoral component and tibial bearing insert of the Osteonics® UNIX Unicompartmental Knee System are substantially equivalent in terms of safety and effectiveness to a number of predicate devices as follows:
 1. S.C.R. Unicompartmental Knee System; Osteonics Corp.
 2. Miller-Galante Unicompartmental Knee System; Zimmer

A comparison of the Osteonics® UNIX Unicompartmental Knee System to the above predicate Osteonics and competitive products is included in Section III of this Premarket Notification.

Continued...

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510(k) Document Mail Center
Premarket Notification Submission
Re: Osteonics® UNIX Unicompartmental Knee System
June 19, 1992
Page 3 - Continued

The following information is submitted in support of the equivalency of the Osteonics® UNIX Unicompartmental Knee System to currently marketed devices. The data are organized as follows:

- * Device Description (see Section I)
- * Draft Labeling (see Section II)
- * Rationale for Substantial Equivalence (see Section III)
- * Appendices

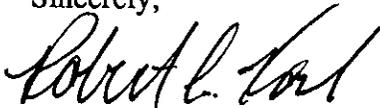
To provide the FDA with complete knowledge of the material composition manufacturing methods and relevant testing methods utilized to ensure that the safety and quality standards of this device are in keeping with Good Manufacturing Practices, specific data are submitted in Sections I, III and Appendix A that sufficiently describe these processes. Please note, specific pages are confidential and so marked.

NOTICE: This submission contains methods, data, and analysis of these data which Osteonics Corporation considers "Trade Secret" and commercially privileged and confidential to Osteonics Corporation. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with the Freedom of Information (FOI) Act.

We understand that the submission to the government of false information is prohibited by Title 18 of the United States Code (USC), Part 1001 and Title 21 of the USC, Part 331(q).

If there are any questions, or if further information is needed, please contact the undersigned at (201) 934-4336.

Sincerely,



Robert A. Koch, J.D.
Manager, Regulatory/Legal Affairs
Osteonics Corp.

Enclosures: 510(k) Premarket Notification Application (submitted in duplicate)

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510(k) Premarket Notification
Summary of Substantial Equivalence Information
for the
Osteonics® UNIX Unicompartmental Knee System

The 510(k) Premarket Notification entitled Osteonics® UNIX Unicompartmental Knee System presents a series of unicompartmental knee femoral components and tibial bearing inserts, which are designed to replace one compartment of the knee joint. The femoral components and tibial bearing inserts are manufactured in the United States and are to be exported for marketed distribution in Europe. The tibial components of the Osteonics® UNIX Unicompartmental Knee System are also intended for marketed distribution in Europe, but are manufactured there as well; thus, they are not addressed in this 510(k) notification.

The femoral components of the Osteonics® UNIX Unicompartmental Knee System are intended for cemented application and are to be used in conjunction with Osteonics® UNIX Unicompartmental Knee System Tibial Components. The Osteonics® UNIX Unicompartmental Knee System includes basic geometric and design characteristics to address most unicompartmental disease needs. The femoral components of the Osteonics® UNIX Unicompartmental Knee System are available in a range of four sizes and the tibial bearing inserts are available in four sizes with four thicknesses ranging from eight to fifteen millimeters for each size. Furthermore, the absolute minimum thickness of the tibial bearing inserts is six millimeters. All components will be available in the size range from #1 to #4. The tibial bearing inserts of the Osteonics® UNIX Unicompartmental Knee System are fabricated from ASTM F-648 ultra-high molecular weight polyethylene (UHMWPE), while the femoral components are fabricated from ASTM F-75 cobalt chromium alloy. Furthermore, the femoral components of the Osteonics® UNIX

Continued . . .

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510(k) Premarket Notification Summary of Substantial Equivalence Information
Re: Osteonics® UNIX Unicompartmental Knee System
Page - 2 - Continued

Unicompartmental Knee System are available with a macrostructured, waffled surface pattern to enhance their cemented fixation.

The predicate Osteonics and competitive components, to which the Osteonics® UNIX Unicompartmental Knee System components have been compared to establish substantial equivalence are:

- Osteonics® S.C.R. Unicompartmental Knee System Osteonics Corp.
- Miller-Galante Unicompartmental Knee System Zimmer

Substantial equivalence of the Osteonics® UNIX Unicompartmental Knee System is based upon:

- The substantial equivalence of the characteristics of the unicompartmental knee components, including the basic geometry, design configuration, materials and indications, to those of the Osteonics® S.C.R. Unicompartmental Knee System;
- The substantial equivalence of the waffled, macrostructured surface pattern and of the cemented application of the Osteonics® UNIX Unicompartmental Knee System Components to those patterns and applications of the predicate Osteonics and competitors' unicompartmental knee components;
- The substantial equivalence of the characteristics of the tibial bearing inserts, including the design configuration, materials, indications, size range and application in conjunction with an

Continued . . .

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510(k) Premarket Notification Summary of Substantial Equivalence Information
Re: Osteonics® UNIX Unicompartmental Knee System
Page - 3 - Continued

associated tibial tray to those of the predicate Osteonics and competitors' unicondylar knee systems' tibial bearing inserts;

- Mechanical testing which demonstrates substantially equivalent safety and effectiveness of the locking mechanism of the tibial bearing inserts to those of the predicate devices.

Stryker® Compartmental Knee

Traditional 510(k)

PCA® Unicompartmental Knee Prosthesis System
(K831143)



DEPARTMENT OF HEALTH & HUMAN SERVICES

RECEIVED HOWMEDICA

Public Health Service

AUG 18 1983

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Regulatory Affairs

AUG 2 1983

Mr. Harry M. Kaufman
Howmedica, Inc.
235 East 42nd Street
New York, New York 10017

Re: K831143
P.C.A.™ Unicompartmental
Knee Prosthesis System
Dated: April 4, 1983
Received: April 7, 1983

Dear Mr. Kaufman:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. This decision is based on sintered bead-surfaced components being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device must prominently state that the device is intended for cemented use only. Additionally, since the mechanical tests described in your submission were only done using low viscosity cement, we believe it prudent to restrict usage of the device to implantation only with low viscosity bone cement. Alternatively, similar mechanical test data could be supplied comparing the results of tests using 'standard' viscosity bone cement with those using the low viscosity formulation.
3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation shall be considered investigators and must receive approval from their respective institutional review boards (IRBs) and FDA to conduct the investigation.

You may market your device until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

CONFIDENTIAL

010346 W10346 312

Howmedica, Inc.

235 EAST 42ND STREET, NEW YORK, NEW YORK 10017 • (212) 573-7827 / 8

HARRY M. KAUFMAN
DIRECTOR
CORPORATE REGULATORY AFFAIRS

April 4, 1983

Bureau of Medical Devices (HFK-20)
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

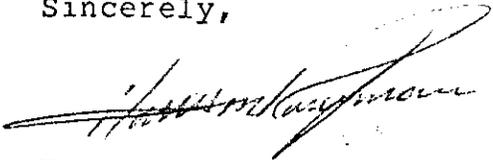
RE: 510(k) Notification
P.C.A.-tm Unicompartmental
Knee Prosthesis System

Gentlemen:

Pursuant to 21 CFR 807, we are herewith submitting the subject Notification on behalf of Orthopaedics Division of Howmedica, Inc.

Your early attention to this submission is appreciated.

Sincerely,



Harry M. Kaufman

HK/myd
Enc.

bcc: S. Cohen ✓

CONFIDENTIAL

W10326

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PRODUCT NAME

P.C.A.[™] Unicompartmental Knee Prosthesis System. Classification name: knee joint, femorotibial, non-constrained metal/polymer/metal prosthesis.

CLASSIFICATION

This class of orthopaedic implant prosthesis has been recommended for placement in Class II by the Surgical and Rehabilitation Panel.

FACILITY

Howmedica, Inc.
Orthopaedics Division
359 Veterans Blvd.
Rutherford, New Jersey 07070

Registration Number 2219689

ADVERTISING AND LABELING

Advertising material has not yet been finalized. Sample labels are in Appendix A.

INTENDED USE

The PCA Unicompartmental Knee Prosthesis is a non-constrained device intended for use in rehabilitating the medial and/or lateral compartments of knees moderately to severely damaged as a result of: osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, avascular necrosis, rheumatoid arthritis, trauma, residuals of infection, gout, non-specific synovitis and chondrolysis. The PCA[™] Unicompartmental Knee System is intended to replace damaged femoral and tibial bearing surfaces, and therefore has minimal inherent constraint. Thus, the posterior cruciate ligament and medial and lateral soft tissue stabilizers must be competent or be suitably reconstructed at the time of surgery. If the knee cannot be satisfactorily reconstructed to provide ligamentous stability, a more constrained device should be used. If significant patello-femoral pathology is anticipated or encountered at the time of surgery, the surgeon should be prepared to perform an arthroplasty which resurfaces the patello-femoral joint.

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PRODUCT DESCRIPTION

The PCA (Porous Coated Anatomic) Unicompartmental Knee Prosthesis consists of two implant components: a distal femoral resurfacing component and a proximal tibial resurfacing component, both of which are intended to be fixed within the bone by methylmethacrylate bone cement.

The femoral component is investment cast from VITALLIUM® Alloy (a cobalt-chromium molybdenum alloy conforming to ASTM F75). It consists of one polished convex condylar bearing surface.

The tibial component consists of an ultra-high molecular weight polyethylene (UHMWPE) bearing surface inserted into a VITALLIUM® Alloy supporting tray. The UHMWPE bearing surfaces are concave to conform with the femoral component's bearing surfaces. A convex surface at the medial tibial border provides a degree of constraint against medial-lateral subluxation.

A porous coating of VITALLIUM® Alloy beads is affixed by a proprietary sintering process to the underside of each of the components. This coating is designed to provide a surface of interconnected three dimensional pores with which the bone cement can achieve a secure mechanical interlock. (Reference is made to 510(k) Notification K800513 for additional information on the sintering process and the properties of the porous coating).

The femoral component is available in left and right configurations and in five basic sizes: extra small, small, medium, medium large, large. Tibial components are likewise available, and in addition, are available in four thicknesses: 7,9,11mm, and 13mm. All components are provided presterilized by exposure to a minimum of 2.5 megarads of gamma radiation.

Photographs of a specimen of each component are provided in Appendix B.

EQUIVALENT PRODUCTS

The PCA Total Knee is substantially equivalent to the following devices in commercial distribution:

1. Savastano Hemi Knee System, Howmedica, Inc. (Appendix C)
2. Compartmental II Knee Prosthesis, Zimmer, U.S.A. (Appendix D)
3. Mod II Total Knee System, Richards Manufacturing Co. (Appendix E)

BASIS OF EQUIVALENCE

The following similarities exist between the PCA Unicompartmental Knee Prosthesis and the named substantially equivalent devices:

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BASIS OF EQUIVALENCE (Con't)

1. All utilize Cobalt-Chromium-Molybdenum Alloy (ASTMF-75) and ultra-high molecular-weight polyethylene materials.
2. All are non-constrained femorotibial prostheses intended for use in the rehabilitation of knees severely damaged by rheumatoid, osteo and post-traumatic arthritis.
3. All are available in a range of sizes and in a range of tibial component thicknesses to accomodate anatomical variations.
4. All femoral components consist of one polished anatomically shaped condylar bearing surface.
5. All tibial and femoral components employ some type of underside surface design to enhance interlocking of the prostheses and bone cement. In the named prostheses, combinations of grooves, undercuts, and waffled or textured surfaces are utilized. In the PCA Knee, this function is performed by a porous coating.

