

K071535

Summary of Safety and Effectiveness

NOV 19 2007

Submitter: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person: Patricia Jenks
Specialist, Corporate Regulatory Affairs
Telephone: (574) 371-8354
Fax: (574) 372-4605

Date: June 4, 2007

Trade Name: BIOLOX[®] *delta** Ceramic Femoral Head

Common Name: Ceramic Femoral Head Prosthesis

Classification Name and Reference: Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis
21 CFR § 888.3353

Predicate Device(s): 36mm Biolox *delta* Ceramic Heads, manufactured by Biomet, K061312, cleared June 6, 2006

DePuy Delta Ceramic Femoral Head, manufactured by DePuy, K062748, cleared November 30, 2006

V40[™] Biolox *delta* Ceramic Femoral Heads, manufactured by Howmedica Osteonics, K052718, cleared October 27, 2005

Device Description: The BIOLOX *delta* Ceramic Femoral Heads are fabricated from an alumina matrix composite and are available in diameters of 28, 32, 36, and 40 mm with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic femoral heads for use in total hip arthroplasty.

* Trademark of CeramTec AG

Intended Use:

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Comparison to Predicate Device(s):

The BIOLOX *delta* Ceramic Femoral Heads are substantially equivalent to the femoral heads listed above as predicate devices. Both the proposed and predicate designs are intended to function as a modular femoral head component in total hip arthroplasty and are manufactured from the same materials.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing was performed and results indicate that the BIOLOX *delta* Ceramic Femoral Heads are equivalent to devices currently on the market and capable of withstanding *in vivo* loading.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.



NOV 19 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
c/o Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K071535
Trade/Device Name: Biolox® *delta* Ceramic Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained
cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: October 25, 2007
Received: October 26, 2007

Dear Ms. Jenks:

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.

Page 2 –

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

K071535

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX[®] delta* Ceramic Femoral Head

Indications for Use:

The BIOLOX delta Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

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)

Barbara Bucher
(Division Sign-off)

Division of General, Restorative,
and Neurological Devices

*Trademark of CeramTec AG

Page 1 of 1

510(k) Number K071535



NOV 19 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
c/o Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

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Sincerely yours,



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

Enclosure

K071535

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510(k) Number (if known):

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BIOLOX[®] delta* Ceramic Femoral Head

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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)

Barbara Bucher
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

*Trademark of CeramTec AG

510(k) Number K071535

October 02, 2007

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

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K071535
Product: BIOLOX DELTA
CERAMIC FEMORAL
HEAD

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 additional information (AI), 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 (21 CFR 807.87(l)). 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". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. 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. 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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 16, 2007

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K071535
Device: BIOLOX DELTA
CERAMIC FEMORAL
HEAD

Extended Until: 17-SEP-2007

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(1)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

CDRH Submission Cover Sheet

Date of Submission: August 15, 2007	FDA Document Number: K071535
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Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input checked="" type="checkbox"/> Additional Information: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission: Request for Extension of Time

Section B Applicant or Sponsor

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-372-4485	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Toni Kingsley, Ph.D., RAC			
Contact Title: Vice President, Corporate Regulatory Affairs		Contact e-mail address: toni.kingsley@zimmer.com	

Section C Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-371-8354	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Patricia Jenks			
Contact Title: Specialist, Corporate Regulatory Affairs		Contact e-mail address: trish.jenks@zimmer.com	

K16

Section D1**Reason for Submission -- PMA, PDP, or HDE**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Material | <input type="checkbox"/> Packager |
| | <input type="checkbox"/> Specifications | <input type="checkbox"/> Distributor |
| | <input type="checkbox"/> Other (specify below) | |
|
 | | |
| <input type="checkbox"/> Process change: | <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Indications | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Sterilization | <input type="checkbox"/> Instructions | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Packaging | <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Shelf life | <input type="checkbox"/> Device defect |
| | <input type="checkbox"/> Trade name | <input type="checkbox"/> Amendment |
| | <input type="checkbox"/> Other (specify below) | |
|
 | | |
| <input type="checkbox"/> Response to FDA correspondence: | | <input type="checkbox"/> Change in ownership |
| <input type="checkbox"/> Request for applicant hold | | <input type="checkbox"/> Change in correspondent |
| <input type="checkbox"/> Request for removal of applicant hold | | |
| <input type="checkbox"/> Request for extension | | |
| <input type="checkbox"/> Request to remove or add manufacturing site | | |
|
 | | |
| <input type="checkbox"/> Other reason (specify): | | |

Section D2**Reason for Submission – IDE**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing process | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol – feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol – other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Notification of emergency use | | |
| <input type="checkbox"/> Compassionate use request | <input type="checkbox"/> Report submission: | |
| <input type="checkbox"/> Treatment IDE | <input type="checkbox"/> Current investigator | |
| <input type="checkbox"/> Continuing availability request | <input type="checkbox"/> Annual progress | |
| | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |
|
 | | |
| <input type="checkbox"/> Other reason (specify): | | |

Section D3**Reason for Submission – 510(k)**

- | | | |
|---|---|--|
| <input checked="" type="checkbox"/> New device | <input type="checkbox"/> Change in technology | <input type="checkbox"/> Change in materials |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in design | <input type="checkbox"/> Change in manufacturing process |
| <input type="checkbox"/> Other reason (specify): Response to reviewer questions | | |

Section E Additional Information on 510(k) Submissions					
Product codes of devices to which substantial equivalence is claimed:					Summary of , or statement concerning, safety and effectiveness data:
1	LZO	2	3	4	<input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
5		6	7	8	
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name				Manufacturer
1	K061312	1 36mm Biolox® <i>delta</i> * Ceramic Heads			1 Biomet
2	K062748	2 DePuy Delta Ceramic Femoral Head			2 DePuy
3	K052718	3 V40™ Biolox <i>delta</i> Ceramic Femoral Heads			3 Howmedica Osteonics
4		4			4
5		5			5
6		6			6
Section F Product Information – Applicable to All Applications					
Common or usual name or classification name: Femoral head for total joint prosthesis					
Trade or proprietary or model name				Model number	
1	BIOLOX <i>delta</i> Ceramic Femoral Head			1 8775-series	
2				2	
3				3	
4				4	
5				5	
FDA document numbers of all prior related submissions (regardless of outcome):					
1	2	3	4	5	6
7	8	9	10	11	12
Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					
Section G Product Classification – Applicable to All Applications					
Product code: LZO	C.F.R. Section 21 CFR 888.3353			Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification panel: Orthopedics/87	Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis				
Indications (from labeling): The BIOLOX <i>delta</i> Ceramic Femoral Heads are modular components used in total hip arthroplasty and are indicated for the following: Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.					
* Trademark of CeramTec AG					

<i>Note:</i> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:	
Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number: 9613350	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Repackager/relabeler
Company/Institution name: Zimmer GmbH			
Division name (if applicable): N/A		Phone number (include area code): +41-52 242 6083	
Street address: Sulzer Allee 8		FAX number (include area code): +41-52 244 3593	
City: Winterthur	State/Province: Zurich	Country: Switzerland	ZIP/Postal Code: CH-8404
Contact name: Peter Krafft			
Contact Title: Vice President, QA & Regulatory Affairs Europe		Contact e-mail address: peter.krafft@zimmer.com	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number: (b)	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: (b)			
Division name (if applicable): (b)		Phone number (include area code): (b)(4)Trade	
Street address: Werk Hard, Hogenweidstrasse 2		FAX number (include area code): (b)(4)Trade	
City: (b)	State/Province: (b)	Country: S t P	ZIP/Postal Code: (b)
Contact name: (b)(4)Trade			
Contact Title: (b)(4)Trade		Contact e-mail address: (b)(4)Trade	

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

July 19, 2007

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K071535
Product: BIOLOX DELTA
CERAMIC FEMORAL
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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 additional information (AI), 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 (21 CFR 807.87(l)). 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". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. 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. 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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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

June 05, 2007

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K071535
Received: 05-JUN-2007
Product: BIOLOX DELTA CERAMIC
FEMORAL HEAD

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (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 510(k) submission.

Please note the following documents as they relate to 510(k) review:
1) 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 (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at 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).
3) 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.

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

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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



KO 71535

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

OR/DGRND

June 4, 2007

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

Dear Sir or Madam:

Subject: Traditional 510(k) Premarket Notification – BIOLOX[®] *delta** Ceramic Femoral Head

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. A CD-ROM with content identical to the paper submission is also included for your convenience.

These devices have not been previously submitted to FDA for identical or different indications, are not currently being reviewed for different indications by the same or different branch within ODE, and have not been previously cleared by FDA for different indications.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8354, by e-mail at trish.jenks@zimmer.com or by fax at (574) 372-4605.

Sincerely,

Patricia Jenks
Specialist, Corporate Regulatory Affairs

tj/me
GmbH-20070201
Enclosure

* Trademark of CeramTec AG

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Write the Payment Identification number on your check.		
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
<ol style="list-style-type: none"> 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. <i>(Note: In no case should payment be submitted with the application.)</i> 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. <i>(Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)</i> 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.html#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) ZIMMER INC 345 EAST MAIN STREET WARSAW IN 46580 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)	2. CONTACT NAME Patricia Jenks 2.1 E-MAIL ADDRESS trish.jenks@zimmer.com 2.2 TELEPHONE NUMBER (include Area code) 574-371-8354 2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-null		
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)			
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <u>Select an application type:</u> <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) </td> <td style="width: 50%; vertical-align: top;"> <u>3.1 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <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) </td> </tr> </table>		<u>Select an application type:</u> <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)	<u>3.1 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <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)
<u>Select an application type:</u> <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)	<u>3.1 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <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.			
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <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 </td> <td style="width: 50%; vertical-align: top;"> <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 </td> </tr> </table>		<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
<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 (b)			
17-Jan-2007			

CDRH Submission Cover Sheet

Date of Submission: June 4, 2007	FDA Document Number:
--	----------------------

Section A Type of Submission

PMA <input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	PDP <input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	510(k) <input checked="" type="checkbox"/> Original submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional Information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	Meeting <input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	Class II Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Evaluation of Automatic Class III Designation <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Other Submission Describe submission:

Section B Applicant or Sponsor

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-372-4485	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Toni Kingsley, Ph.D., RAC			
Contact Title: Vice President, Corporate Regulatory Affairs		Contact e-mail address: toni.kingsley@zimmer.com	

Section C Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-371-8354	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Patricia Jenks			
Contact Title: Specialist, Corporate Regulatory Affairs		Contact e-mail address: trish.jenks@zimmer.com	

Section D1	Reason for Submission -- PMA, PDP, or HDE	
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Reponse to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in design, component or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent
Section D2	Reason for Submission -- IDE	
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Compassionate use request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing process <input type="checkbox"/> Protocol – feasibility <input type="checkbox"/> Protocol – other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting
Section D3	Reason for Submission – 510(k)	
<input checked="" type="checkbox"/> New device <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in technology <input type="checkbox"/> Change in design	<input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process

Section E Additional Information on 510(k) Submissions

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

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K061312	1 36mm BioloX® <i>delta</i> * Ceramic Heads	1 Biomet
2 K062748	2 DePuy Delta Ceramic Femoral Head	2 DePuy
3 K052718	3 V40™ BioloX delta Ceramic Femoral Heads	3 Howmedica Osteonics
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications

Common or usual name or classification name:
Femoral head for total joint prosthesis

Trade or proprietary or model name	Model number
1 BIOLOX <i>delta</i> Ceramic Femoral Head	1 8775-series
2	2
3	3
4	4
5	5

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

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

Data included in submission: Laboratory testing Animal trials Human trials

Section G Product Classification – Applicable to All Applications

Product code: LZO	C.F.R. Section 21 CFR 888.3353	Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification panel: Orthopedics/87	Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis	

Indications (from labeling):

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and are indicated for the following:
 Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

* Trademark of CeramTec AG

<i>Note:</i> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:
--	----------------------

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number: 9613350	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Repackager/relabeler
Company/Institution name: Zimmer GmbH			
Division name (if applicable): N/A		Phone number (include area code): +41-52 242 6083	
Street address: Sulzer Allee 8		FAX number (include area code): +41-52 244 3593	
City: Winterthur	State/Province: Zurich	Country: Switzerland	ZIP/Postal Code: CH-8404
Contact name: Peter Krafft			
Contact Title: Vice President, QA & Regulatory Affairs Europe		Contact e-mail address: peter.krafft@zimmer.com	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number: (b) (4)T d	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
Company/Institution name: (b) (4)Trade			
Division name (if applicable): (b) (4)Trade		Phone number (include area code): (b) (4)Trade	
Street address: (b) (4)Trade Secret Process		FAX number (include area code): (b) (4)Trade Secret Process	
(b) (4)Trade	State/Province: (b) (4)T d	Country: (b) (4)Trade S t	ZIP/Postal Code: (b) (4)T d 8
Contact name: (b) (4)Trade			
Contact Title: (b) (4)Trade Secret		Contact e-mail address: (b) (4)Trade Secret	



P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

June 4, 2007

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

Dear Sir or Madam:

Subject: Traditional 510(k) Premarket Notification – BIOLOX[®] *delta** Ceramic Femoral Head

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. A CD-ROM with content identical to the paper submission is also included for your convenience.

These devices have not been previously submitted to FDA for identical or different indications, are not currently being reviewed for different indications by the same or different branch within ODE, and have not been previously cleared by FDA for different indications.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8354, by e-mail at trish.jenks@zimmer.com or by fax at (574) 372-4605.

Sincerely,

Patricia Jenks
Specialist, Corporate Regulatory Affairs

tj/me
GmbH-20070201
Enclosure

* Trademark of CeramTec AG

BILOX *delta*
Ceramic Femoral Head

Traditional 510(k)



Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

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Truthful and Accurate Statement

The Truthful and Accurate Statement has been included as [Exhibit A \(see Pg. 20 \)](#).

Device Name

BIOLOX *delta* Ceramic Femoral Head

Section 514 Compliance

Section 514 of the Act does not apply to this type of device at this time.

Summary of Safety and Effectiveness

A summary of information regarding safety and effectiveness for the proposed device is presented in [Exhibit B \(see Pg. 21 \)](#).

Device Description

Overview

The BIOLOX *delta* Ceramic Femoral Heads are fabricated from an alumina matrix composite. This composite combines the material properties of alumina ceramic in terms of chemical and hydrothermal stability along with extremely low wear, improved mechanical strength and fracture toughness. Alumina provides the material's hardness and wear resistance while zirconia, together with other additives, provides the improved mechanical properties of high strength, high density, and small grain size of the alumina matrix.

The heads are purchased from (b)(4)Trade Secret Process and are marketed under the trade name BIOLOX *delta*. (b)(4)Trade Secret master file (b)(4)Trade Secret is available for review of the items pertinent to this submission. [Exhibit C \(see Pg. 23 \)](#) contains a letter authorizing FDA to access (b)(4)Trade Secret master file on behalf of Zimmer, Inc.

(b)(4)Trade Secret uses toughening mechanisms in the fabrication of BIOLOX *delta* material. Nano-sized, yttria-stabilized tetragonal zirconia particles (Y-TZP) are introduced in a stable alumina matrix. These Y-TZP grains are spatially separated from one another in order to reduce the likelihood of structural transformation as well as to prevent the initiation and propagation of cracks. Furthermore, the dispersion of fine particles in the matrix improves the strength and toughness of BIOLOX *delta* components (see Figure 1).

(b)(4)Trade Secret Process



Figure 1 –

The principle of transformation toughening by nano-sized, yttria-stabilized, zirconia particles (Y-TZP)

The second toughening mechanism is achieved by the addition of strontium oxide which forms platelet-like crystals of the delta material. These platelets dissipate energy by deflecting cracks, thereby increasing material strength and toughness (see Figure 2).

(b)(4)Trade Secret Process



Figure 2 –

The principle of reinforcement by platelet-like crystals in an alumina matrix

(b) (4)Trade Secret fabricates the heads from the aluminum oxide matrix composite ceramic consisting of approximately (b) (4)T alumina (Al_2O_3), (b) (4)T zirconia (ZrO_2) and (b) (4)T trace elements. The pink color is due to the trace presence of chromium oxide (Cr_2O_3).



Figure 3-
Examples of BIOLOX *delta* heads

The BIOLOX *delta* heads are available in 28, 32, 36, and 40 mm diameters with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic heads for use in total hip arthroplasty. The modular heads may be used with Zimmer 12/14 hip stems manufactured from:

- Ti-6Al-4V
- Ti-6Al-7Nb
- CoCrMo

These alloys are known under the trade names of *Tivanium*[®], *Protasul*[®] 64WF, *Protasul*[®] 100, *Zimaloy*[®], *Protasul*[®] 20 and feature proximal neck tapers as specified in the table provided in [Exhibit D \(see Pg. 24 \)](#).

A table of key dimensions of the BIOLOX *delta* Ceramic Femoral Heads is provided in [Exhibit E \(see Pg. 25 \)](#).

The proposed heads are designed to articulate upon the ultra high molecular-weight polyethylene (UHMWPE) bearing surface of an acetabular component. The following acetabular components are compatible for use with the BIOLOX *delta* heads:

Description	510(k) Number	Clearance Date
Müller Acetabular Cup	Preenactment Device	N/A
Zimmer® Poly Cup (previous name TR-28 Acetabular Cup)	Preenactment Device	N/A
Harris/Galante Porous Total Hip System Acetabular Component	K840643	04/17/84
Non-Metal Backed All-Poly Acetabular Cup (previously manufactured by Astel)	K901240	03/26/90
BIAS® Total Hip System Acetabular Component	K921557	02/22/94
HGP II Acetabular Shell and Liner	K921308	02/22/94
Trilogy® Acetabular System	K934765 K953490 K954698	04/29/94 10/20/95 01/17/96
APR® Acetabular System	K941617	10/06/94
CLS® Acetabular Component	K953688	11/29/95
Epsilon™ Polyethylene Inserts	K983509	02/03/99
Trilogy Acetabular System Longevity® Crosslinked Polyethylene Liners	K990135	07/12/99
Trilogy Large Head Liners	K002960 K003478	12/11/00 02/05/01
Allofit™ Acetabular System	K003758 K013935	03/07/01 12/13/01
Converge® Acetabular System	K012961 K012739	10/18/01 11/14/01
Trabecular Metal™ Modular Acetabular System	K021891	09/05/02
ZCA® All Poly Acetabular Cup, Snap-In	K030153	04/01/03
ZCA All Poly Acetabular System*	K901240	03/26/90
Trabecular Metal Revision Shell Liners	K051516	07/27/05

*documented to file

Indications for Use

See [Exhibit F \(see Pg. 26 \)](#) for the Indications for Use.

Predicate Device(s)

Predicates for this device are the Biolox *delta* Ceramic Heads manufactured by Biomet (K061312, cleared June 6, 2006), the DePuy Delta Ceramic Femoral Head manufactured by DePuy (K062748, cleared November 30, 2006), and the V40™ Biolox *delta* Ceramic Femoral Heads manufactured by Howmedica Osteonics (K052718, cleared October 27, 2005). Copies of the substantial equivalence letters demonstrating commercial availability are presented in [Exhibit G \(see Pg. 27 \)](#).

Substantial Equivalence

All three predicate devices are fabricated from the same alumina matrix composite material (BIOLOX *delta*) and are offered in a range of head sizes including 28, 32, and 36 mm diameters with a variety of neck lengths. The proposed device is a ceramic head consisting of the identical alumina oxide matrix composite ceramic (BIOLOX *delta*) and is offered in 28, 32, 36 and 40 mm diameters with a variety of neck lengths. Both the predicate and proposed devices mate directly with femoral stems with corresponding tapers. The proposed device has the same intended use and similar design, indications and manufacturing method as the predicate devices. See [Exhibit H \(see Pg. 36 \)](#) for a comparison table between the predicate and proposed devices.

Engineering Drawings

Representative engineering drawings for the proposed device are included in [Exhibit I \(see Pg. 37 \)](#).

Item Numbers

All item numbers for the proposed device are listed in [Exhibit J \(see Pg. 82 \)](#).

Materials

The BIOLOX *delta* Ceramic Femoral Head consists of an aluminum oxide matrix composite ceramic consisting of approximately (b) alumina (b)(4)Trade Secret zirconia (b) and trace elements. (4)Trad

Surface Characteristics

The articulating surface of the proposed device is polished to an R_a value of (b) micrometers (b)(4)Trade Secret to minimize friction. (4)T

Mechanism of Action

The proposed device is intended to be placed onto a new, undamaged 12/14 femoral stem taper and to articulate with a highly crosslinked or conventional polyethylene acetabular component for total hip arthroplasty.

Surgical Instrumentation Unique to the Device

Provisional (trial) devices are used to determine the appropriate implant size immediately prior to implantation of the prosthesis. Instruments are also available for securing the head onto the femoral stem and for removing the head if its diameter or neck length is not appropriate. These instruments are Class I, exempt devices.

Methods, Facilities and Controls

Method of Manufacturing

The proposed devices are fabricated by (b)(4)Trade Secret Process where each part must successfully pass through a large number of inspection checkpoints. Every head is laser marked with a unique number which permits traceability for the entire production history of each individual part. After final inspection at (b)(4)Trade Secret the parts are cleaned, packed and shipped to the manufacturer (Zimmer GmbH). The following steps are performed by the manufacturer: visual examination of the surface and marking, washing, final inspection, visual size identification and marking control. The heads are washed before entering the clean room and wrapped in an inner tray, outer tray, and protective pouch. Parts then proceed through sterile packaging, labeling, sterilization, storage and distribution.

Packaging

Package Design

The product is packaged in the Standard Double Tray System. The device is placed into an inner Polystyrene (PS) tray. It is fixed by a threaded retainer. As protection between the retainer and product, a 2 mm (b)(4)Trade Secret foam is used. The tray is heat sealed with a TYVEK lid. This sealed tray is then placed into an outer Polyethylene Terephthalate Glycol (PETG) tray and is heat sealed with a TYVEK lid, creating a double sterile barrier. Sterile package protection is afforded by a solid folding carton and shrink film.

Sterile Trays (Inner and Outer)

The inner sterile tray is a Polystyrene Butadiene copolymer (PS K Resin) injection molded tray. The outer sterile tray is a (b)(4)Trade Secret Process thermoformed tray.

Lid Stock material (Inner and Outer)

Perfecseal TYVEK, Style 1073 B, coated with Perfecseal SBP2000 heat sealing coating

Foam Lid material (Inner Tray)

PE-Foam, Brand name "Alveolux 3000"

Outer Packaging

Folding carton, Swissboard RS white 600g/m2

Dust Cover

Polyolefin-Shrink Film, cross-linked SORELIN FP-PLUS

Labeling

Representative labeling for the proposed device is presented in [Exhibit K \(see Pg. 83 \)](#) including the package insert and product labels.

Sterilization

Sterilization Method

Gamma Irradiation (Cobalt 60) at a contract sterilizer

Absorbed Radiation Dose

Minimum to maximum dose range is (b)(4)Trade Secret

Sterility Assurance Level

SAL of (b)(4) or better

Sterilization Validation Method

The minimum sterilization dose was verified using ANSI/AAMI/ISO 11137, 1994, "Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization," Method 1, Dose Setting Validation. Gamma radiation processing and dose mapping were conducted according to ANSI/AAMI/ISO 11137, 1994, "Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization."

Biocompatibility

The materials used in this device have been tested for biocompatibility (short-term toxicity) per ISO 10993-1 and Good Laboratory Practices as described in 21 CFR Part 58 and which data are available for review in (b)(4)Trade Secret master file (b)(4)Trade

Color Additives

This device contains no color additives. No additional biocompatibility testing is required.

Pyrogenicity

This device is not labeled as nonpyrogenic. Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants.

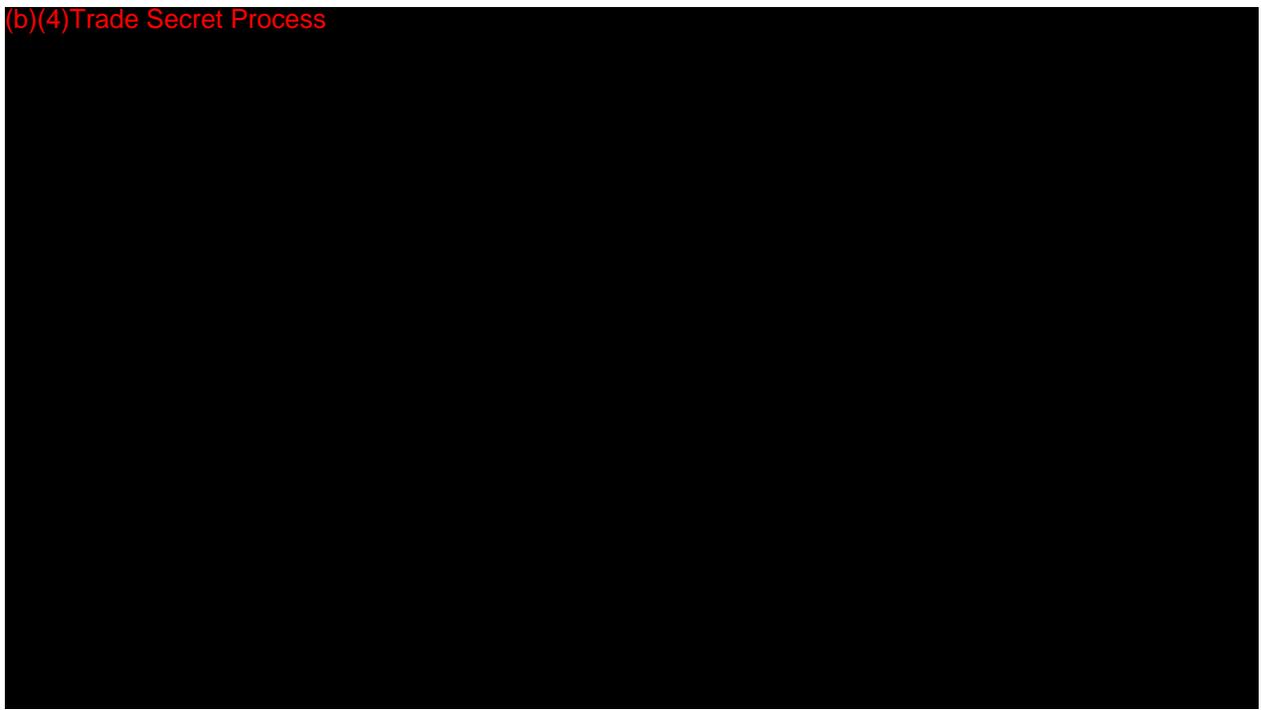
Latex

There is no natural latex rubber in this product or its packaging.

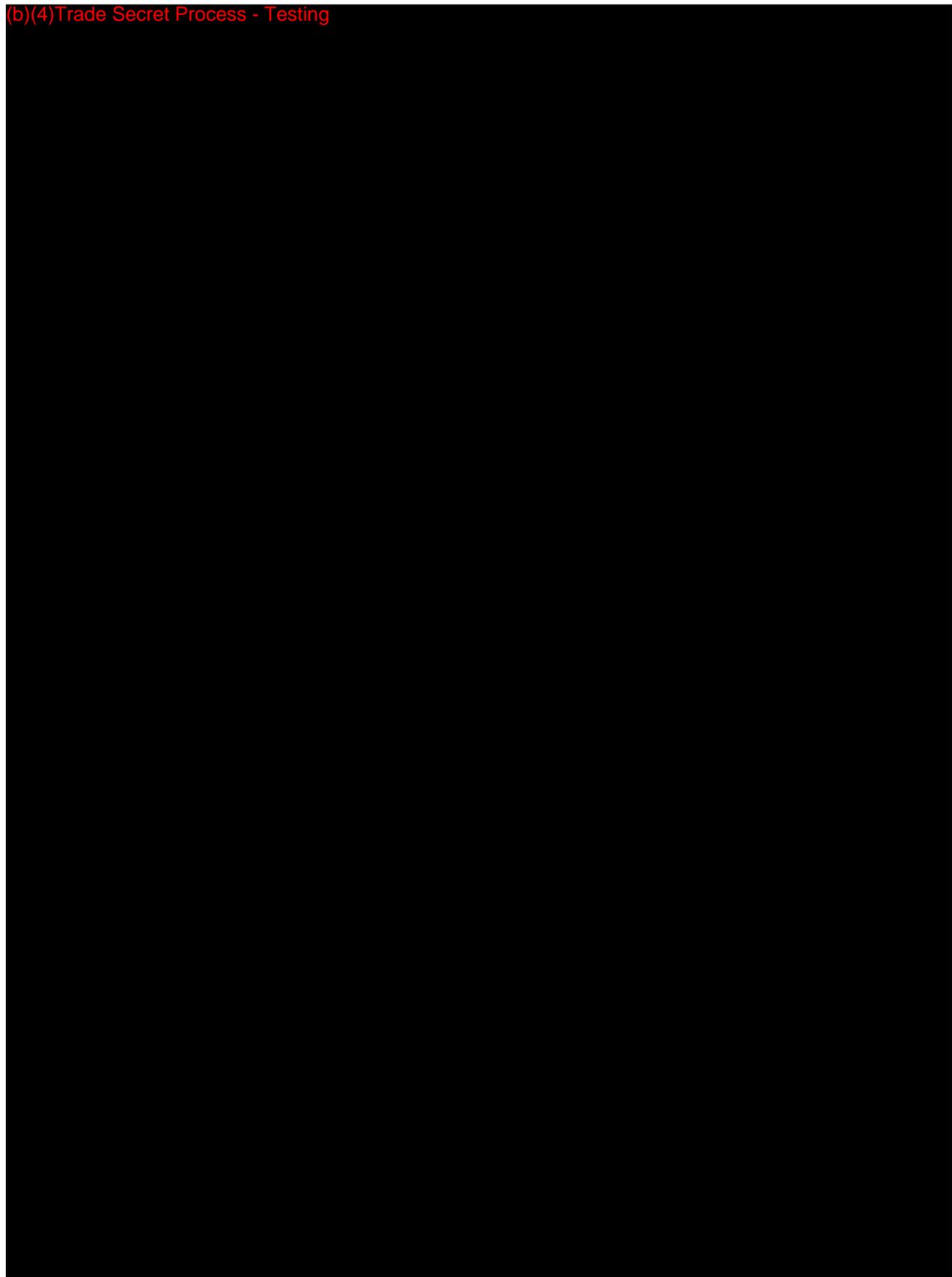
Performance Testing

Testing as described below was performed per the FDA Draft *Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems*, dated January 10, 1995.

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

[As Required by 21 CFR 807.87(k)]

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



(Signature)

Patricia Jenks

(Typed Name)

5/30/07

(Date)

(Premarket Notification [510(k)] Number)

Summary of Safety and Effectiveness

Submitter: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person: Patricia Jenks
Specialist, Corporate Regulatory Affairs
Telephone: (574) 371-8354
Fax: (574) 372-4605

Date: June 4, 2007

Trade Name: BIOLOX[®] *delta** Ceramic Femoral Head

Common Name: Ceramic Femoral Head Prosthesis

Classification Name and Reference: Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis
21 CFR § 888.3353

Predicate Device(s): 36mm Biolox *delta* Ceramic Heads, manufactured by Biomet, K061312, cleared June 6, 2006

DePuy Delta Ceramic Femoral Head, manufactured by DePuy, K062748, cleared November 30, 2006

V40[™] Biolox *delta* Ceramic Femoral Heads, manufactured by Howmedica Osteonics, K052718, cleared October 27, 2005

Device Description: The BIOLOX *delta* Ceramic Femoral Heads are fabricated from an alumina matrix composite and are available in diameters of 28, 32, 36, and 40 mm with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic femoral heads for use in total hip arthroplasty.

* Trademark of CeramTec AG

Intended Use:

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Comparison to Predicate Device(s):

The BIOLOX *delta* Ceramic Femoral Heads are substantially equivalent to the femoral heads listed above as predicate devices. Both the proposed and predicate designs are intended to function as a modular femoral head component in total hip arthroplasty and are manufactured from the same materials.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing was performed and results indicate that the BIOLOX *delta* Ceramic Femoral Heads are equivalent to devices currently on the market and capable of withstanding *in vivo* loading.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX[®] *delta** Ceramic Femoral Head

Indications for Use:

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Trademark of CeramTec AG



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Biomet Manufacturing Corp.
c/o Ms. Patricia Sandborn Beres,
Senior Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K061312

Trade/Device Name: 36mm Biolox[®] *delta* Ceramic Heads

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: May 9, 2006

Received: May 10, 2006

Dear Ms. Beres:

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.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Mark N. Melkerson

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): K061312

Device Name: 36mm BioloX® delta Ceramic Heads

Indications For Use: BioloX® delta Ceramic Heads are indicated for use in total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- 5) Revision procedures where other treatment or devices have failed.

Specific indications for compatible components that can be used with the above modular heads include:

Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthroplasty. (K974558, K002757, K021380, K033871)

Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)

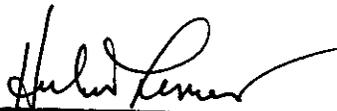
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(21 CFR 807 Subpart C)

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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 K061312



DePuy Orthopaedics, Inc.
% Ms. Anne M. Schuler
Sr. Regulatory Affairs Associate
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 30 2006

Re: K062748

Trade/Device Name: DePuy Delta Ceramic Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or
nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: September 13, 2006
Received: November 6, 2006

Dear Ms. Schuler:

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.

Page 2 – Ms. Anne M. Schuler

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large loop at the end.

Mark N. Melkerson
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): K062748
Device Name: DePuy Delta Ceramic Femoral Head

Indications for Use:

The DePuy Delta Ceramic Femoral Head is indicated for use as the femoral head component in total hip arthroplasty procedures.

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

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

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Juliana Buehler
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K062748



OCT 27 2005

Karen Ariemma
Senior Regulatory Affairs Specialist
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K052718

Trade/Device Name: V40™ BioloX® delta Ceramic Femoral Heads (Line Extension to the Alumina V40™ Ceramic Femoral Heads)

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: September 28, 2005

Received: September 29, 2005

Dear Ms. Ariemma:

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.

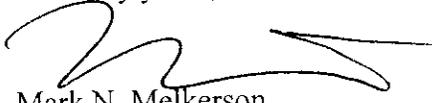
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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,


s/ 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): K052718

Device Name: BioloX® delta V40™ Ceramic Femoral Heads

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)

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

510(k) Number K052718

Substantial Equivalence Comparison between the Proposed Device and the Predicates

Property or Characteristic	Proposed Device BILOX[®] <i>delta</i>* Ceramic Femoral Head	Predicate Device(s): 36mm Biolox <i>delta</i> Ceramic Heads, K061312 DePuy Delta Ceramic Femoral Head, K062748 V40 Biolox <i>delta</i> Ceramic Femoral Heads, K052718
Indications for Use	The proposed device is indicated for total hip replacement for patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.	Similar to proposed device (see Exhibit G).
Geometry/ Anatomy	The BILOX <i>delta</i> Ceramic Femoral Head prostheses are offered in 4 head diameters (28, 32, 36 and 40 mm) with 4 neck length options (-3.5, +0, +3.5, +7.0; the +7.0 option is not available for the 28 mm diameter head).	Similar to proposed device: 36mm head diameters with (-3, 0, +3, and +6) neck lengths (Biomet); 36mm head diameters with (+9 and +12) neck lengths (DePuy); 28, 32, and 36mm head diameters with a variety of neck lengths (Howmedica Osteonics).
Sterility	The proposed device is sold sterile. It is terminally sterilized by gamma radiation. Gamma irradiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. The products are accepted for release as sterile through a validated dosimetric release program designed to provide a sterility assurance level (SAL) of (b) (4) or better.	Unknown.
Fixation Method	The proposed device is intended for cemented or cementless Total Hip Arthroplasty (THA) using Zimmer modular femoral stems with a corresponding 12/14 proximal neck taper.	Same classification as proposed device: i.e., cemented or cementless.
Materials	Alumina matrix composite ceramic material is used, consisting of (b) alumina (Al ₂ O ₃), (b) zirconia (ZrO ₂), and (b) trace elements including chromium oxide (Cr ₂ O ₃). (4)	Same as proposed device.

* Trademark of CeramTec AG

BIOLOX[®] *delta** Ceramic Femoral Head Implant

Catalog Numbers

Description	Catalog Numbers
Ceramic Femoral Head, 12/14, 28 x -3.5	00-8775-028-01
Ceramic Femoral Head, 12/14, 28 x +0	00-8775-028-02
Ceramic Femoral Head, 12/14, 28 x +3.5	00-8775-028-03
Ceramic Femoral Head, 12/14, 32 x -3.5	00-8775-032-01
Ceramic Femoral Head, 12/14, 32 x +0	00-8775-032-02
Ceramic Femoral Head, 12/14, 32 x +3.5	00-8775-032-03
Ceramic Femoral Head, 12/14, 32 x +7.0	00-8775-032-04
Ceramic Femoral Head, 12/14, 36 x -3.5	00-8775-036-01
Ceramic Femoral Head, 12/14, 36 x +0	00-8775-036-02
Ceramic Femoral Head, 12/14, 36 x +3.5	00-8775-036-03
Ceramic Femoral Head, 12/14, 36 x +7.0	00-8775-036-04
Ceramic Femoral Head, 12/14, 40 x -3.5	00-8775-040-01
Ceramic Femoral Head, 12/14, 40 x +0	00-8775-040-02
Ceramic Femoral Head, 12/14, 40 x +3.5	00-8775-040-03
Ceramic Femoral Head, 12/14, 40 x +7.0	00-8775-040-04

*Trademark of CeramTec AG

BIOLOX® delta

Ceramic Femoral Head



Zimmer GmbH
P.O. Box
CH-8404 Winterthur, Switzerland
Telephone +41/ (0)52 262 60 70
Fax +41/ (0)52 262 01 39
www.zimmer.com

Important information for the operating surgeon

CE 0123 (The CE mark is valid only if it is also printed on the product label)

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

Manufacturer: Zimmer GmbH Sulzer-Allee 8 CH-8404 Winterthur, Switzerland	Representative in the USA: Zimmer, Inc. 1800 West Center Street Warsaw, Indiana 46580, USA	Art. No. D011 500 245 - e/d/f/i/sp/sw - Ed. 01/07
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1. Instructions for use

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the product-specific information (technical product description, description of the surgical technique, catalogue sheet, etc.). Additional product information can be found in the description of the surgical technique, in the technical description of the product or on the appropriate catalogue sheet.

The manufacturer, the importer and the suppliers of Zimmer products are not liable for complications or other effects that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on.