SAFETY/EFFICACY IMPACT

The major difference between the PCA Unicompartmental Knee Prosthesis and the named equivalent knee prostheses is that that PCA Knee utilizes a sintered VITALLIUM® porous coating to enhance interlocking with bone cement, whereas the other prostheses employ various waffled, textured or undercut surfaces to achieve interlock.

This difference in the PCA Unicompartmental Knee will not have an adverse impact on safety or efficacy for the following reasons:

1. The material of the porous coating is the same as the substrate, namely VITALLIUM® ALLOY, which has a demonstrated successful clincial history over many years.
2. The mechanical properties of the substrate material are not significantly changed by the sintering process and exceed the requirements of ASTM F75. (Reference data supplied in 510(k) Notification K800513).
3. Shear and tensile strengths of the bone cement/porous coating interface are typically 1500 psi or more and when tested to failure the separation occurs in the bone cement and not in the porous layer or at the coating to substrate interface. The bond strength of the porous coating itself is over 3500 psi in tension and over 5900 psi in shear. (Reference data supplied in 510(k) Notification K800513). All of these load values are significantly higher than would be expected in the intended use of the prostheses.

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SAFETY/EFFICACY IMPACT (Con't)

4. Comparative bench simulations under dynamic loading have shown the fatigue strength of the porous coating/bone cement interface to be 250% greater than a waffled surface/bone cement interface. As in static testing, when failure is induced in dynamic testing, the separation occurs in the bone cement and not in the porous layer or at coating to substrate interface.
5. Clinical testing of the primary PCA Knee to date indicates acceptable results with no incidences of implant loosening or breakage, dislocation, infection, reoperation or deaths. (Reference data previously submitted as a supplement to 510(k) Notification K800513).

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HLB

CONTENTS STERILE

UNLESS DAMAGED OR OPENED

INDICATOR DOT DARKENS WHEN RADIATION STERILIZED
DO NOT USE IF DOT IS YELLOW

CAT. NO. 6635-1-020 SAMPLE LABEL

Howmedica Inc. **Orthopaedics Division**
359 Veterans Blvd. Rutherford, N.J. 07070

STERILITY LOT

P.C.A.™ UNICOMPARTMENTAL
KNEE SYSTEM
MEDIUM LEFT FEMORAL COMPONENT
20mm WIDTH XX CMB
MFG. LOT CODE: XXXXXX

CL8 CAUTION: FEDERAL LAW IN USA AND CANADA RESTRICTS THIS
DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR HOSPITAL

AIL 0095-1-044

DO NOT RESTERILIZE
STORE IN A COOL, DRY PLACE

PEEL BACK TO BREAK SEAL

HLB

CONTENTS STERILE

UNLESS DAMAGED OR OPENED

INDICATOR DOT DARKENS WHEN RADIATION STERILIZED
DO NOT USE IF DOT IS YELLOW

CAT. NO. 6635-1-311 SAMPLE LABEL

Howmedica Inc. **Orthopaedics Division**
359 Veterans Blvd. Rutherford, N.J. 07070

STERILITY LOT

P.C.A.™ UNICOMPARTMENTAL
KNEE SYSTEM
MEDIUM 11mm THICK TIBIAL COMPONENT
LEFT/MEDIAL RIGHT/LATERAL XX CMB
MFG. LOT CODE: XXXXXX

CL8 CAUTION: FEDERAL LAW IN USA AND CANADA RESTRICTS THIS
DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR HOSPITAL

AIL 0095-1-044

DO NOT RESTERILIZE
STORE IN A COOL, DRY PLACE

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PEEL BACK TO BREAK SEAL

318

HLB

CONTENTS STERILE

UNLESS DAMAGED OR OPENED

INDICATOR DOT DARKENS WHEN RADIATION STERILIZED
DO NOT USE IF DOT IS YELLOW

CAT. NO. 6635-1-020 **SAMPLE LABEL** Gallium® Alloy
STERILITY LOT

P.C.A.™ UNICOMPARTMENTAL
KNEE SYSTEM

MEDIUM LEFT FEMORAL COMPONENT
20mm WIDTH XX CMB

MFG. LOT CODE: XXXXXX

CLB CAUTION: FEDERAL LAW IN USA AND CANADA RESTRICTS THIS
DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR HOSPITAL

Howmedica Inc. Orthopaedics Division
359 Veterans Blvd, Rahway, N.J. 07065

AIL 0095-1-044

DO NOT RESTERILIZE
STORE IN A COOL, DRY PLACE

PEEL BACK TO BREAK SEAL

HLB

CONTENTS STERILE

UNLESS DAMAGED OR OPENED

INDICATOR DOT DARKENS WHEN RADIATION STERILIZED
DO NOT USE IF DOT IS YELLOW

CAT. NO. 6635-1-311 **SAMPLE LABEL** Gallium® Alloy
STERILITY LOT

P.C.A.™ UNICOMPARTMENTAL
KNEE SYSTEM

MEDIUM 11mm THICK TIBIAL COMPONENT
LEFT/MEDIAL RIGHT/LATERAL XX CMB

MFG. LOT CODE: XXXXXX

CLB CAUTION: FEDERAL LAW IN USA AND CANADA RESTRICTS THIS
DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR HOSPITAL

Howmedica Inc. Orthopaedics Division
359 Veterans Blvd, Rahway, N.J. 07065

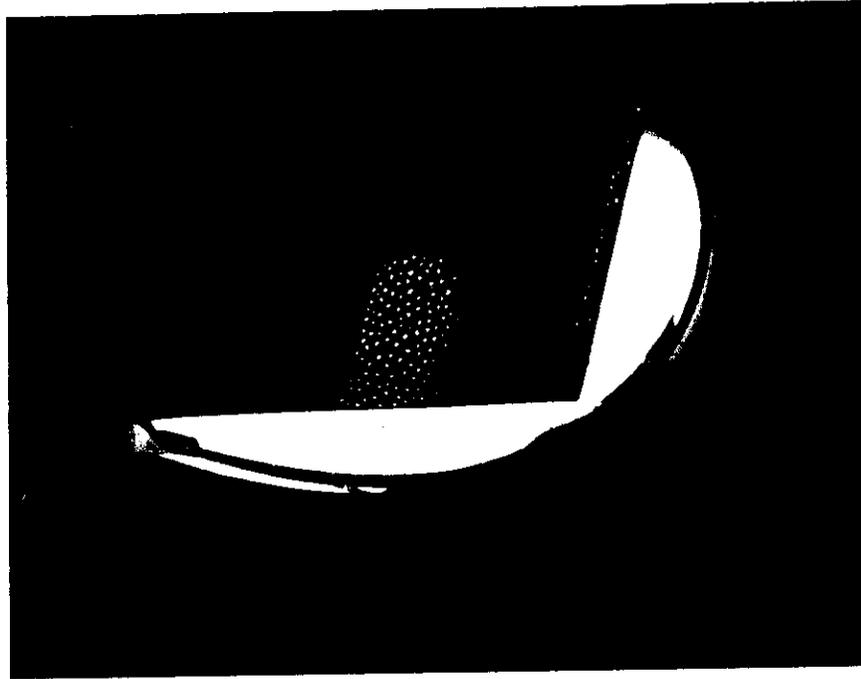
AIL 0095-1-044

DO NOT RESTERILIZE
STORE IN A COOL, DRY PLACE

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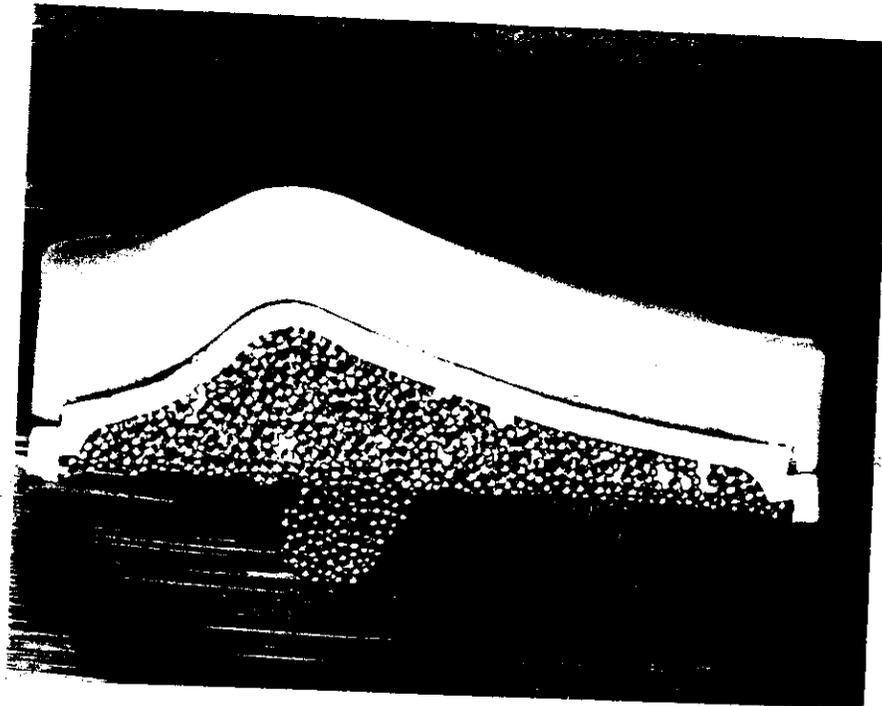
PEEL BACK TO BREAK SEAL

319



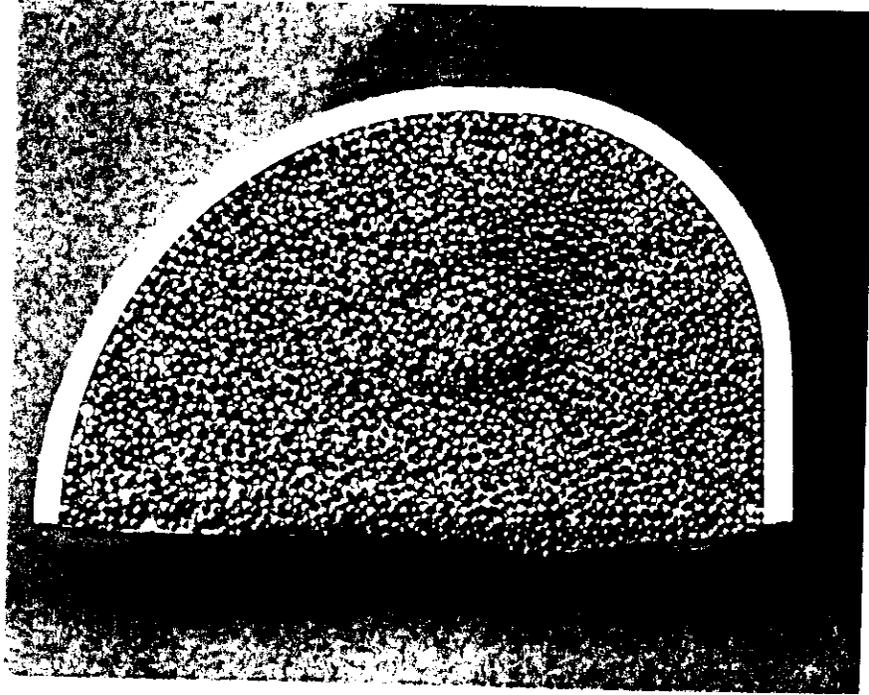
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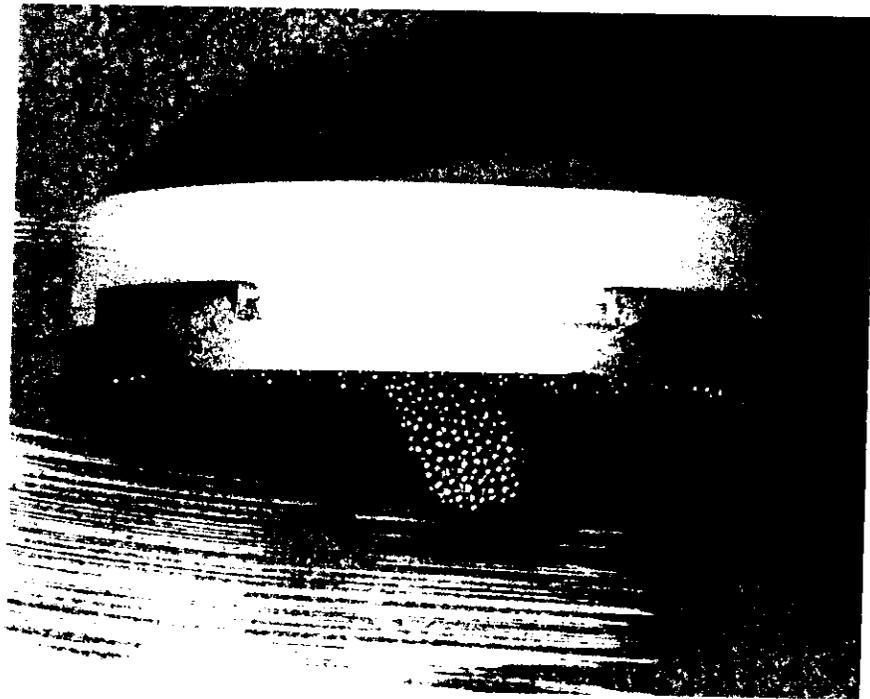


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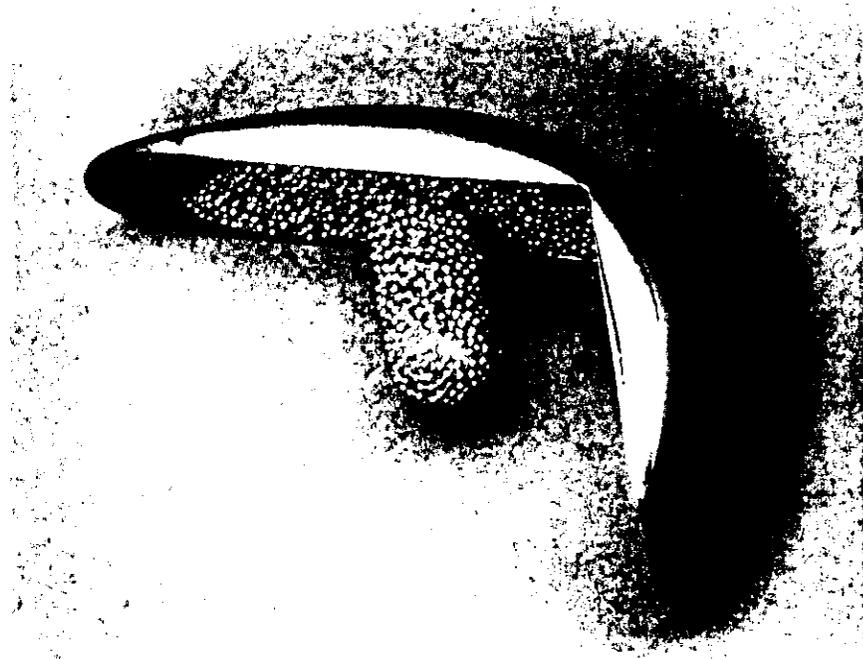
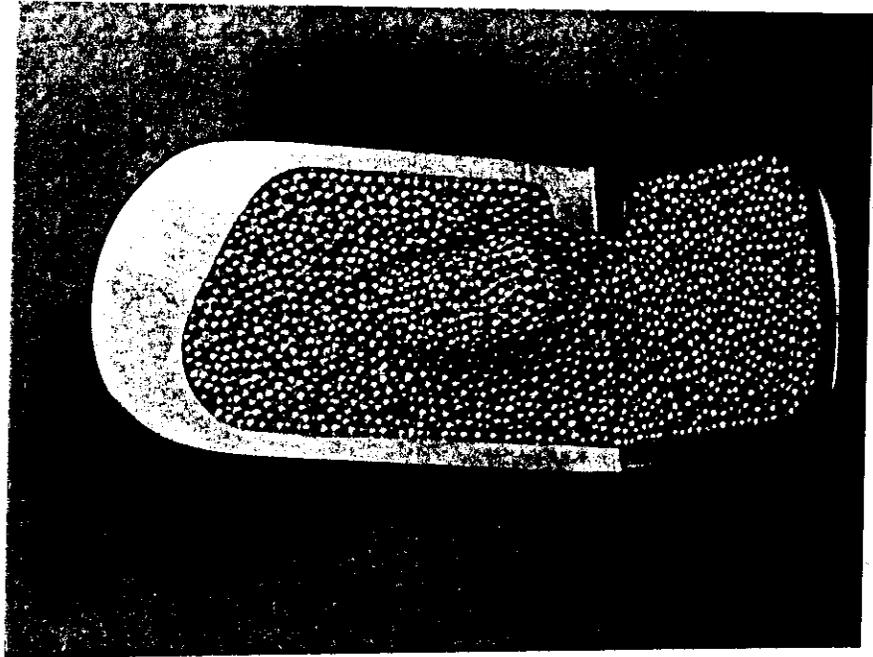


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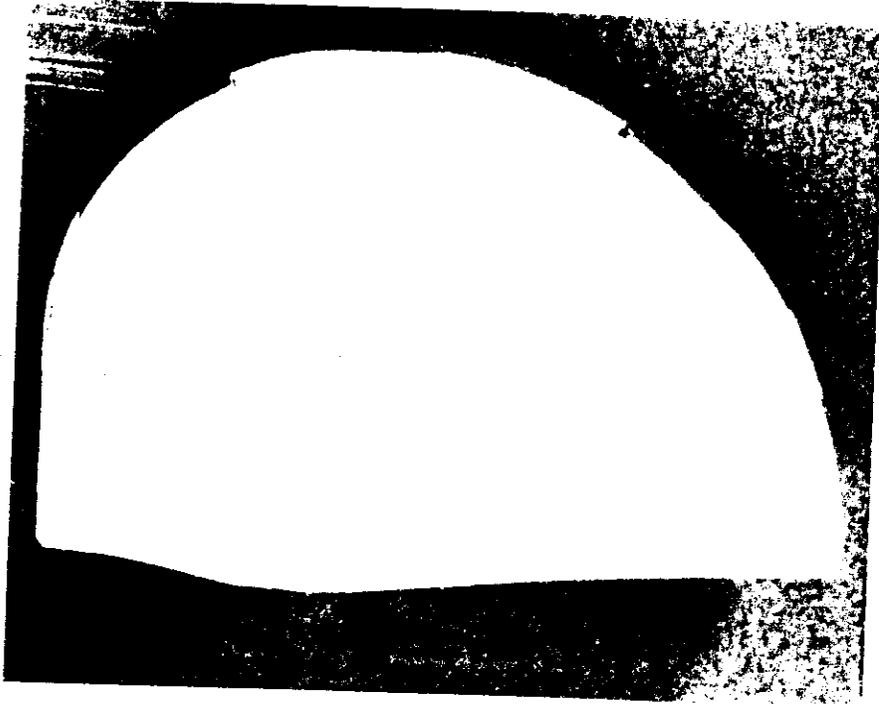


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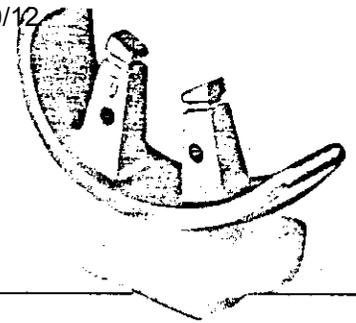


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CONFIDENTIAL

SAVASTANO HEMI-KNEE SYSTEM

Vitallium Alloy
Ultra-High Molecular Weight Polyethylene (RCH-1000)



Cat. No.	Savastano Hemi-Knee Prostheses
6999-6-902	Small Femoral Component 17mm M/L 52mm A/P
6999-7-902	Standard Femoral Component 18mm M/L 59mm A/P
6999-8-013	Small 6mm Tibial Component
6999-8-023	Small 9mm Tibial Component
6999-8-033	Small 12mm Tibial Component
6999-8-043	Small 15mm Tibial Component
6999-8-012	Medium 6mm Tibial Component
6999-8-022	Medium 9mm Tibial Component
6999-8-032	Medium 12mm Tibial Component
6999-8-042	Medium 15mm Tibial Component
6999-8-011	Large 6mm Tibial Component
6999-8-021	Large 9mm Tibial Component
6999-8-031	Large 12mm Tibial Component
6999-8-041	Large 15mm Tibial Component

Cat. No.	Savastano Trial Prostheses
6780-3-000	Small Femoral Trial 17mm M/L
6780-2-000	Standard Femoral Trial 18mm M/L
6780-1-013	Small 6mm Tibial Trial
6780-1-023	Small 9mm Tibial Trial
6780-1-033	Small 12mm Tibial Trial
6780-1-043	Small 15mm Tibial Trial
6780-1-012	Medium 6mm Tibial Trial
6780-1-022	Medium 9mm Tibial Trial
6780-1-032	Medium 12mm Tibial Trial
6780-1-042	Medium 15mm Tibial Trial
6780-1-011	Large 6mm Tibial Trial
6780-1-021	Large 9mm Tibial Trial
6780-1-031	Large 12mm Tibial Trial
6780-1-041	Large 15mm Tibial Trial



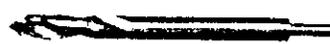
6780-4-000
Savastano Femoral Drill



6780-7-000
Drill Guide/Template Holder



6780-6-000
Templates (Set of 3)



6804-3-000
3/8" - 437 Dia. Drill (11.0 Individually Packaged)

CONFIDENTIAL

Howmedica, Inc.
Orthopaedics Division

W10336
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324.

COMPARTMENTAL® II knee prosthesis

NON-CONSTRAINED KNEE PROSTHESIS

COMPARTMENTAL® II KNEE PROSTHESES

An improved condylar type knee system, which allows the surgeon greater flexibility in the selection and implantation of femoral and tibial components.