Patient Counseling Information

Complications and/or failure of total hip prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients that fail to follow through with the required rehabilitation program. Patients should be cautioned that these devices do not have the strength, elasticity, and/or durability characteristics of healthy bone. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail, or need to be removed and/or replaced.

1.1 General instructions

- Zimmer has not tested the safety or effectiveness of these devices for use in combination with non-Zimmer products or components. If surgeons elect to assemble and implant a construct that includes components not manufactured or distributed by Zimmer, they do so in reliance on their own clinical judgment and should so inform their patients.
- Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the **compatibility of these devices** with implants and components made or distributed by other Zimmer companies, including those of Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer, Inc., Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations should be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.). Former Centerpulse and Implex products that are now packaged in Zimmer boxes, and for which compatibility could be an issue, have been labeled «former Centerpulse» and «former Implex» to provide clarification for the user.
- Implants and the relevant instruments should be carefully checked before they are used or implanted. Implants or implant parts that are contaminated, not sterile, damaged (e.g., if the ball head is dropped on the floor) or scratched (e.g., if the stem taper is scratched by an instrument or if the head and stem taper are attached then detached) or that have been improperly handled or processed without authorization may not be implanted or used

under any circumstances. The use of damaged implants or instruments that have been processed without authorization in any way may lead to premature failure.

- Implants must not be machined or altered in any way.
- Reliable seating of the femoral head on the stem taper is only possible when both mating surfaces are completely intact. If the corresponding stem taper is damaged in any way, the stem must be replaced. **It is absolutely essential that the taper of the femoral stem fit perfectly with the taper of the head.**
- Femoral heads featuring a variety of neck lengths provide for surgical latitude in hip reconstruction. The reduced cross-sectional geometry of small hip stems causes increased tensile stresses in the femoral component. The increased loads can result in failure of the device. Consideration must be given to these biomechanical factors and, therefore, **+7mm heads must not be used with the smallest stem sizes.**
- If a Zimmer product is passed on to a third party, the party who passes it on must ensure that the relevant batch-tracking is possible at any time (traceability).

1.2 Product description and implant materials

The *BIOLOX delta* Ceramic Femoral Head is used in conjunction with compatible acetabular and femoral stem components in total hip arthroplasty. A variety of sizes and neck lengths are available for various patient anatomies and adjustment of the tension of the ligaments and reconstruction of the center of the natural head of the femur.

A taper is incorporated in the design of the head to interlock it with the femoral stem.

The *BIOLOX delta* Ceramic Femoral Head is designed for use in total hip arthroplasty with an acetabular component with an inner articulating surface. The size of the femoral head used must match the inner diameter of the articulating surface.

The *BIOLOX delta* Ceramic Femoral Head may only be used in combination with highly crosslinked or conventional polyethylene (PE), or authorized ceramics, where available. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. **Wear couples with other ceramics or with metal are prohibited.**

Zimmer *BIOLOX delta* Femoral Heads are to be used only with femoral stems labelled “May be used with Ceramic Femoral Head.” The package insert for the stem should be consulted to determine the compatibility of the stem and the ceramic head.

BIOLOX delta

The *BIOLOX delta* Ceramic Femoral Head consists of the material *BIOLOX delta*, an aluminum oxide matrix composite ceramic consisting of approx. 75% alumina (Al₂O₃), 24% zirconia (ZrO₂) and trace elements. The pink color is due to Cr₂O₃.

1.3 Indications

The *BIOLOX delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

2. Warnings

- Do not use another manufacturer's femoral components with *BIOLOX delta* Ceramic Femoral Heads. The ceramic heads are designed and intended to be used with Zimmer modular femoral stems that have a corresponding 12/14 proximal neck taper.
- Using a stem not tested for compatibility with these heads may increase the risk that the head will fracture.
- Do not use the femoral heads for trial reductions. Provisional (trial) implants are available for this purpose.
- Do not use a seating instrument with a metal face to seat the *BIOLOX delta* Ceramic Femoral Head — use a femoral head driver with a plastic face. Contact between ceramic components and any metal instrument may compromise the integrity of the device.
- Do not attempt removal of a head from the tapered-neck femoral stem with any instrument other than the specifically designed (12/14) distraction instrument.

- Do not use the *BIOLOX delta* Ceramic Femoral Head in revision surgery unless the femoral stem is also being revised.
- These devices are for single patient use only. Do not reuse.
- Do not use this product for other than labeled indications (off-label use).

2.1. Precautions

- Prior to impacting of the femoral head onto a femoral stem, remove any blood or debris from the stem taper and examine the inside of the femoral head to ensure that no particulate matter is present. Implants parts must be thoroughly cleaned and dried before they are used. Failure to ensure that mating surfaces are clean could result in inadequate seating of one component upon the other and subsequent fracture of the head or disassembly of the femoral head from the femoral stem.
- Notching, scratching, or striking the prosthesis could result in accelerated wear or sudden failure.

2.2. Adverse effects

The following adverse effects have been reported:

- Disassembly of modular components
- Wear
- Inflammatory reactions and osteolysis
- Loosening
- Fracture of the ceramic head
- Noise (ceramic pairings only)

2.3 Sterilization

The *BIOLOX delta* Ceramic Femoral Heads are supplied sterile by prior exposure to gamma irradiation and remain sterile as long as the package integrity has not been violated.

***BIOLOX delta* Ceramic Heads should not be resterilized by any method.**

3. Storage and Handling

- Implants must be stored unopened in their original packaging.
- Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached, or if the expiration date has been exceeded. Once opened, the component must be used or discarded.
- If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer. (Not applicable for the USA).
- Protective caps or other protective devices must not be removed until immediately before use.
- Implants, implant parts and instruments that can no longer be used may be returned to the manufacturer for proper disposal free of charge. (Not applicable for the USA).
- Implants are extremely sensitive to damage; careful handling is strongly recommended.

4. Pictograms



Symbol for «Follow the Instructions for Use»



Symbol for «Not to be re-used »



Symbol for «To be used by... » (Year, Month)



Symbol for «By Prescription Only»



Symbol for «Manufacture Date»



Symbol for «Manufacturer»

not sterile

Symbol for «Contents packed without sterilization»

STERILE R

Symbol for «Sterile» and «Sterilization by radiation»

5. Trademarks

BIOLOX[®] delta is a trademark of CeramTec AG.

Product Label

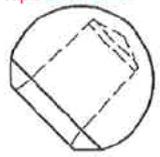
Alumina Matrix Composite (BioloX® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-028-01 LOT XXX

Taper 12/14 - 5° 43'



BioloX® delta
BioloX® delta Ceramic Femoral Head
ø 28/-3.5 'S' Taper 12/14

STERILE R 2011-12

		HEAD	28/-3.5 'S'
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47247-001

LB1-000

H844008775028011/11365XXXA07R

(FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-028-01 EDI: 00877502801

LOT XXX Qty. 001

BioloX® delta Ceramic Femoral Head ø 28/-3.5 'S' Taper 12/14

BioloX® delta Keramik Kopf ø 28/-3.5 'S' Konus 12/14

BioloX® delta Tête femorale céramique ø 28/-3.5 'S' Cône 12/14

BioloX® delta Testa femorale di ceramica ø 28/-3.5 'S' Cono 12/14

BioloX® delta Cabeza femoral de cerámica ø 28/-3.5 'S' Cono 12/14



H844008775028011/11365XXXA07R

0123

CE Rx only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

(FORMER CENTERPULSE)

BioloX® delta

26974-00 - LB1v00

Translation Label



Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-028-01 EDI: 00877502801

LOT XXX Qty. 001

DE: BioloX® delta Keramik Kopf ø 28/-3.5 'S' Konus 12/14

FR: BioloX® delta Tête femorale céramique ø 28/-3.5 'S' Cône 12/14

IT: BioloX® delta Testa femorale di ceramica ø 28/-3.5 'S' Cono 12/14

ES: BioloX® delta Cabeza femoral de cerámica ø 28/-3.5 'S' Cono 12/14

25960-003 - LB1v00

Patient Chart Sticker

REF 00-8775-028-01 EDI: 00877502801

LOT XXX 2011-12 Qty: 001

BioloX® delta Ceramic Femoral Head ø 28/-3.5 'S' Taper 12/14

Alumina Matrix Composite (BioloX® delta)

Taper 12/14 - 5° 43'




H844008775028011/11365XXXA07R

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

25955w02 - LB1v00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey

Product Label

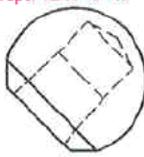
Alumina Matrix Composite (Bioblox® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-028-03 LOT XXX

Taper 12/14 - 5° 43'



Bioblox® delta
Bioblox® delta Ceramic Femoral Head
ø 28/+3.5 'L' Taper 12/14

STERILE R 2011-12

		HEAD	28/+3.5 'L'
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+H844008775028031 / 11365XXXA07T

(FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-028-03 EDI: 00877502803

LOT XXX Qty. 001

Bioblox® delta Ceramic Femoral Head ø 28/+3.5 'L' Taper 12/14

Bioblox® delta Keramik Kopf ø 28/+3.5 'L' Konus 12/14

Bioblox® delta Tête femorale céramique ø 28/+3.5 'L' Cône 12/14

Bioblox® delta Testa femorale di ceramica ø 28/+3.5 'L' Cono 12/14

Bioblox® delta Cabeza femoral de cerámica ø 28/+3.5 'L' Cono 12/14



+H844008775028031 / 11365XXXA07T

0123 CE R only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

(FORMER CENTERPULSE)

Translation Label



Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-028-03 EDI: 00877502803

LOT XXX Qty. 001

DE: Bioblox® delta Keramik Kopf ø 28/+3.5 'L' Konus 12/14

FR: Bioblox® delta Tête femorale céramique ø 28/+3.5 'L' Cône 12/14

IT: Bioblox® delta Testa femorale di ceramica ø 28/+3.5 'L' Cono 12/14

ES: Bioblox® delta Cabeza femoral de cerámica ø 28/+3.5 'L' Cono 12/14

Patient Chart Sticker

REF 00-8775-028-03 EDI: 00877502803

LOT XXX Qty: 001

Bioblox® delta Ceramic Femoral Head ø 28/+3.5 'L' Taper 12/14

Alumina Matrix Composite (Bioblox® delta)

Taper 12/14 - 5° 43'



+H844008775028031 / 11365XXXA07T

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

25955v02 - LB1v00

Warning Label

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Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey

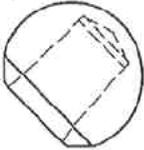
Product Label

Alumina Matrix Composite (Biobx® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-032-01 LOT XXX
Taper 12/14 - 5° 43'



Biobx® delta
Biobx® delta Ceramic Femoral Head
ø 32/-3.5 'S' Taper 12/14

STERILE R 2011-12

		HEAD	32/-3.5 'S'
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47247 - 001

LB1 - 000

(H844008775032011/11365XXXA07N) (FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-032-01 EDI: 00877503201
LOT XXX Qty. 001

Biobx® delta Ceramic Femoral Head ø 32/-3.5 'S' Taper 12/14
Biobx® delta Keramik Kopf ø 32/-3.5 'S' Konus 12/14
Biobx® delta Tête femorale céramique ø 32/-3.5 'S' Cône 12/14
Biobx® delta Testa femorale di ceramica ø 32/-3.5 'S' Cono 12/14
Biobx® delta Cabeza femoral de cerámica ø 32/-3.5 'S' Cono 12/14

Biobx® delta

2597503 - LB1V00

(H844008775032011/11365XXXA07N)

0123 R_x only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com (FORMER CENTERPULSE)

Translation Label

! 0123 R_x only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-032-01 EDI: 00877503201
LOT XXX Qty. 001

DE: Biobx® delta Keramik Kopf ø 32/-3.5 'S' Konus 12/14
FR: Biobx® delta Tête femorale céramique ø 32/-3.5 'S' Cône 12/14
IT: Biobx® delta Testa femorale di ceramica ø 32/-3.5 'S' Cono 12/14
ES: Biobx® delta Cabeza femoral de cerámica ø 32/-3.5 'S' Cono 12/14

2595003 - LB1V00

Patient Chart Sticker

REF 00-8775-032-01 EDI: 00877503201
LOT XXX Qty: 001

Biobx® delta Ceramic Femoral Head ø 32/-3.5 'S' Taper 12/14
Alumina Matrix Composite (Biobx® delta) Taper 12/14 - 5° 43'

25955v02 - LB1V00

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey

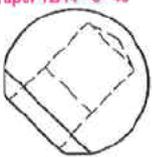
Product Label

Akamina Matrix Composite (Biobx® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-032-04 LOT XXX
Taper 12/14 - 5° 43'



Biobx® delta
Biobx® delta Ceramic Femoral Head
ø 32/+7 'XL' Taper 12/14

STERILE R 2011-12

		HEAD	32/+7 'XL'
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+H844008775032041/11365XXXA07P

(FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-032-04 EDI: 00877503204
LOT XXX Qty: 001

Biobx® delta Ceramic Femoral Head ø 32/+7 'XL' Taper 12/14
Biobx® delta Keramik Kopf ø 32/+7 'XL' Konus 12/14
Biobx® delta Tête femorale céramique ø 32/+7 'XL' Cône 12/14
Biobx® delta Testa femorale di ceramica ø 32/+7 'XL' Cono 12/14
Biobx® delta Cabeza femoral de cerámica ø 32/+7 'XL' Cono 12/14



+H844008775032041/11365XXXA07P

CE R_X only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com
(FORMER CENTERPULSE)

Translation Label



Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-032-04 EDI: 00877503204
LOT XXX Qty: 001

DE: Biobx® delta Keramik Kopf ø 32/+7 'XL' Konus 12/14
FR: Biobx® delta Tête femorale céramique ø 32/+7 'XL' Cône 12/14
IT: Biobx® delta Testa femorale di ceramica ø 32/+7 'XL' Cono 12/14
ES: Biobx® delta Cabeza femoral de cerámica ø 32/+7 'XL' Cono 12/14

Patient Chart Sticker

REF 00-8775-032-04 EDI: 00877503204
LOT XXX Qty: 001

Biobx® delta Ceramic Femoral Head ø 32/+7 'XL' Taper 12/14
Akamina Matrix Composite (Biobx® delta)

Taper 12/14 - 5° 43'



+H844008775032041/11365XXXA07P

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com 25955v02 - LB1v00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey

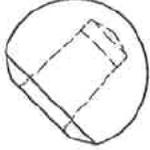
Product Label

Alumina Matrix Composite (Bioblox® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-036-01 LOT XXX
Taper 12/14 - 5° 43'



Bioblox® delta
Bioblox® delta Ceramic Femoral Head
ø 36/-3.5 'S' Taper 12/14

STERILE R 2011-12

		HEAD	36/-3.5 'S'
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47247 - v01

47247 - v01

LB1 - v00

(H844008775036011/11365XXXA07Q (FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-036-01 EDI: 00877503601
LOT XXX Qty. 001

Bioblox® delta Ceramic Femoral Head ø 36/-3.5 'S' Taper 12/14
Bioblox® delta Keramik Kopf ø 36/-3.5 'S' Konus 12/14
Bioblox® delta Tête femorale céramique ø 36/-3.5 'S' Cône 12/14
Bioblox® delta Testa femorale di ceramica ø 36/-3.5 'S' Cono 12/14
Bioblox® delta Cabeza femoral de cerámica ø 36/-3.5 'S' Cono 12/14



0123 CE R_X only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

25979v03 - LB1v00 (FORMER CENTERPULSE)

Translation Label



Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-036-01 EDI: 00877503601
LOT XXX Qty. 001

DE: Bioblox® delta Keramik Kopf ø 36/-3.5 'S' Konus 12/14
FR: Bioblox® delta Tête femorale céramique ø 36/-3.5 'S' Cône 12/14
IT: Bioblox® delta Testa femorale di ceramica ø 36/-3.5 'S' Cono 12/14
ES: Bioblox® delta Cabeza femoral de cerámica ø 36/-3.5 'S' Cono 12/14

25979v03 - LB1v00

Patient Chart Sticker

REF 00-8775-036-01 EDI: 00877503601
LOT XXX Qty: 001

Bioblox® delta Ceramic Femoral Head ø 36/-3.5 'S' Taper 12/14
Alumina Matrix Composite (Bioblox® delta) Taper 12/14 - 5° 43'



25955v02 - LB1v00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey

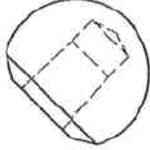
Product Label

Alumina Matrix Composite (Biobx® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-036-04 LOT XXX
 Taper 12/14 - 5° 43'



Biobx® delta
 Biobx® delta Ceramic Femoral Head
 ø 36/+7 'XL' Taper 12/14

STERILE R 2011-12

		HEAD	36/+7 'XL'
--	--	------	------------

H844008775036041/11365XXXA07T

(FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-036-04 EDI: 00877503604
 LOT XXX Qty. 001

Biobx® delta Ceramic Femoral Head ø 36/+7 'XL' Taper 12/14
 Biobx® delta Keramik Kopf ø 36/+7 'XL' Konus 12/14
 Biobx® delta Tête femorale céramique ø 36/+7 'XL' Cône 12/14
 Biobx® delta Testa femorale di ceramica ø 36/+7 'XL' Cono 12/14
 Biobx® delta Cabeza femoral de cerámica ø 36/+7 'XL' Cono 12/14



H844008775036041/11365XXXA07T

0123 CE R_X only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com
 (FORMER CENTERPULSE)

Translation Label



Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-036-04 EDI: 00877503604
 LOT XXX Qty. 001

DE: Biobx® delta Keramik Kopf ø 36/+7 'XL' Konus 12/14
 FR: Biobx® delta Tête femorale céramique ø 36/+7 'XL' Cône 12/14
 IT: Biobx® delta Testa femorale di ceramica ø 36/+7 'XL' Cono 12/14
 ES: Biobx® delta Cabeza femoral de cerámica ø 36/+7 'XL' Cono 12/14

Patient Chart Sticker

REF 00-8775-036-04 EDI: 00877503604
 LOT XXX 2011-12 Qty: 001

Biobx® delta Ceramic Femoral Head ø 36/+7 'XL' Taper 12/14
 Alumina Matrix Composite (Biobx® delta) Taper 12/14 - 5° 43'



H844008775036041/11365XXXA07T

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com 25955v02 - LB1V00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey

Product Label

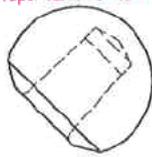
Alumina Matrix Composite (Bilox® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-040-01 LOT XXX

Taper 12/14 - 5° 43'



Bilox® delta
Bilox® delta Ceramic Femoral Head
ø 40/-3.5 'S' Taper 12/14

STERILE R 2011-12

		HEAD	40/-3.5 'S'
--	--	------	-------------

H844008775040011 / 11365XXXA07L

(FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-040-01 EDI: 00877504001

LOT XXX Qty. 001

Bilox® delta Ceramic Femoral Head ø 40/-3.5 'S' Taper 12/14
Bilox® delta Keramik Kopf ø 40/-3.5 'S' Konus 12/14
Bilox® delta Tête femorale céramique ø 40/-3.5 'S' Cône 12/14
Bilox® delta Testa femorale di ceramica ø 40/-3.5 'S' Cono 12/14
Bilox® delta Cabeza femoral de cerámica ø 40/-3.5 'S' Cono 12/14



H844008775040011 / 11365XXXA07L

0123 R only STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

(FORMER CENTERPULSE)

Translation Label



Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-040-01 EDI: 00877504001

LOT XXX Qty. 001

DE: Bilox® delta Keramik Kopf ø 40/-3.5 'S' Konus 12/14

FR: Bilox® delta Tête femorale céramique ø 40/-3.5 'S' Cône 12/14

IT: Bilox® delta Testa femorale di ceramica ø 40/-3.5 'S' Cono 12/14

ES: Bilox® delta Cabeza femoral de cerámica ø 40/-3.5 'S' Cono 12/14

Patient Chart Sticker

REF 00-8775-040-01 EDI: 00877504001

LOT XXX 2011-12 Qty: 001

Bilox® delta Ceramic Femoral Head ø 40/-3.5 'S' Taper 12/14
Alumina Matrix Composite (Bilox® delta) Taper 12/14 - 5° 43'



H844008775040011 / 11365XXXA07L

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com 2595v02 - LB1v00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey

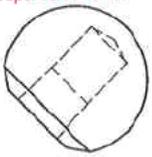
Product Label

Alumina Matrix Composite (Biobx® delta)

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.

If this seal is broken, the product may not be returned for credit!

REF 00-8775-040-04 LOT XXX
 Taper 12/14 - 5° 43'



Biobx® delta
 Biobx® delta Ceramic Femoral Head
 ø 40/+7 'XL' Taper 12/14

STERILE R 2011-12

		HEAD	40/+7 'XL'
--	--	------	------------

H844008775040041 / 11365XXXA070

(FORMER CENTERPULSE)

Bar Code Label

REF 00-8775-040-04 EDI: 00877504004
 LOT XXX Qty. 001

Biobx® delta Ceramic Femoral Head ø 40/+7 'XL' Taper 12/14
 Biobx® delta Keramik Kopf ø 40/+7 'XL' Konus 12/14
 Biobx® delta Tête femorale céramique ø 40/+7 'XL' Cône 12/14
 Biobx® delta Testa femorale di ceramica ø 40/+7 'XL' Cono 12/14
 Biobx® delta Cabeza femoral de cerámica ø 40/+7 'XL' Cono 12/14



H844008775040041 / 11365XXXA070

0123 **R_x only** STERILE R 2011-12 2007-01

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com
 (FORMER CENTERPULSE)

Translation Label



Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com

REF 00-8775-040-04 EDI: 00877504004
 LOT XXX Qty. 001

DE: Biobx® delta Keramik Kopf ø 40/+7 'XL' Konus 12/14
 FR: Biobx® delta Tête femorale céramique ø 40/+7 'XL' Cône 12/14
 IT: Biobx® delta Testa femorale di ceramica ø 40/+7 'XL' Cono 12/14
 ES: Biobx® delta Cabeza femoral de cerámica ø 40/+7 'XL' Cono 12/14

Patient Chart Sticker

REF 00-8775-040-04 EDI: 00877504004
 LOT XXX 2011-12 Qty. 001

Biobx® delta Ceramic Femoral Head ø 40/+7 'XL' Taper 12/14
 Alumina Matrix Composite (Biobx® delta) Taper 12/14 - 5° 43'



H844008775040041 / 11365XXXA070

Zimmer GmbH, CH-8404 Winterthur, Switzerland / www.zimmer.com 25955v02 - LB1v00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul® Magenta Cerasul® Grey



COVER SHEET MEMORANDUM

From: Reviewer Name Gantenberg
Subject: 510(k) Number K071535/S2
To: The Record

Please list CTS decision code SE
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 Hold (Additional Information or **Telephone Hold**).
 Final Decision (**SE**, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page (p.26)	Attach IFU	X	
510(k) Summary /510(k) Statement (p.21)	Attach Summary	X	
Truthful and Accurate Statement (Original, p.10)	Must be present for a Final Decision		
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB REVIATED STANDARDS DATA FORM.DOC)			N/A
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		X

Regulation Number 21 CFR 888.3353 **Class*** II (87 Panel) **Product Code** LZO
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [Signature] (Branch Chief) OTDB (Branch Code) 11/16/07 (Date)

Final Review: [Signature] (Division Director) 11/16/07 (Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional**

K071535/S2

Date: 11/15/07
To: The Record
From: Gantenberg

Office: ODE
Division/Branch: DGRND/OJDB

510(k) Holder: Zimmer
Device Name: BIOLOX® delta Ceramic Femoral Head
Contact: Ms. Patricia Jenks
Phone: 574-371-8354
Fax: 574-372-4605
Email: trish.jenks@zimmer.com permission to email granted in cover letter.

I. Purpose

The 510(k) holder would like to introduce BIOLOX® delta Ceramic Femoral Heads into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: <u>Prescription</u> or OTC) – Orig, p.26	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement – Summary provided in Original, p.21	X		
Standards Form	N/A		

III. Device Description (Executive summary and Premarket Notification Sections)

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

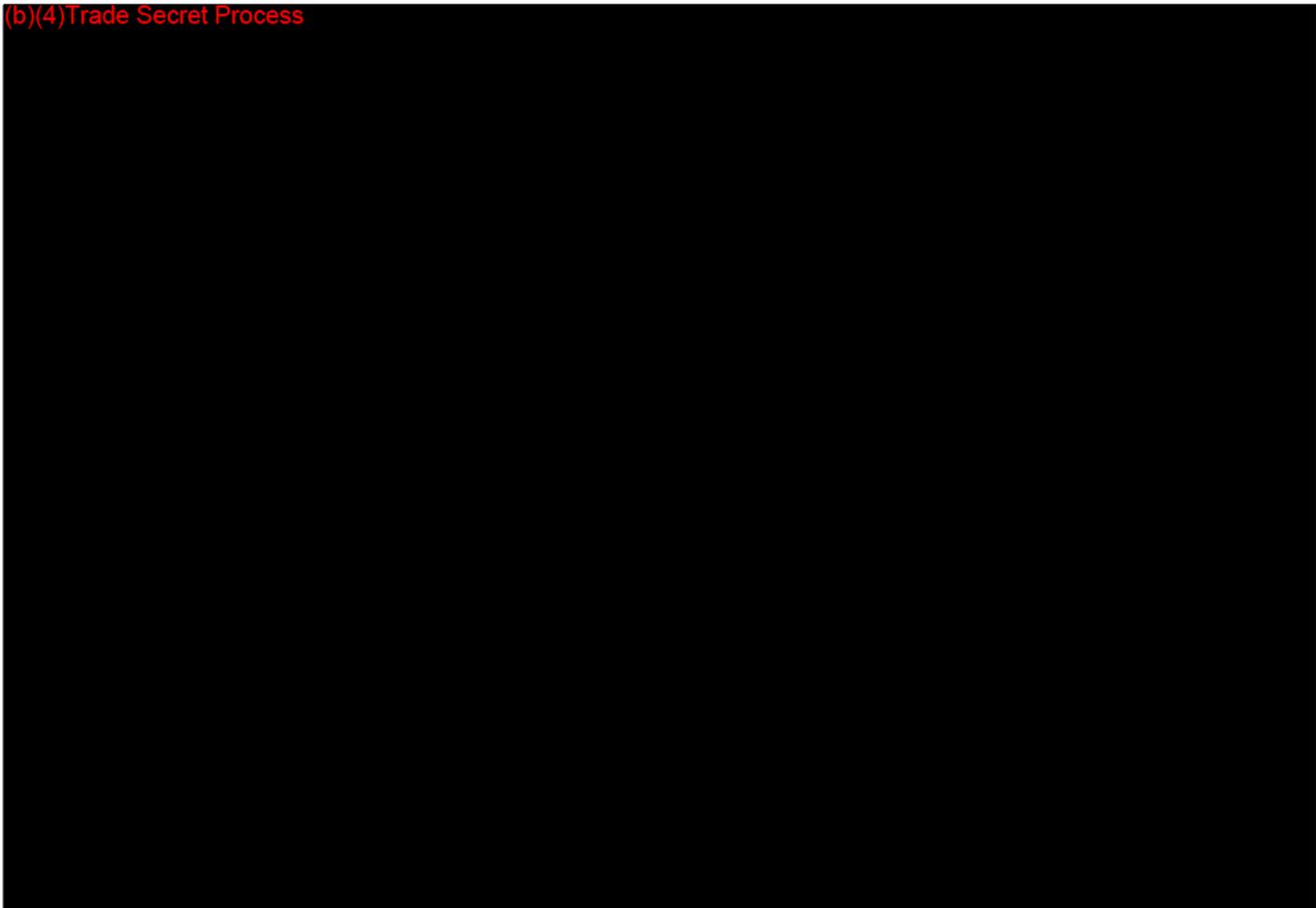
A predicate comparison table was provided in Original, p.36.

(b)(4)Trade Secret Process

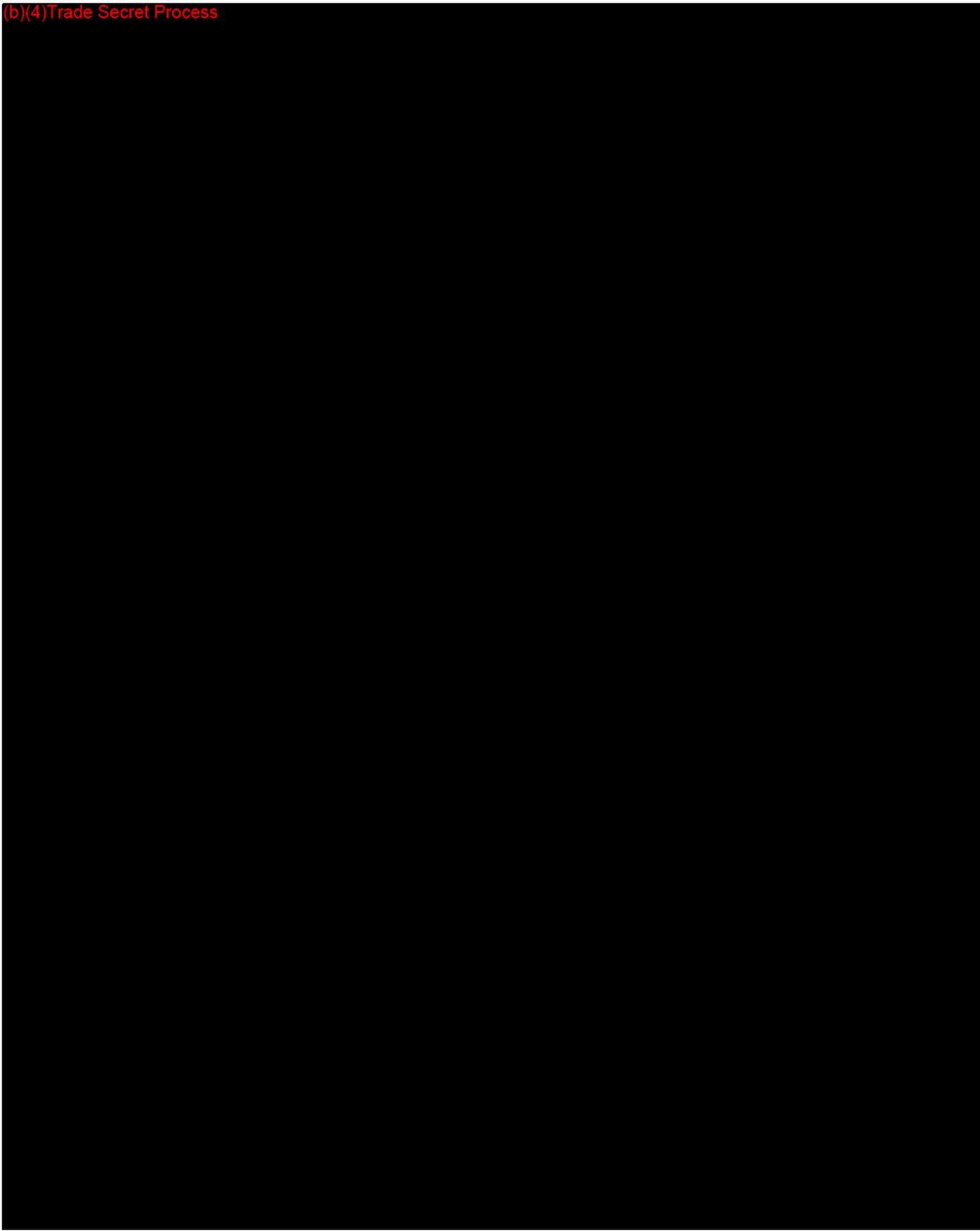


MATERIAL: Zirconia-Toughened Aluminum Oxide. Tradename is BioloX Delta (b)(4)Trade Secret Process

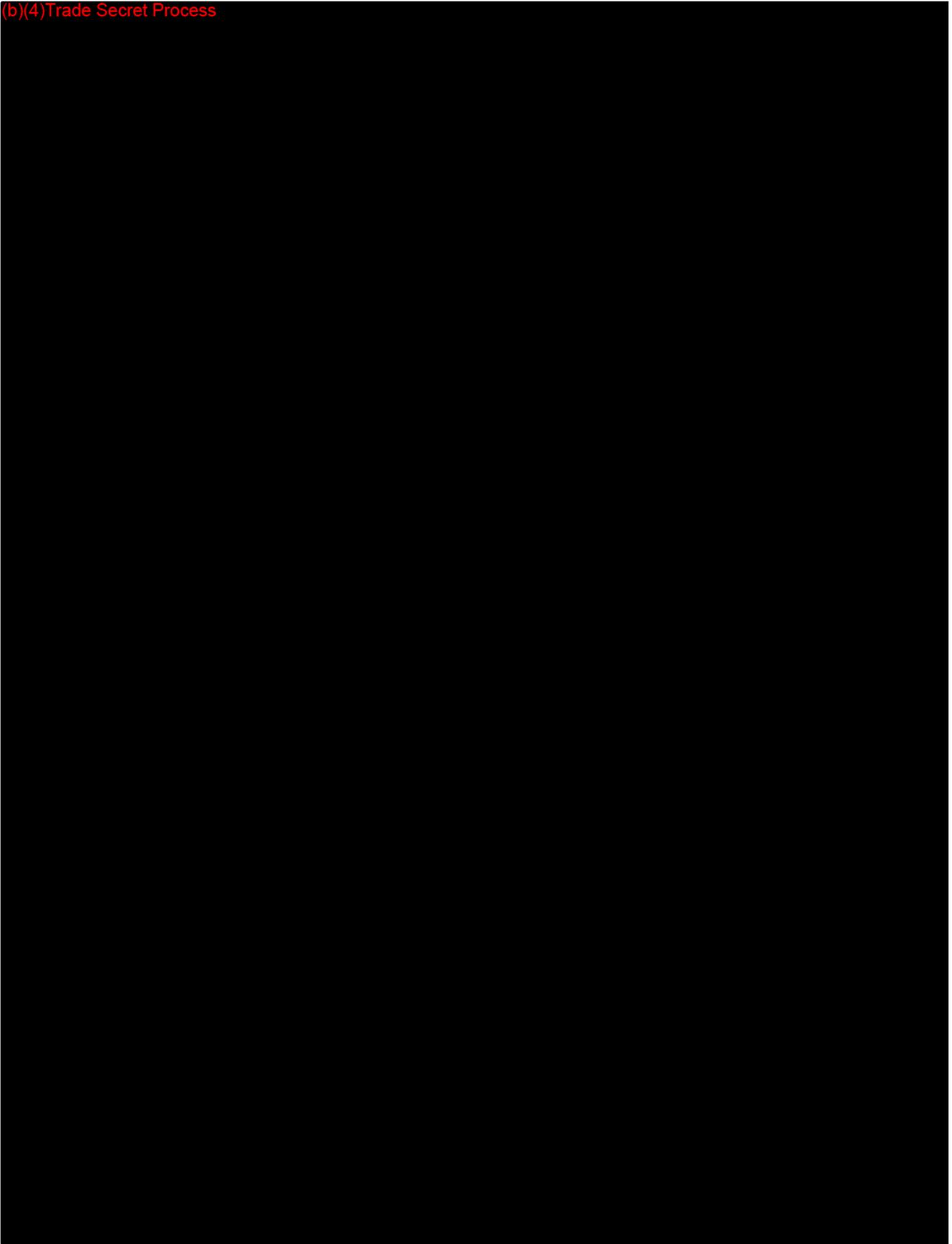
(b)(4)Trade Secret Process



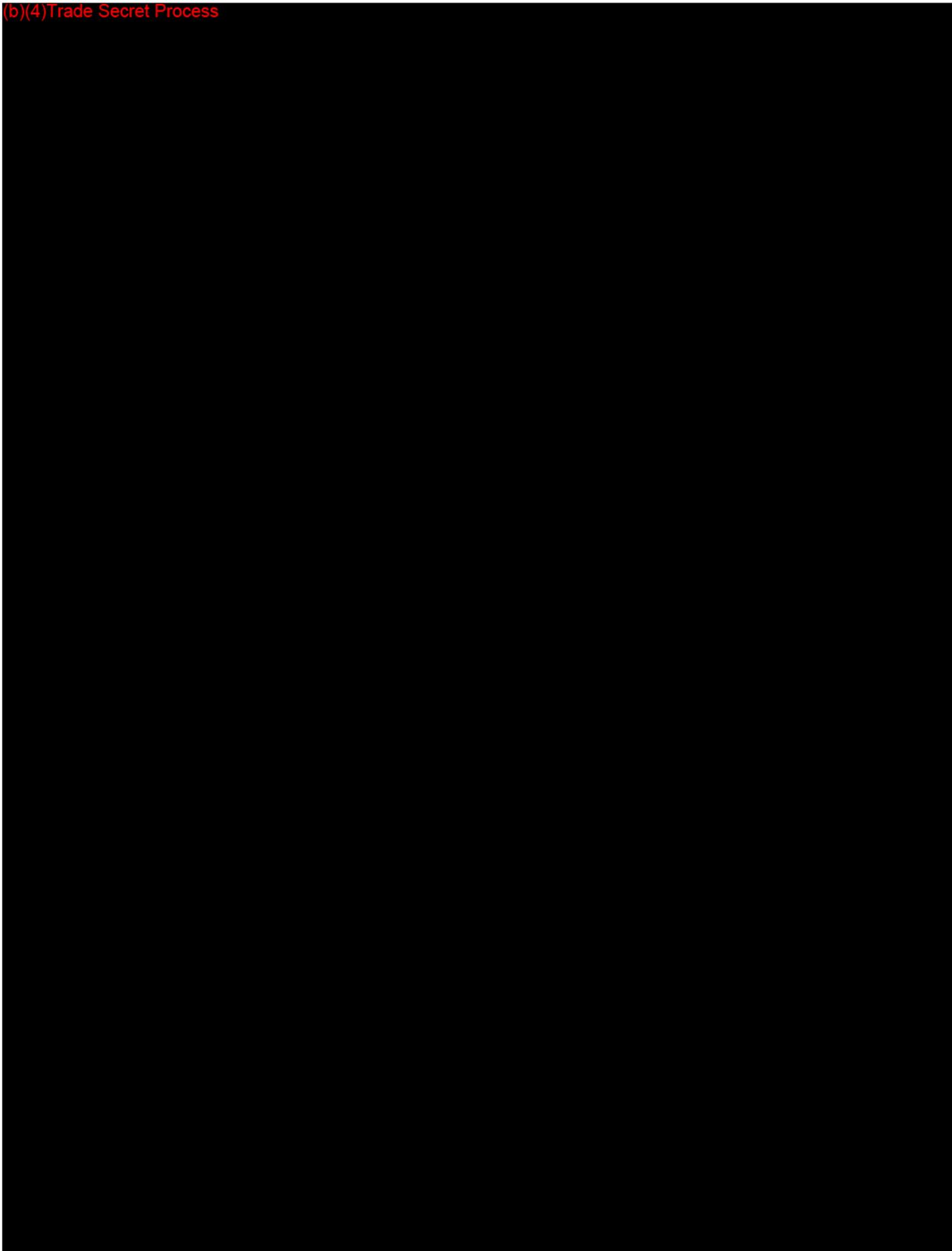
(b)(4)Trade Secret Process



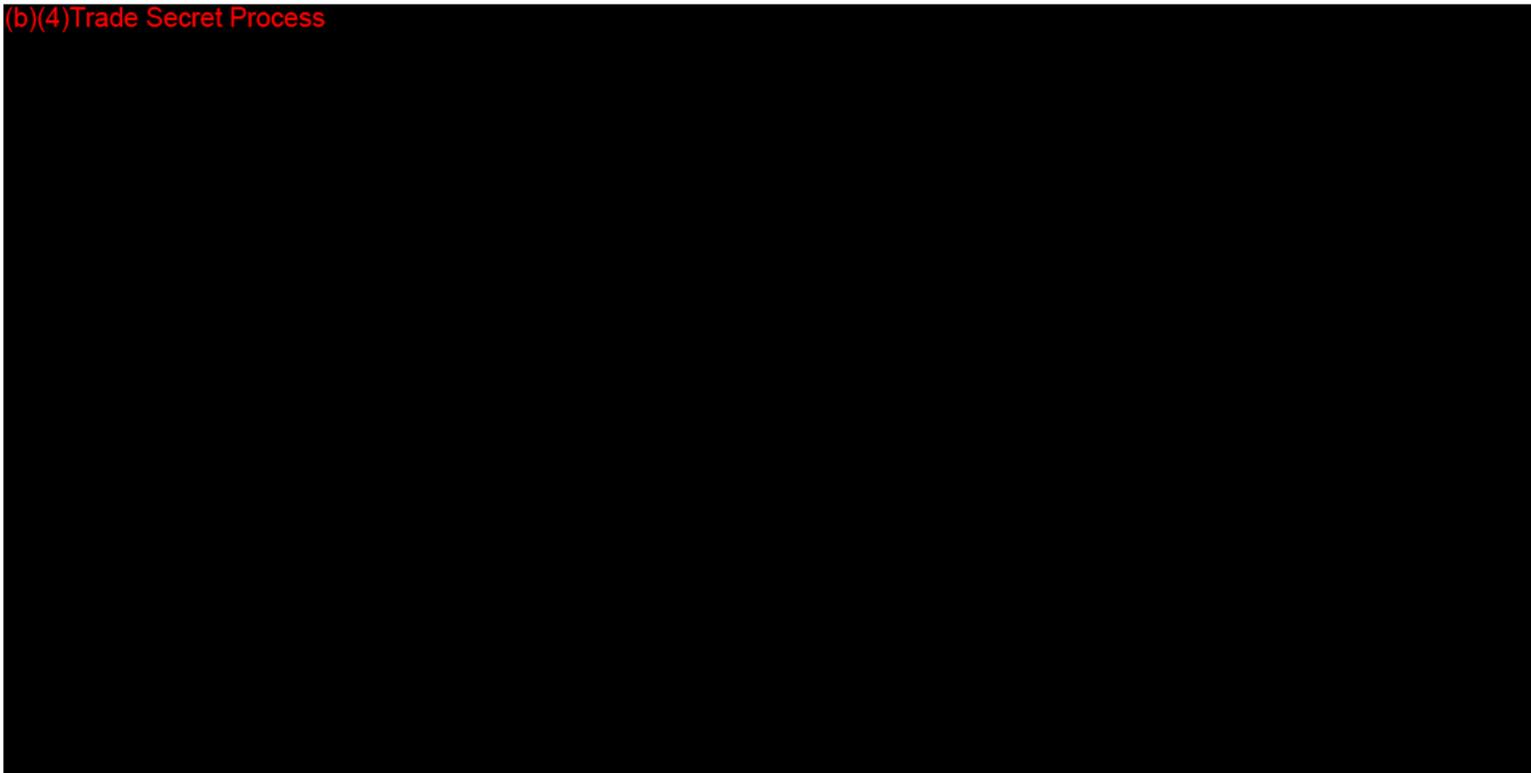
(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



VI. Labeling

Package label, package insert provided.