The modular implant design provides for a variety of interchangeable femoral and tibial components which allows latitude in correction of varus and valgus deformities and reconstruction of articulating surfaces. The design of the COMPARTMENTAL® II Non-Constrained Knee Prosthesis permits replacement of only the medial or lateral compartment or both compartments where intact collateral and cruciate ligaments exist to provide inherent joint stability. Removal of sound cortical bone is minimal, preserving later surgical alternatives.

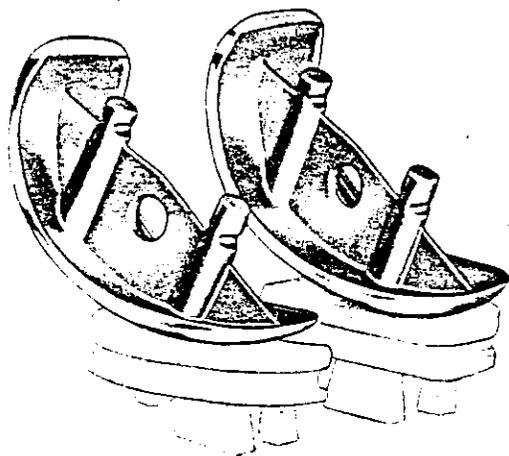
Since this is primarily a surface-type replacement, a good fit of the prosthesis to bone is possible. An additional radius is added to the anterior aspect of the femoral prosthesis to provide a smooth metal to bone transition to minimize patellar impingement. This radius also eliminates the additional step of undercutting the bone to inlay the anterior tip of the prosthesis. The femoral prosthesis is locked in place by bone cement through the cross hole in the fin.

Five femoral component sizes and 18 tibial variations accommodate a wide range of anatomical requirements. The six different thicknesses of the tibial component, each available in three diameters, allow for correction of varus and valgus deformities. Component sizes are interchangeable for use with medial and lateral components.

Dovetailed lugs are also incorporated on the underside of the tibial component to minimize rocking, a phenomenon which has been attributed to loosening of the tibial component.

Molded ultra-high molecular weight polyethylene (UHMWP) tibial components present an ultra smooth, concave, disc-shaped articular surface which allows for optimal rotation and femoral gliding of the knee joint.

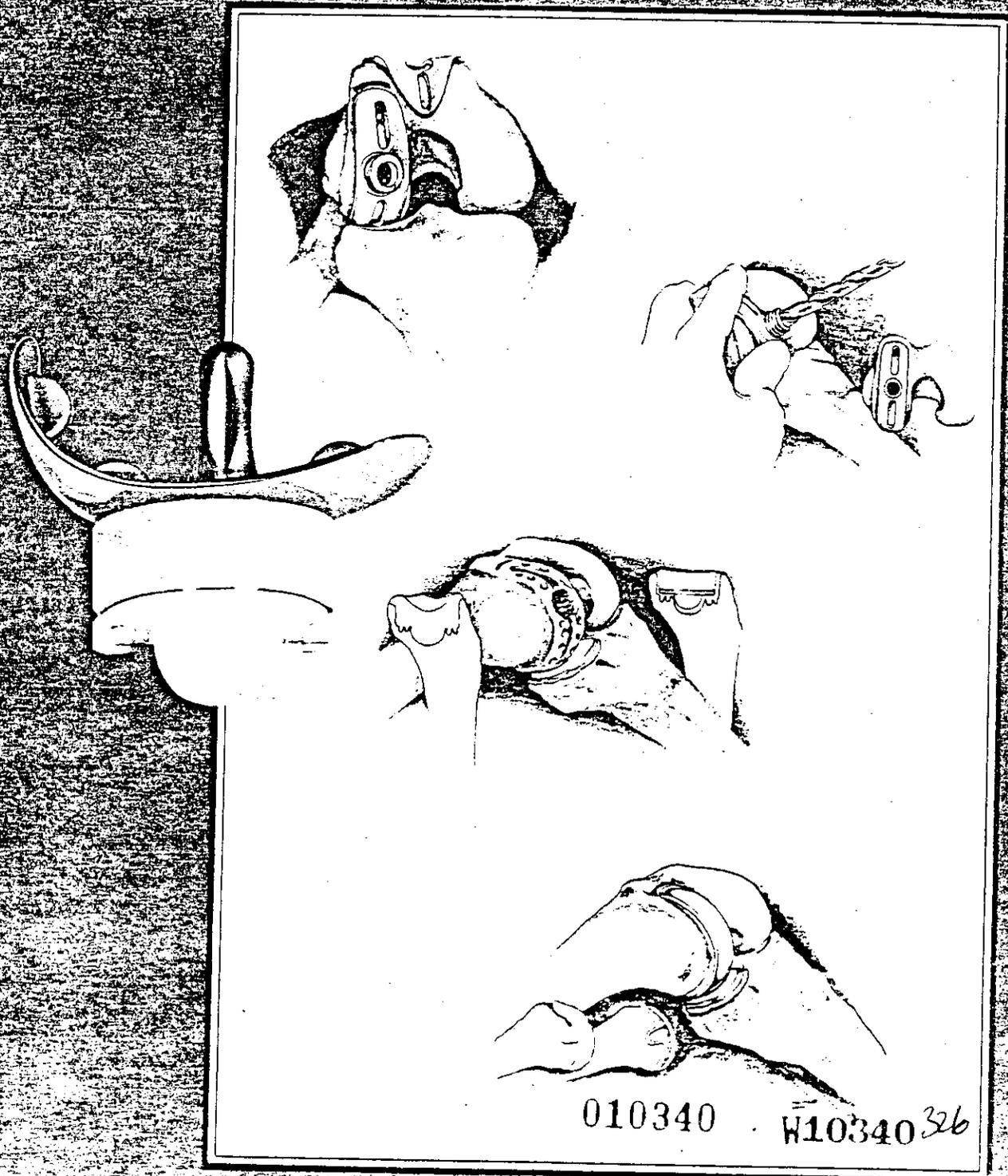
- References:**
1. Laskin RS: Modular total knee replacement arthroplasty. *JBJS*, 58A: 776-773, 1976.
 2. Ranawat CS, Shine JJ: Duo-condylar total knee arthroplasty. *Clin. Orthop.*, 94:185-195, 1973.
 3. Ewald FC: Metal to plastic knee replacement. *Orthop. Clin. North Am.*, 6:811-821, 1973.
 4. COMPARTMENTAL®II Surgical Technique. Zimmer (Lit. No. 81-038-2121-1011)



W10338

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325

MOD II, Total KNEE system



Mod II TOTAL KNEE

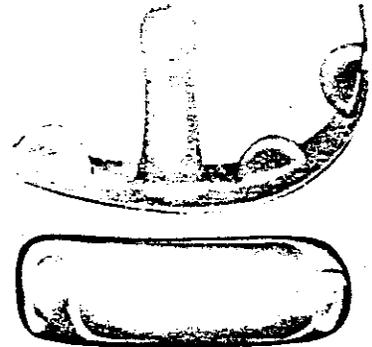
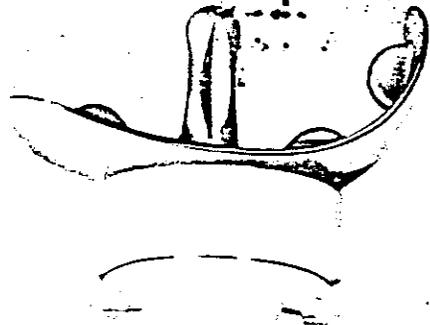
Patent Pending

The Richards Mod II Total Knee combines the features commonly requested by orthopedic surgeons:

- Five femoral component sizes, varying both length and width, provide greater latitude in patient needs.
- The highly-polished articulating surface fits snugly to the condyle throughout its length to present a near-normal condylar surface.
- Available in Certified Stainless Steel or Richards Certified Cobalt-Chromium (ASTM F-75).

Grooved post and undercut lugs provide secure cement fixation without cutting edges.

Tibial components available in two styles (with or without foot) for inlay or "L" resection surgical techniques, and six heights (7.5mm through 21mm). Four sizes available; with X-ray marking wires in choice of Richards Certified Stainless Steel (ASTM F-138) or Richards Certified Cobalt-Chromium (ASTM F-90). Ultra-high molecular weight polyethylene, sterile packaged.

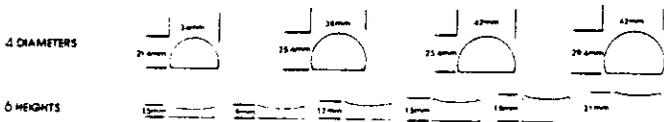


FEMORAL COMPONENT

Stainless Steel CAT. NO.	Cobalt-Chromium CAT. NO.	SIZE	LENGTH	WIDTH
12-1269	12-1249	X-Small	46mm ✓	14mm ✓
12-1270	12-1250	Small	50mm ✓	16mm ✓
12-1272	12-1252	Medium	54mm ✓	17mm ✓
12-1275	12-1255	Large	58mm ✓	20mm ✓
12-1280	12-1260	X-Large	64mm ✓	22mm ✓

TIBIAL COMPONENT

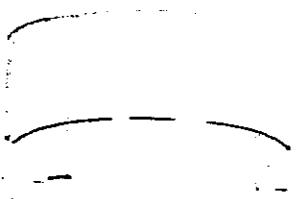
Ultra-High Molecular Weight Polyethylene.



WITHOUT FOOT		WITH FOOT		DIAMETER	HEIGHT
STAINLESS STEEL INDICATOR WIRE CAT. NO.	COBALT CHROME INDICATOR WIRE CAT. NO.	STAINLESS STEEL INDICATOR WIRE CAT. NO.	COBALT CHROME INDICATOR WIRE CAT. NO.		
12-1300	12-1400	12-1350	12-1450	34mm	7.5mm
12-1301	12-1401	12-1351	12-1451	34mm	9mm
12-1302	12-1402	12-1352	12-1452	34mm	12mm
12-1303	12-1403	12-1353	12-1453	34mm	15mm
12-1304	12-1404	12-1354	12-1454	34mm	18mm
12-1305	12-1405	12-1355	12-1455	34mm	21mm
12-1310	12-1410	12-1360	12-1460	38mm	7.5mm
12-1311	12-1411	12-1361	12-1461	38mm	9mm
12-1312	12-1412	12-1362	12-1462	38mm	12mm
12-1313	12-1413	12-1363	12-1463	38mm	15mm
12-1314	12-1414	12-1364	12-1464	38mm	18mm
12-1315	12-1415	12-1365	12-1465	38mm	21mm
12-1320	12-1420	12-1370	12-1470	42mm	7.5mm
12-1321	12-1421	12-1371	12-1471	42mm	9mm
12-1322	12-1422	12-1372	12-1472	42mm	12mm
12-1323	12-1423	12-1373	12-1473	42mm	15mm
12-1324	12-1424	12-1374	12-1474	42mm	18mm
12-1325	12-1425	12-1375	12-1475	42mm	21mm
12-1340	12-1440	12-1390	12-1490	42mm "Wide Track"	7.5mm
12-1341	12-1441	12-1391	12-1491	42mm "Wide Track"	9mm
12-1342	12-1442	12-1392	12-1492	42mm "Wide Track"	12mm
12-1343	12-1443	12-1393	12-1493	42mm "Wide Track"	15mm
12-1344	12-1444	12-1394	12-1494	42mm "Wide Track"	18mm
12-1345	12-1445	12-1395	12-1495	42mm "Wide Track"	21mm



Without Foot



With Foot

CONFIDENTIAL

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327

Stryker® Compartmental Knee

Traditional 510(k)

APPENDIX E
INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known):

Device Name: Stryker® Compartmental Knee System

Indications for Use:

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartamental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartamental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

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 OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

329

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Ronald P Jean
Subject: 510(k) Number K052917/S'
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices. SE
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this device subject to the Tracking Regulation?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Was clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this a prescription device?	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Special 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO

Truthful and Accurate Statement Requested Enclosed
 A 510(k) summary OR A 510(k) statement
 The required certification and summary for class III devices
 The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) no

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 day

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

NPS/II 888.3530 KRR, HSX, HRY/II 888.3540, 888.3520, 888.3530

Review: [Signature] 0020B 12/23/05
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 12/23/05
(Division Director) (Date)

4

TRADITIONAL 510(K) MEMORANDUM

TO: K052917/S1
FROM: Ronald P. Jean, Ph.D. *RPJ 12/22/2005*
 General Engineer, FDA/CDRH/ODE/DGRND/ORDB *12/21/05*
DATE: 12/22/2005
SUBJECT: Stryker Compartmental Knee System
 Product/Panel Code: NPJ,KRR,HSX,HRY/87 Class: II
 Classification: 888.3530, 888.3540, 888.3520, 888.3530

RECOMMENDATION SUMMARY:

I received Supplement 1 of Traditional 510(k) K052917 on 12/14/2005. The Stryker Compartmental Knee System consists of patellofemoral components from the Avon Patello-femoral Joint (PFJ) Prosthesis, and unicompartmental components from the EIUS, SCR and UNIX Unicompartmental Knee Systems. In essence, this 510(k) submission is for clearance to implant patellofemoral and unicondylar femorotibial components simultaneously, and to update the labeling accordingly. The Indications for Use Statement adequately describes the intended use of the subject system, and all indications are acceptable. All components of the subject system have been cleared for use through previous 510(k) submissions. The sponsor has also provided a risk analysis to address concerns of implanting patellofemoral and unicondylar components concurrently, and the surgical technique provided for the current system mitigates these risks. In this supplement, the sponsor has addressed most concerns identified after the original 510(k) review by including an accessory label on each component package (labeling it as part of the Stryker Compartmental Knee System) and referring to the package insert for indications and component compatibility. Additionally, the sponsor has included a warning statement in the package insert to preclude the use of bicondylar replacement in the same knee. Lastly, the 510(k) Summary has been revised to include all relevant product codes for the intended use of this device. All outstanding issues have been addressed. Therefore, I recommend that the Stryker Compartmental Knee System be found substantially equivalent (SE) to the other legally marketed predicate devices.

I. COMPANY IDENTIFICATION:

Proprietary Name:	Stryker Compartmental Knee System
Applicant/Sponsor:	Howmedica Osteonics Corp.
Address:	325 Corporate Drive Mahwah, NJ 07430
Phone Number:	(201) 831-5581
Fax Number:	(201) 831-6038
Contact Person:	Vivian Kelly Regulatory Affairs Specialist
Registration Number:	2249697

II. PREDICATE DEVICE(S):

K042896	Hybrid Knee Femoral Components	Smith & Nephew
K010100, K020841, K041160	Avon Patello-femoral Joint Prosthesis	Howmedica
K992287, K033769	EIUS Unicompartmental Knee System	Howmedica
K896856, K911373	SCR Unicompartmental Knee System	Howmedica
K923011	UNIX Unicompartmental Knee System	Howmedica
K831143	PCA Unicompartmental Knee System	Howmedica

III. INTENDED USE/INDICATIONS:

The Stryker Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,

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- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previously unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartamental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartamental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

The indications listed above are similar to those for the Smith & Nephew Hybrid Knee (K042896), Howmedica Osteonics Avon Patello-Femoral Joint Prosthesis (K041160), and the Howmedica Osteonics EIUS Unicompartamental Knee System (K033769). The final indication, "where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau," is not present in predicate statements. However, it produces no safety concern due to the restriction to cases where other techniques cannot be used. ORDB Joint Team Leader Peter Allen agreed that the last indication was acceptable.

IV. DEVICE DESCRIPTION & MATERIALS:

A. General Device Description:

This 510(k) is for the clearance of components of the Stryker Compartmental Knee System. The subject device components are intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The system includes components for patellofemoral and unicompartamental arthroplasty from the followed cleared predicates: Avon Patello-femoral Joint Prosthesis (K010100, K020841, K041160, and K051948, and K051977); EIUS Unicompartamental Knee System (K992287, K033769); SCR Unicompartamental Knee Prosthesis (K896856, K911373); and, UNIX Unicompartamental Knee System (K923011).

V. DEFICIENCY RESPONSES:

1. The Stryker Compartmental Knee System consists of components intended for unicondylar femorotibial arthroplasty from the EIUS, SCR and UNIX Unicompartamental Knee Systems. However, the different components belonging to each unicondylar knee system cannot be mixed. While you have provided a compatibility table in the package insert, there is no warning on the outer package label. To mitigate the risk of unicondylar component mismatch, please provide a warning statement on the outer package labeling of the unicondylar knee components. For example, you may consider including the statement "Warning: Only compatible with other UNIX Unicompartamental Knee System components" on the UNIX Unicompartamental Knee System labels, and so forth.

RESPONSE: The sponsor will place a label on each component package with the following statement: "The Stryker Compartmental Knee System: See package insert for indications and component compatibility." *This response mitigates the risk of component mismatch, since there is a compatibility table in the package insert. This response is acceptable.*

2. The Stryker Compartmental Knee System is intended for patellofemoral and/or unicondylar arthroplasty. However, on page 11 of the Device Description section, you state "the Stryker Compartmental Knee System includes different styles of uni-compartmental knee components so the physician can choose the most appropriate type of femorotibial components, i.e., a resurfacing or resectioning design to address both right and left compartment needs." This latter statement may be construed as inferring that the two condyles of the same knee may be replaced concurrently, resulting in a procedure that falls outside of a unicondylar arthroplasty. Therefore, please include a warnings statement in the draft package insert for the Stryker Compartmental Knee System to advise against misuse of the unicompartamental knee components outside of their intended use. For example, you might include a statement akin to the following: "The femorotibial components of the Stryker Compartmental Knee System are not intended for repair of both condyles of the same knee simultaneously."

RESPONSE: The sponsor provided a revised draft package insert containing the following statement in the "Warnings" section: "The femorotibial components of the Stryker Compartmental Knee System are not intended for repair of both condyles of the same knee simultaneously." *This response is acceptable.*

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3. The current 510(k) submission is for review of the Stryker Compartmental Knee System. However, while you included a draft package insert for the Stryker Compartmental Knee in Appendix B-2, you also provided a draft package insert for the Stryker Unicompartmental Knees in Appendix B-3, and a draft package insert for the Avon Patello-Femoral Joint Prosthesis in Appendix B-4. A change of labeling for the Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis must be done through separate 510(k) submissions. Therefore, please remove the draft package inserts for the Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis from the current submission. Additionally, while the subject device components have been cleared through predicate 510(k) submissions, the package labeling should be consistent with the package insert provided for the device. Therefore, please provide a package label referencing the Stryker Compartmental Knee System that will be provided with the subject device.

RESPONSE: The sponsor stated on page 8 of Supplement 1 that the Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis package inserts have been removed from the submission as requested. The sponsor will place a label on each component package with the following statement: "The Stryker Compartmental Knee System: See package insert for indications and component compatibility." *This adequately refers to the Stryker Compartmental Knee System for each system component. The response is adequate.*

4. You provided an Indications for Use Statement identifying that the subject device components are intended for patellofemoral and/or unicondylar arthroplasty. However, you have not included all Product Codes and Regulations Numbers associated with the subject device, since the system components can be used individually for patellofemoral arthroplasty only or unicondylar arthroplasty only. Therefore, please provide a revised 510(k) Summary to include all relevant Product Codes and Regulation Numbers.

RESPONSE: The sponsor provided a revised 510(k) Summary with all pertinent Product Codes and Regulation Numbers. *This response is adequate.*

VI. CONTACT RECORD:

11/21/2005. The ORDB Joint Team was asked whether or not the indications for use precluded the subject device from being intended for a total knee arthroplasty by use of two unicompartmental knee systems. The consensus was that the indications for use are adequate in delineating the subject device for use in patellofemoral and/or unicompartmental arthroplasty procedures.

11/28/2005. The ORDB Joint Team was asked whether or not the sponsor should provide an incompatibility warning on the package label, since the femoral and tibial components of the different unicondylar systems are not compatible. The consensus was that a warning should be present on the package label, though it need not be in the format of a table (like the compatibility warning in the package insert).

11/30/2005. The sponsor was notified that this 510(k) submission would be placed on **telephone hold**, and the deficiencies were communicated to the sponsor.

12/07/2005. The sponsor participated in a teleconference call to clarify the deficiencies and discuss corrective actions. The responses provided in Supplement 1 are a result of those discussions.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?	n/a	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	n/a	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	n/a	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	n/a	

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 052917/S'

Reviewer: Ronald P. Jean

Division/Branch: DGRND/ORDB

Device Name: Stryker Compartmental Knee System

Product To Which Compared (510(K) Number If Known): K042896, K051948, K033769, K911373, K923011

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?		✓	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision: <u>SE</u>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