Package Label – (Original, p.87)

1. System Name / Sponsor Address: yes
2. Component Name, Article #, lot number: Yes
3. Sample package labeling reflects type of Sterile notation? Yes.

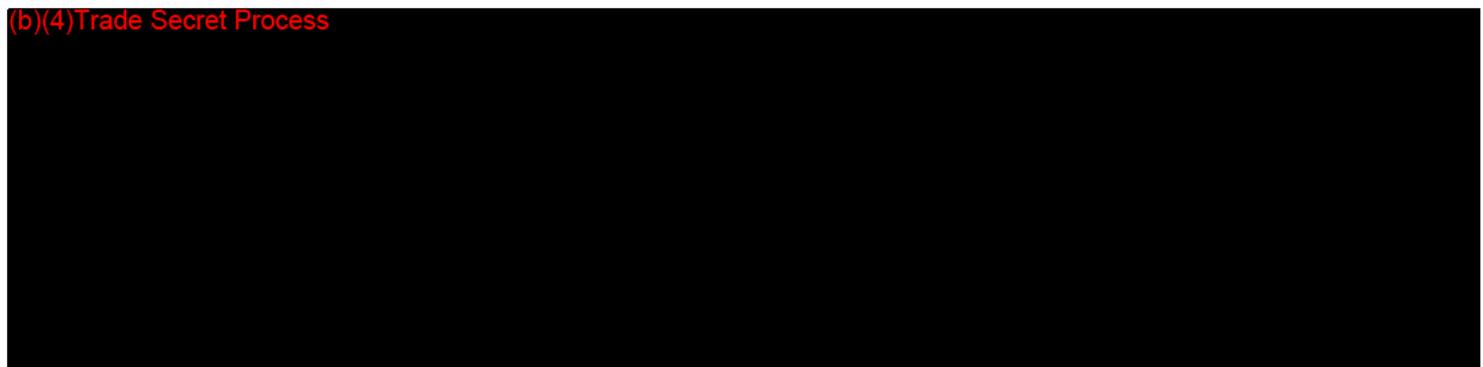
(b)(4)Trade Secret Process



Package Insert – A draft package insert was revised (S1, p.72).

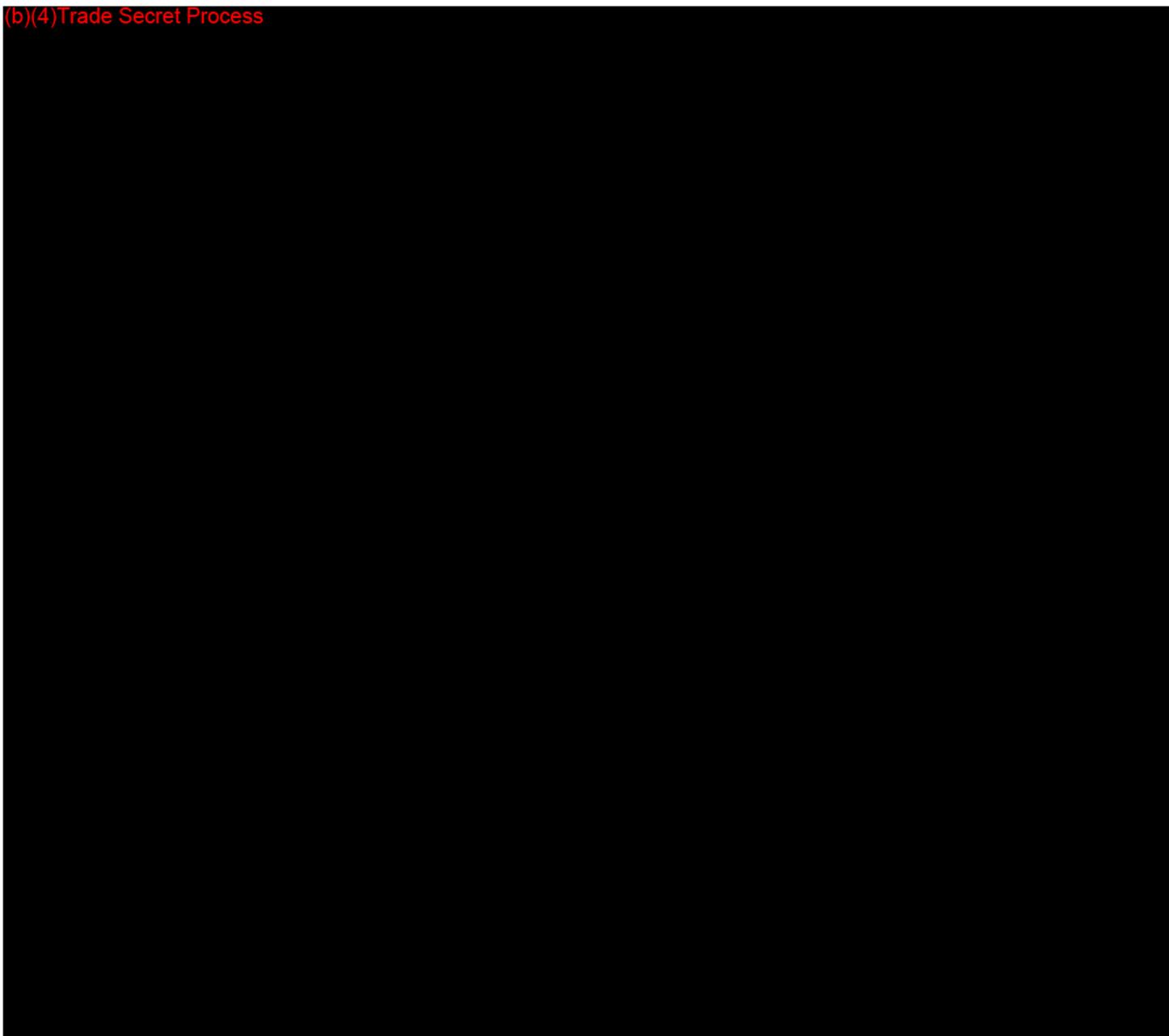
1. System name? Yes
2. Specific intended uses and indications? Same as on the Indications for Use enclosure.
3. List of contraindications, warnings, precautions and potential risks, adverse effects provided.
4. “Sterile” notation provided? Yes
5. Nonsterile Recommended process parameters: N/A

(b)(4)Trade Secret Process



VII. Sterilization/Shelf Life/Reuse (Original, pp.15-16)

(b)(4)Trade Secret Process



Review: Adequate.

VIII. Biocompatibility

(b)(4)Trade Secret Process

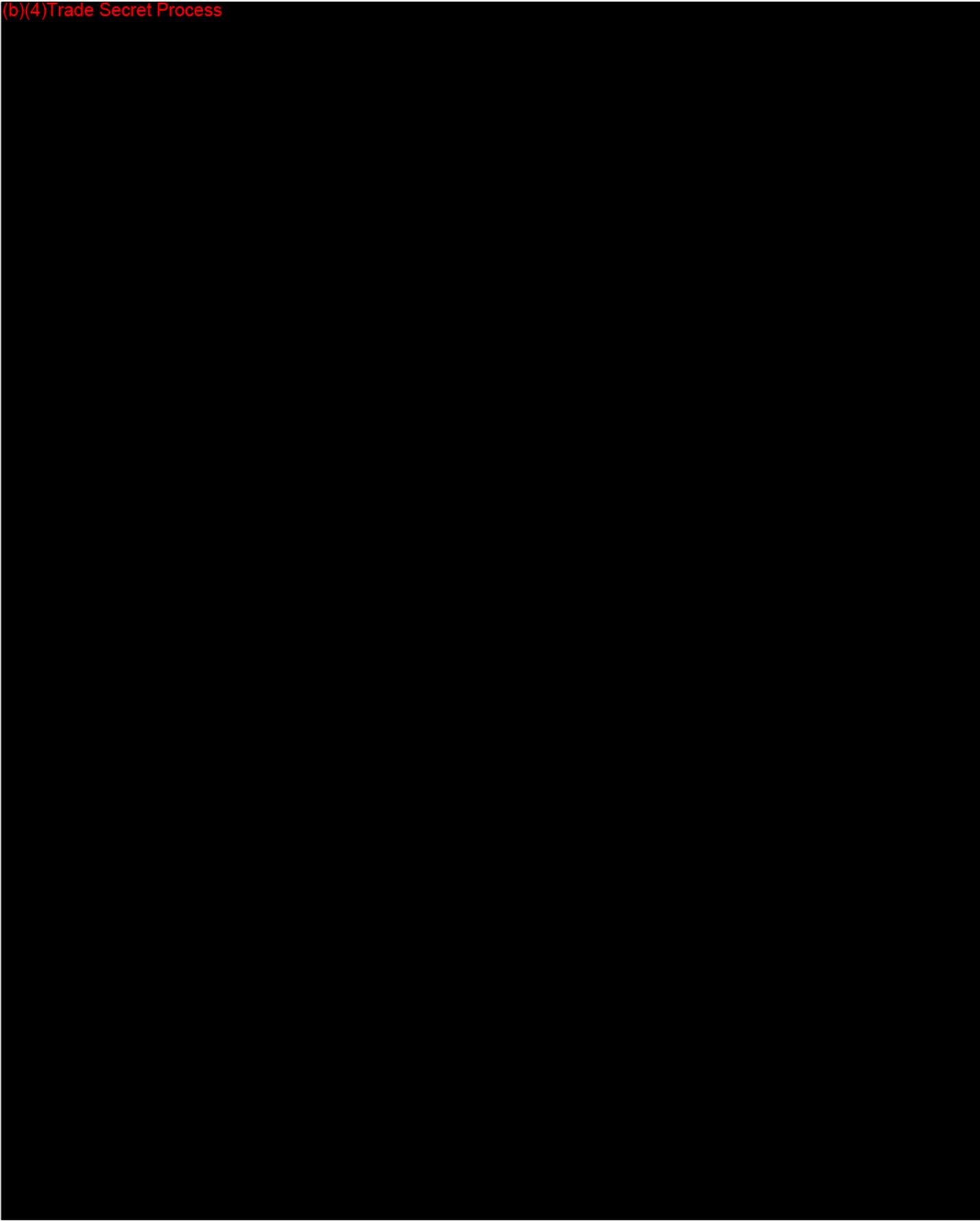


IX. Software N/A

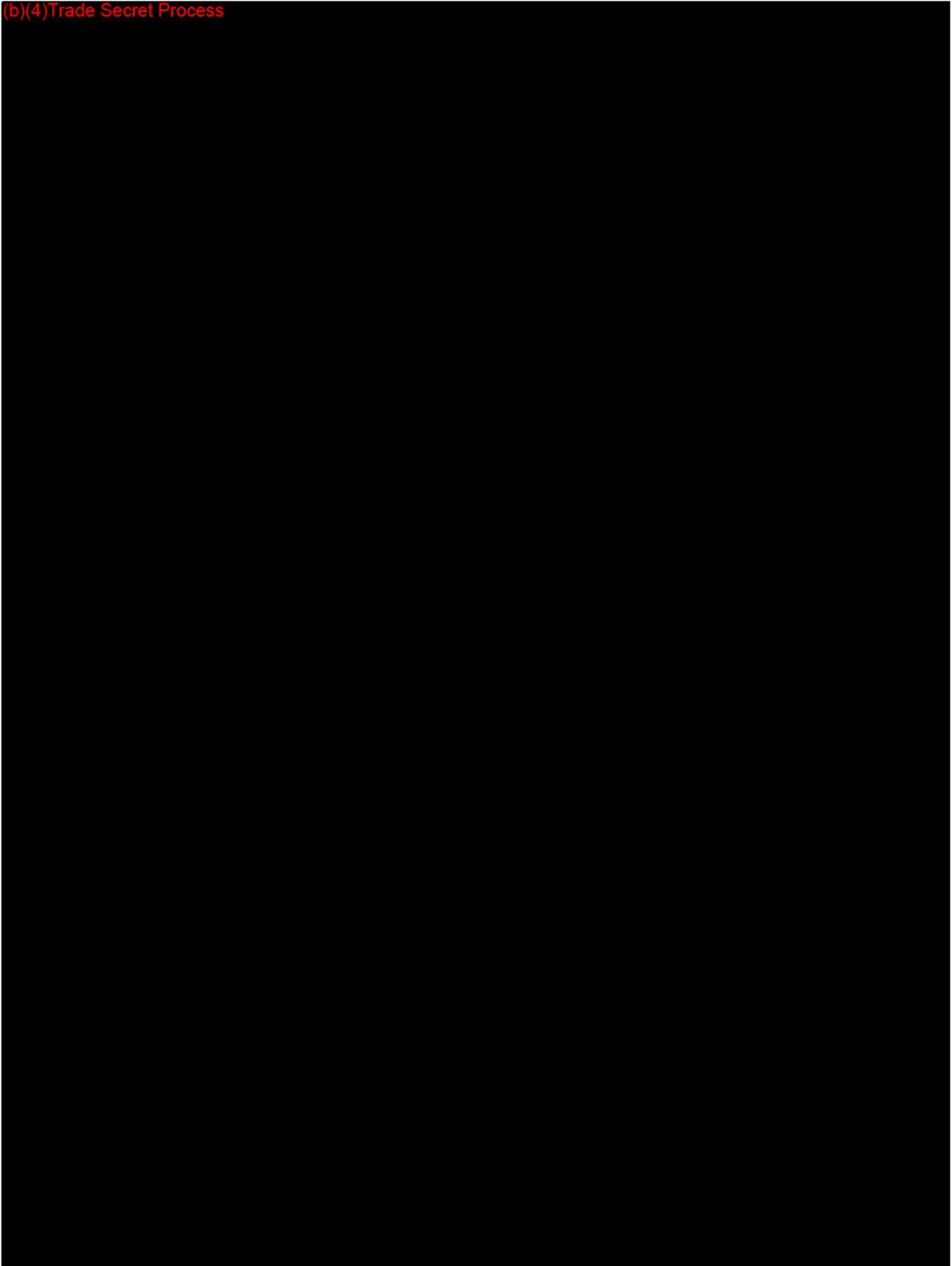
X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety N/A

XI. Performance Testing – Bench

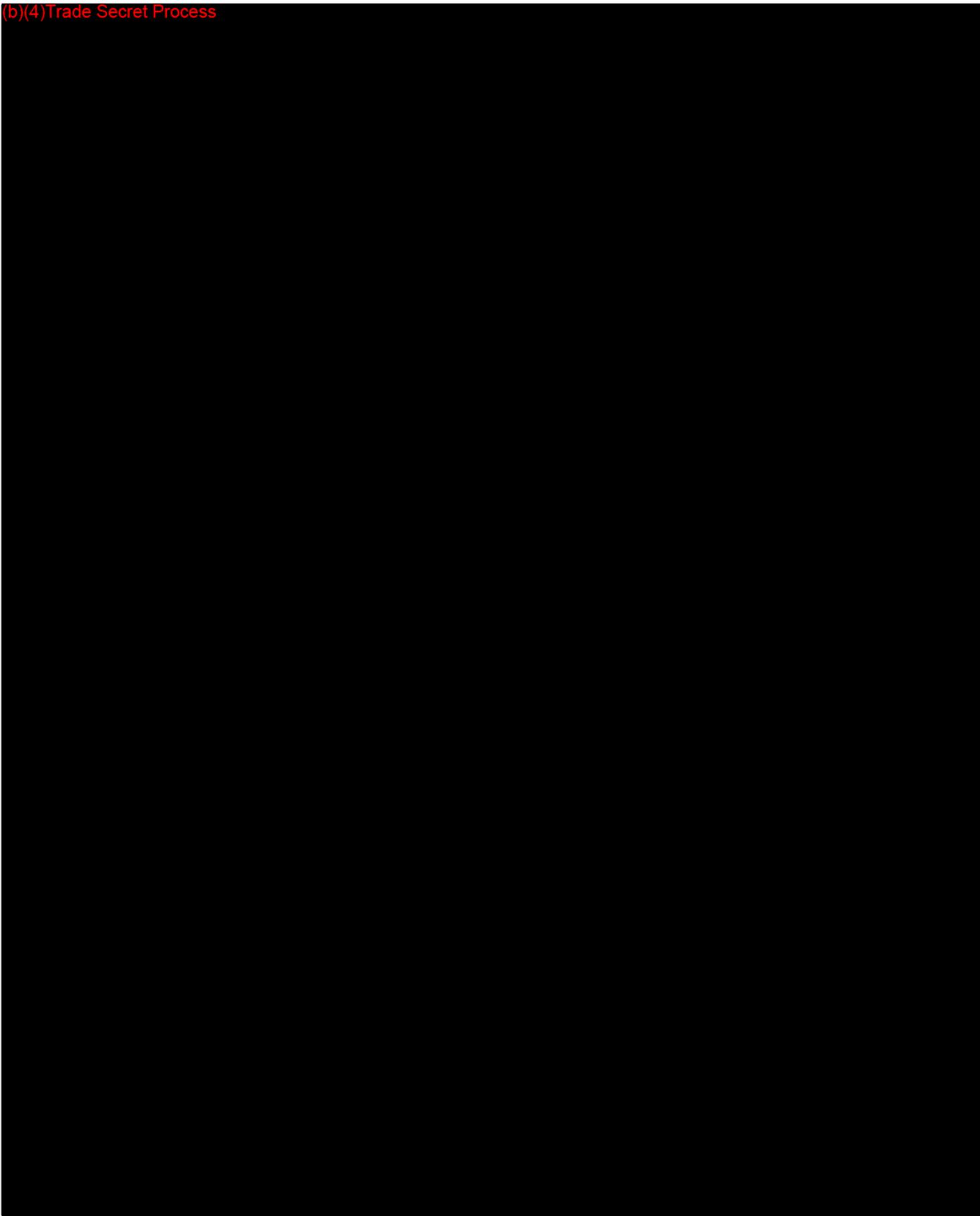
(b)(4)Trade Secret Process



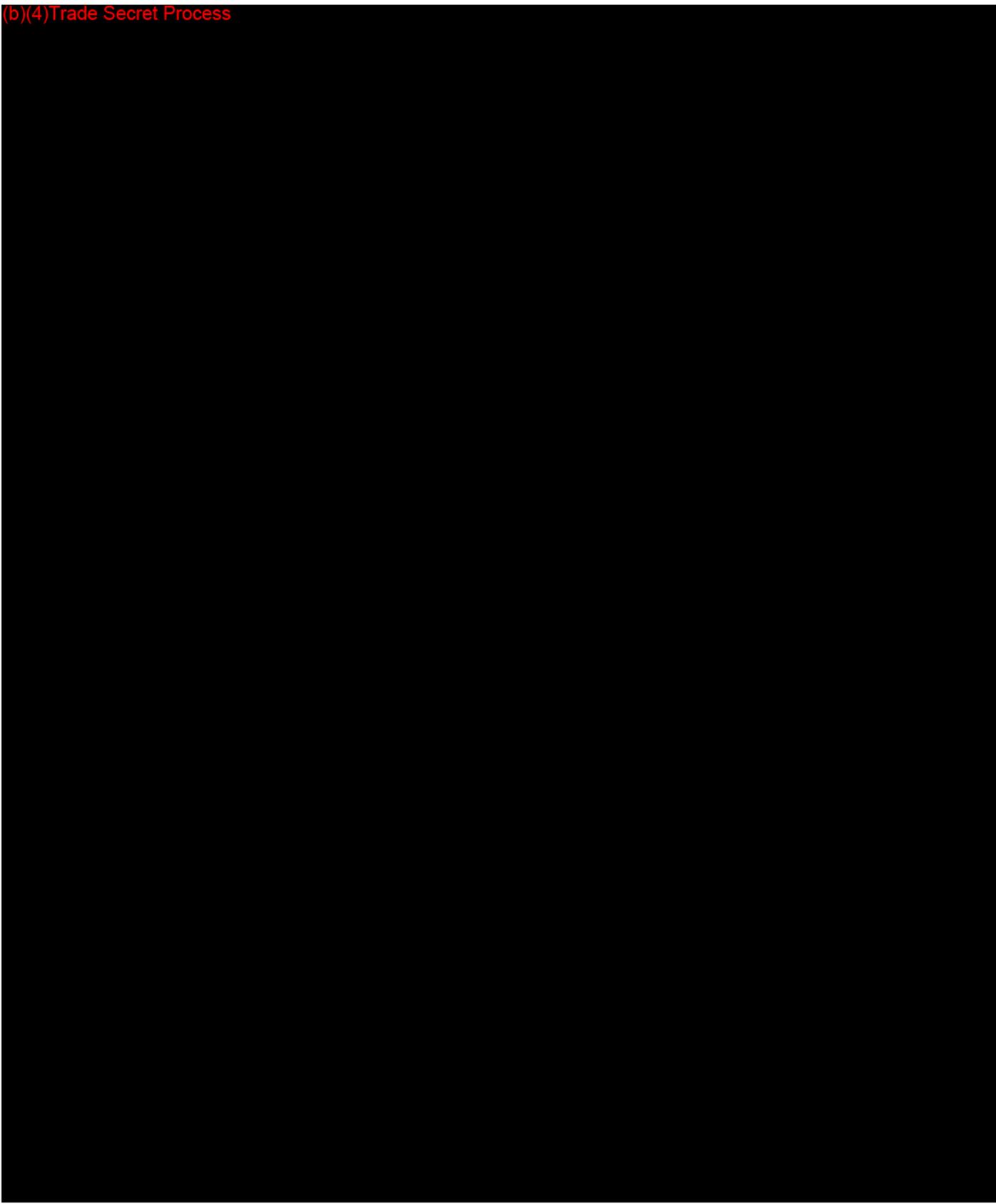
(b)(4)Trade Secret Process



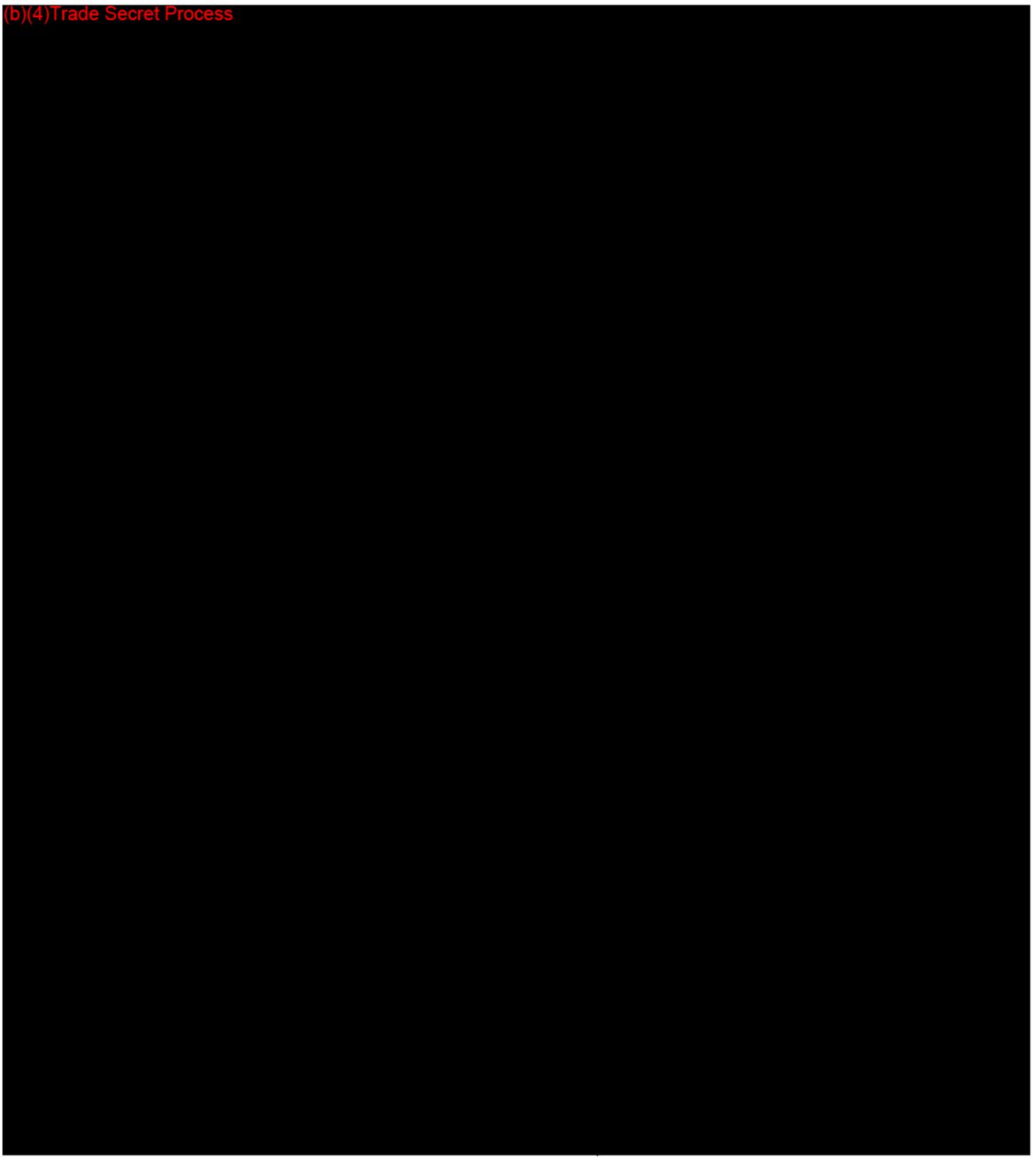
(b)(4) Trade Secret Process



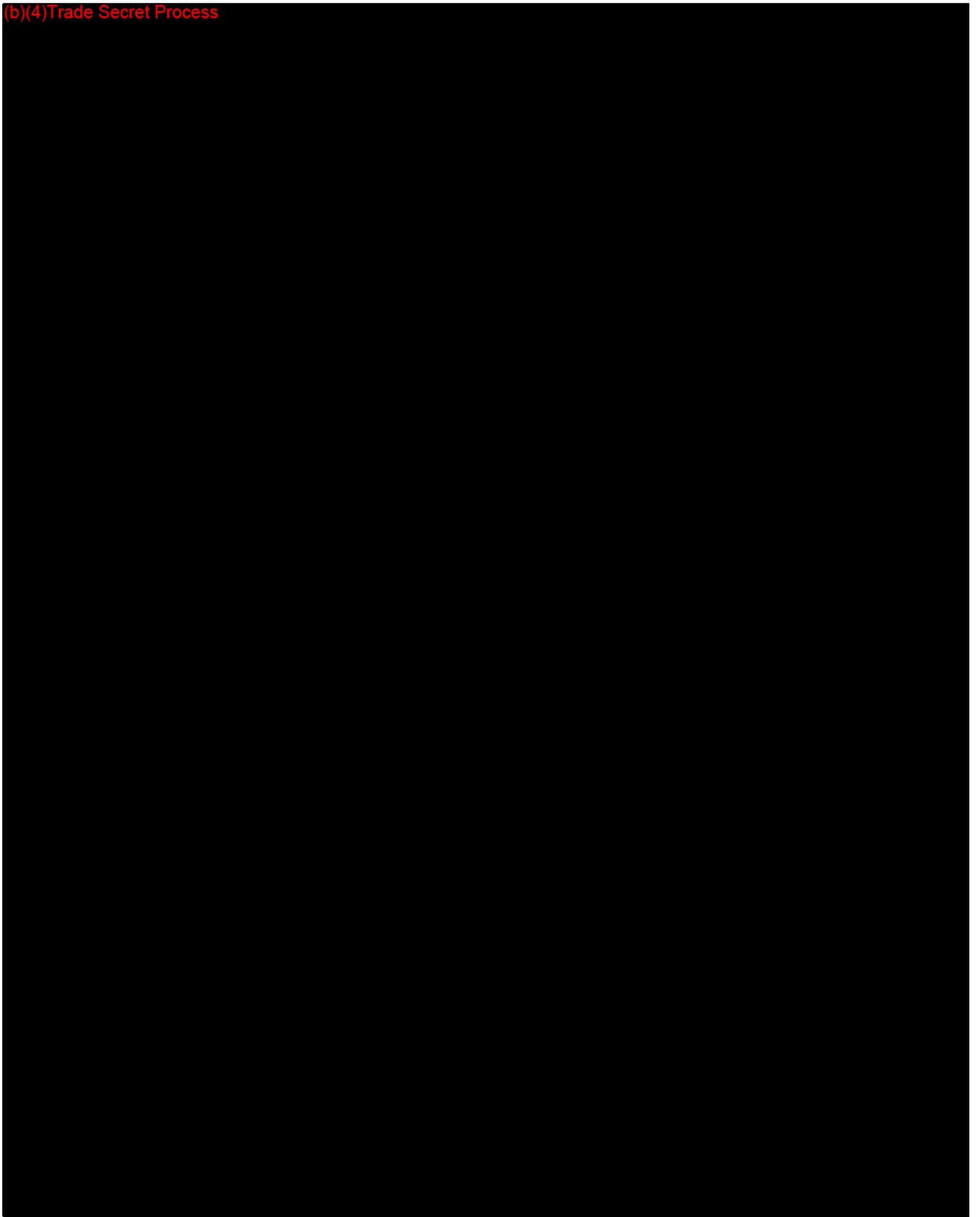
(b)(4)Trade Secret Process



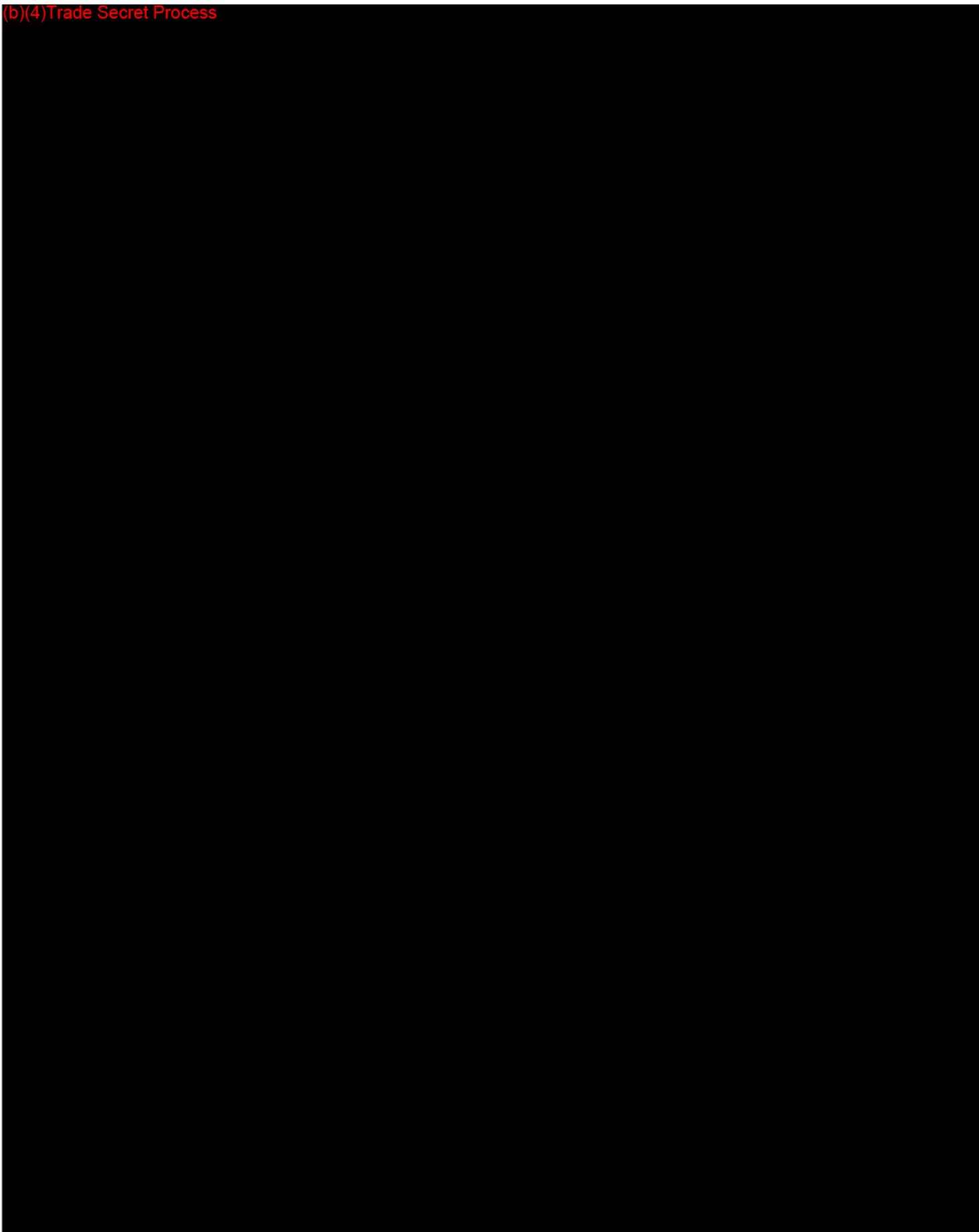
(b)(4)Trade Secret Process



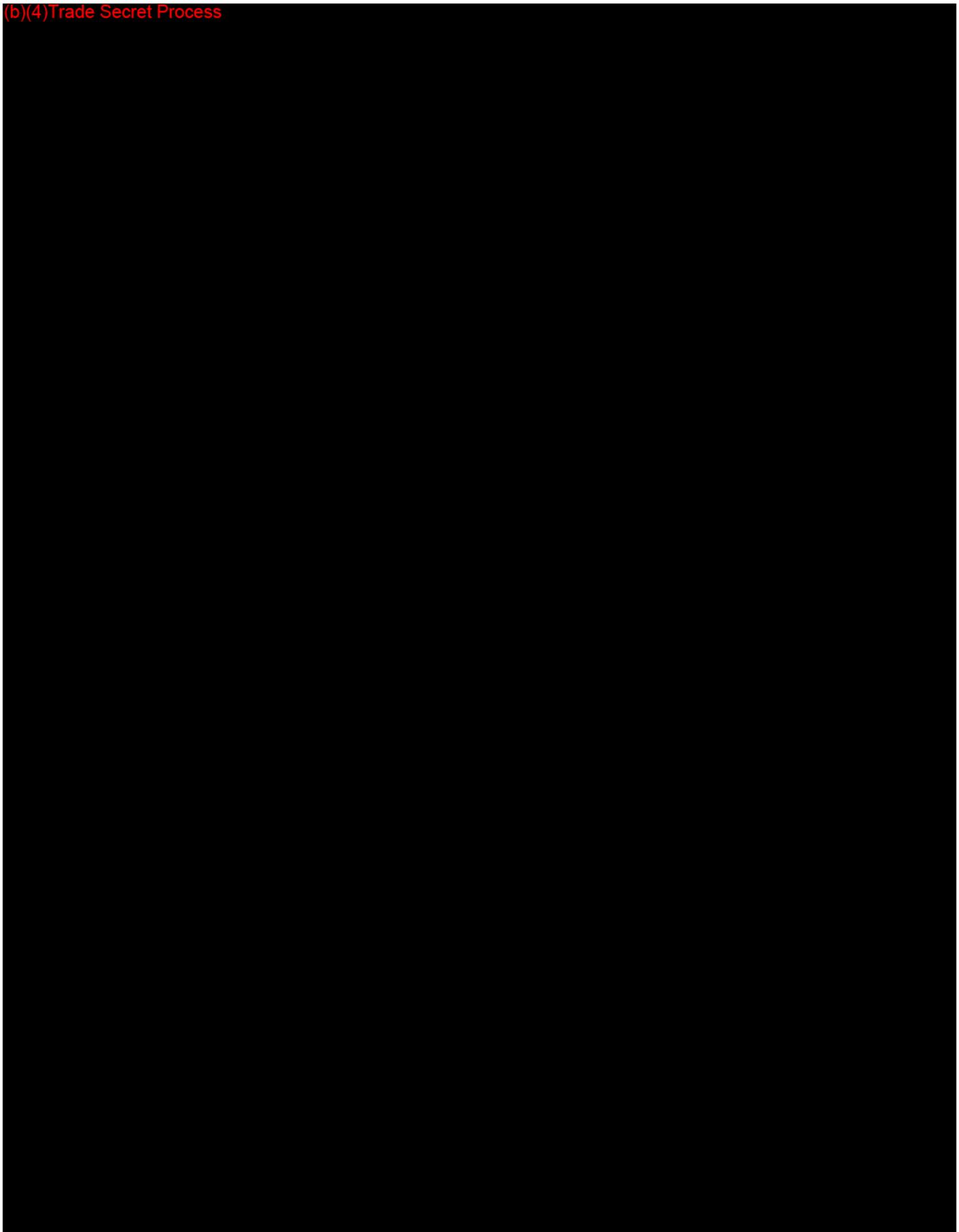
(b)(4)Trade Secret Process



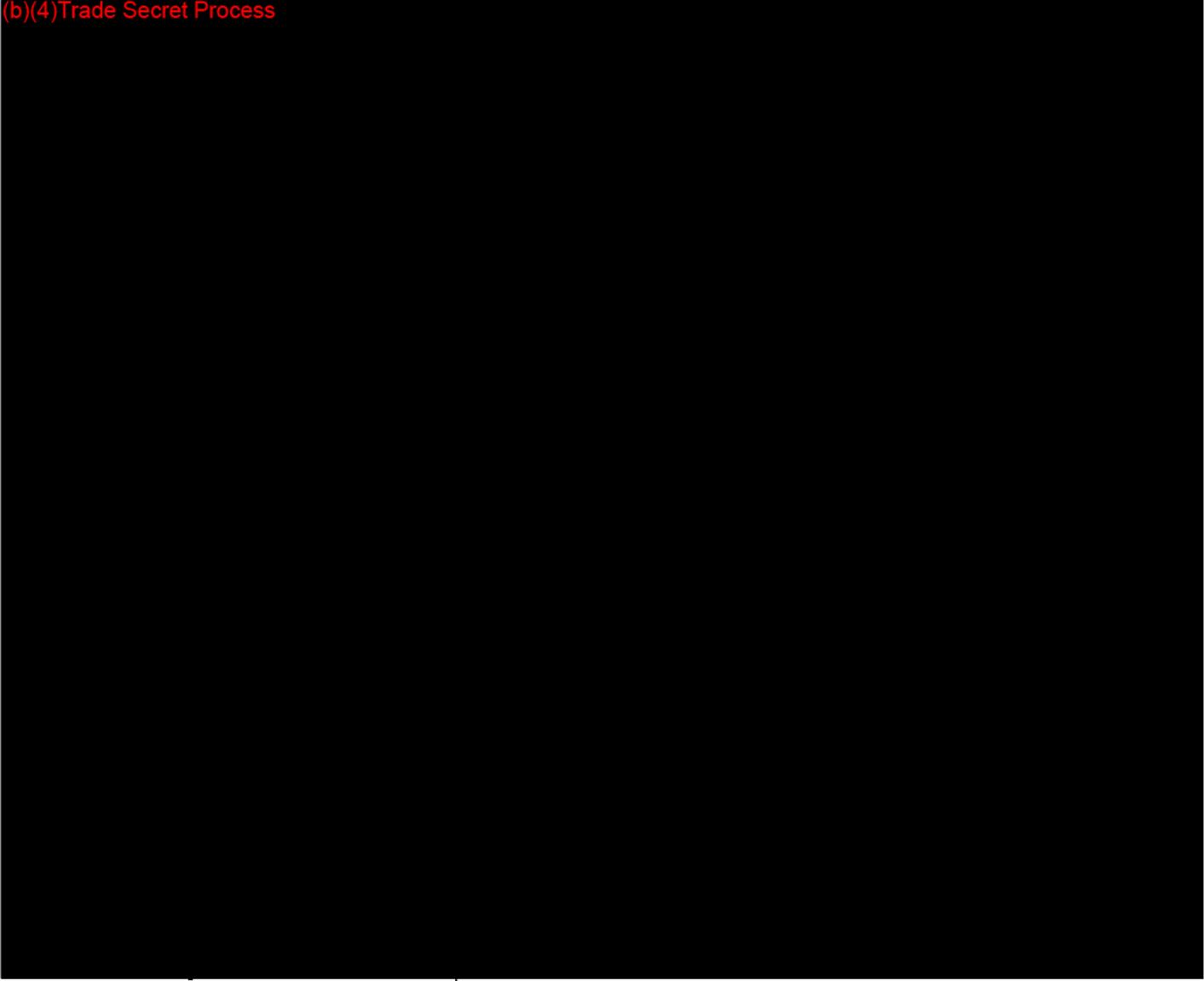
(b)(4) Trade Secret Process



(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



XII. Performance Testing – Animal N/A

XIII. Performance Testing – Clinical N/A

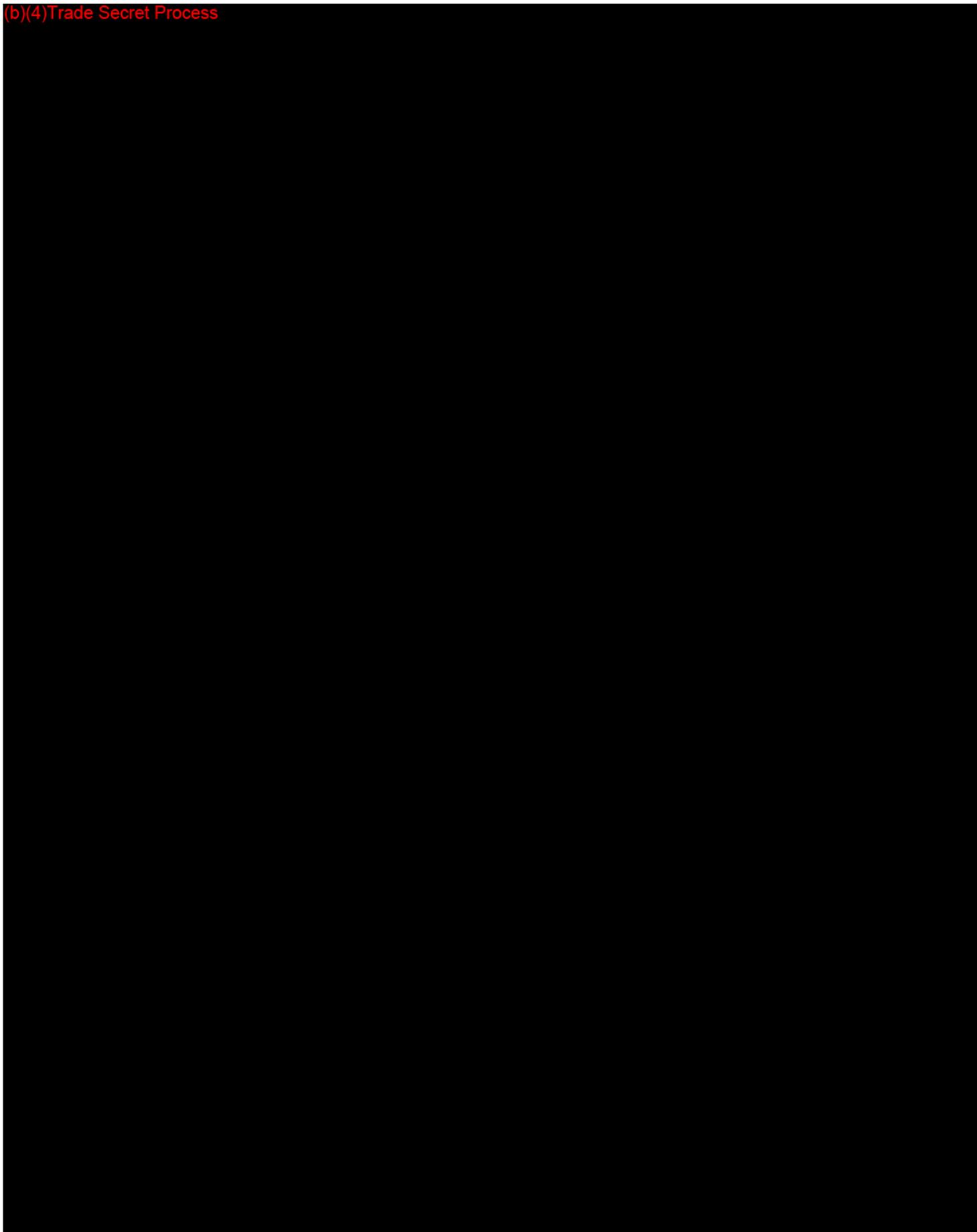
XIV. Substantial Equivalence Discussion

	Yes	No
1. Is Product A Device	X	If NO = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X	If NO = Stop, see 510(k) staff
3. Same Indication Statement?	X	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
5. Same Technological Characteristics?	X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	X	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
9. Accepted Scientific Methods Exist?		If NO = Stop NSE
10. Performance Data Available?		If NO = Request Data
11. Data Demonstrate Equivalence?		Final Decision:

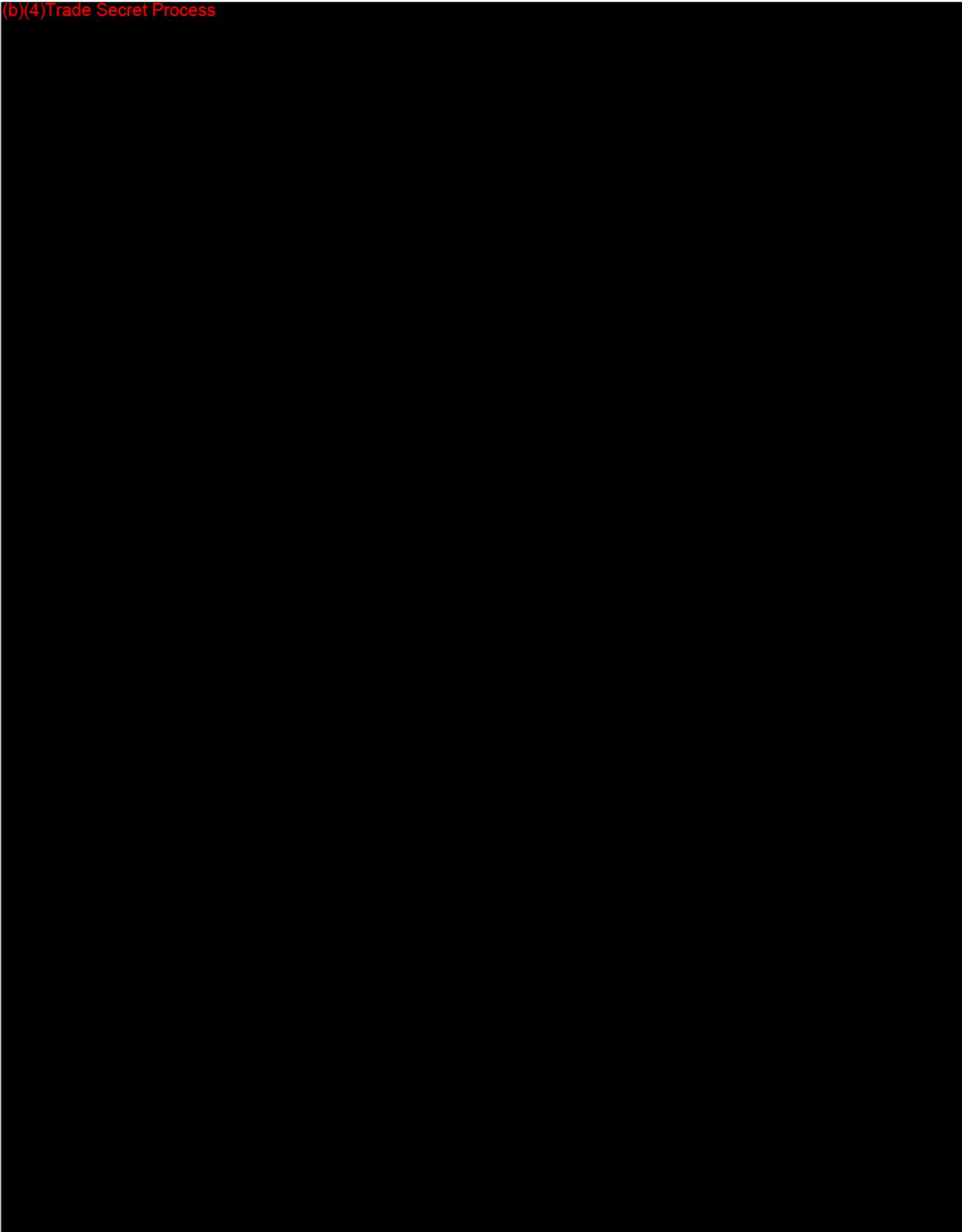
(b)(4) Trade Secret Process

(b)(4) Trade Secret Process

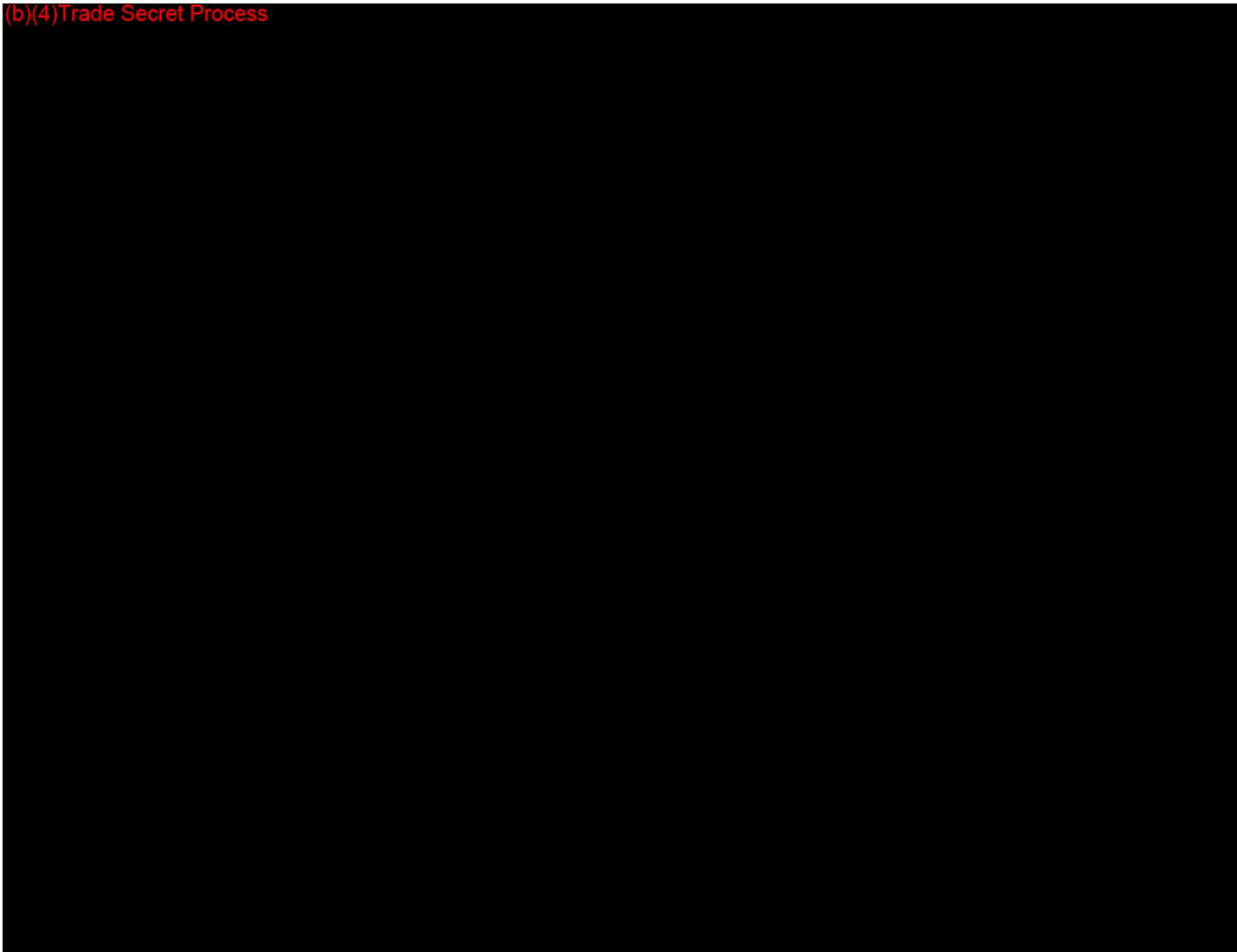
(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



(b)(4)Trade Secret Process

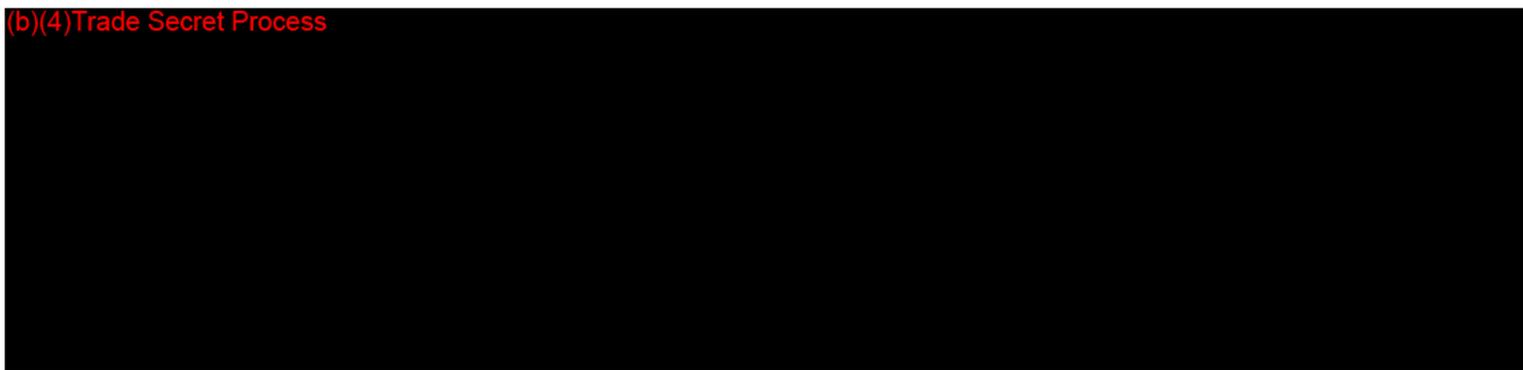


XVI. Contact History

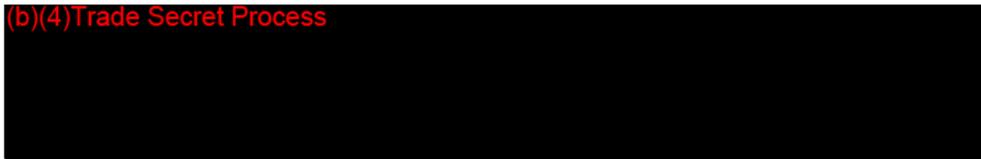
From: Gantenberg, Julie *
Sent: Wednesday, July 18, 2007 12:18 PM
To: 'trish.jenks@zimmer.com'
Cc: Gantenberg, Julie *; Foy, Jonette
Subject: K071535 (b) [REDACTED]
Importance: High

Dear Ms. Jenks,

(b)(4)Trade Secret Process



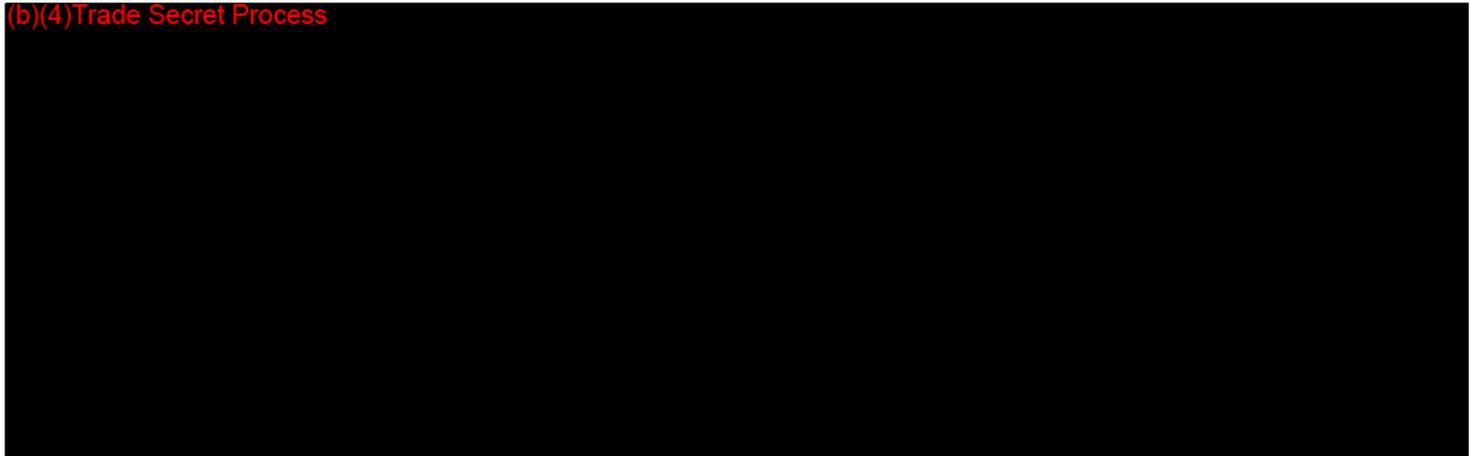
(b)(4)Trade Secret Process



Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

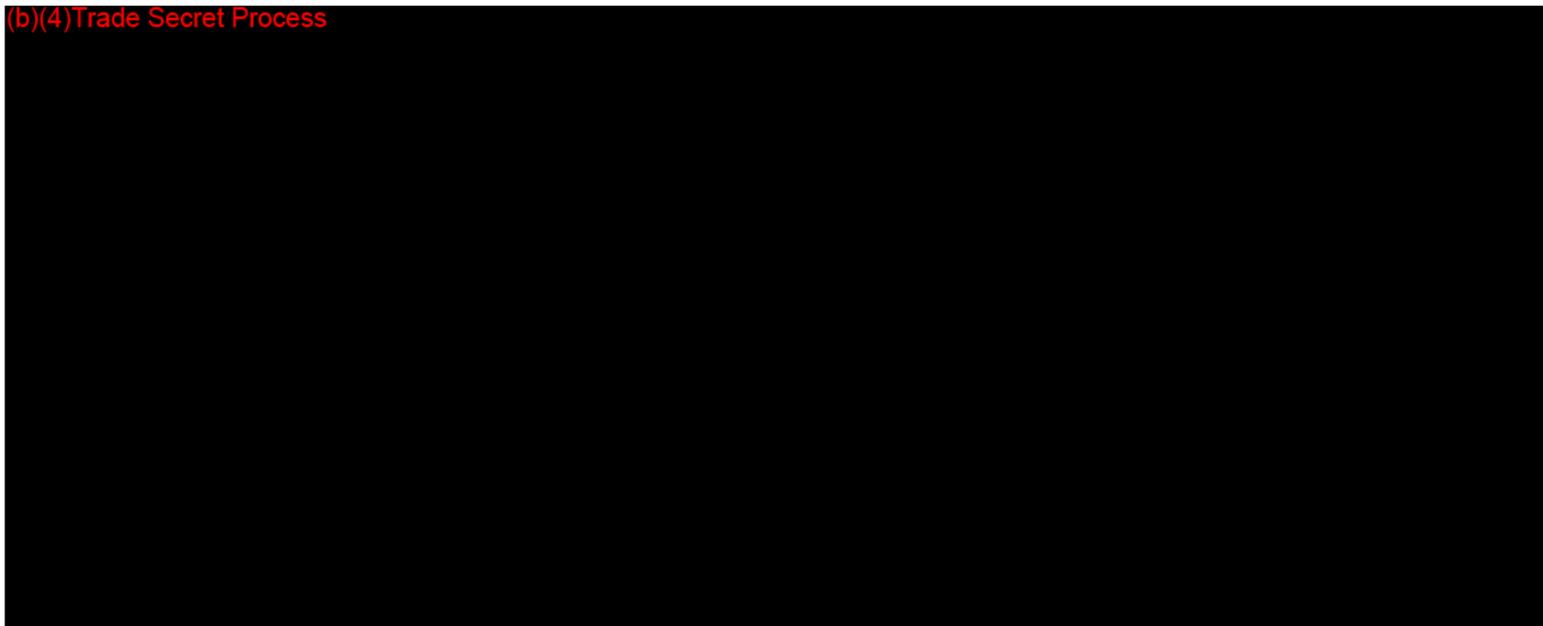
(b)(4)Trade Secret Process



From: Gantenberg, Julie *
Sent: Friday, September 28, 2007 11:21 AM
To: 'trish.jenks@zimmer.com'
Cc: Gantenberg, Julie *; Foy, Jonette
Subject: RE: K071535 (b)(4)Trade Secret Process
Importance: High

Dear Ms. Jenks,

(b)(4)Trade Secret Process



Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

(b)(4)Trade Secret Process



From: Trish Jenks [mailto:trish.jenks@zimmer.com]
Sent: Tuesday, October 09, 2007 9:35 AM
To: Gantenberg, Julie *
Cc: Gilbertson, Leslie N; Heck, Natalie S.
Subject: K071535 Teleconference

Hello Julie,

(b)(4)Trade Secret Process



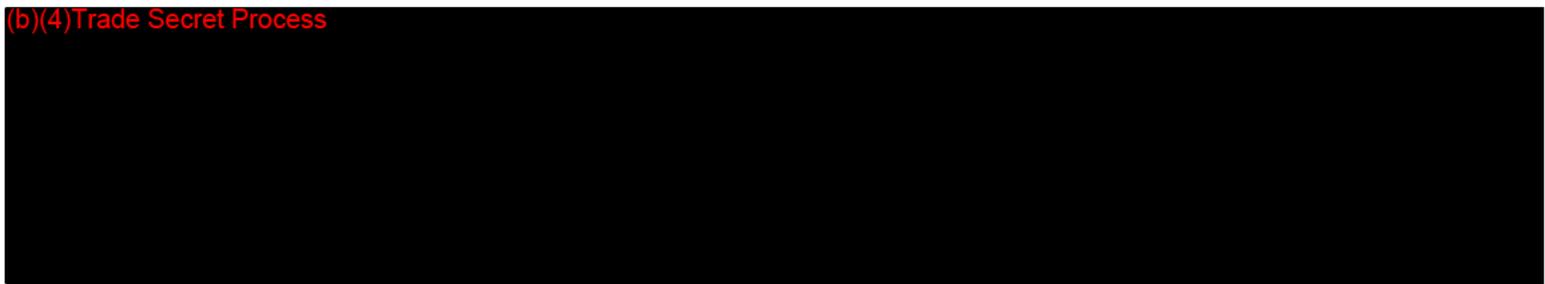
Thank you.

Sincerely,
Trish
Trish Jenks, BSN, RN,C
Specialist, Regulatory Affairs
Zimmer, Inc.
574.371.8354

From: Trish Jenks [mailto:trish.jenks@zimmer.com]
Sent: Wednesday, October 10, 2007 2:40 PM
To: Gantenberg, Julie *
Subject: RE: K071535 Teleconference

Dear Julie,

(b)(4)Trade Secret Process



Thank you.

Sincerely,
Trish
Trish Jenks, BSN, RN,C

Specialist, Regulatory Affairs
Zimmer, Inc.

From: Trish Jenks [mailto:trish.jenks@zimmer.com]
Sent: Monday, October 15, 2007 4:40 PM
To: Gantenberg, Julie *
Subject: Follow-up to Teleconference

Hello Julie,

(b)(4)Trade Secret Process



Thank you,
Trish
Trish Jenks, BSN, RN,C
Specialist, Regulatory Affairs
Zimmer, Inc.
574.371.8354

(b)(4)Trade Secret Process



The reviewer's contact information is as follows:

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

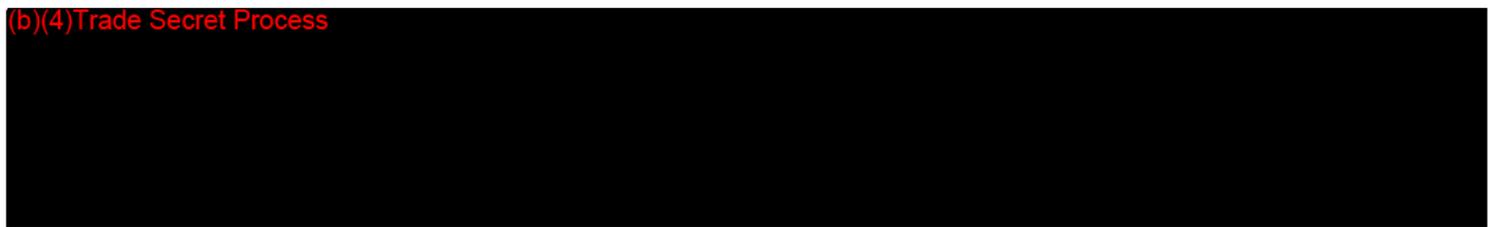
If you have any questions for us prior to contacting the FDA, please do not hesitate to ask.

With Zimmer's sincere thanks and best regards,
Trish
Trish Jenks, BSN, RN,C
Specialist, Regulatory Affairs
Zimmer, Inc.
574.371.8354

From: Gantenberg, Julie * [mailto:julie.gantenberg@fda.hhs.gov]
Sent: Tuesday, October 16, 2007 9:42 AM
To: trish.jenks@zimmer.com
Cc: Foy, Jonette; Gantenberg, Julie *
Subject: RE: Follow-up to Teleconference

Dear Trish,

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

Thanks,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

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From: (b)(4)Trade Secret Process
Sent: Wednesday, October 17, 2007 12:50 PM
To: Gantenberg, Julie *
Cc: trish.jenks@zimmer.com; (b)(4)Trade Secret Process
Subject: (b)

Dear Mrs Gantenberg,

(b)(4)Trade Secret Process

From: Gantenberg, Julie *
Sent: Wednesday, October 17, 2007 11:59 AM
To: (b)(4)Trade
Cc: trish.jenks@zimmer.com; (b)(4)Trade Secret Process; Foy, Jonette; Allen, Peter; Gantenberg, Julie *
Subject: (b)(4)Trade Secret Process

Dear (b)(4)Trad

Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

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From: Trish Jenks [mailto:trish.jenks@zimmer.com]
Sent: Wednesday, October 17, 2007 1:26 PM
To: Gantenberg, Julie *
Subject: FW: Follow-up to Teleconference

Dear Julie,

(b)(4)Trade Secret Process

Sincerely,
Trish

Trish Jenks, BSN, RN,C
Specialist, Regulatory Affairs
Zimmer, Inc.
574.371.8354

From: Gantenberg, Julie * [mailto:julie.gantenberg@fda.hhs.gov]
Sent: Tuesday, November 13, 2007 11:15 AM
To: trish.jenks@zimmer.com
Cc: Gantenberg, Julie *; Foy, Jonette
Subject: K071535/S2 additional information needed ASAP
Importance: High

Dear Trish,

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process



Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

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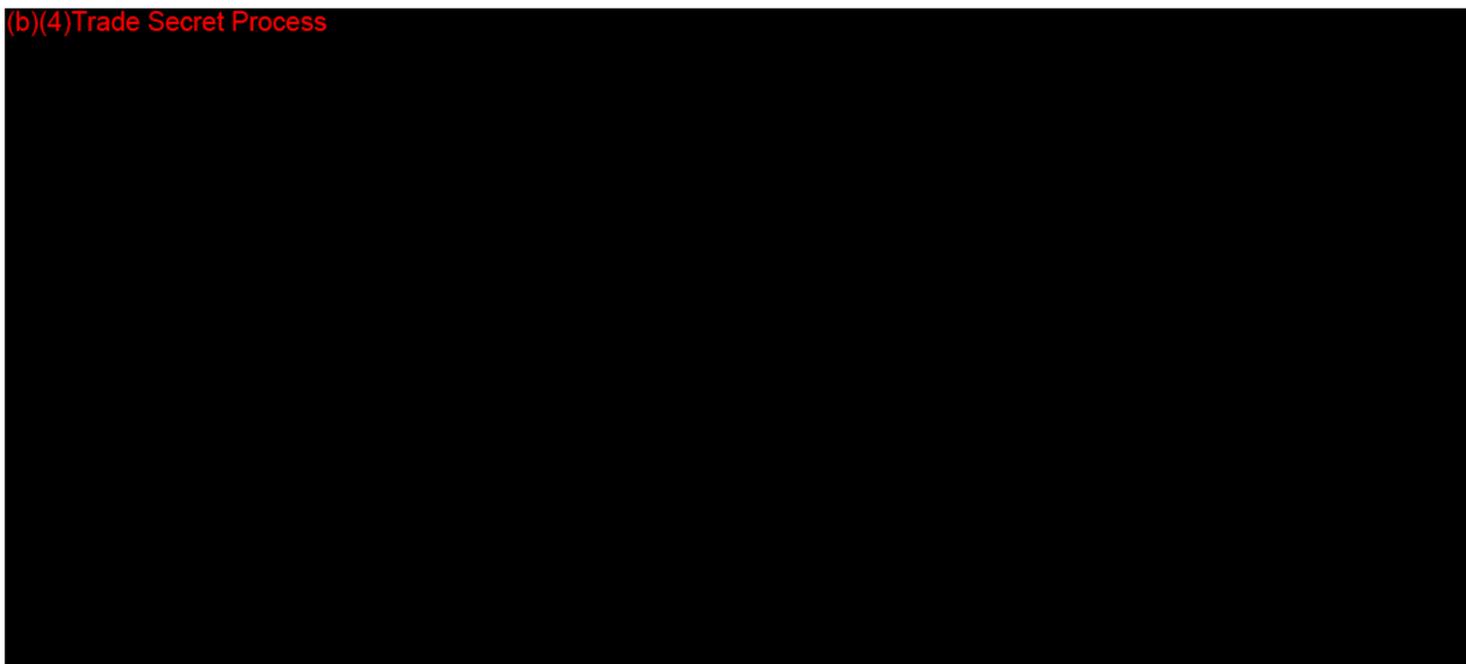
(b)(4)Trade Secret Process



From: Trish Jenks [mailto:trish.jenks@zimmer.com]
Sent: Wednesday, November 14, 2007 4:45 PM
To: Gantenberg, Julie *
Cc: Foy, Jonette
Subject: RE: K071535/S2 additional information needed ASAP

Dear Julie,

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

Thank you.

Sincerely,
Trish
Trish Jenks, BSN, RN,C
Specialist, Regulatory Affairs
Zimmer, Inc.
574.371.8354

XVII. Recommendation

(b)(4)Trade Secret Process

Gantenberg _____
Reviewer

 _____
Branch Chief

11/15/07 _____
Date

11/16/07 _____
Date



COVER SHEET MEMORANDUM

From: Reviewer Name Gantenberg
Subject: 510(k) Number K071535/S1
To: The Record

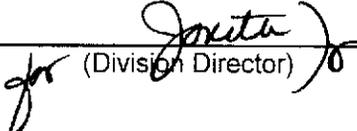
Please list CTS decision code _____
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 Hold (Additional Information or **Telephone Hold**).
 Final Decision (**SE**, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page (p.26)	Attach IFU	X	
510(k) Summary /510(k) Statement (p.21)	Attach Summary	X	
Truthful and Accurate Statement (Original, p.10)	Must be present for a Final Decision		
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATEDSTANDARDSDATAFORM.DOC)			N/A
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		X

Regulation Number 21 CFR 888.3353 **Class*** II (87 Panel) **Product Code** LZO
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review:  OTDB 9/28/07
(Branch Chief) (Branch Code) (Date)

Final Review:  9/28/07
(Division Director) (Date)



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K071535/S1

Date: 9/28/07
To: The Record
From: Gantenberg

Office: ODE
Division/Branch: DGRND/OJDB

510(k) Holder: Zimmer
Device Name: BIOLOX® delta Ceramic Femoral Head
Contact: Ms. Patricia Jenks
Phone: 574-371-8354
Fax: 574-372-4605
Email: trish.jenks@zimmer.com permission to email granted in cover letter.

I. Purpose

The 510(k) holder would like to introduce BIOLOX® delta Ceramic Femoral Heads into interstate commerce.