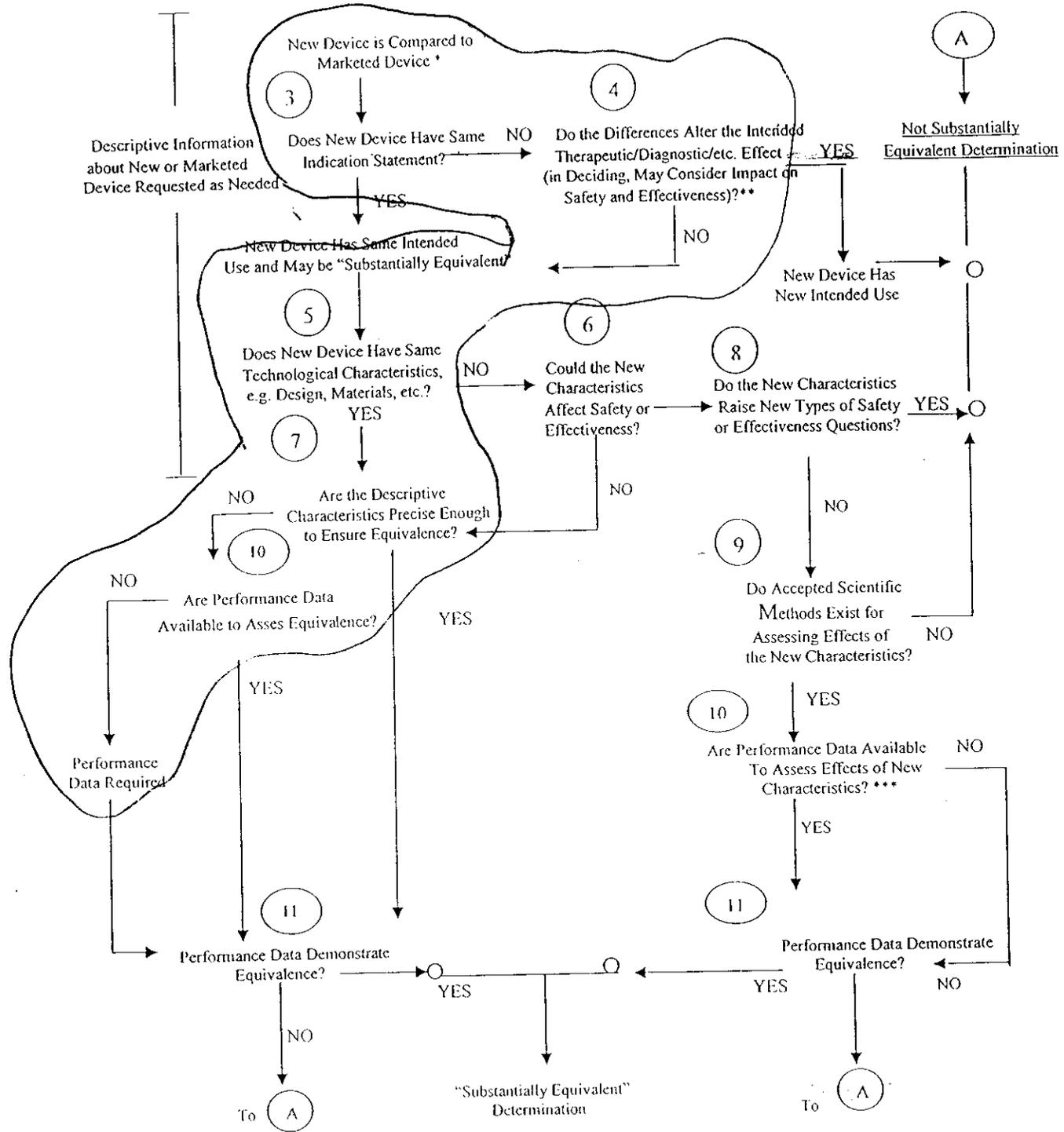
1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device: see memo:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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



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

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

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

TRADITIONAL 510(K) MEMORANDUM

TO: K052917
FROM: Ronald P. Jean, Ph.D. *RPJ*
 General Engineer, FDA/CDRH/ODE/DGRND/ORDB
DATE: 11/30/2005 *DR 11/30/05*
SUBJECT: Stryker Compartmental Knee System
 Product/Panel Code: NPJ/87 Class: II Classification: 888.3530

RECOMMENDATION SUMMARY:

I received Traditional 510(k) K052917 on 10/19/2005. The Stryker Compartmental Knee System consists of patellofemoral components from the Avon Patello-femoral Joint (PFJ) Prosthesis, and unicompartmental components from the EIUS, SCR and UNIX Unicompartmental Knee Systems. In essence, this 510(k) submission is for clearance to implant patellofemoral and unicondylar femorotibial components simultaneously, and to update the labeling accordingly. The Indications for Use Statement adequately describes the intended use of the subject system, and all indications are acceptable. All components of the subject system have been cleared for use through previous 510(k) submissions. The sponsor has also provided a risk analysis to address concerns of implanting patellofemoral and unicondylar components concurrently, and the surgical technique provided for the current system mitigates these risks. However, there are a few issues that the sponsor needs to address. First, a warning in the package insert is necessary to prevent implantation of two unicompartmental components on both condyles of a single knee, since this is outside of the intended use (but is vaguely alluded to in the device description). Secondly, a warning is necessary on package labels to prevent unicompartmental component mismatch, since the EIUS, SCR and UNIX components are not interchangeable. The sponsor will be asked to provide revised package inserts and labels reflecting these changes. Additionally, the sponsor will be asked to withdraw the package inserts of the unicondylar and patellofemoral devices, since those changes in labeling fall outside of the current 510(k) review. Lastly, the sponsor will be asked to include all relevant product codes and regulation numbers for the subject device. Therefore, based upon these findings, I recommend that this submission be placed on **telephone hold** for additional information (**AI**) before a final SE/NSE decision can be made.

I. COMPANY IDENTIFICATION:

Proprietary Name:	Stryker Compartmental Knee System
Applicant/Sponsor:	Howmedica Osteonics Corp.
Address:	325 Corporate Drive Mahwah, NJ 07430
Phone Number:	(201) 831-5581
Fax Number:	(201) 831-6038
Contact Person:	Vivian Kelly Regulatory Affairs Specialist
Registration Number:	2249697

II. PREDICATE DEVICE(S):

K042896	Hybrid Knee Femoral Components	Smith & Nephew
K010100, K020841, K041160	Avon Patello-femoral Joint Prosthesis	Howmedica
K992287, K033769	EIUS Unicompartmental Knee System	Howmedica
K896856, K911373	SCR Unicompartmental Knee System	Howmedica
K923011	UNIX Unicompartmental Knee System	Howmedica
K831143	PCA Unicompartmental Knee System	Howmedica

III. INTENDED USE/INDICATIONS:

The Stryker Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,

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- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previously unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

The indications listed above are similar to those for the Smith & Nephew Hybrid Knee (K042896), Howmedica Osteonics Avon Patello-Femoral Joint Prosthesis (K041160), and the Howmedica Osteonics EIUS Unicompartmental Knee System (K033769). The final indication, "where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau," is not present in predicate statements. However, it produces no safety concern due to the restriction to cases where other techniques cannot be used. ORDB Joint Team Leader Peter Allen agreed that the last indication was acceptable.

IV. DEVICE DESCRIPTION & MATERIALS:

A. General Device Description:

This 510(k) is for the clearance of components of the Stryker Compartmental Knee System. The subject device components are intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The system includes components for patellofemoral and unicompartmental arthroplasty from the followed cleared predicates: Avon Patello-femoral Joint Prosthesis (K010100, K020841, K041160, and K051948, and K051977); EIUS Unicompartmental Knee System (K992287, K033769); SCR Unicompartmental Knee Prosthesis (K896856, K911373); and, UNIX Unicompartmental Knee System (K923011).

B. Patellofemoral Components:

The patellofemoral components of the subject system were cleared as part of the Avon Patello-femoral Joint Prosthesis, and will not be modified.

1. Femoral Components:

The femoral component is for resurfacing the patellar groove on the femur for patellofemoral arthroplasty and articulates with a patellar component (see section below). The femoral component is made of cobalt chromium alloy (ASTM F-75), and is available in extra small, small, medium, and larger sizes (K041160, K010100).

2. Patellar Components:

The patellar components for use with patellofemoral arthroplasty are made of UHMWPe (ASTM F-648), and consist of the following: Avon Polyethylene Patellas (K020841); Kinemax Patellar Components (K010100); Duracon Patellar Components (K961483, K965173, cleared for use with the Avon PFJ in K051948); Scorpio Patellar Components (K972967, cleared for use with the Avon PFJ in K051948); Scorpio X3 UHMWPe Patellar Components (K051977); Triathlon Patellar Components (cleared in K051948 for use with the Avon PFJ);

C. Femorotibial Components:

The femorotibial components of the subject system were cleared as part of the EIUS, SCR and UNIX Unicompartmental Knee Systems.

1. EIUS Components:

The EIUS Unicompartmental Knee System consists of a cobalt chromium distal femoral resurfacing component and an UHMWPe proximal tibial resurfacing component (K033769, K992287).

2. SCR Components:

The SCR Unicompartmental Knee Prosthesis consists of cobalt chromium femoral components and cobalt chromium tibial components with a polyethylene tibial insert made from UHMWPe (K896856, K911373)

K052917 – Page 3**3. UNIX Components:**

The Osteonics UNIX Unicompartmental Knee System consists of cobalt chromium femoral components and cobalt chromium tibial trays with an UHMWPe tibial insert (K923011).

A components listing is provided in Appendix A-1, and engineering drawings are included in Appendix A-2. The material properties of the UHMWPe tibial components meet the material properties of ASTM F-648 GUR 1020 as described in K033769.

V. TELEPHONE HOLD DEFICIENCIES:

1. The Stryker Compartmental Knee System consists of components intended for unicondylar femorotibial arthroplasty from the EIUS, SCR and UNIX Unicompartmental Knee Systems. However, the different components belonging to each unicondylar knee system cannot be mixed. While you have provided a compatibility table in the package insert, there is no warning on the outer package label. To mitigate the risk of unicondylar component mismatch, please provide a warning statement on the outer package labeling of the unicondylar knee components. For example, you may consider including the statement "Warning: Only compatible with other UNIX Unicompartmental Knee System components" on the UNIX Unicompartmental Knee System labels, and so forth.
2. The Stryker Compartmental Knee System is intended for patellofemoral and/or unicondylar arthroplasty. However, on page 11 of the Device Description section, you state "the Stryker Compartmental Knee System includes different styles of uni-compartmental knee components so the physician can choose the most appropriate type of femorotibial components, i.e., a resurfacing or resectioning design to address both right and left compartment needs." This latter statement may be construed as inferring that the two condyles of the same knee may be replaced concurrently, resulting in a procedure that falls outside of a unicondylar arthroplasty. Therefore, please include a warnings statement in the draft package insert for the Stryker Compartmental Knee System to advise against misuse of the unicompartmental knee components outside of their intended use. For example, you might include a statement akin to the following: "The femorotibial components of the Stryker Compartmental Knee System are not intended for repair of both condyles of the same knee simultaneously."
3. The current 510(k) submission is for review of the Stryker Compartmental Knee System. However, while you included a draft package insert for the Stryker Compartmental Knee in Appendix B-2, you also provided a draft package insert for the Stryker Unicompartmental Knees in Appendix B-3, and a draft package insert for the Avon Patello-Femoral Joint Prosthesis in Appendix B-4. A change of labeling for the Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis must be done through separate 510(k) submissions. Therefore, please remove the draft package inserts for the Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis from the current submission. Additionally, while the subject device components have been cleared through predicate 510(k) submissions, the package labeling should be consistent with the package insert provided for the device. Therefore, please provide a package label referencing the Stryker Compartmental Knee System that will be provided with the subject device.
4. You provided an Indications for Use Statement identifying that the subject device components are intended for patellofemoral and/or unicondylar arthroplasty. However, you have not included all Product Codes and Regulations Numbers associated with the subject device, since the system components can be used individually for patellofemoral arthroplasty only or unicondylar arthroplasty only. Therefore, please provide a revised 510(k) Summary to include all relevant Product Codes and Regulation Numbers.

VI. STERILITY AND PACKAGING:

The sponsor provided the following sterilization information on page 13:

Method of Sterilization: Cobalt 60 Gamma Irradiation

Minimum Dosage: 25 kGy

Method of Validation: ANSI/AAMI/ISO 11137

Sterility Assurance Level: 10^{-6}

Description of Packaging: All components will be packaged as described in their associated premarket notifications: K896856, K923011, K992287, K010100, K02084[1], K033769, and K041160. The components are packaged in a double blister tray then placed in a cardboard container, sealed via the primary package labels, and enveloped in shrink wrap. In order to create an inert environment for the UHMWPe components, the inner blister is flushed with

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nitrogen after the device is placed in it, and then sealed under vacuum. The outer blister is also flushed with nitrogen and sealed under vacuum.

Pyrogen Statement: No claims regarding pyrogenicity are made.

VII. LABELING:

The sponsor provided draft package labels in Appendix B-1. The product name, manufacturer's information, sterilization method, and expiration date are all present. Additionally, the sponsor has added the wording, "Warning: Device is intended for cemented use only in USA." However, since the unicompartamental components are not interchangeable, a warning should be present on the respective package labels to caution against component mismatch. The sponsor will be asked to include such a warning.

VIII. PACKAGE INSERT:

The sponsor provided a draft package insert for the Compartmental Knee in Appendix B-2, a draft package insert for the unicompartamental knees in Appendix B-3, and a draft package insert in Appendix B-4 for the Avon PFJ Prosthesis (this is the same as that contained in K051948, which has been cleared since receipt of this 510(k) submission). The indications in the Compartmental Knee package insert are the same as those presented on the Indications for Use Statement. The sponsor also provides contact information and describes the sterilization method. To preclude the misuse of the unicompartamental knee components for purposes other than those intended (e.g., replacement of both medial and lateral condyles of the same knee), the sponsor will be asked to provide a warning statement. Additionally, the sponsor will be asked to remove the package inserts for the unicompartamental knee and patellofemoral joint prosthesis components, since those must be reviewed under a separate 510(k) submission.

IX. RISK ANALYSIS:

The sponsor provided a risk analysis in Appendix C associated with implanting a unicompartamental knee and a patellofemoral replacement simultaneously. The identified risks are described below.

A. Unicompartamental Femoral Component and Patellofemoral Component Incompatibility:

There is a concern that the patellofemoral and unicompartamental femoral components will impede on each other. To mitigate this risk, the sponsor has provided a surgical technique that describes proper alignment and selection of the system components. The surgical technique includes instructions to check the alignment, along with clearance in the intercondylar notch region. The guidelines in the surgical technique are not specific to the implantation order. *Additionally, the sponsor included a CAD layout to check for impingement between the various components. Using the larger sized components (which would have a greater risk of impingement), placement on a representative distal femur was simulated for the Avon PFJ Prosthesis and the EIUS and SCR unicompartamental femoral components. The Scorpio femoral and Avon PFJ produced the worst case scenario, with a separation distance of 0.115" between the two components. The profile tolerance of the unicompartamental and Avon components is 0.015". Therefore, if the worst theoretical case scenario is chosen, there is still a minimum of 0.085" clearance.*

B. Patellar Button Articulation on Distal Femur:

During deep flexion, the patellar component will articulate on the distal femur. The patellar component will articulate against the intact intercondylar notch, but there is a chance of contact with the unicondylar femoral component. However, the contact area would not be that much different than that for the natural femur. *Additionally, proper component size selection as recommended per the surgical technique mitigates this risk resulting from a unicondylar femoral component being placed too close to the intercondylar notch.*

C. Patellar Button Impingement with the Unicompartamental Femoral Component:

Impingement of the patellar button on the anterior tip of the unicompartamental femoral component is a risk during movement of the knee joint from extension to flexion. Currently, the unicompartamental components are used with an intact, unresurfaced patella, with no adverse events noted. This risk is present when the patellofemoral components are used, and in such an instance, the patellar button will articulate on the sulcus of the patellofemoral component, which extends past the tip of the anterior portion of the unicompartamental prosthesis. Thus, the patella will clear the unicondylar component. The sponsor also stated that several cadaver labs were held to test for this risk, and no patellar clunk or catching in the notch was found. *This risk is also mitigated by proper component size selection as recommended per the surgical technique. Since the patellar component articulates within the patellofemoral groove of the Avon PFJ component, and there is a distance of separation between the lateral edge of the Avon PFJ femoral component and the unicondylar component with proper implantation, this risk is minimized.*

D. Incorrect Placement of Components:

The fact that the patellofemoral and femorotibial components are separate entities adds to the risk of malpositioning. To mitigate this risk, the sponsor has developed a recommended surgical technique for the subject system. The

K052917 – Page 5

surgical technique addresses proper placement, which is specific to the unicompartmental and patellofemoral procedures individually. *The supplied surgical technique reduces the risk of malpositioning, and since the components have been cleared previously for their respective compartments within the knee, there are no additional risks with the individual component procedures.*

X. 510K SUMMARY:

The sponsor provided a 510(k) Summary that adequately described the subject device, company information, subject device, and predicate devices. However, since the subject system can be used for patellofemoral arthroplasty, unicompartmental arthroplasty, or both, additional product codes and regulation numbers are necessary to describe each procedural option. The sponsor will be asked to provide a revised 510(k) Summary reflecting this information.

XI. SE DETERMINATION:

Additional information (AI) is required before an SE/NSE determination can be made.

XII. CONTACT RECORD:

11/21/2005. The ORDB Joint Team was asked whether or not the indications for use precluded the subject device from being intended for a total knee arthroplasty by use of two unicompartmental knee systems. The consensus was that the indications for use are adequate in delineating the subject device for use in patellofemoral and/or unicompartmental arthroplasty procedures.

11/28/2005. The ORDB Joint Team was asked whether or not the sponsor should provide an incompatibility warning on the package label, since the femoral and tibial components of the different unicompartmental systems are not compatible. The consensus was that a warning should be present on the package label, though it need not be in the format of a table (like the compatibility warning in the package insert).

11/30/2005. The sponsor was notified that this 510(k) submission would be placed on **telephone hold**, and the deficiencies were communicated to the sponsor.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

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(4)

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

510(k) Number: K052917

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		/
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	/	
510(k) Summary or 510(k) Statement.	/	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N/A	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - May not be applicable for Special 510(k)s.
 ** - Required for Class III devices, only.
 *** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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(5)

	Present	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.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

(6)

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging	✓	
v) specify nitrogen free	✓	
vi) ETO residues	N/A	
vii) radiation dose	✓	
viii) Traditional Method or Non-Traditional Method	✓	
c) Software Documentation:	N/A	

Items with checks in the "Present or Adequate" column do not require e 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: Ronald P. Jean

Concurrence by Review Branch: [Signature]

Date: 11/30/2005

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(7)

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>

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 052917

Reviewer: Ronald P. Jean

Division/Branch: DGRND/ORDB

Device Name: Compartmental Knee System

Product To Which Compared (510(K) Number If Known): K042876, K051948, K033769, K911373,

K923611

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?		✓	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?		✓	If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

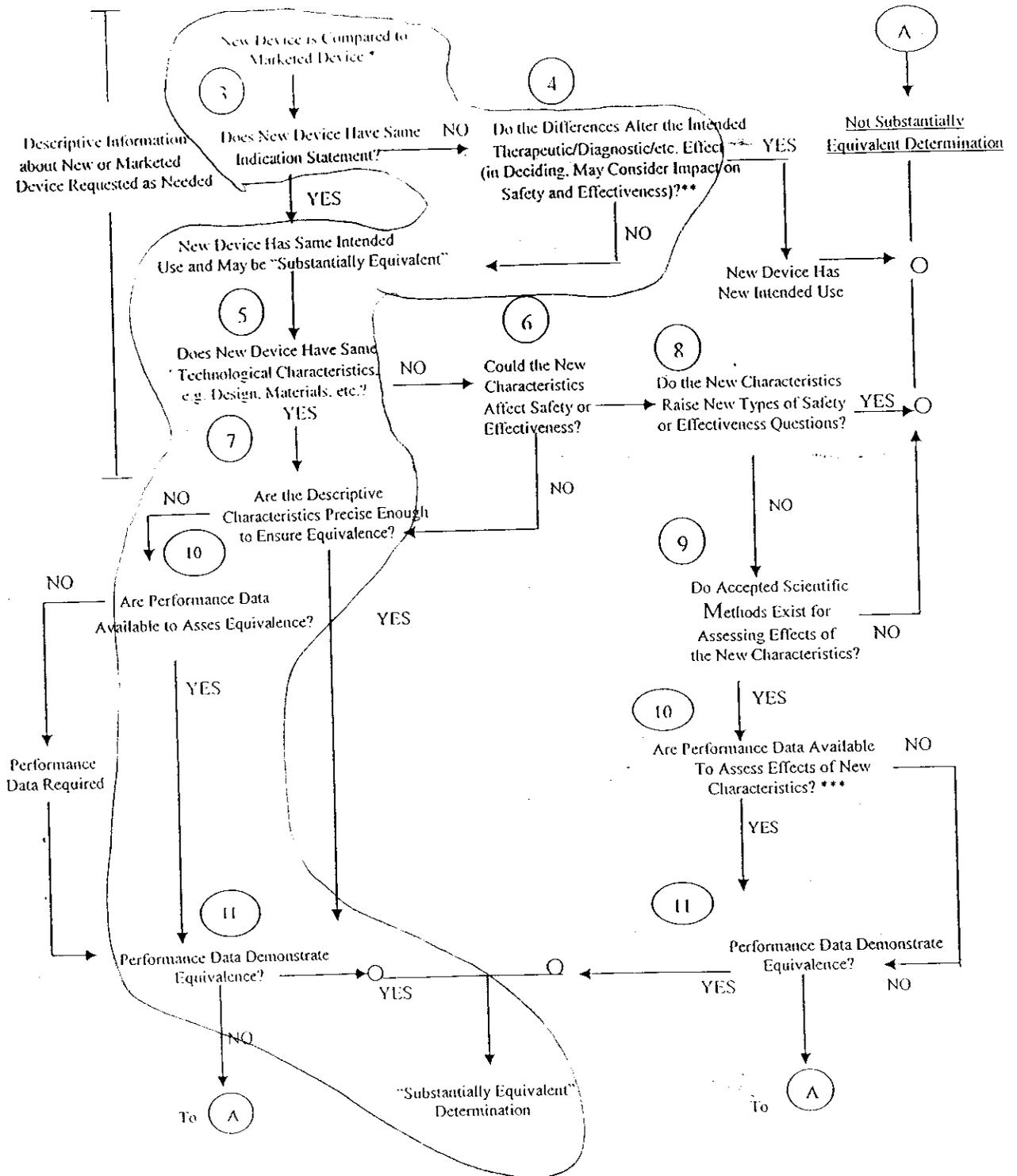
EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device: see memo
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

December 14, 2005

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

HOWMEDICA OSTEONICS CORP
325 CORPORATE DR.
MAHWAH, NJ 07430
ATTN: VIVIAN KELLY

510(k) Number: K052917
Product: STRYKER
COMPARTMENTAL
KNEE SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

12

1052917/S'
stryker
Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

December 13, 2005

Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Attention: Ronald P. Jean, Ph.D.
DGRND/ORDB

Re: K052917- Stryker Compartmental Knee System Deficiency Response

Dear Dr. Jean,

This email is in response to the outstanding issues raised in your email on November 30, 2005. The question is stated in bold text and is followed by the Stryker Howmedica Osteonics' response. A hard copy will be sent to the Document Mail Center in duplicate as you requested.

If you need any additional information, please contact the undersigned of the Stryker Howmedica Osteonics Regulatory Affairs Department at (201) 831-5581 or by email at Vivian.Kelly@Stryker.com.