II. Administrative Requirements

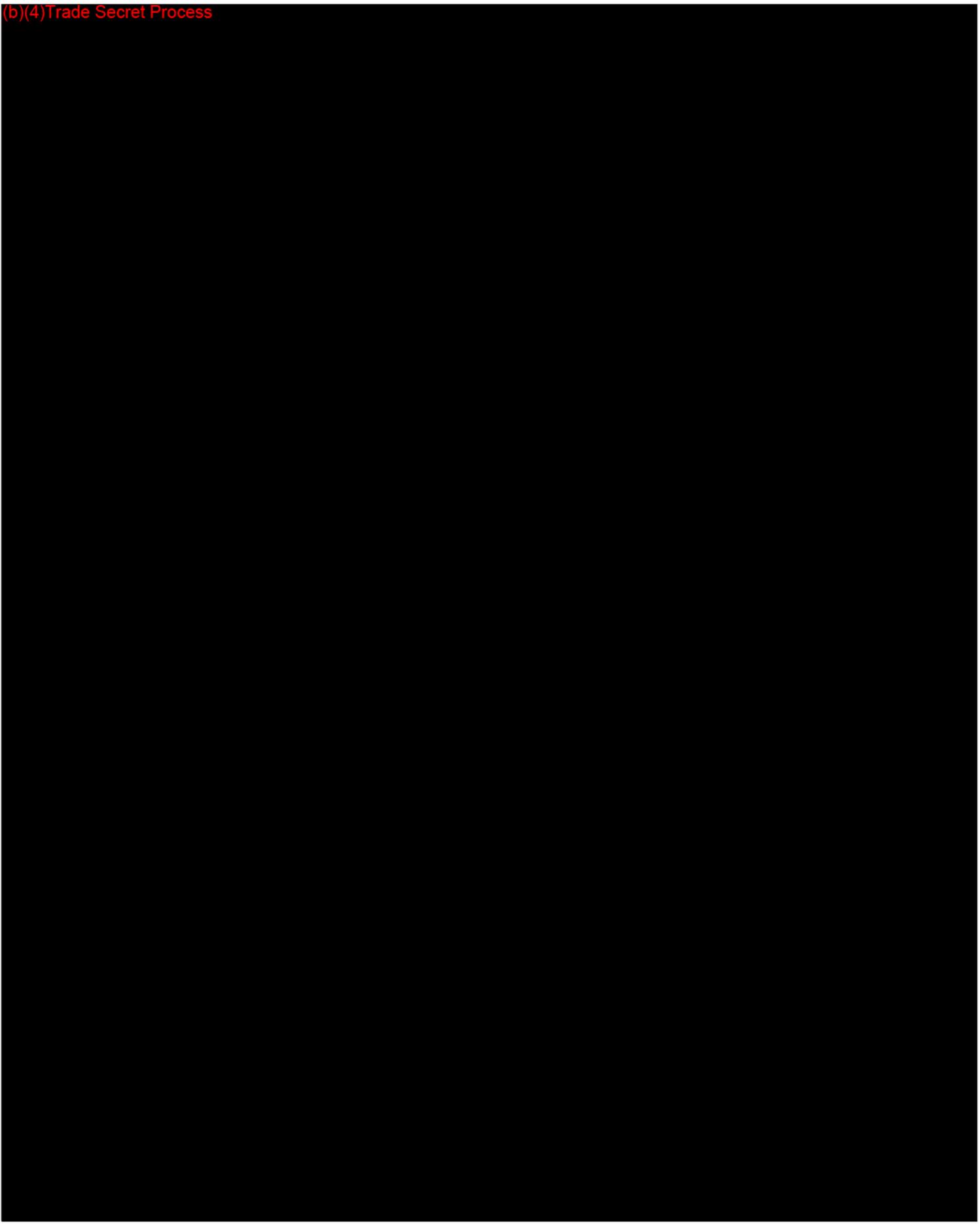
Table with 4 columns: Requirement, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

III. Device Description (Executive summary and Premarket Notification Sections)

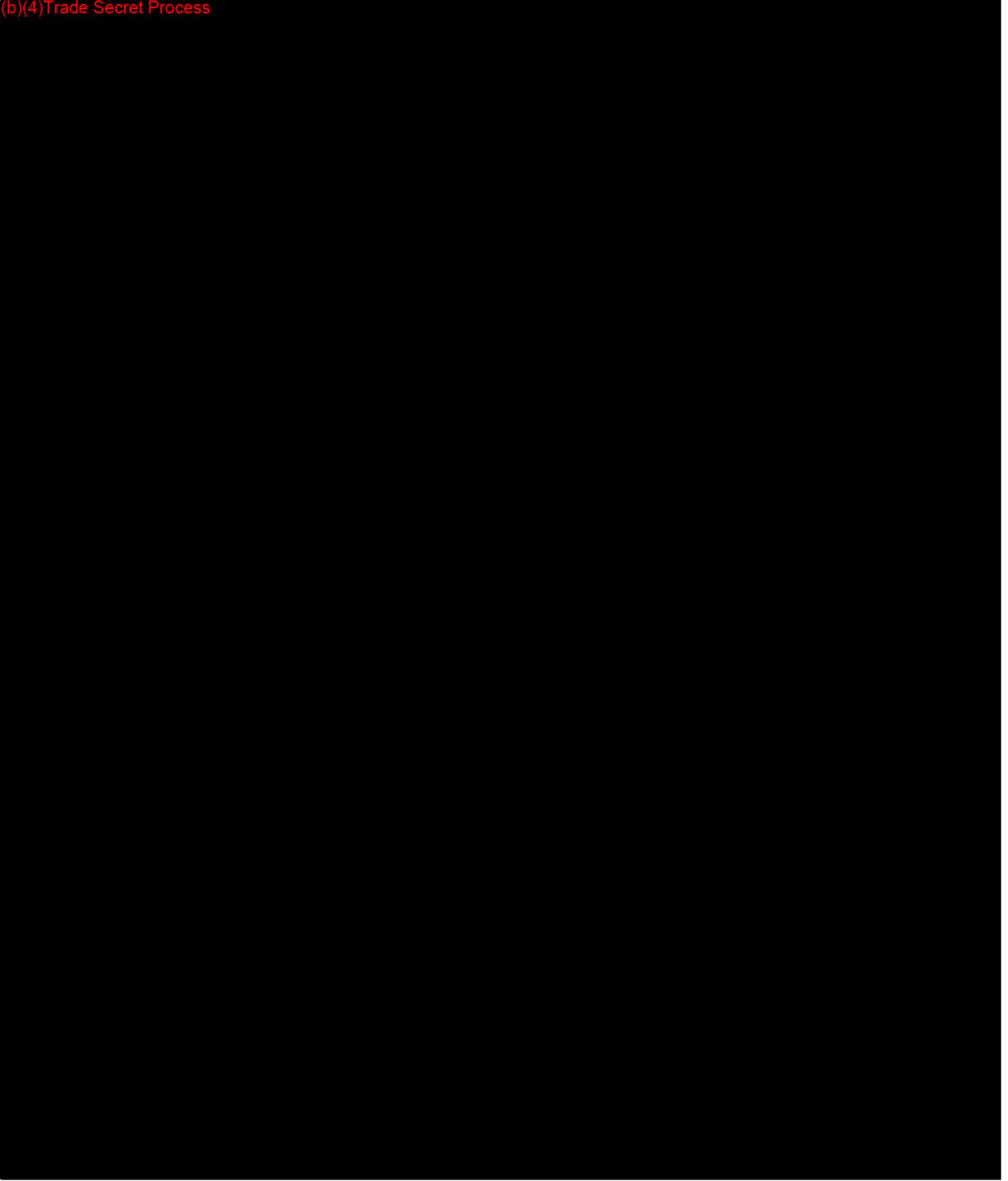
Table with 4 columns: Question, Yes, No, N/A. Rows include questions about device life-supporting, implantation, software use, sterility, reusability, and cleaning instructions.

A predicate comparison table was provided in Original, p.36.

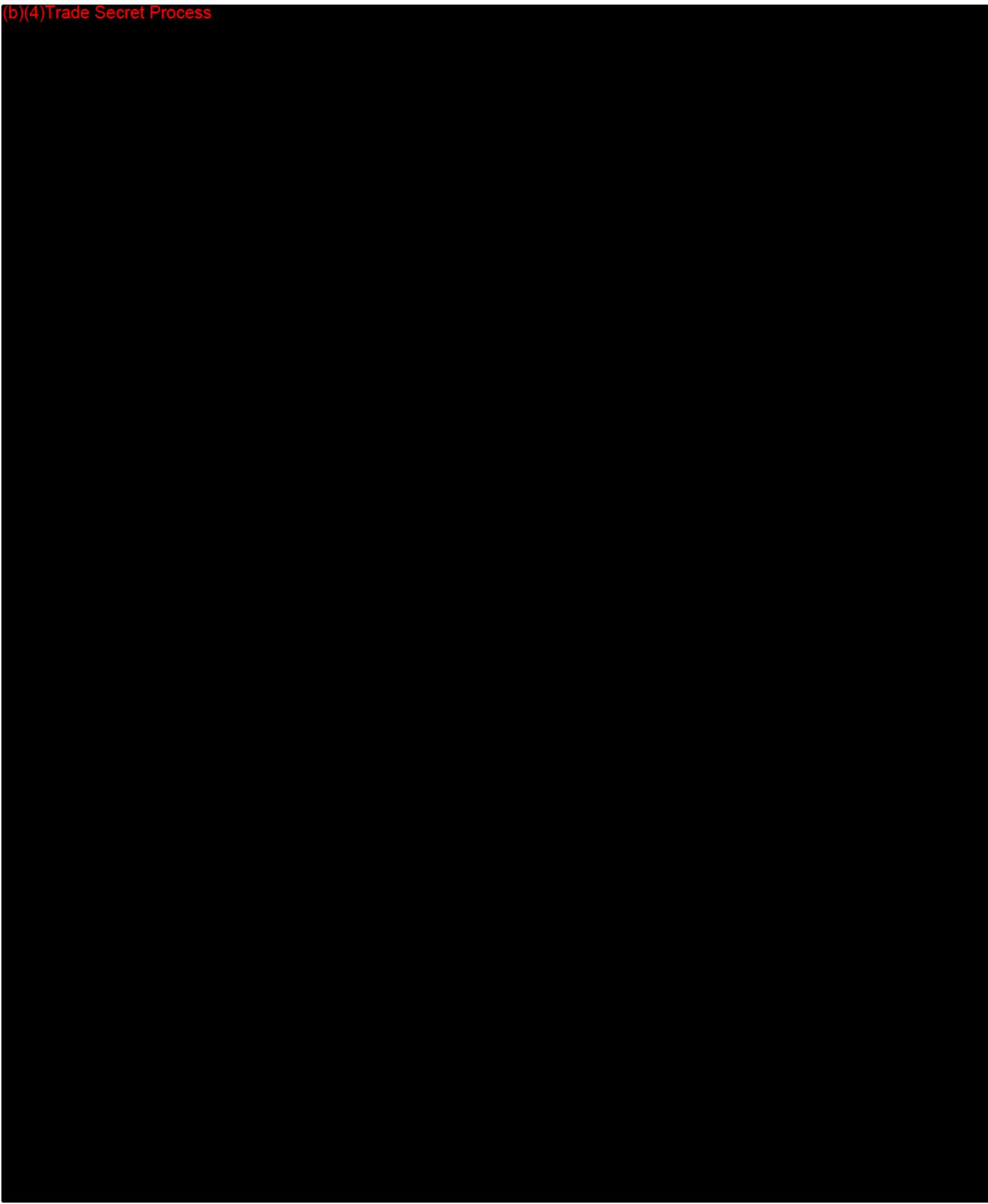
(b)(4) Trade Secret Process



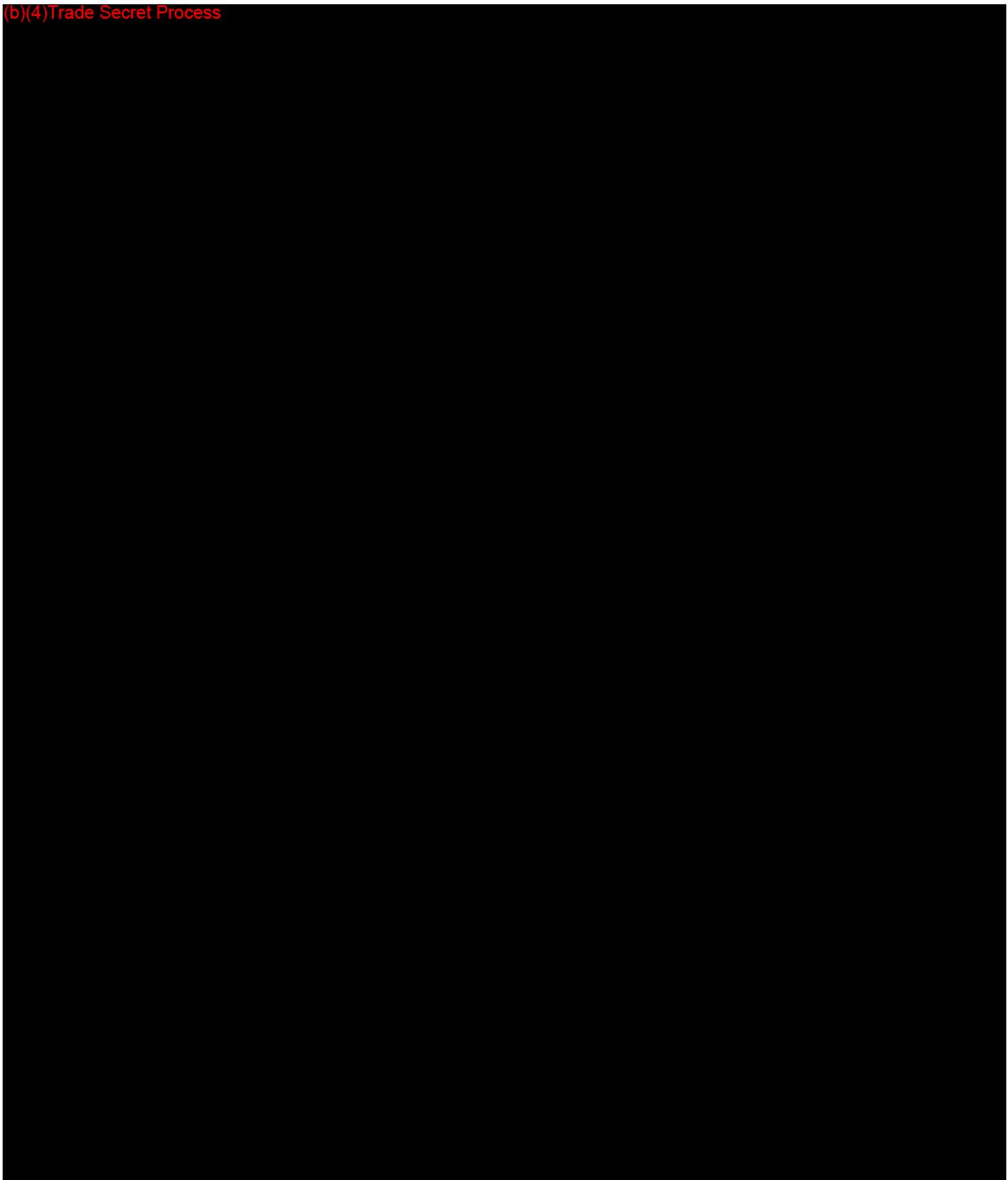
(b)(4)Trade Secret Process



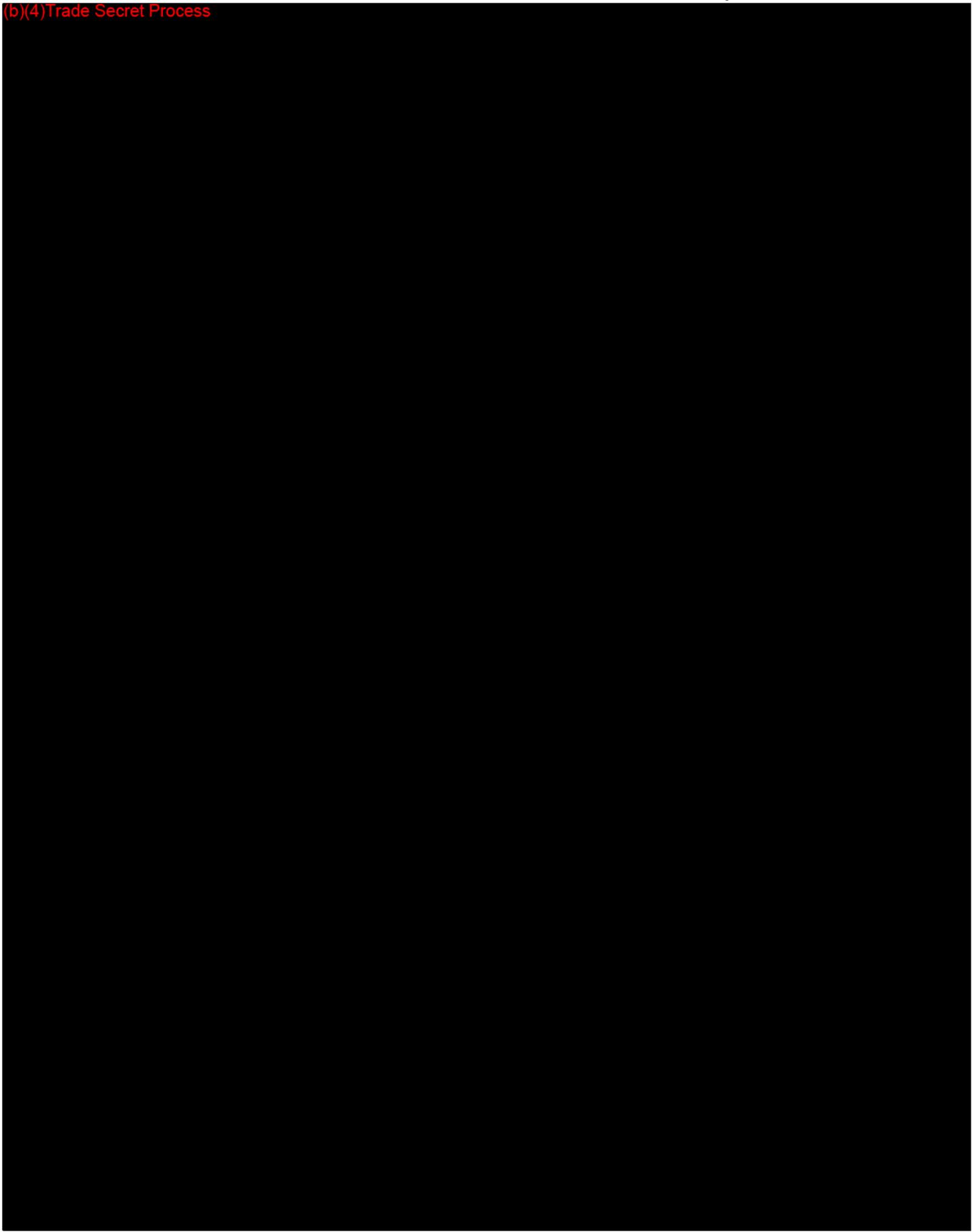
(b)(4)Trade Secret Process



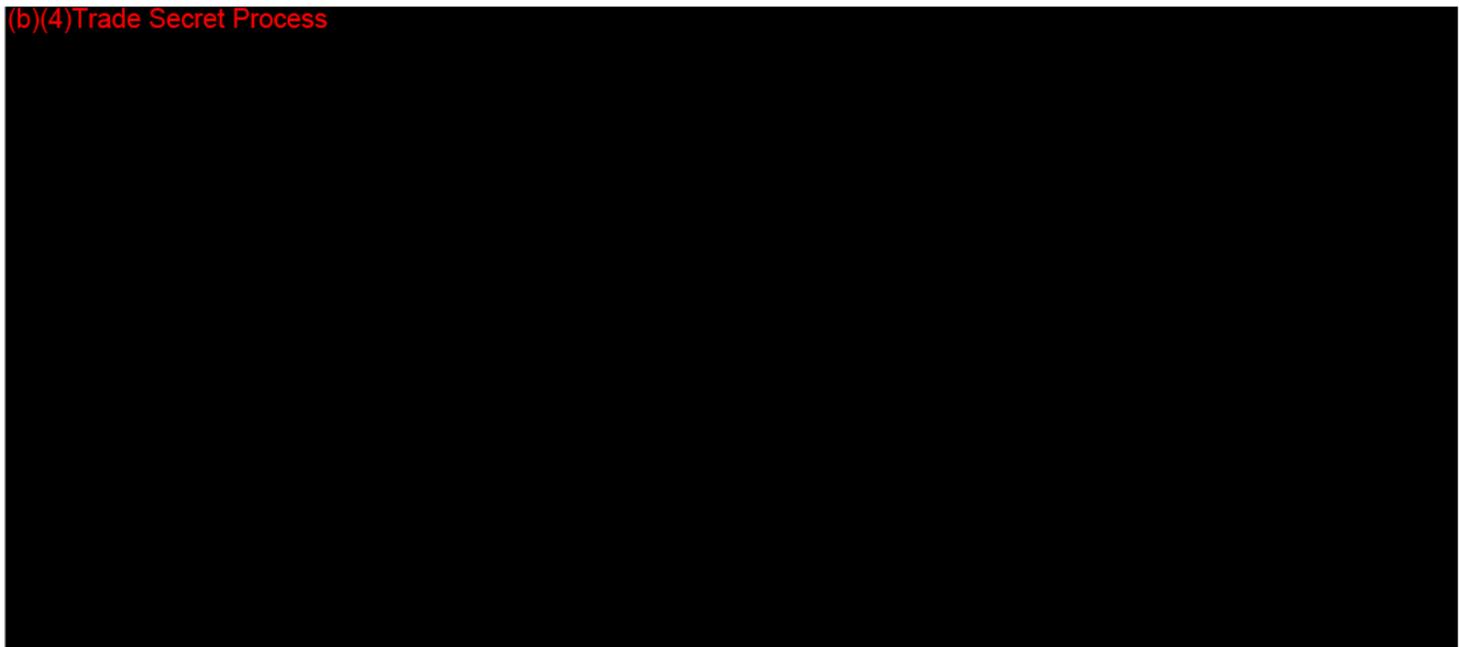
(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



Review: Adequate.

VIII. Biocompatibility

(b)(4)Trade Secret Process

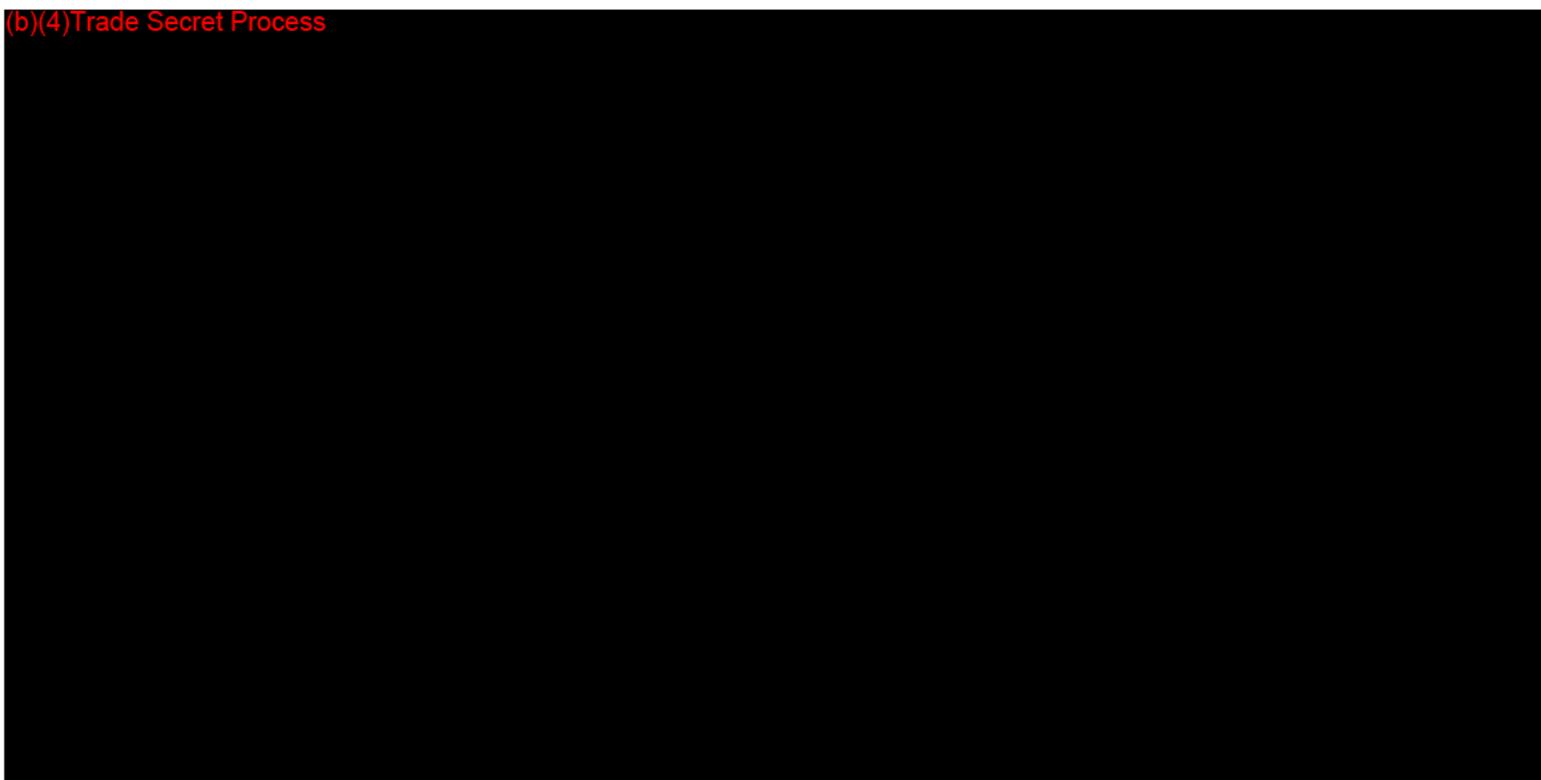


IX. Software N/A

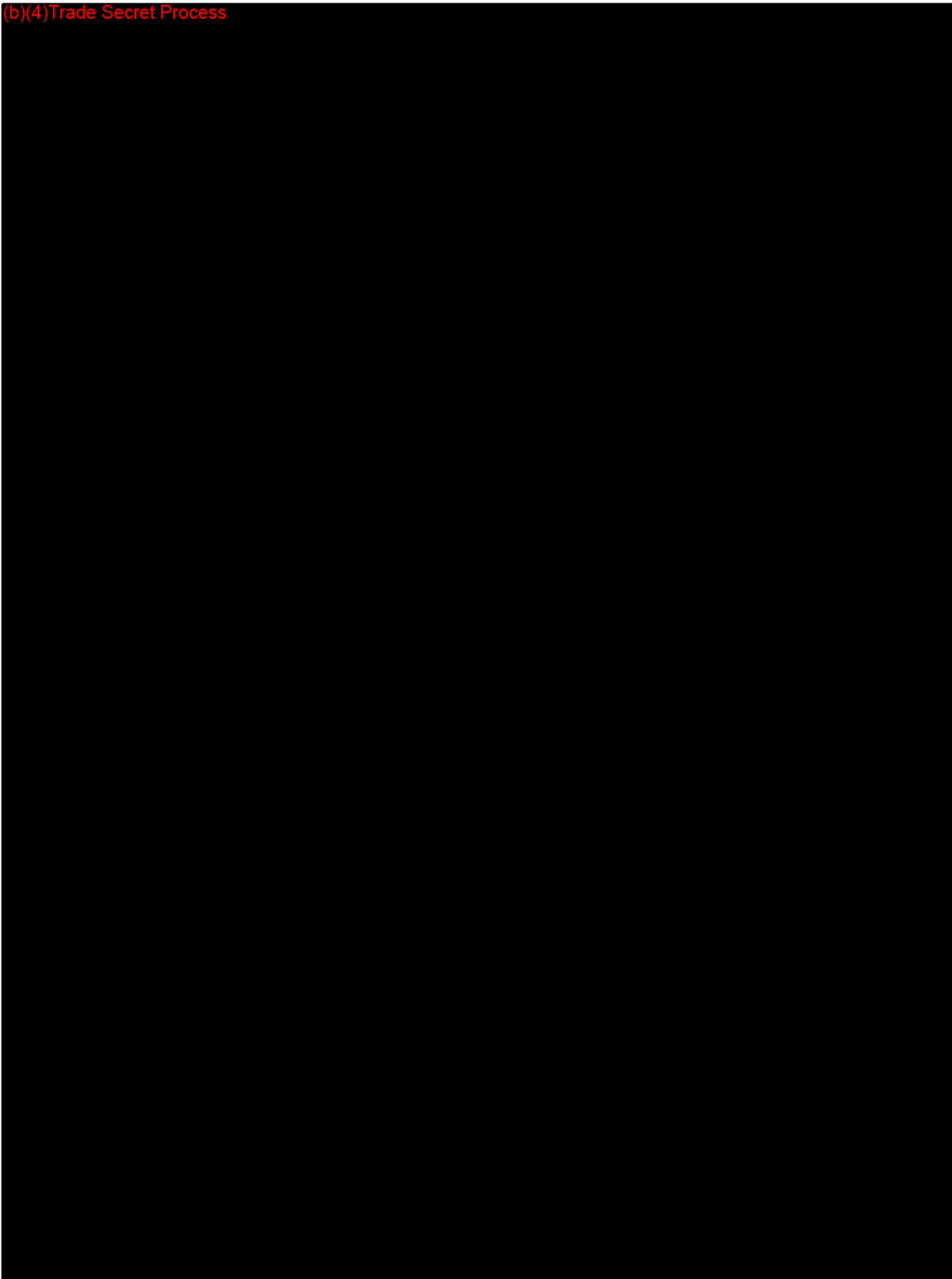
X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety N/A

XI. Performance Testing – Bench

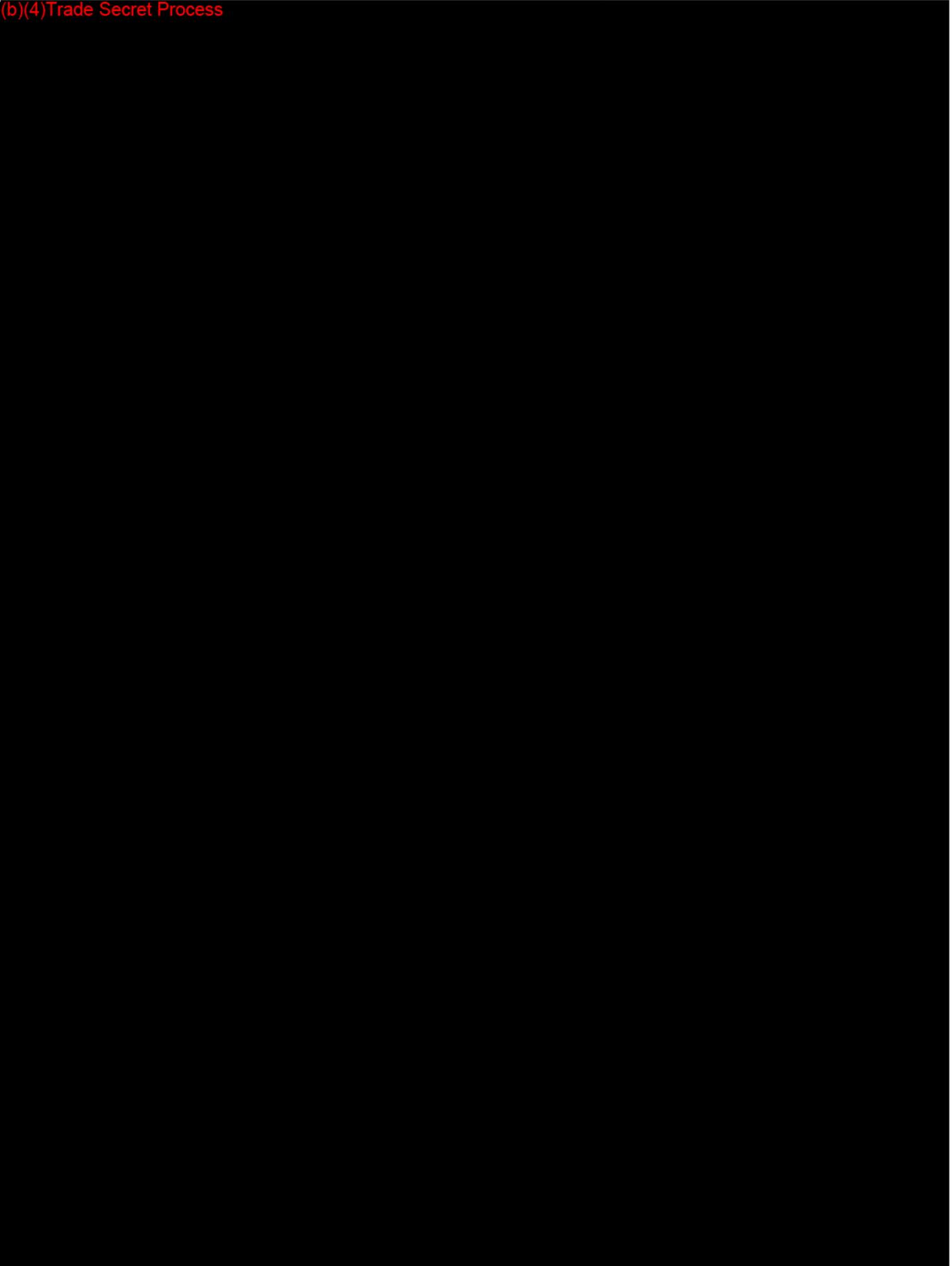
(b)(4)Trade Secret Process



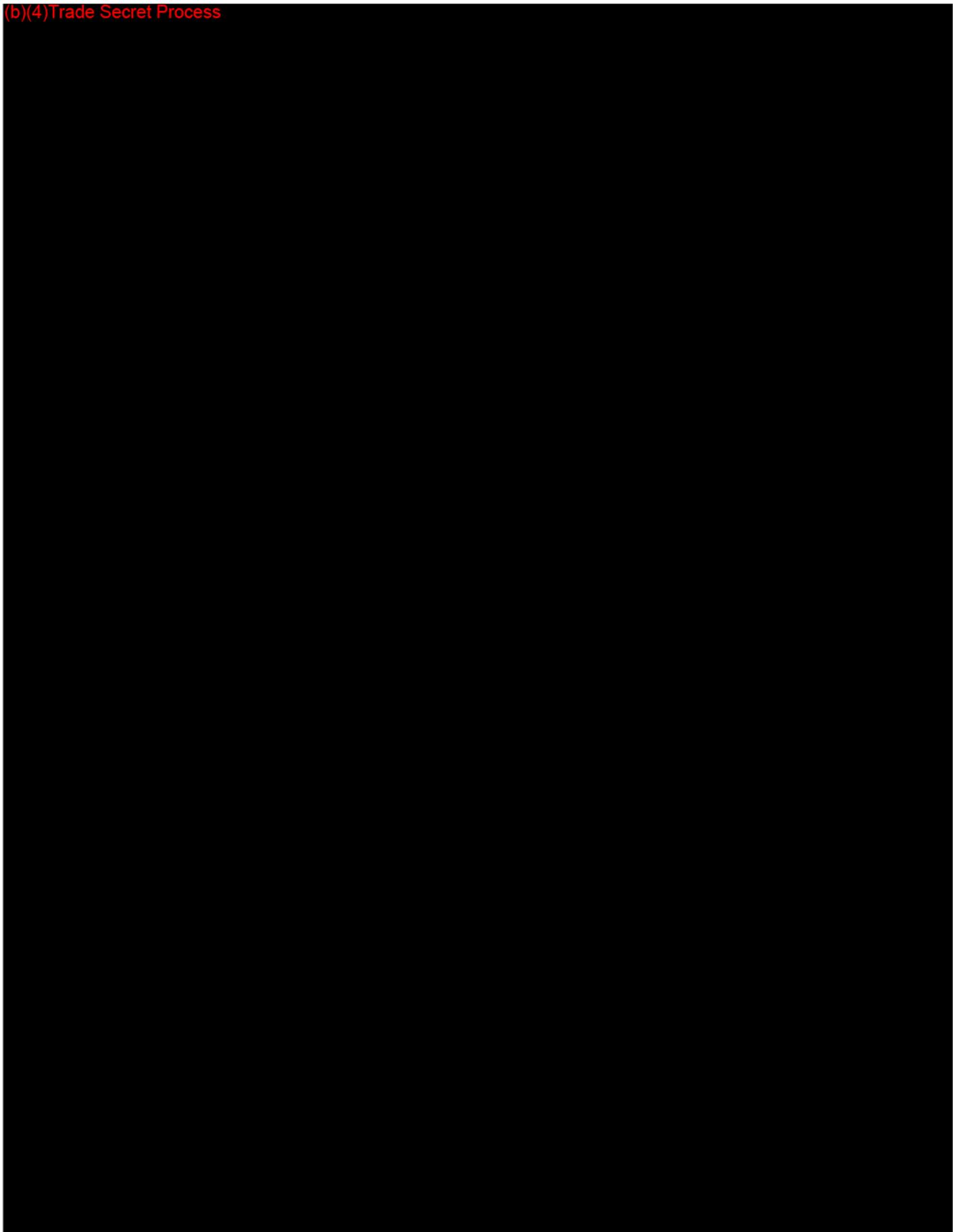
(b)(4) Trade Secret Process



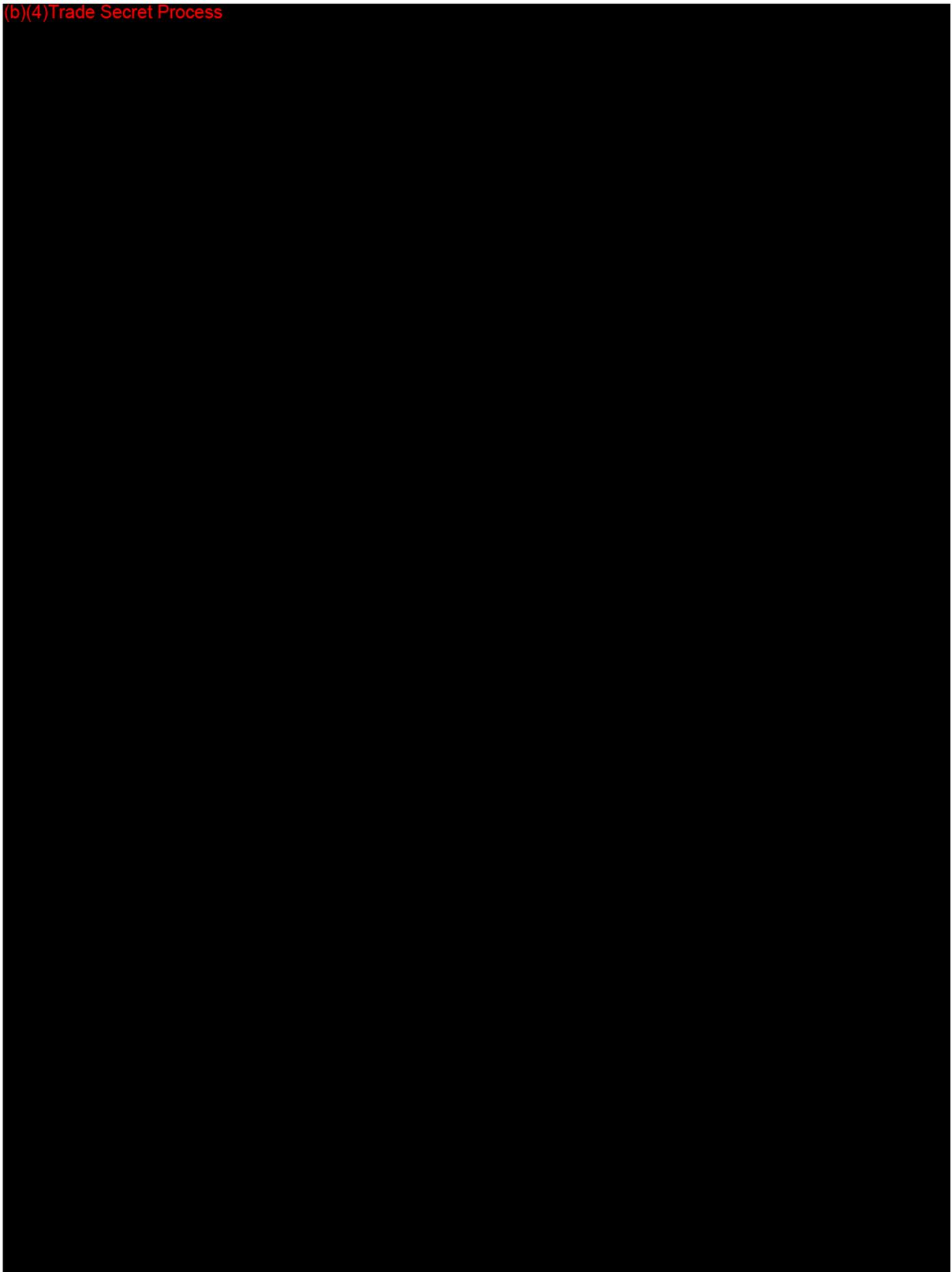
(b)(4)Trade Secret Process



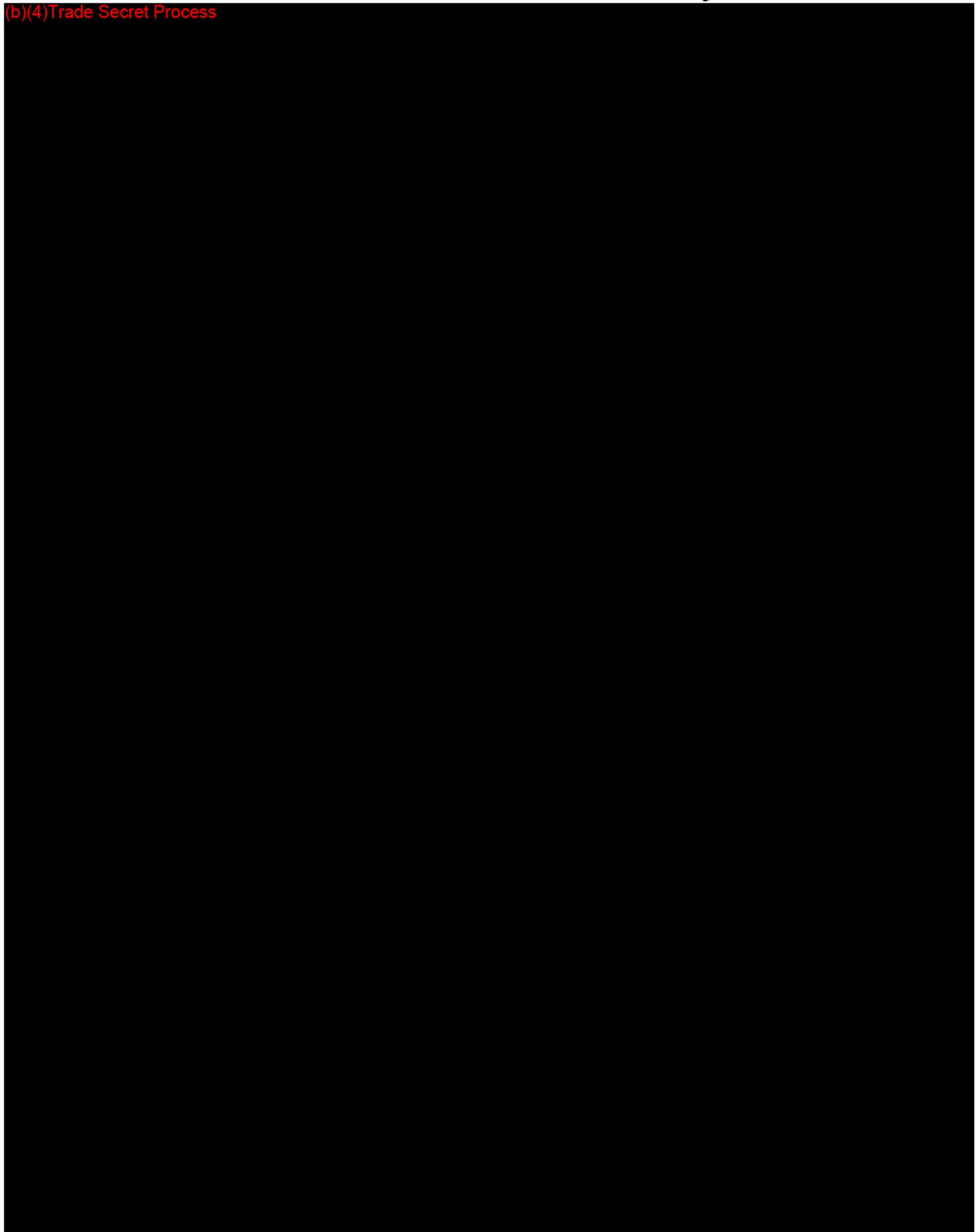
(b)(4) Trade Secret Process



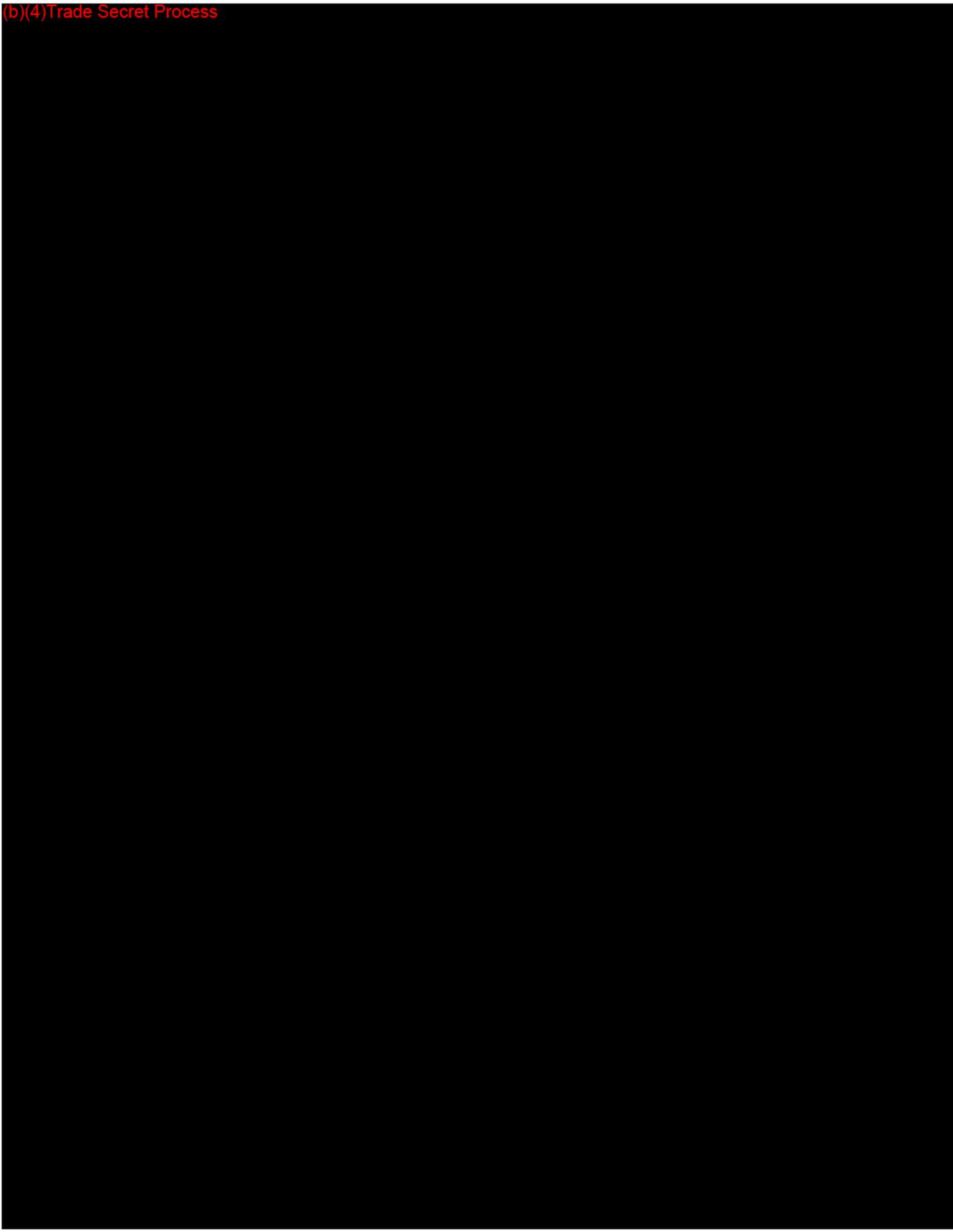
(b)(4)Trade Secret Process



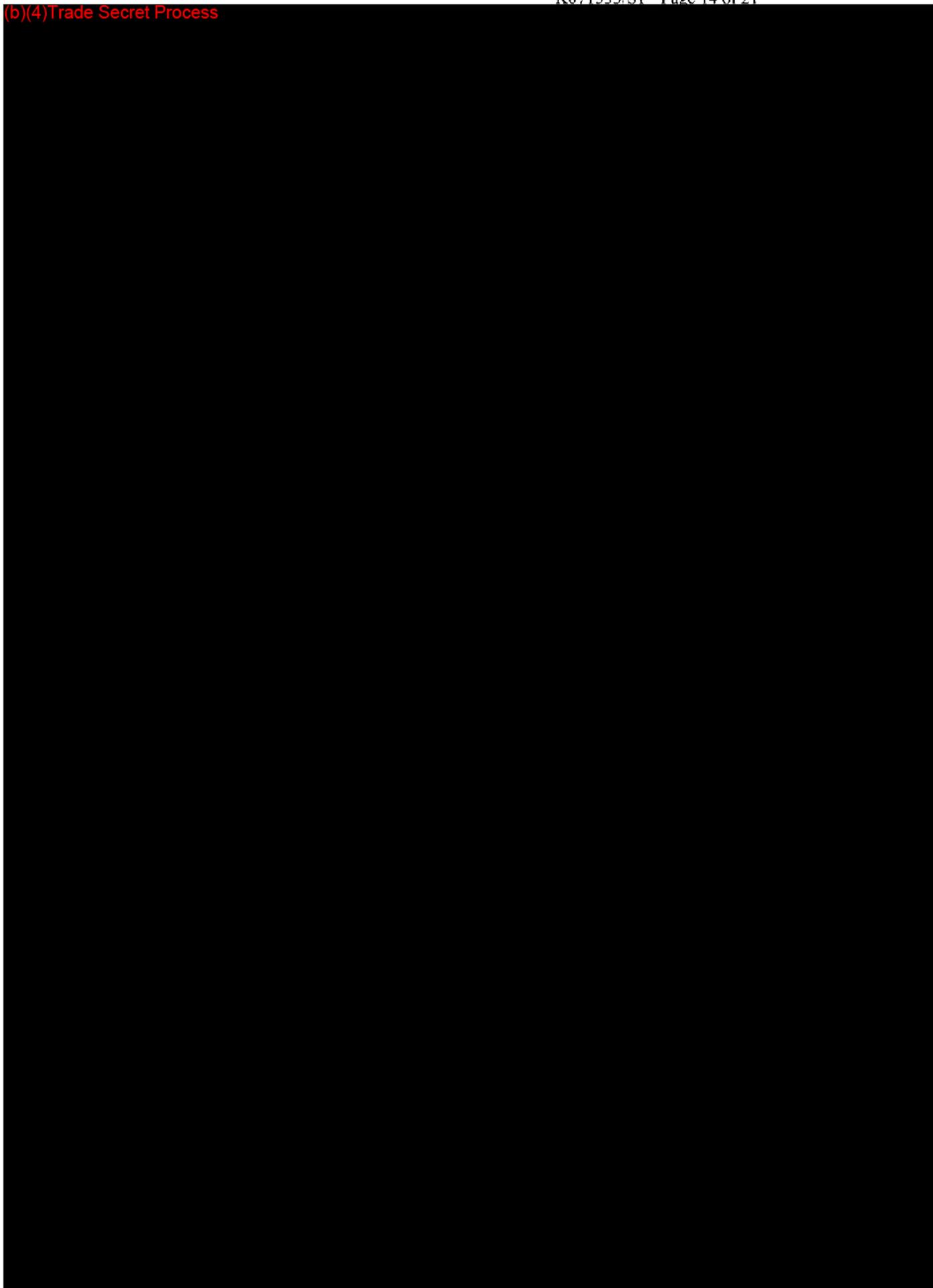
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



(b)(4)Trade Secret Process

XII. Performance Testing – Animal N/A

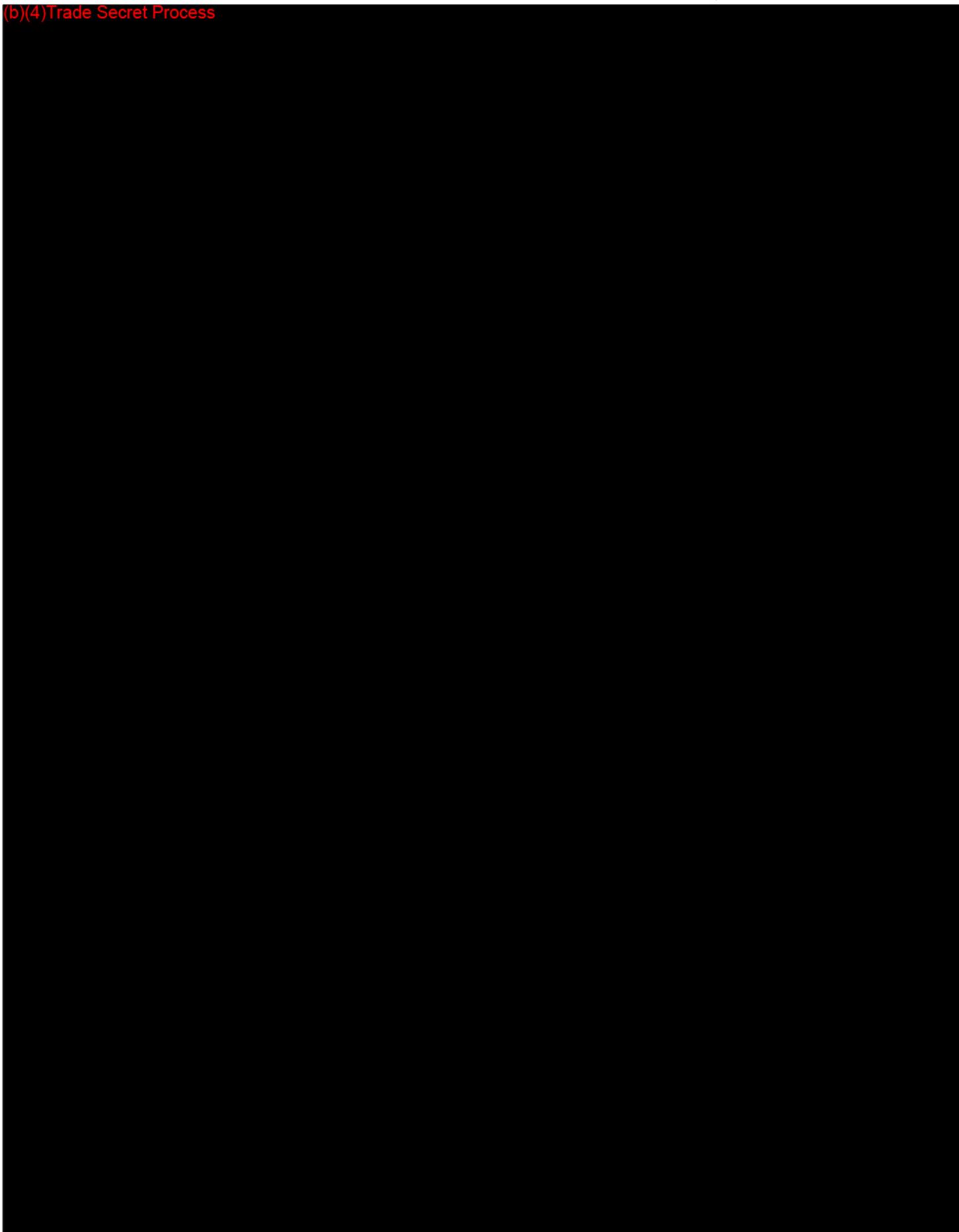
XIII. Performance Testing – Clinical N/A

XIV. Substantial Equivalence Discussion

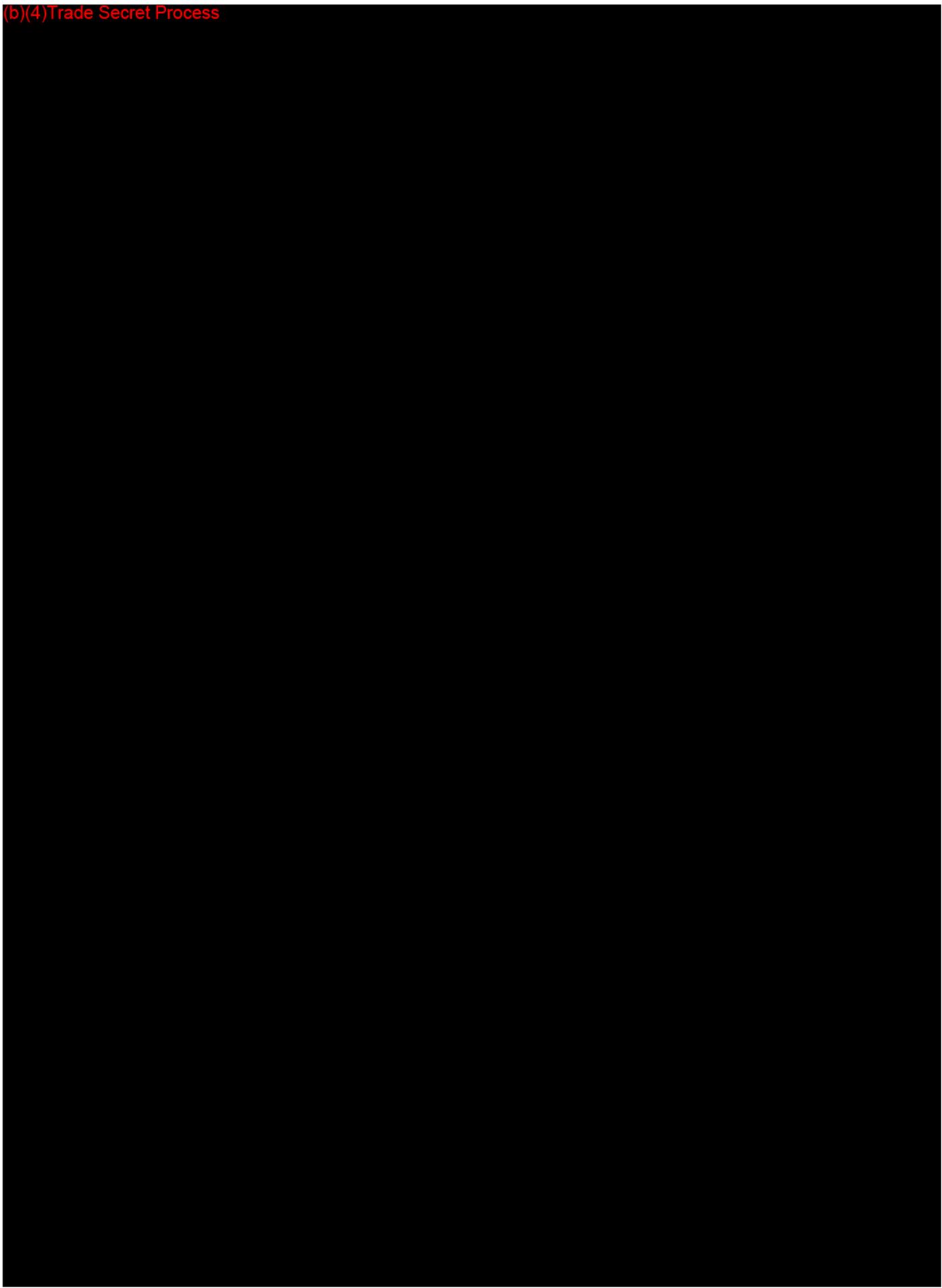
	Yes	No
1. Is Product A Device	X	If NO = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X	If NO = Stop, see 510(k) staff
3. Same Indication Statement?	X	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
5. Same Technological Characteristics?	X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 8
7. Descriptive Characteristics Precise Enough? No, see #10 below.		X If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
9. Accepted Scientific Methods Exist?		If NO = Stop NSE
10. Performance Data Available? Some performance data is available; however, testing information regarding the hydrothermal study is needed.		X If NO = Request Data
11. Data Demonstrate Equivalence?		Final Decision:

(b)(4)Trade Secret Process

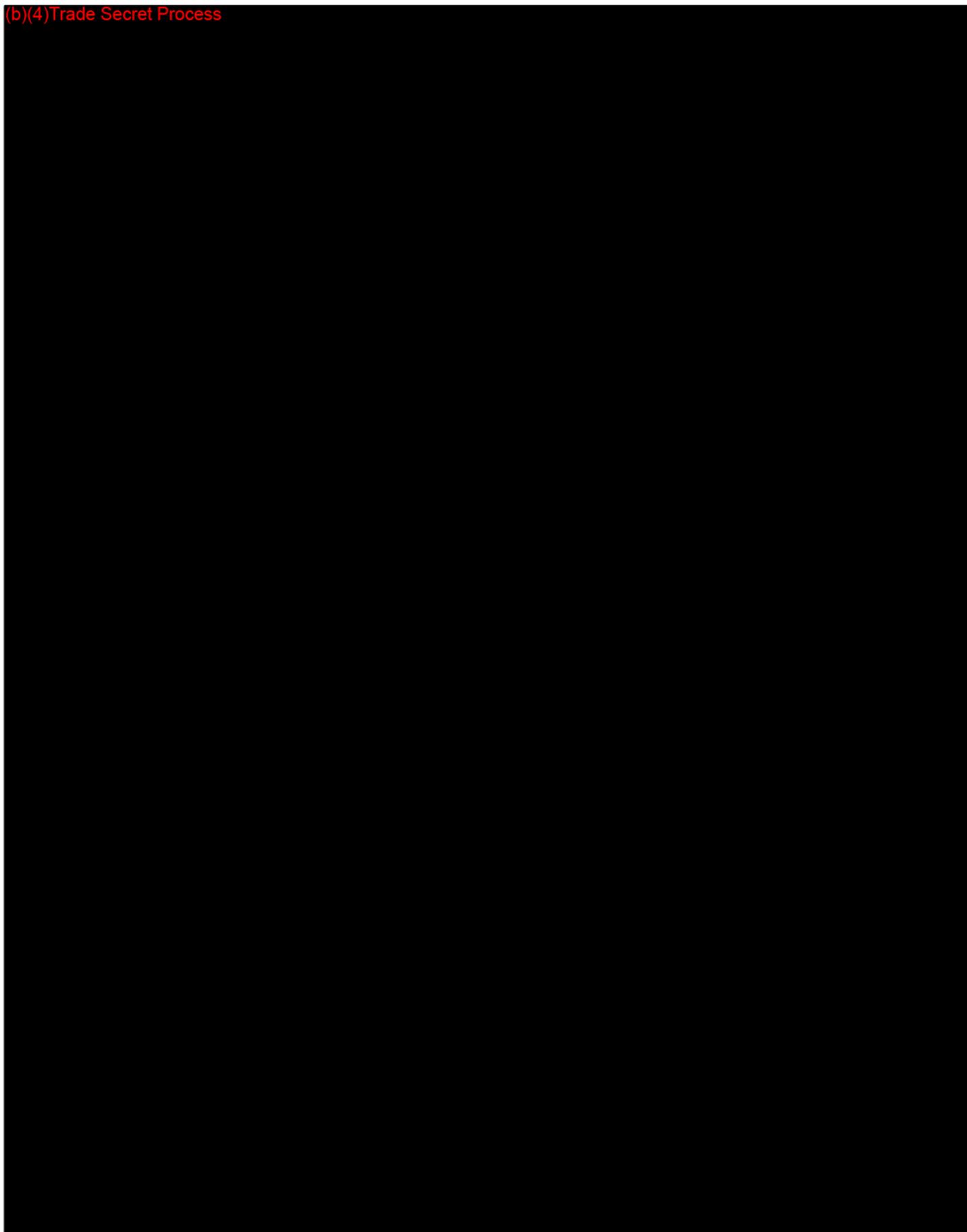
(b)(4) Trade Secret Process



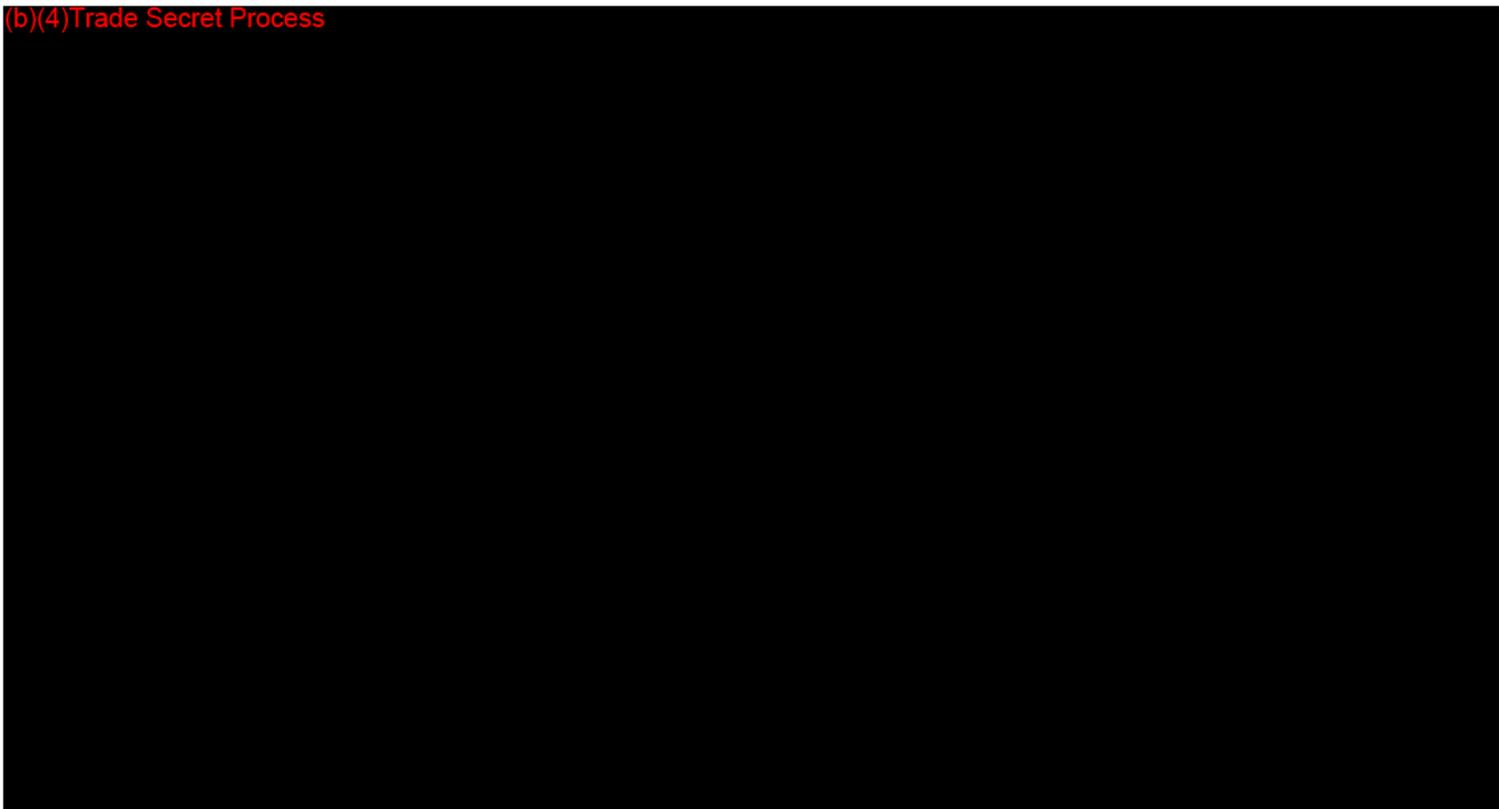
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



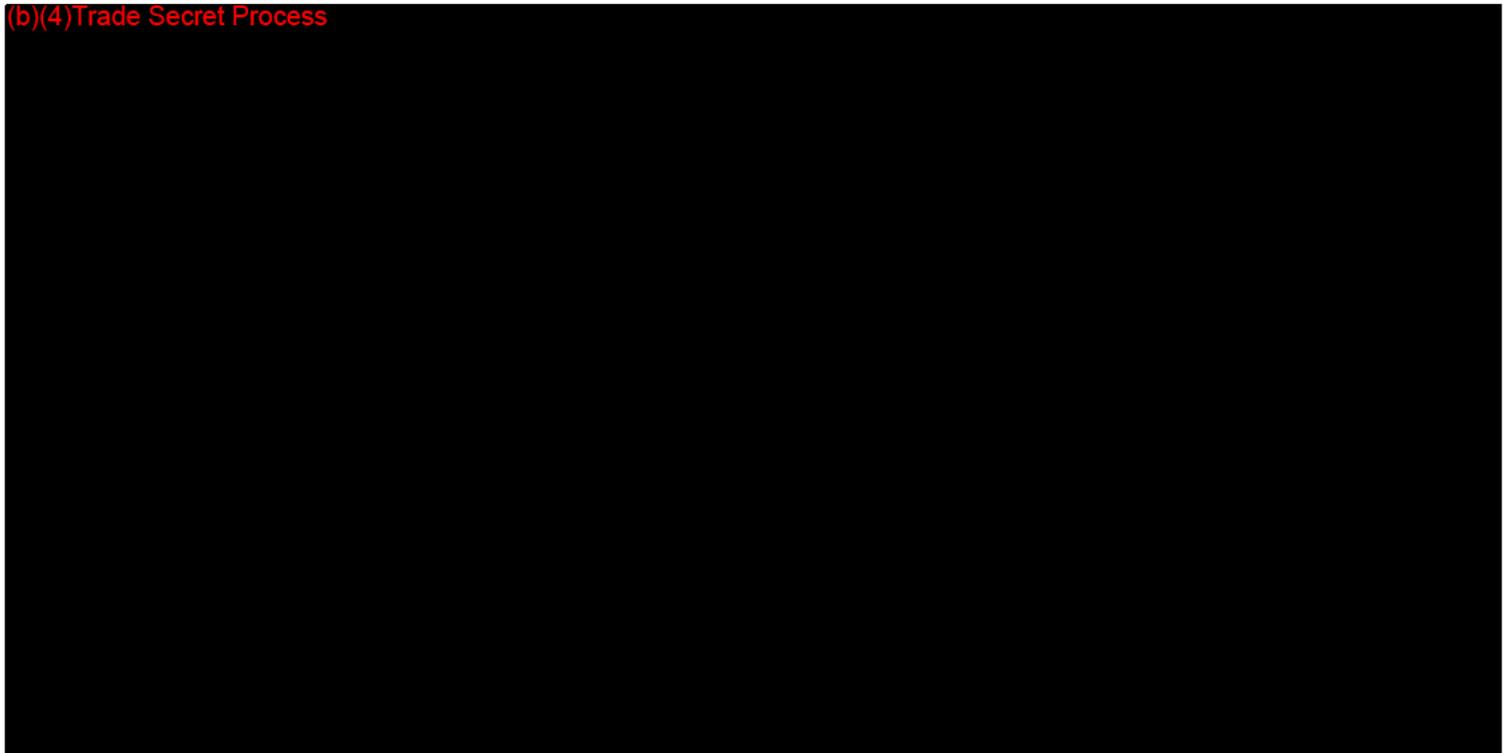
(b)(4)Trade Secret Process



Sincerely,
Julie B. Gantenberg, M.S.
Biomedical Engineer
FDA Reviewer for DGRND/OJDB

XVI. Contact History

(b)(4)Trade Secret Process



Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

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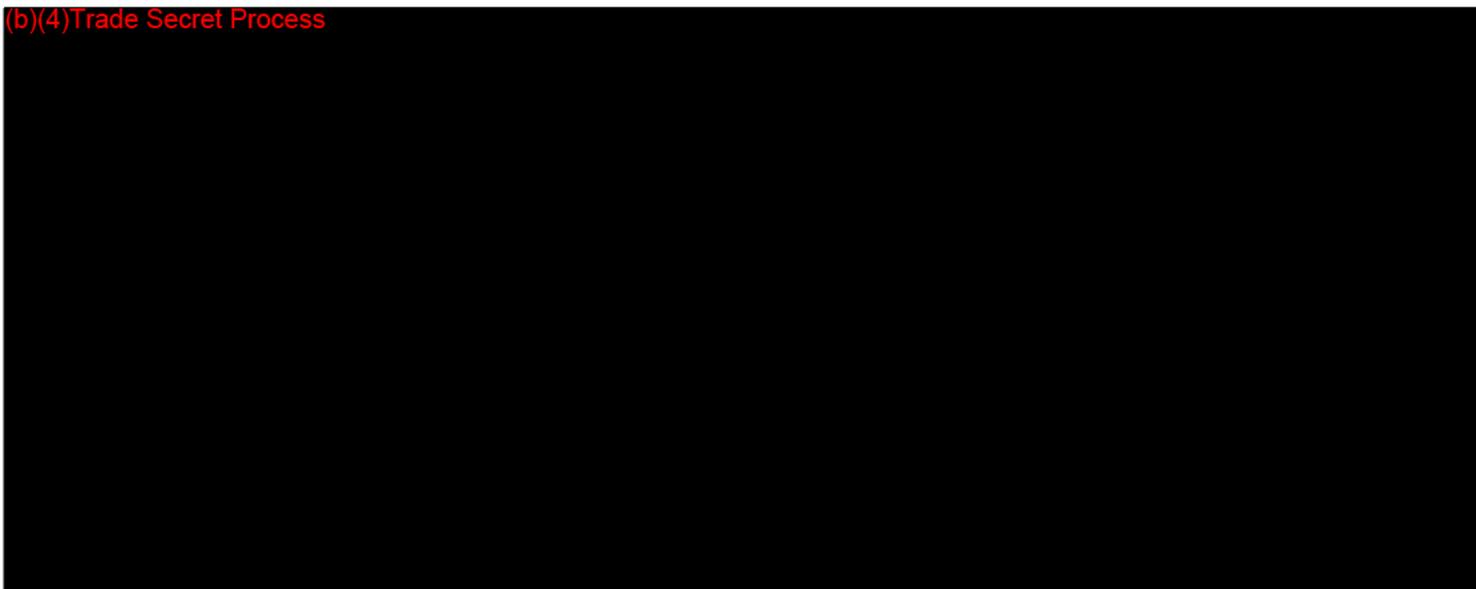
(b)(4)Trade Secret Process



From: Gantenberg, Julie *
Sent: Friday, September 28, 2007 11:21 AM
To: 'trish.jenks@zimmer.com'
Cc: Gantenberg, Julie *; Foy, Jonette
Subject: RE: K071535/S1 (b) [REDACTED]
Importance: High

Dear Ms. Jenks,

(b)(4)Trade Secret Process

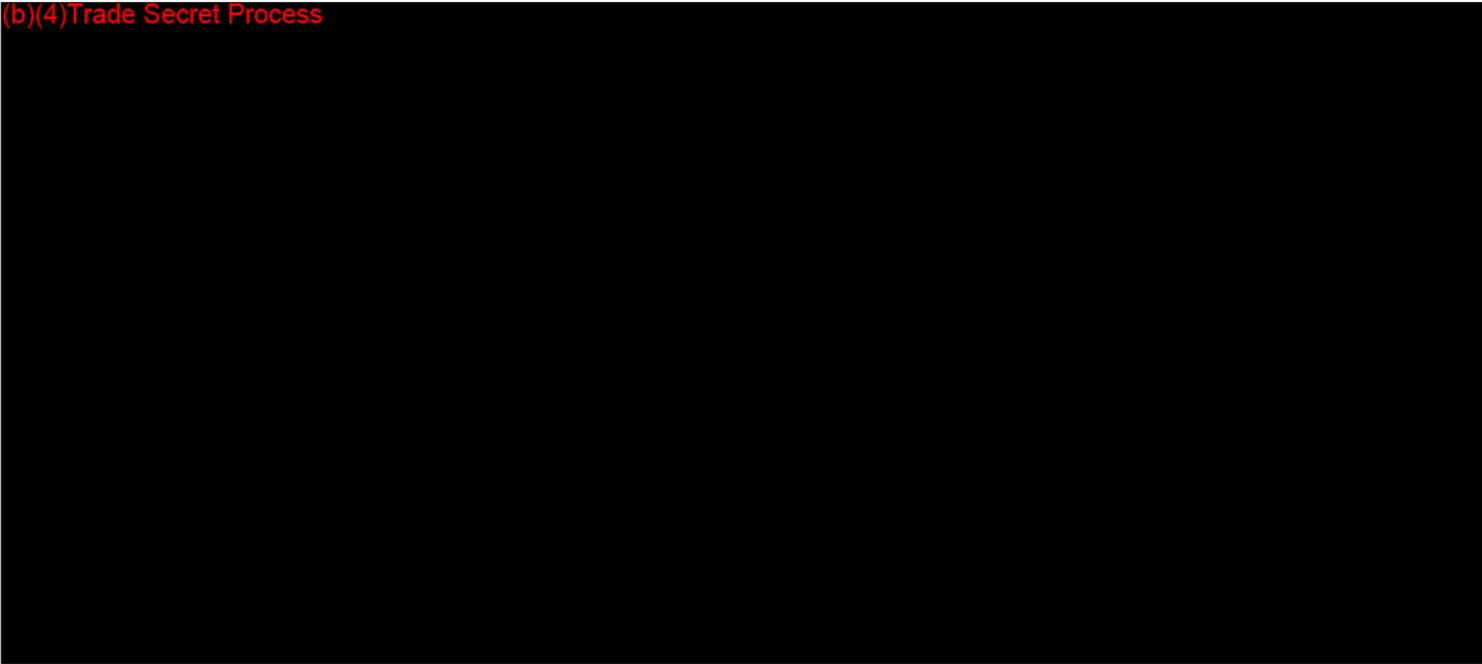


Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3676 (tel)
240-276-3602 (fax)
julie.gantenberg@fda.hhs.gov

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(b)(4)Trade Secret Process





COVER SHEET MEMORANDUM

From: Reviewer Name Gantenberg
Subject: 510(k) Number K071535
To: The Record

Please list CTS decision code AI
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 Hold (Additional Information or **Telephone Hold**).
 Final Decision (**SE**, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page (p.26)	<i>Attach IFU</i>	X	
510(k) Summary /510(k) Statement (p.21)	<i>Attach Summary</i>	X	
Truthful and Accurate Statement (Original, p.10)	<i>Must be present for a Final Decision</i>		
Is the device Class III?			X
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATEDSTANDARDSDATAFORM.DOC)			N/A
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	<i>Contact OSB.</i>		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	<i>Contact OC.</i>		X

Regulation Number 21 CFR 888.3353 **Class*** II (87 Panel) **Product Code** LZO
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: *[Signature]* *OTDB* *7/18/07*
 (Branch Chief) (Branch Code) (Date)

Final Review: *[Signature]* *7/18/07*
 (Division Director) (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		X
2. Is the device exempt from 510(k) by regulation (Please see http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		X
3. Does this device type require a PMA by regulation? (Please see management.)		X
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRH_PremarketNotification_510kProgram/_Screening_Checklist)		X
5. a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		X
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	X
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		X



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K071535

Date: 7/18/07
To: The Record
From: Gantenberg

Office: ODE
Division/Branch: DGRND/OJDB

510(k) Holder: Zimmer
Device Name: BIOLOX® delta Ceramic Femoral Head
Contact: Ms. Patricia Jenks
Phone: 574-371-8354
Fax: 574-372-4605
Email: trish.jenks@zimmer.com permission to email granted in cover letter.