Sincerely,
Stryker Howmedica Osteonics



Vivian Kelly, RAC
Regulatory Affairs Specialist

K27
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1. **The Stryker Compartmental Knee System consists of components intended for unicondylar femorotibial arthroplasty from the EIUS, SCR and UNIX Unicompartmental Knee Systems. However, the different components belonging to each unicondylar knee system cannot be mixed. While you have provided a compatibility table in the package insert, there is no warning on the outer package label. To mitigate the risk of unicondylar component mismatch, please provide a warning statement on the outer package labeling of the unicondylar knee components. For example, you may consider including the statement "Warning: Only compatible with other UNIX Unicompartmental Knee System components" on the UNIX Unicompartmental Knee System labels, and so forth.**

Per our conversation on December 7, 2005, we will place the following label on each component in Stryker Compartmental Knee System to address the compatibility issue and to mitigate the risk of unicondylar mismatch:

"The Stryker Compartmental Knee System: See package insert for indications and component compatibility."

2. **The Stryker Compartmental Knee System is intended for patellofemoral and/or unicondylar arthroplasty. However, on page 11 of the Device Description section, you state "the Stryker Compartmental Knee System includes different styles of uni-compartmental knee components so the physician can choose the most appropriate type of femorotibial components, i.e., a resurfacing or resectioning design to address both right and left compartment needs." This latter statement may be construed as inferring that the two condyles of the same knee may be replaced concurrently, resulting in a procedure that falls outside of a unicondylar arthroplasty. Therefore, please include a warnings statement in the draft package insert for the Stryker Compartmental Knee System to advise against misuse of the unicompartamental knee components outside of their intended use. For example, you might include a statement akin to the following: "The femorotibial components of the Stryker Compartmental Knee System are not intended for repair of both condyles of the same knee simultaneously."**

The above recommended statement will be added to the draft package insert of Stryker Compartmental Knee System. See attached revised IFU. For review purposes, the text has been bolded.

DRAFT PACKAGE INSERT

STRYKER[®] COMPARTMENTAL KNEE SYSTEM

Description

The Stryker[®] Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patello-femoral joint and/or the condyle region(s) of the femoral joint. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and/or unicondylar arthroplasty. The characteristics specific for each component are detailed on the product label.

Materials

Femoral Components	ASTM F-75 cobalt chromium alloy
Modular Tibial Trays	ASTM F-75 cobalt chromium alloy
Tibial Inserts	ASTM F-648, Ultra-high molecular weight polyethylene
Tibial Components	ASTM F-648, Ultra-high molecular weight polyethylene
Patellar Components	ASTM F-648, Ultra-high molecular weight polyethylene

Indications for Use

The Stryker[®] Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicondylar arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker[®] Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartamental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartamental osteoarthritis, or
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

Contraindications

1. For patellofemoral arthroplasty, use of these prostheses would be contraindicated in patients with untreated advanced arthritic changes in other compartments of the knee beyond the patello-femoral articulation.
2. Patient has an active or suspected latent infection in or about the knee joint.
3. Patient has a malignancy in the area of the involved knee joint.
4. Patient has a known sensitivity to device materials.

5. Patient's bone stock is compromised by disease and/or infection, or prior implantation which cannot provide adequate support and/or fixation cannot be provided to the prosthesis.
6. Patients with inflammatory arthritis.
7. Patients with major deformity affecting the mechanical axis of the knee or neuromuscular disorders compromising motor control and/or stability.
8. Any mental neuromuscular disorder, which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in post-operative care.
9. Skeletal immaturity.
10. Ligamentous instability such that the postoperative stability afforded by the unicompartmental knee prosthesis would be compromised such as multidirectional/ACL instability
11. For unicondylar arthroplasty, untreated damage to the contralateral compartment of the ipsilateral knee
12. For unicondylar arthroplasty, untreated deterioration or destruction of the patello-femoral joint,
13. Severe deformity and/or recurrent subluxation of the knee joint.
14. Obesity. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of fixation of the device or failure of the device itself.
15. Severe tibial bone loss/deformity (ver 15 degrees varus)

Precautions

Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected in normal healthy bone, and the patient should not have unrealistic functional expectations.

Appropriate selection, placement and fixation of the knee components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service. The Patient should be warned about these limitations.

Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched as a result of contact with metal or abrasive objects.

Utilization and Implantation

The appropriate surgical protocol provides additional procedural information.

The recommended trial components are used for size determination, trial reduction and range of motion evaluation. This preserves the integrity of the actual implants and their sterile packaging. Radiographic templates are also available to assist in the preoperative predication of component size.

Warnings

Choose the correct size of implant. Position it and fix into place with bone cement with care.

The femorotibial components of the Stryker Compartmental Knee System are not intended for repair of both condyles of the same knee simultaneously.

The alignment of the patello-femoral implants in the knee is important. Care should also be taken to ensure correct alignment of patella implants and correct tensioning of the patellar tendon.

Discard all damaged or mishandled implants.

Never reuse an implant, even though it may appear undamaged.

Polished bearing areas must not come in contact with hard or abrasive surfaces.

Bearing areas must always be clean and free of debris prior to assembly.

Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.

Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Except where noted, Howmedica Osteonics strongly advises against the use of another manufacturer's knee component with any Howmedica Osteonics knee component. Any such use will negate the responsibility of Howmedica Osteonics for the performance of the resulting mixed component implant.

Intentional removal of a knee component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces.

Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

Take to use components from the appropriate system. The Table below lists compatible components. The components from the different unicondylar prostheses cannot be mixed and matched. For example, A EUIS® femoral component must be used with an EUIS® tibial component and not a SCR tibial component.

	Polyethylene Patellas	EUIS® Tibial Components	SCR® Tibial Components	UNIX™ Tibial Component	UNIX™ Tibial Insert Component
Avon® Femoral Components	✓				
EUIS® Femoral Components		✓			
SCR® Femoral Components			✓		
UNIX™ Femoral Component				✓	✓
UNIX™ Tibial Component					✓

✓ = Compatible

Adverse Effects

While the expected life of knee replacement components is difficult to estimate, it is finite.

These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Dislocation of the prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.

Loosening of knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.

Fatigue fracture of knee components, including tibial, femoral and patellar components, has occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.

Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.

Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.

Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.

Metal sensitivity reactions have been reported following joint replacement.

Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.

With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondly, particulate can also be generated by third-body wear.

Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

Sterilization

This knee component has been sterilized by gamma radiation.

The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile.

Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.

Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.

If the package is opened, but the product is not used, the component must not be resterilized and must be discarded or returned to the supplier.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

WARNING: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.

Howmedica Osteonics Inc.
Mahwah, NJ

2005-12
XXX-X-XXX

- 3. The current 510(k) submission is for review of the Stryker Compartmental Knee System. However, while you included a draft package insert for the Stryker Compartmental Knee in Appendix B-2, you also provided a draft package insert for the Stryker Unicompartmental Knees in Appendix B-3, and a draft package insert for the Avon Patello-Femoral Joint Prosthesis in Appendix B-4. A change of labeling for the Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis must be done through separate 510(k) submissions. Therefore, please remove the draft package inserts for the Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis from the current submission. Additionally, while the subject device components have been cleared through predicate 510(k) submissions, the package labeling should be consistent with the package insert provided for the device. Therefore, please provide a package label referencing the Stryker Compartmental Knee System that will be provided with the subject device.**

As agreed to in our conversation on December 7, 2005, we will place the following label on each component in Stryker Compartmental Knee System to inform the user that the component is part of the Stryker Component System:

"The Stryker Compartmental Knee System: See package insert for indications and component compatibility."

Additionally, as agreed, we will also package the components in the Stryker Compartmental Knee System with the information included in draft package insert for the Stryker[®] Compartmental Knee System (see response to Question 2) and the package insert information for the individual patellofemoral or femorotibial components as they were cleared for the Avon Patello-Femoral Joint Prosthesis or the EIUS[®], SCR[®] or UNIX[™] Unicompartmental Knee Systems. The Stryker Unicompartmental Knees and Avon Patello-Femoral Joint Prosthesis package inserts have been removed from the submission as requested.

Also, a draft package label is attached for components, which may be packaged as individual Stryker Compartmental Knee System components.

Stryker Compartment Knee System
Draft Label

Stryker Compartmental Knee System

Cat. No. XXXX-XXXX

Lot No. XXXXXXXX

Component Name

Size: _____

See package insert for indications and component compatibility.

Howmedica Osteonics Corp.
Stryker Ireland
Carrigrohilly Industrial Estate
Carrigrohilly, County Cork
Ireland



48254540021003



138010810CASECASECA3W

Autorisée Représentative en Europe
Stryker France
ZAC Sables Green Putyran
Av. de Sables Green EC65* Mayze
Cedex France



Material Type

2010-08

STERILE R



CE0086



CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a Physician

Warning: Device is intended for cemented use only in USA

4. You provided an Indications for Use Statement identifying that the subject device components are intended for patellofemoral and/or unicondylar arthroplasty. However, you have not included all Product Codes and Regulations Numbers associated with the subject device, since the system components can be used individually for patellofemoral arthroplasty only or unicondylar arthroplasty only. Therefore, please provide a revised 510(k) Summary to include all relevant Product Codes and Regulation Numbers.

The 510(k) Summary has been updated to include the requested product codes and regulation numbers. See attached revised 510(k) Summary.

510(k) Summary of Safety and Effectiveness
Stryker® Compartmental Knee System

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission:

Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430

For Information contact:

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Date Summary Prepared:

December 9, 2005

Device Identification

Proprietary Name:

Stryker® Compartmental Knee System

Common Name:

Knee Prosthesis Components

Proposed Regulatory Class:

Class II

Classification Name, Reference and Product Code:

Knee Joint, Femorotibial, Polymer/Metal, Semi-constrained, Cemented Prosthesis, 21 CFR §888.3530, 87 NPJ
Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis, 21 CFR 888.3540, 87 KRR
Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer, 21 CFR 888.3520, 87 HSX
Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer, 21 CFR §888.3530, 87 HRY

Description:

The Stryker® Compartmental Knee System consists of sterile, single-use components intended for replacement of the femoral side of the patellofemoral joint and/or the condyle region(s) of the femoral joint as needed. The system includes patellofemoral, femoral, and tibial components from currently marketed Howmedica Osteonics' knee systems for patellofemoral and unicompartmental arthroplasty. The system allows the physician to choose the most appropriate option to treat the patient with patellofemoral arthroplasty and/or unicompartmental arthroplasty as needed.

Indications for Use

The Stryker® Compartmental Knee System is intended to be used in cemented patellofemoral and/or unicompartmental arthroplasty in patients where conditions exist that cannot be addressed by a single device to treat the femorotibial or patellofemoral regions of the knee. The indications for the different components of the Stryker® Compartmental Knee System include conditions when the patellofemoral and/or condylar region(s) have been affected by one or more of the following conditions:

- Degenerative arthritis in the distal femur and patella,
- Patients with a history of patellar dislocation or patella fracture,
- Patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists,
- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis,
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of an unicompartmental knee prosthesis,
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis, or

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- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the femoral condyle/tibial plateau.

These components are single use only and are intended for implantation with bone cement.

Substantial Equivalence:

The device is substantially equivalent to its predicates for patellofemoral arthroplasty and femorotibial arthroplasty in regards to intended use, design, materials, and operational principles. The analyses demonstrate that the components from these systems are compatible when used for patellofemoral and/or femorotibial replacement.