I. Purpose

The 510(k) holder would like to introduce BIOLOX® delta Ceramic Femoral Heads into interstate commerce.

II. Administrative Requirements

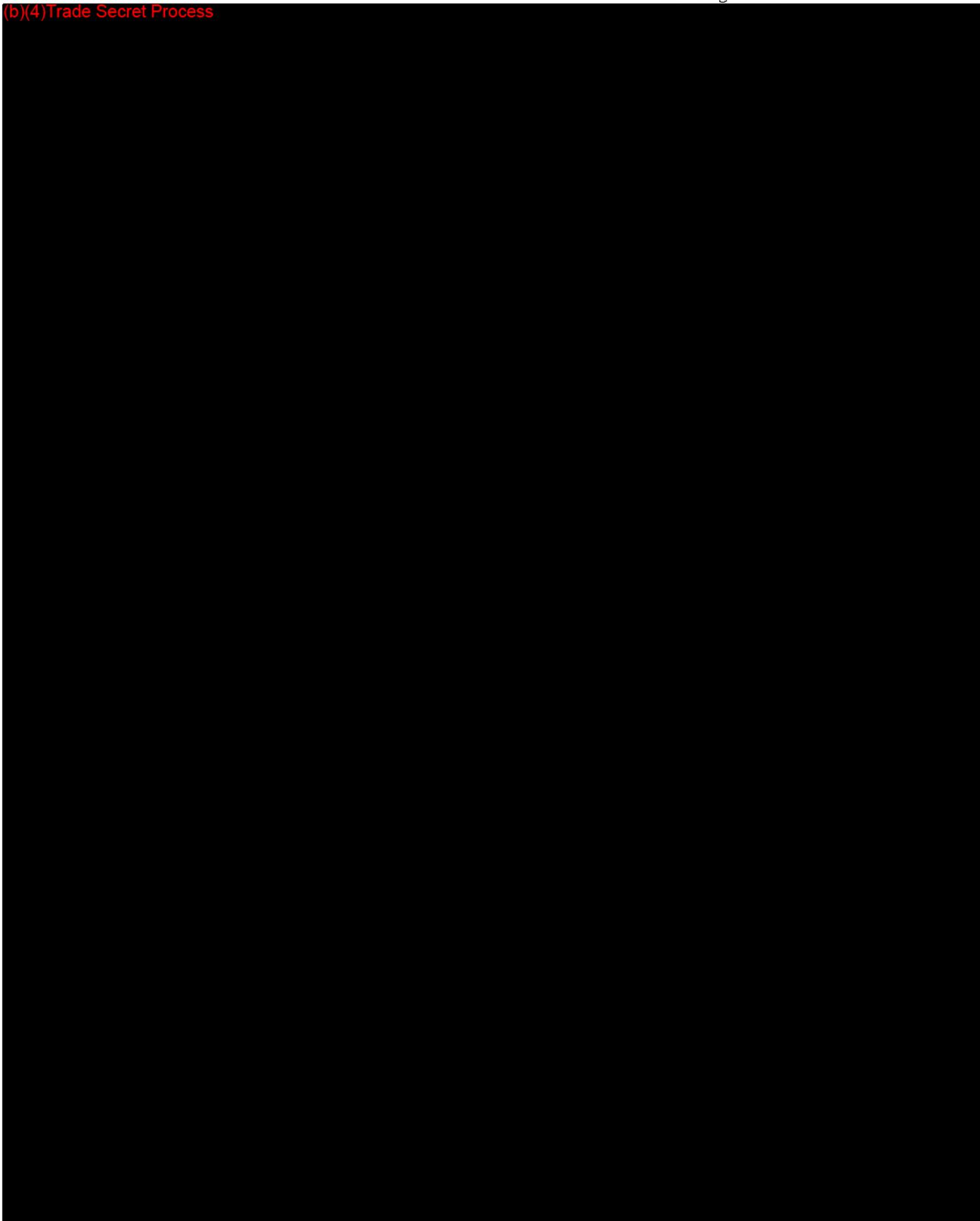
	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) – Orig, p.26	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement – Summary provided in Original, p.21	X		
Standards Form	N/A		

III. Device Description (Executive summary and Premarket Notification Sections)

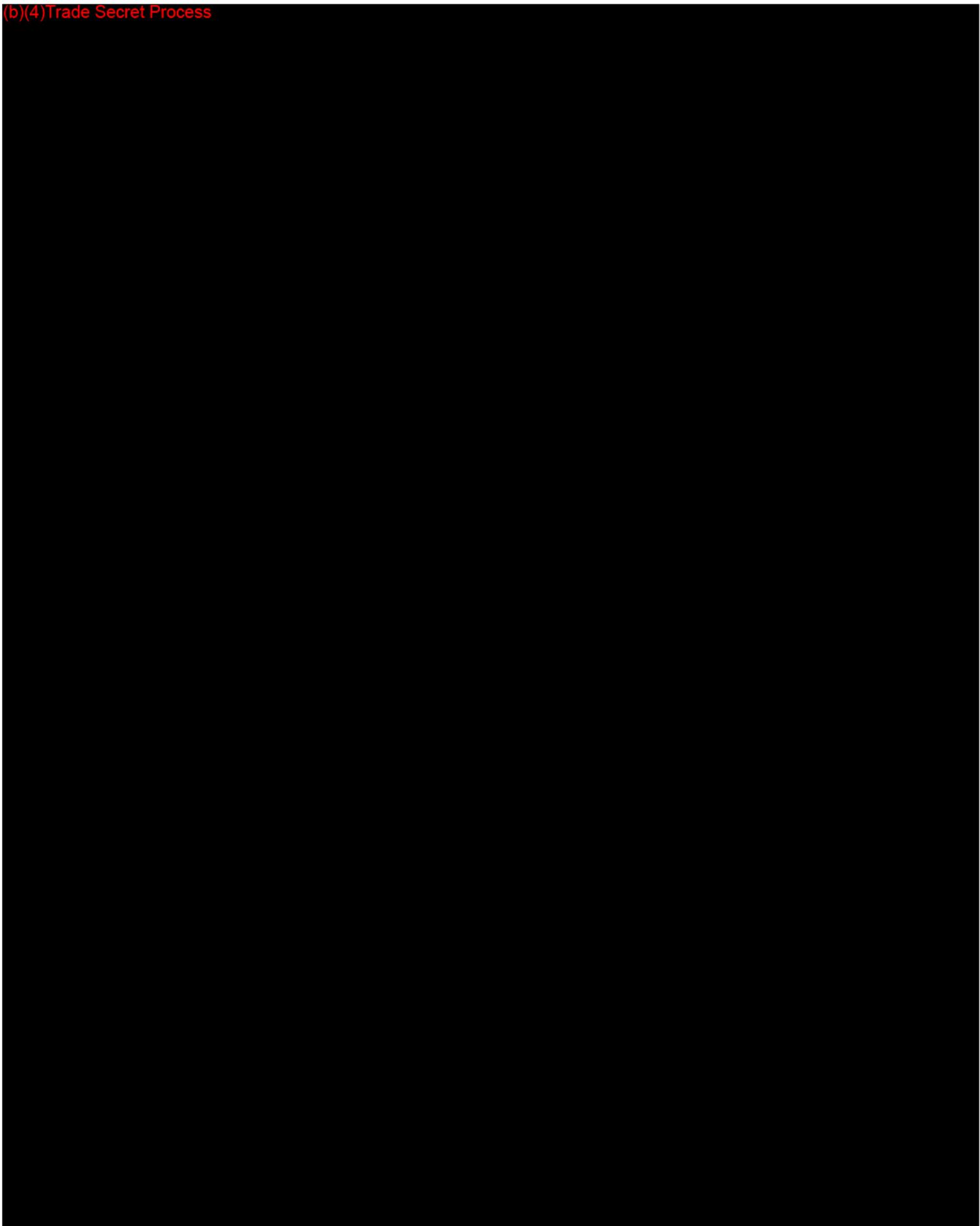
	Yes	No	N/A
Is the device life-supporting or life-sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?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

A predicate comparison table was provided in Original, p.36.

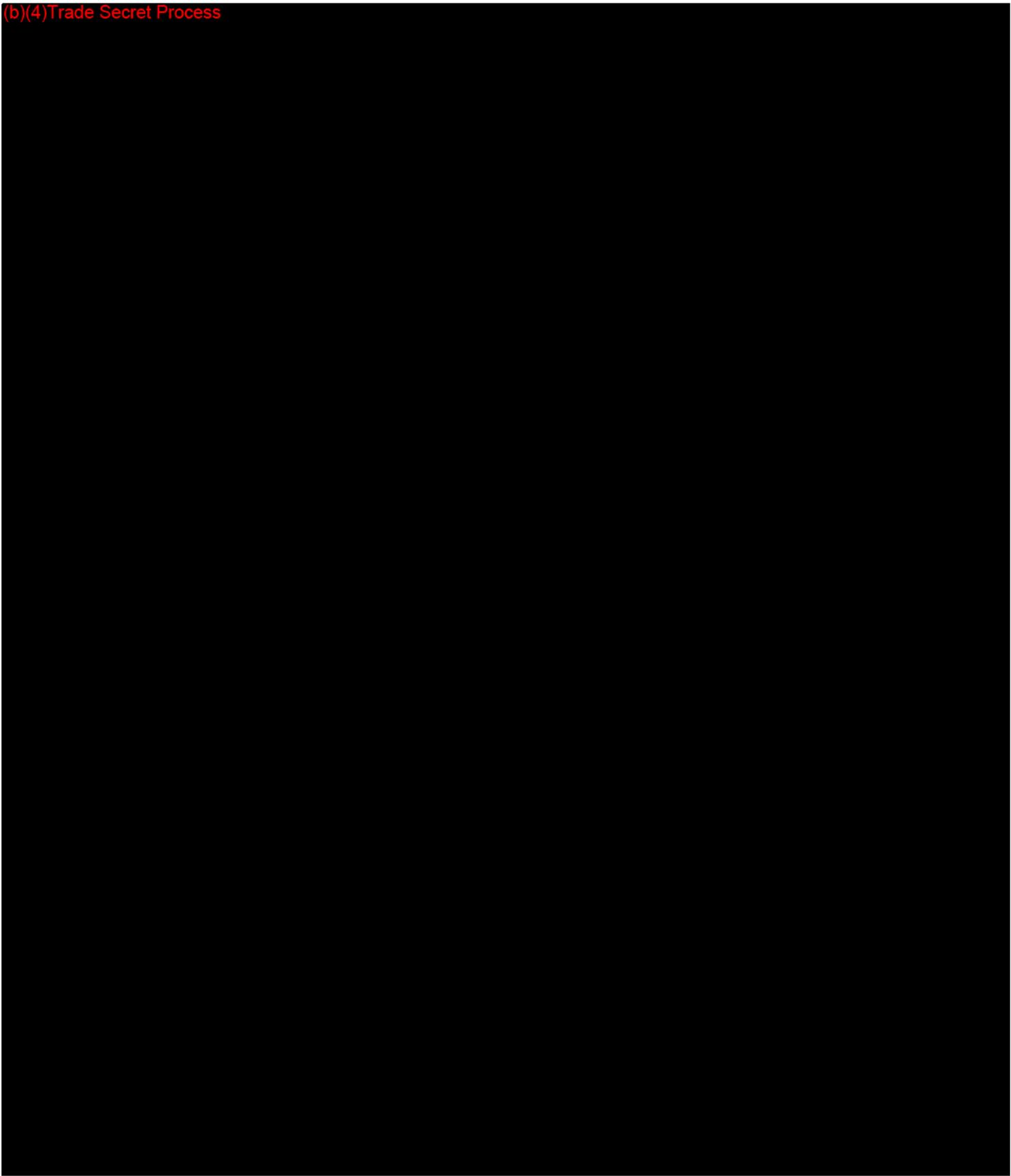
(b)(4) Trade Secret Process



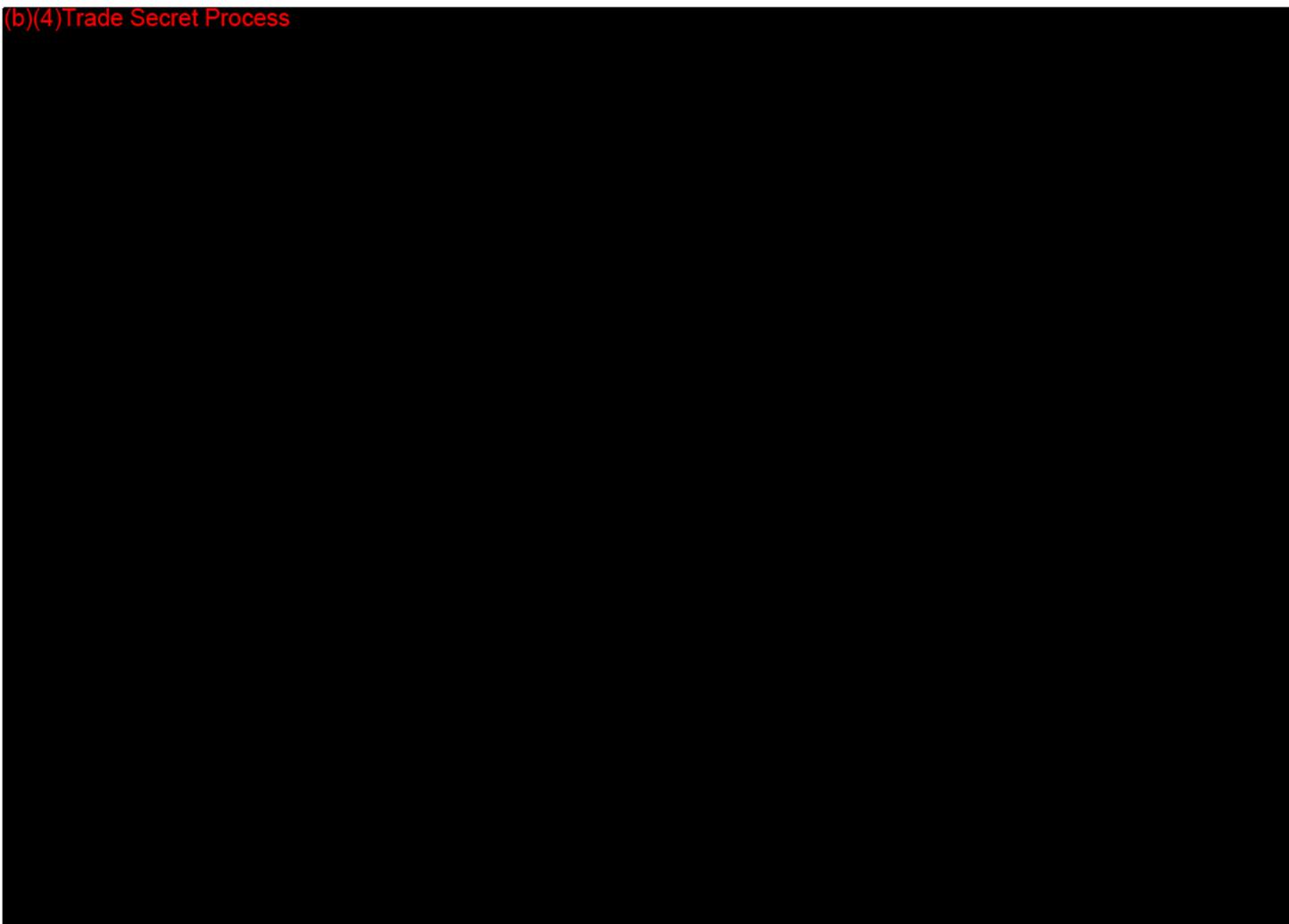
(b)(4) Trade Secret Process



(b)(4)Trade Secret Process

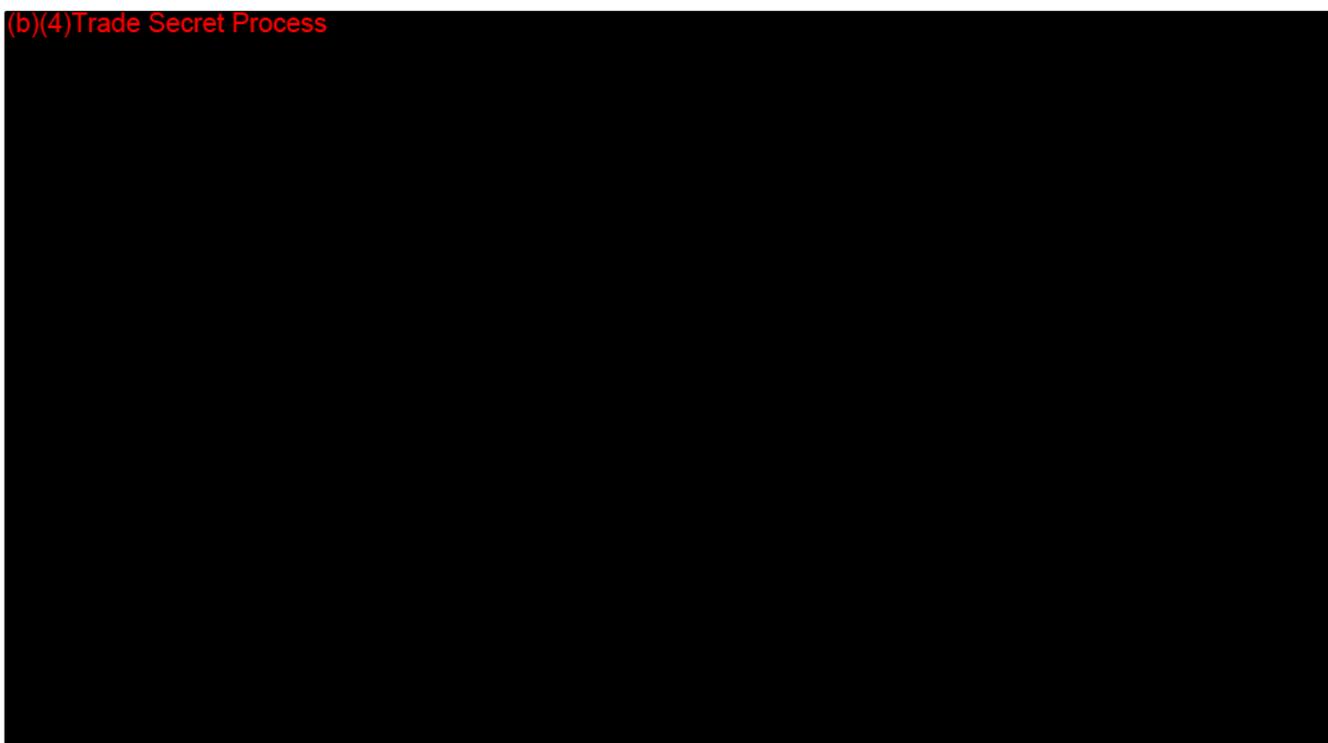


(b)(4)Trade Secret Process



VII. Sterilization/Shelf Life/Reuse (Original, pp.15-16)

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



VIII. Biocompatibility

(b)(4)Trade Secret Process

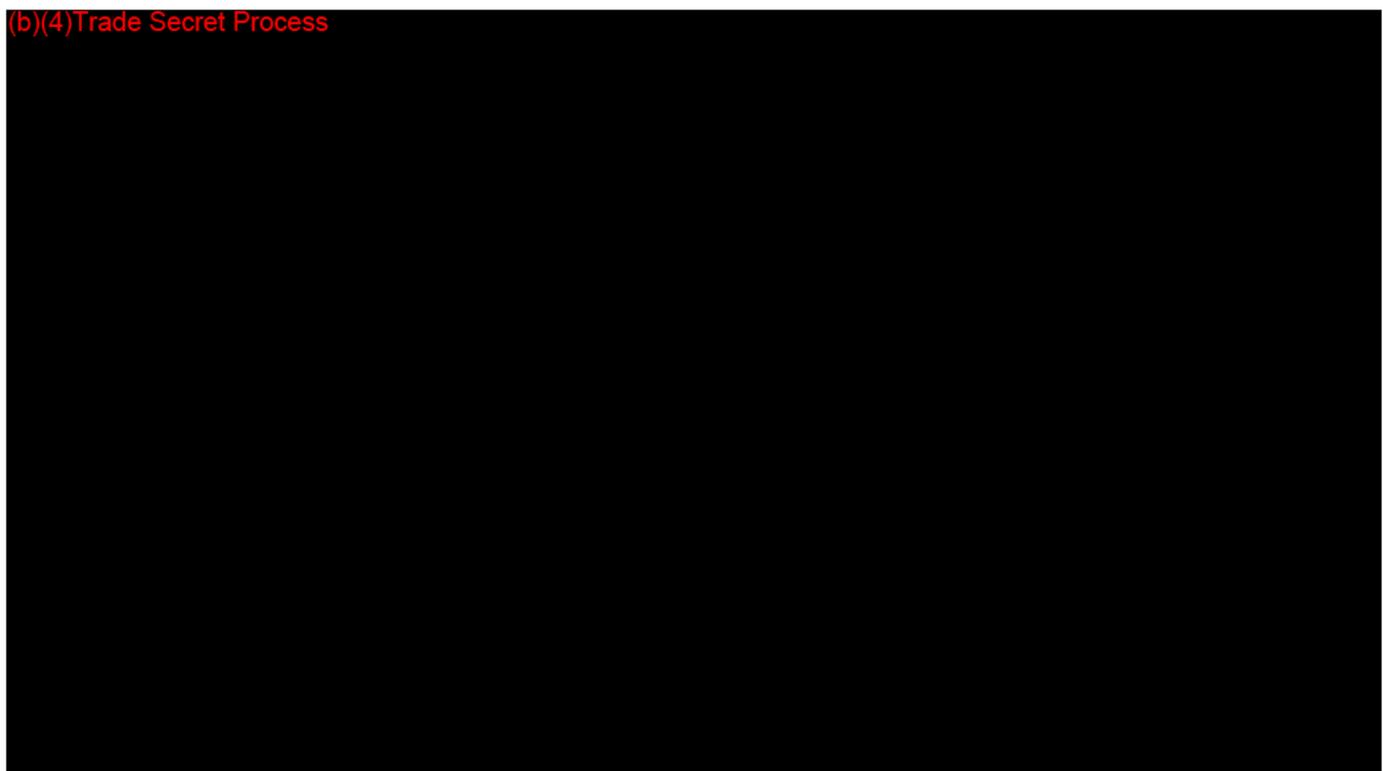


IX. Software N/A

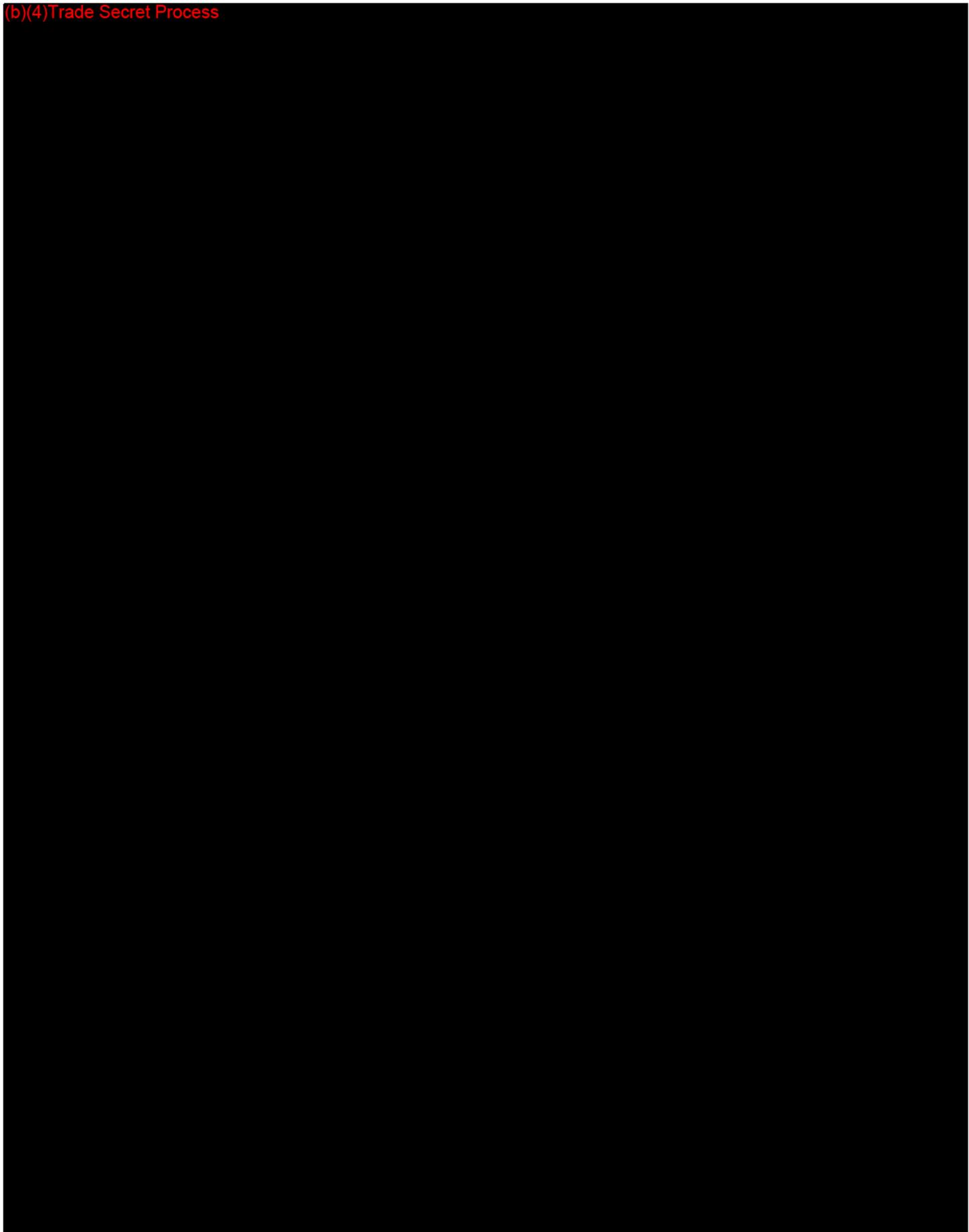
X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety N/A

XI. Performance Testing – Bench

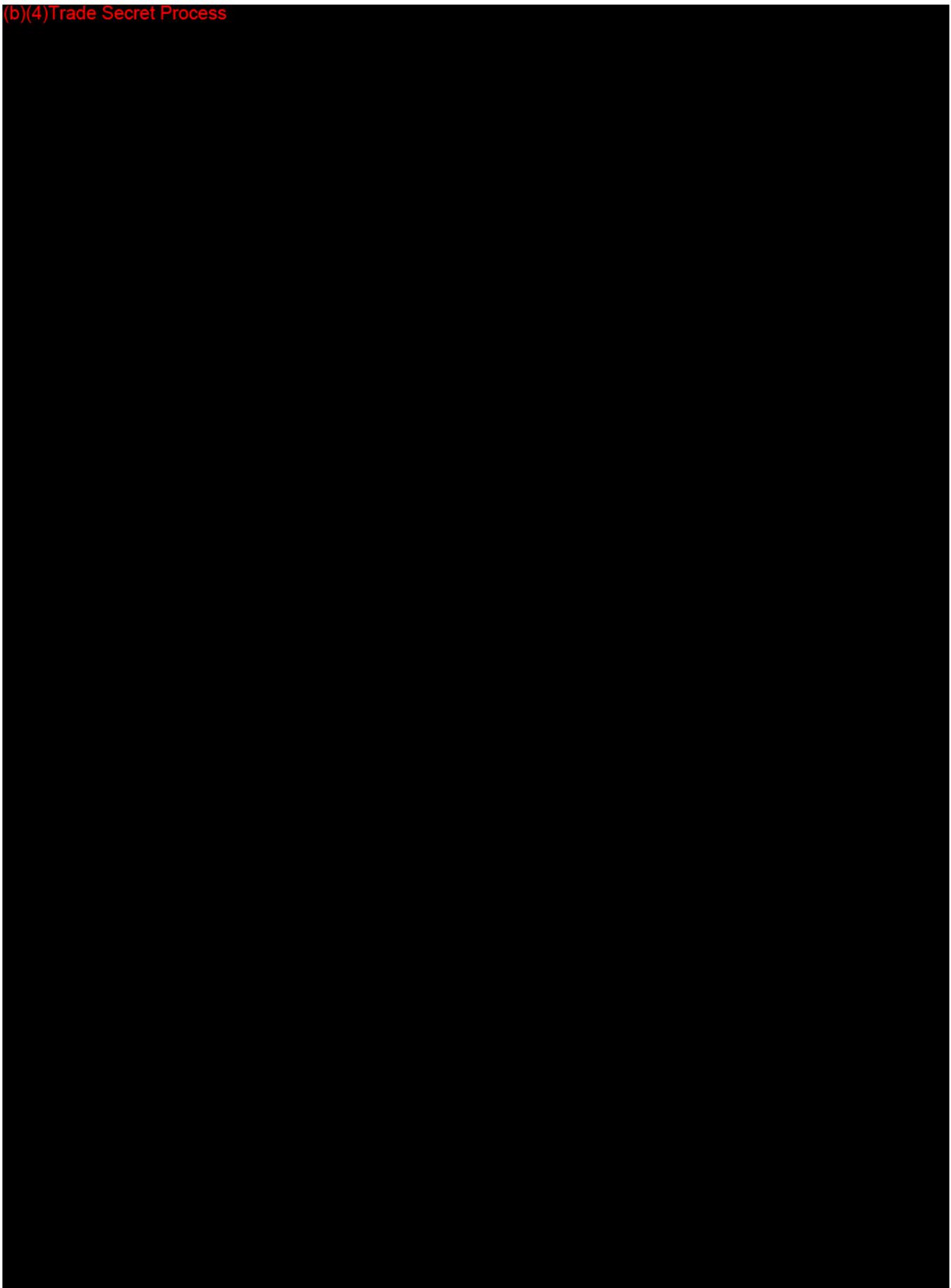
(b)(4)Trade Secret Process



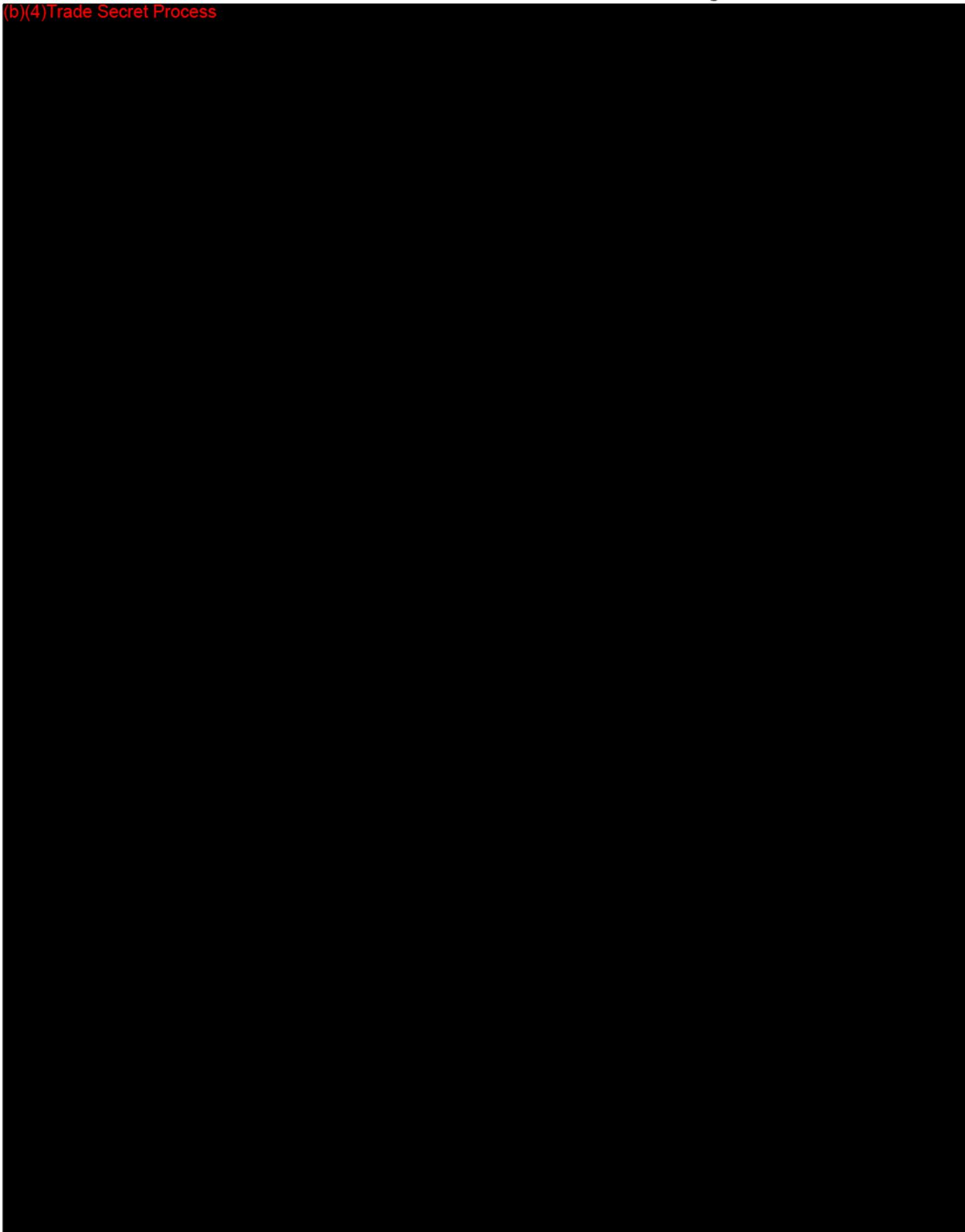
(b)(4)Trade Secret Process



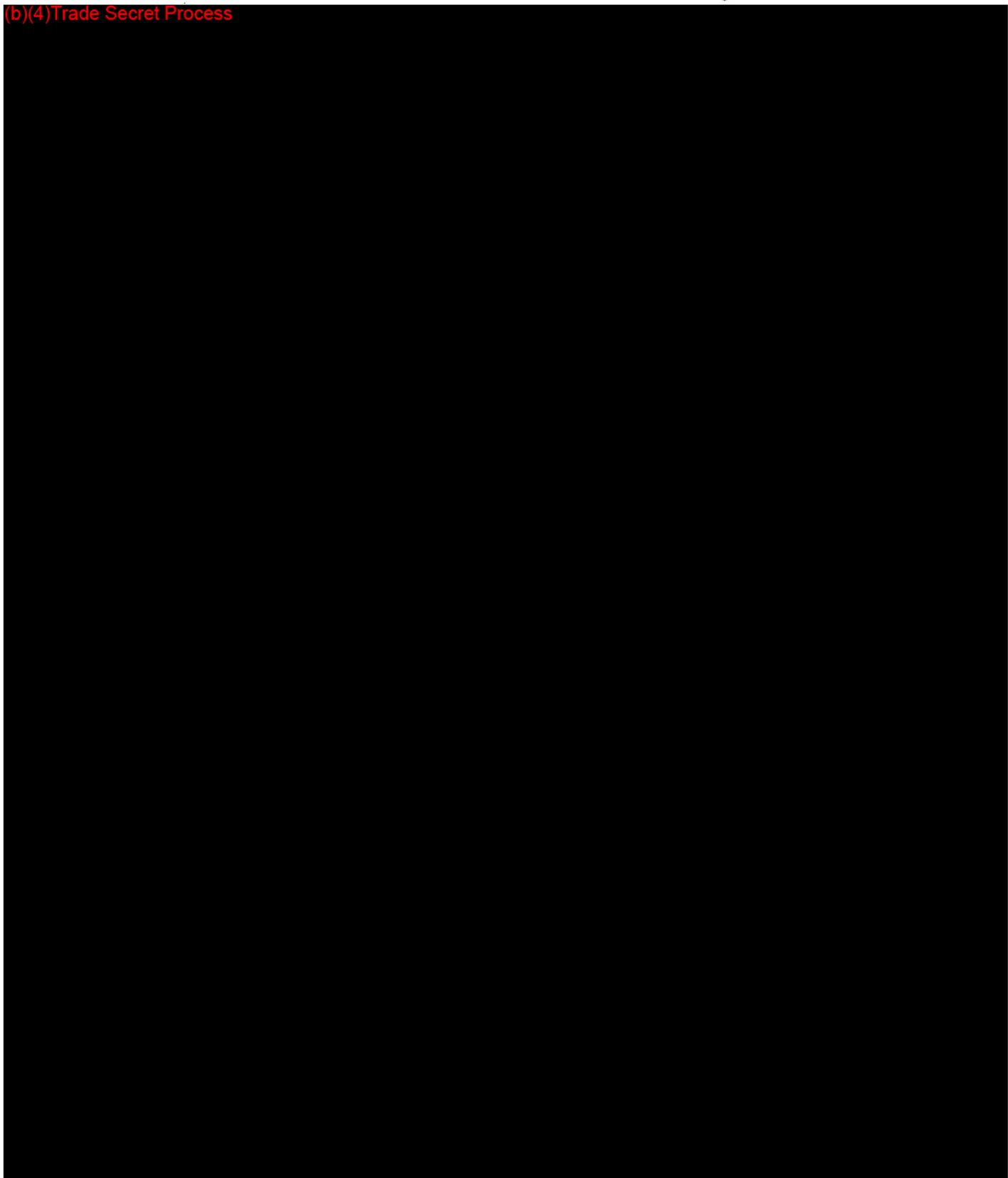
(b)(4)Trade Secret Process



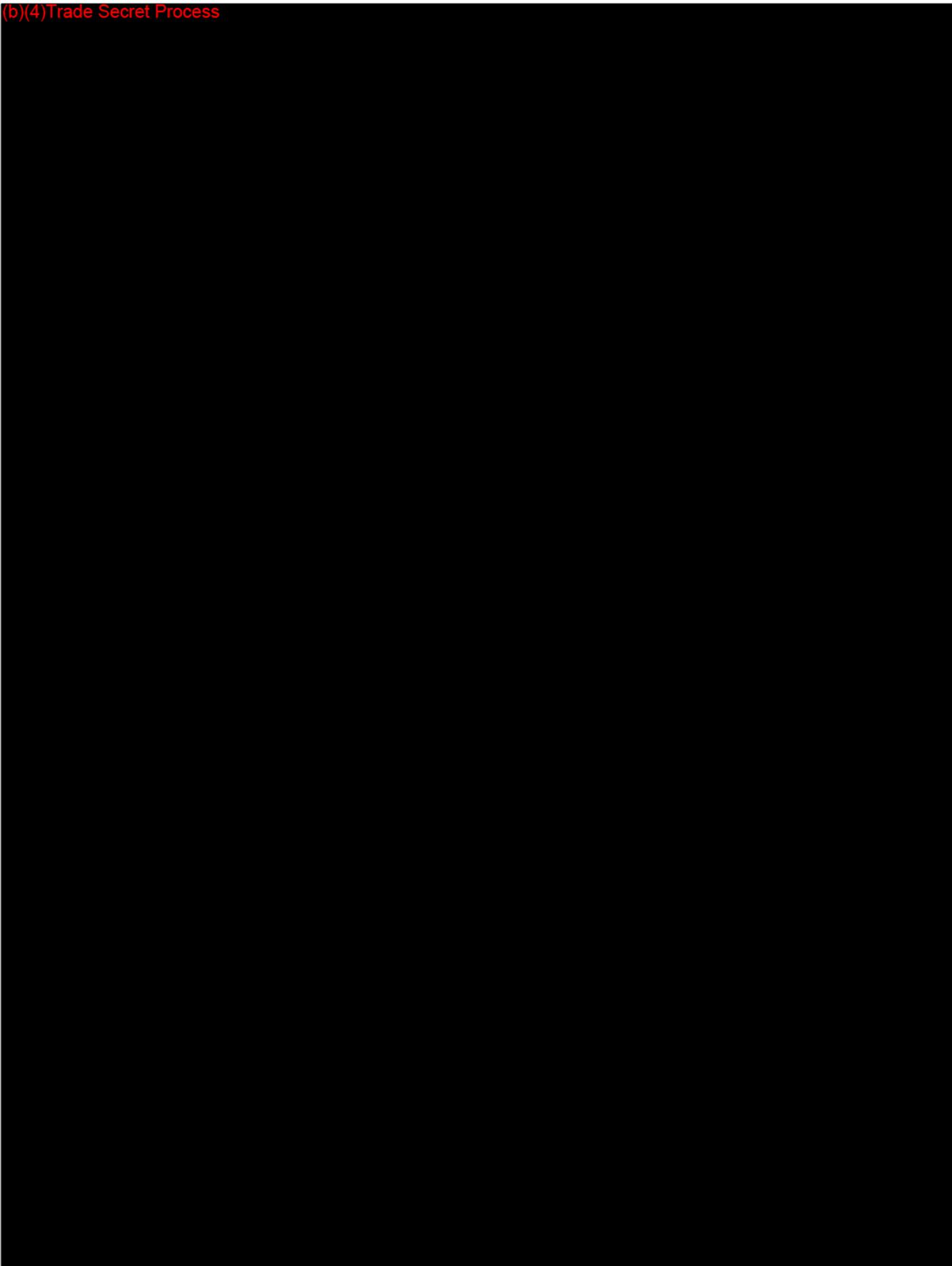
(b)(4) Trade Secret Process



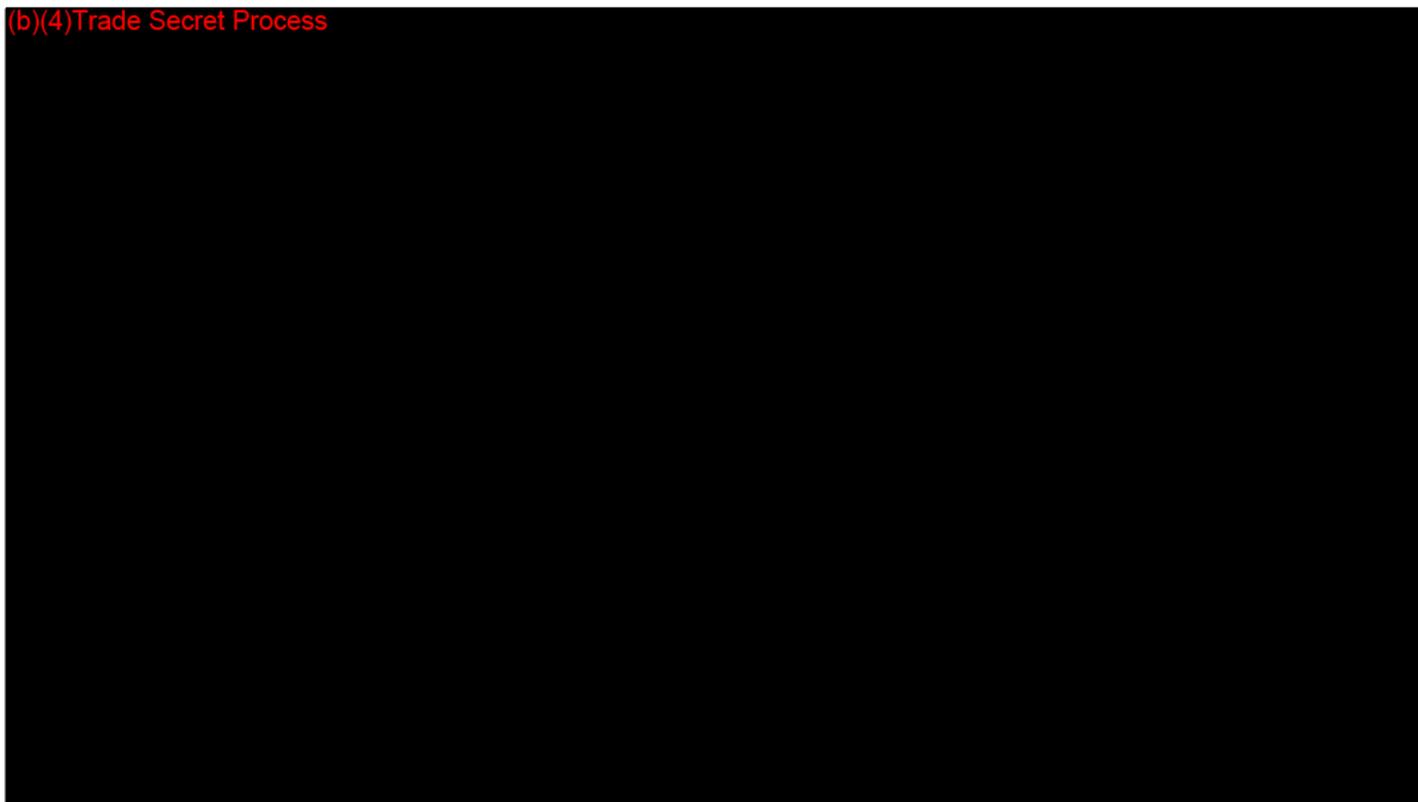
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



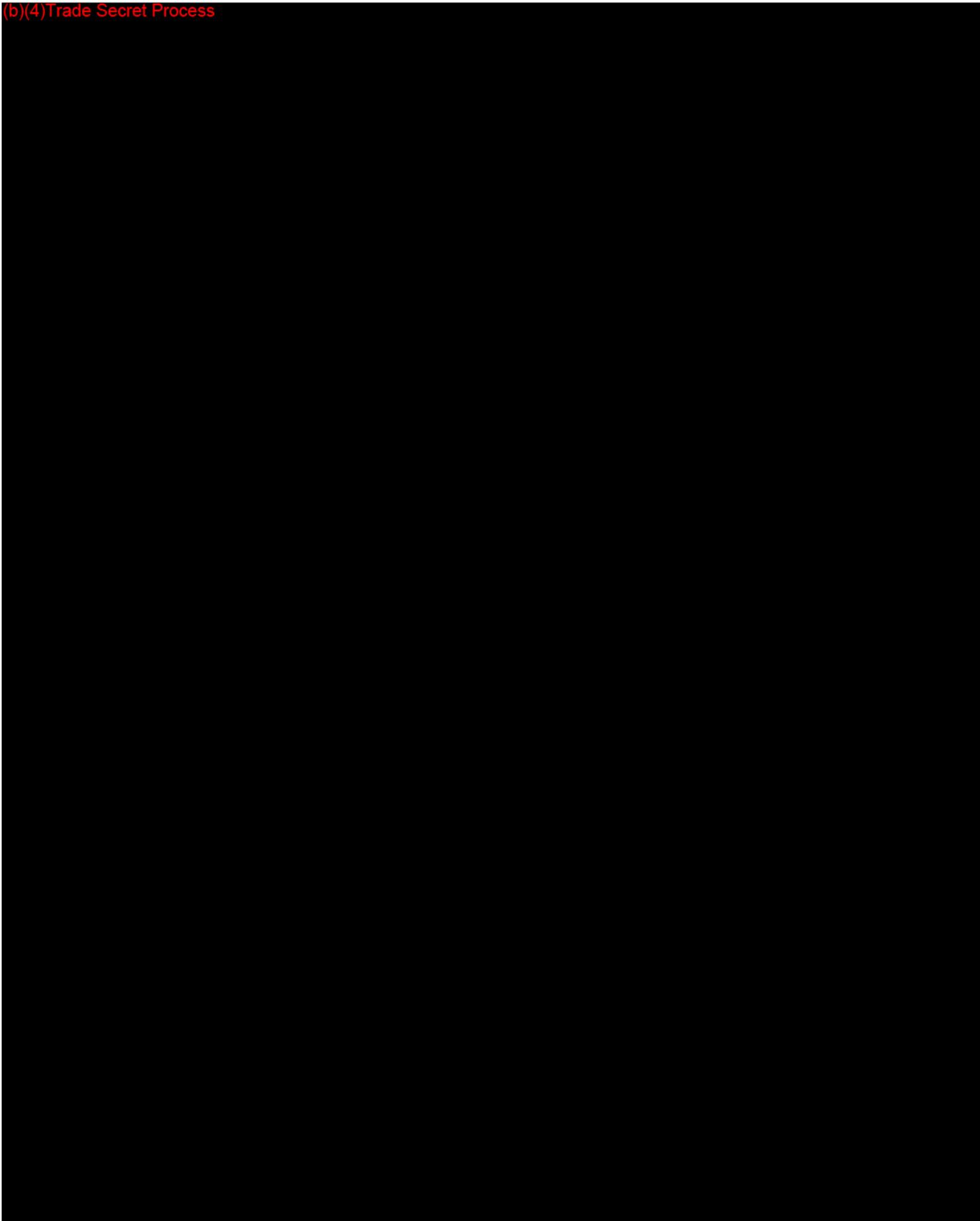
XII. Performance Testing – Animal N/A

XIII. Performance Testing – Clinical N/A

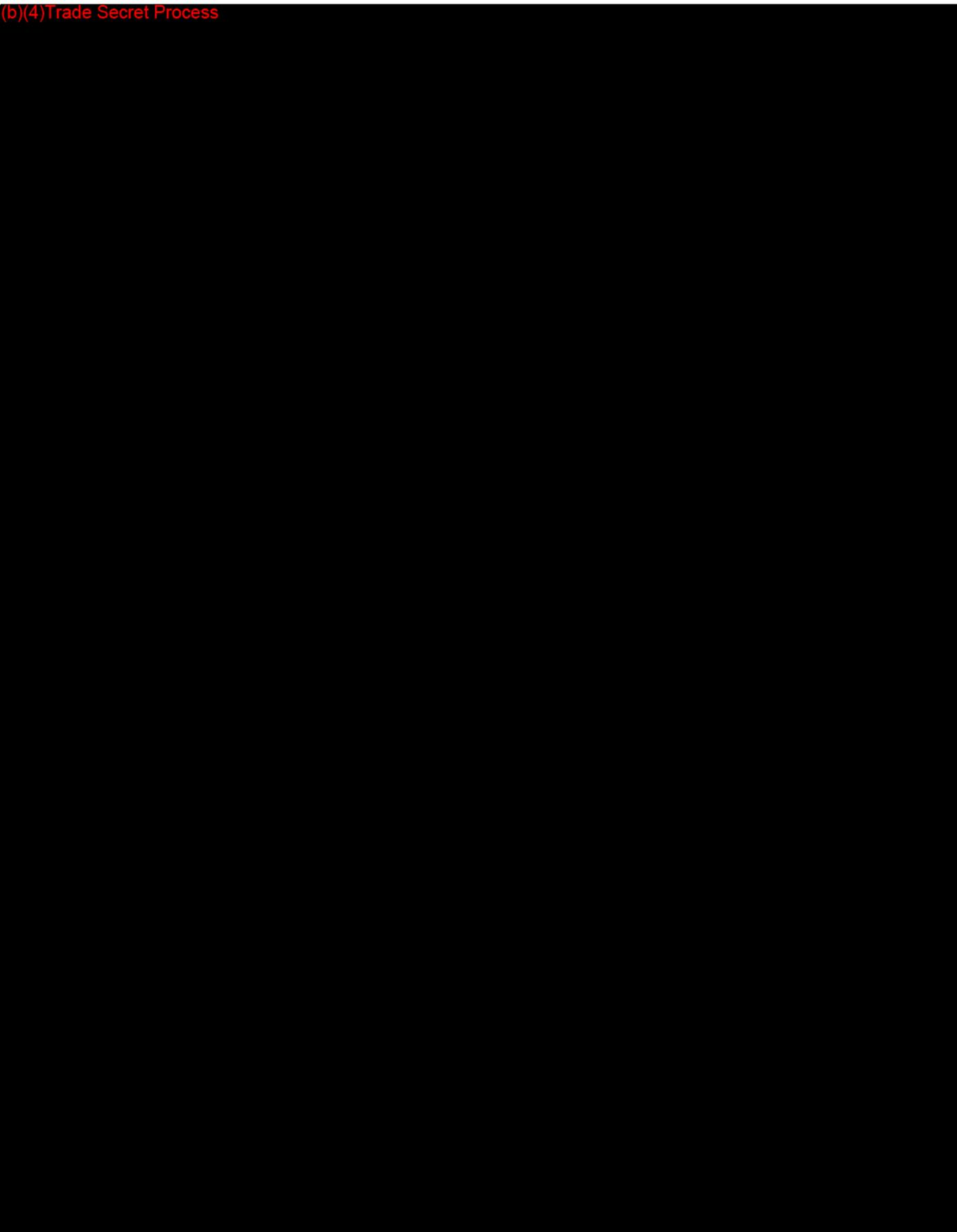
XIV. Substantial Equivalence Discussion

	Yes	No
1. Is Product A Device	X	If NO = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X	If NO = Stop, see 510(k) staff
3. Same Indication Statement?	X	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
5. Same Technological Characteristics?	X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 8
7. Descriptive Characteristics Precise Enough? No, see #10 below.		X If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
9. Accepted Scientific Methods Exist?		If NO = Stop NSE
10. Performance Data Available? Some performance data is available; however, clarifications and device description information are needed. Additional testing may be needed depending on sponsor's response.		X If NO = Request Data
11. Data Demonstrate Equivalence?		Final Decision:

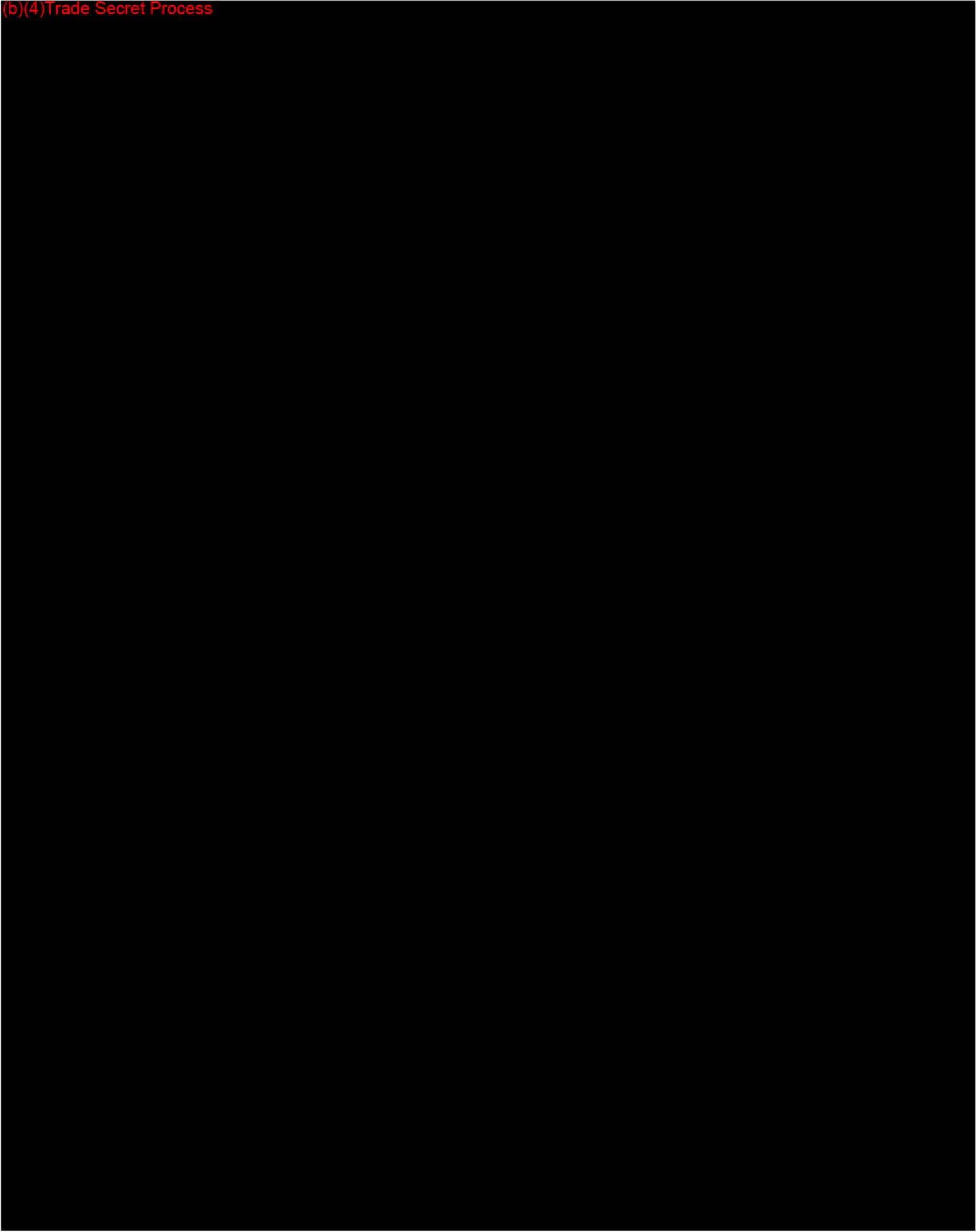
(b)(4)Trade Secret Process



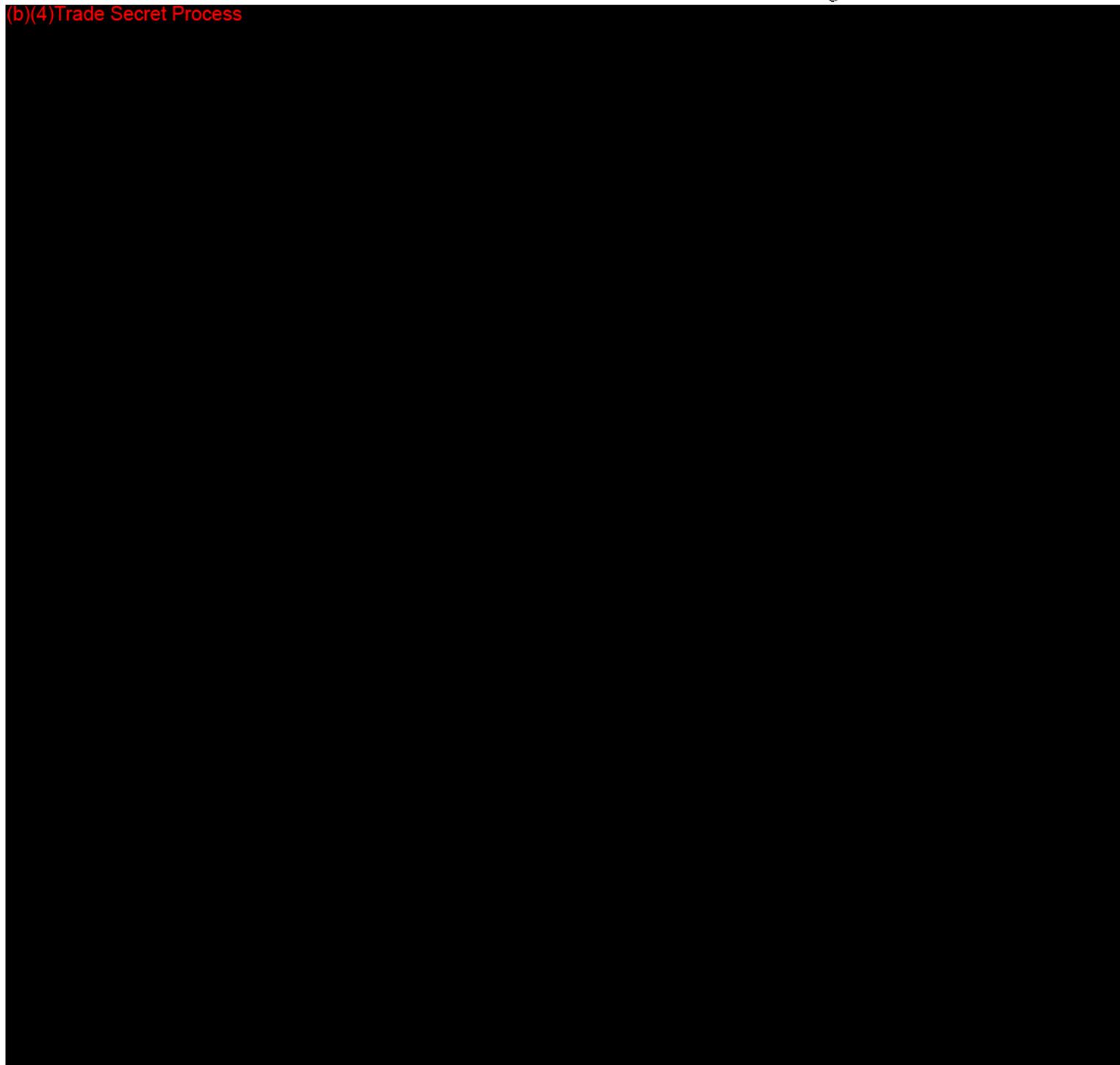
(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff

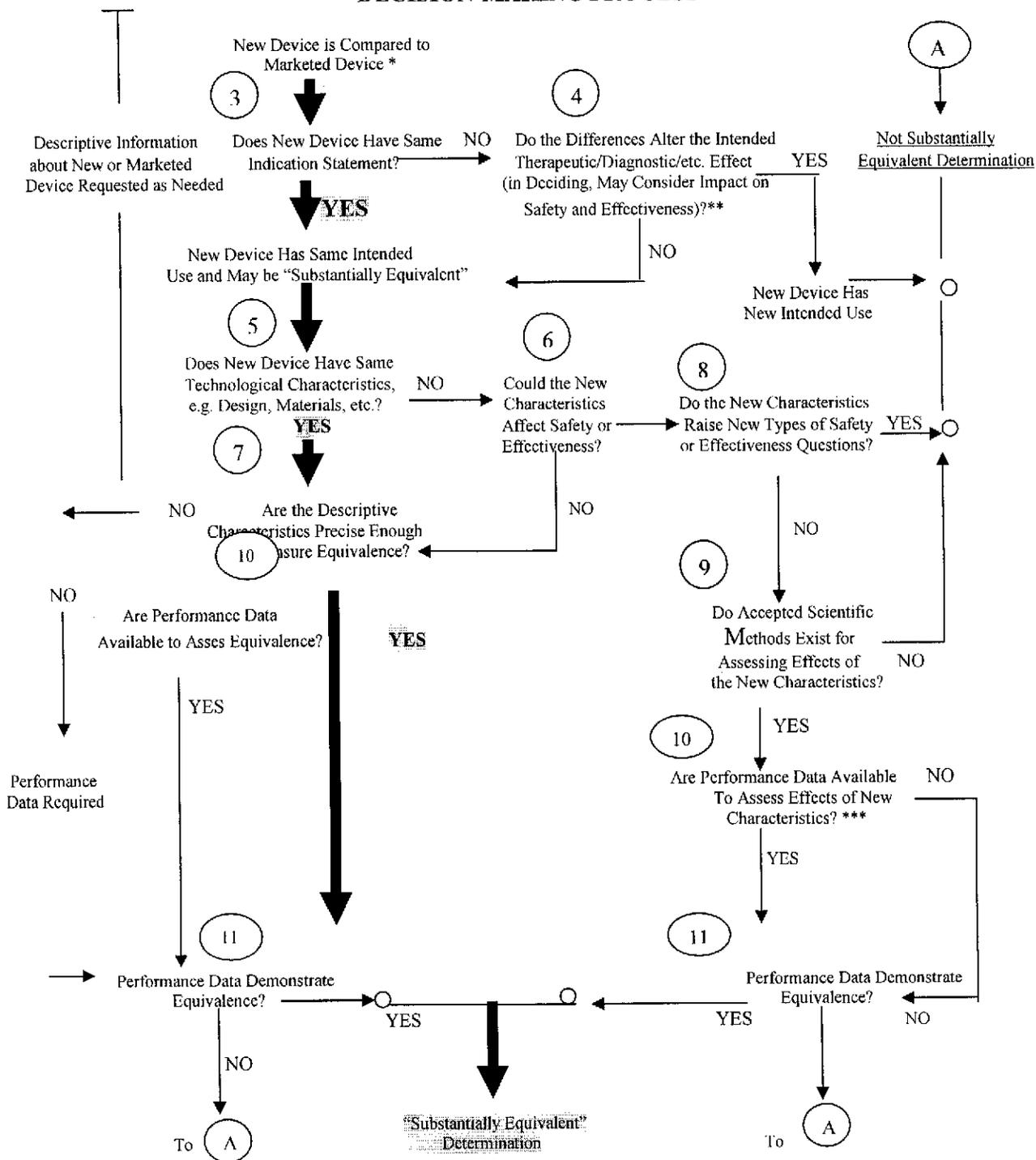
Format for Traditional and Abbreviated 510(k)s

<http://www.fda.gov/cdrh/ode/guidance/1567.html>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html			
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf			
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6			
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7			
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9			
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html			
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html FDA Standards program www.fda.gov/cdrh/stdsprog.html Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/regrecstand.html			
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			

Title	Related Information	Present	Inadequate	N/A
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html			
Proposed Labeling	Device Advice "Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10			
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html			
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html			
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html			
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1-2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf			
Kit Certification	See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance			

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.

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

September 17, 2007

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K071535
Product: BIOLOX DELTA
CERAMIC FEMORAL
HEAD

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 in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

CDRH Submission Cover Sheet

Date of Submission: September 13, 2007	FDA Document Number: K071535 / SJ
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Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input checked="" type="checkbox"/> Additional Information: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:

Section B Applicant or Sponsor

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-372-4485	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Toni Kingsley, Ph.D., RAC			
Contact Title: Vice President, Corporate Regulatory Affairs		Contact e-mail address: toni.kingsley@zimmer.com	

Section C Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-371-8354	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Patricia Jenks			
Contact Title: Specialist, Corporate Regulatory Affairs		Contact e-mail address: trish.jenks@zimmer.com	

Section D1**Reason for Submission -- PMA, PDP, or HDE**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Material | <input type="checkbox"/> Packager |
| | <input type="checkbox"/> Specifications | <input type="checkbox"/> Distributor |
| | <input type="checkbox"/> Other (specify below) | |
| <input type="checkbox"/> Process change: | <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Indications | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Sterilization | <input type="checkbox"/> Instructions | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Packaging | <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Shelf life | <input type="checkbox"/> Device defect |
| | <input type="checkbox"/> Trade name | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Reponse to FDA correspondence: | <input type="checkbox"/> Other (specify below) | |
| <input type="checkbox"/> Request for applicant hold | | <input type="checkbox"/> Change in ownership |
| <input type="checkbox"/> Request for removal of applicant hold | | <input type="checkbox"/> Change in correspondent |
| <input type="checkbox"/> Request for extension | | |
| <input type="checkbox"/> Request to remove or add manufacturing site | | |
| <input type="checkbox"/> Other reason (specify): | | |

Section D2**Reason for Submission -- IDE**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing process | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol – feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol – other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Notification of emergency use | | |
| <input type="checkbox"/> Compassionate use request | <input type="checkbox"/> Report submission: | |
| <input type="checkbox"/> Treatment IDE | <input type="checkbox"/> Current investigator | |
| <input type="checkbox"/> Continuing availability request | <input type="checkbox"/> Annual progress | |
| | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |
| <input type="checkbox"/> Other reason (specify): | | |

Section D3**Reason for Submission – 510(k)**

- | | | |
|---|---|--|
| <input checked="" type="checkbox"/> New device | <input type="checkbox"/> Change in technology | <input type="checkbox"/> Change in materials |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in design | <input type="checkbox"/> Change in manufacturing process |
| <input type="checkbox"/> Other reason (specify): Response to reviewer questions | | |

Section E Additional Information on 510(k) Submissions

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

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K061312	1 36mm BioloX® <i>delta</i> * Ceramic Heads	1 Biomet
2 K062748	2 DePuy Delta Ceramic Femoral Head	2 DePuy
3 K052718	3 V40™ BioloX <i>delta</i> Ceramic Femoral Heads	3 Howmedica Osteonics
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications

Common or usual name or classification name:
Femoral head for total joint prosthesis

Trade or proprietary or model name	Model number
1 BIOLOX <i>delta</i> Ceramic Femoral Head	1 8775-series
2	2
3	3
4	4
5	5

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

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

Data included in submission: Laboratory testing Animal trials Human trials

Section G Product Classification – Applicable to All Applications

Product code: LZO	C.F.R. Section 21 CFR 888.3353	Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification panel: Orthopedics/87	Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis	

Indications (from labeling):
 The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and are indicated for the following:
 Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

* Trademark of CeramTec AG

<i>Note:</i> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:	
Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment registration number: 9613350	
		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Repackager/relabeler
Company/Institution name: Zimmer GmbH			
Division name (if applicable): N/A		Phone number (include area code): +41-52 242 6083	
Street address: Sulzer Allee 8		FAX number (include area code): +41-52 244 3593	
City: Winterthur	State/Province: Zurich	Country: Switzerland	ZIP/Postal Code: CH-8404
Contact name: Peter Krafft			
Contact Title: Vice President, QA & Regulatory Affairs Europe		Contact e-mail address: peter.krafft@zimmer.com	

(b)(4) Trade Secret Process



zimmer

P.O. Box 708
Warsaw, IN 46581-0708
(574) 267-6131

September 13, 2007

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

Dear Sir or Madam:

Subject: Additional Information – Traditional 510(k) Premarket Notification – BIOLOX[®]
*delta** Ceramic Femoral Head (K071535)

Enclosed are Zimmer's responses to FDA's questions regarding the above-referenced submission.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8354, by e-mail at trish.jenks@zimmer.com or by fax at (574) 372-4605.

Sincerely,


Patricia Jenks
Specialist, Corporate Regulatory Affairs

tj/me
GmbH-20070201
Enclosure

* Trademark of CeramTec AG

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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 26, 2007

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: PATRICIA JENKS

510(k) Number: K071535
Product: BIOLOX DELTA
CERAMIC FEMORAL
HEAD

The additional information you have submitted has been received.

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

CDRH Submission Cover Sheet

Date of Submission:
October 25, 2007

FDA Document Number:
K071535

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input checked="" type="checkbox"/> Additional Information: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:

Section B Applicant or Sponsor

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-372-4485	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Toni Kingsley, Ph.D., RAC			
Contact Title: Vice President, Corporate Regulatory Affairs		Contact e-mail address: toni.kingsley@zimmer.com	

Section C Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-371-8354	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Patricia Jenks			
Contact Title: Specialist, Corporate Regulatory Affairs		Contact e-mail address: trish.jenks@zimmer.com	

K-11

Section D1 Reason for Submission -- PMA, PDP, or HDE		
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Response to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in design, component or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent
Section D2 Reason for Submission -- IDE		
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Compassionate use request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing process <input type="checkbox"/> Protocol – feasibility <input type="checkbox"/> Protocol – other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting
Section D3 Reason for Submission – 510(k)		
<input type="checkbox"/> New device <input type="checkbox"/> Additional or expanded indications <input checked="" type="checkbox"/> Other reason (specify): Response to reviewer questions	<input type="checkbox"/> Change in technology <input type="checkbox"/> Change in design	<input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process

Section E Additional Information on 510(k) Submissions

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

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K061312	1 36mm Biolox® <i>delta</i> * Ceramic Heads	1 Biomet
2 K062748	2 DePuy Delta Ceramic Femoral Head	2 DePuy
3 K052718	3 V40™ Biolox delta Ceramic Femoral Heads	3 Howmedica Osteonics
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications

Common or usual name or classification name:
Femoral head for total joint prosthesis

Trade or proprietary or model name	Model number
1 BIOLOX <i>delta</i> Ceramic Femoral Head	1 8775-series
2	2
3	3
4	4
5	5

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

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

Data included in submission: Laboratory testing Animal trials Human trials

Section G Product Classification – Applicable to All Applications

Product code: LZO	C.F.R. Section 21 CFR 888.3353	Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification panel: Orthopedics/87	Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis	

Indications (from labeling):

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and are indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

* Trademark of CeramTec AG

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

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number: 9613350	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Repackager/relabeler
--	--	--	--

Company/Institution name:
Zimmer GmbH

Division name (if applicable): N/A	Phone number (include area code): +41-52 242 6083
--	---

Street address: Sulzer Allee 8	FAX number (include area code): +41-52 244 3593
--	---

City: Winterthur	State/Province: Zurich	Country: Switzerland	ZIP/Postal Code: CH-8404
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Contact name:
Peter Krafft

Contact Title: Vice President, QA & Regulatory Affairs Europe	Contact e-mail address: peter.krafft@zimmer.com
---	---

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number: 8043792	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler
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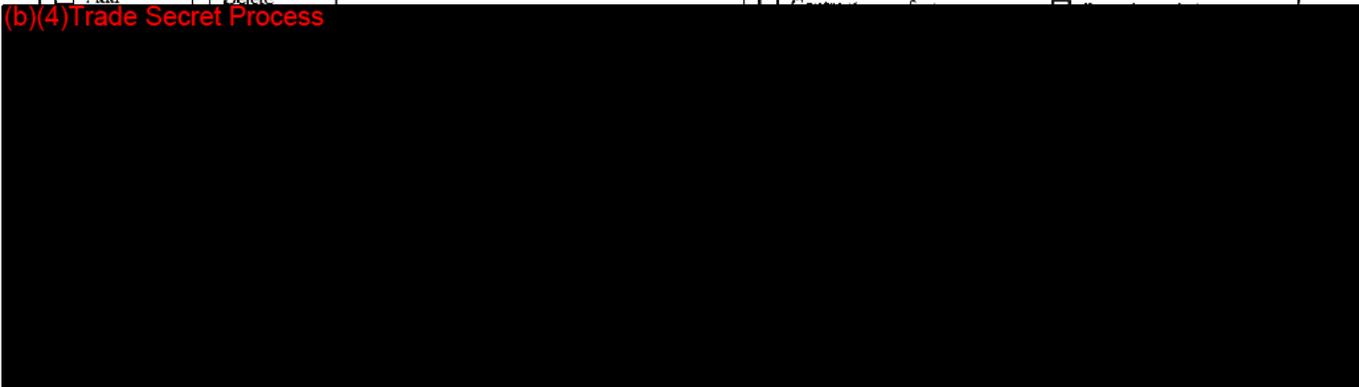


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K07175 35/52



zimmer

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October 25, 2007

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

Received

OCT 26 2007

FDA CDRH DMC

Dear Sir or Madam:

Subject: Additional Information – BIOLOX® *delta** Ceramic Femoral Head– Traditional
510(k) Premarket Notification (K071535)

Enclosed are Zimmer's responses to FDA's questions regarding the above-referenced submission.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8354, by e-mail at trish.jenks@zimmer.com or by fax at (574) 372-4605.

Sincerely,

Patricia Jenks
Specialist, Corporate Regulatory Affairs

tj/me
GmbH-20070201
Enclosure

* Trademark of CeramTec AG

