

K103120
P.1/2

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.: FEB 28 2011
2. Contact Person: Lucinda Gerber BA (Hons)
Regulatory Affairs Associate
Corin USA
813-977-4469
Lucinda.gerber@coringroup.com
3. Proprietary Name: Corin BIOLOX delta Modular Femoral Heads
4. Common Name: Femoral Head
5. Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)
6. Legally Marketed Devices to which Substantial Equivalence is claimed:
- Zyranox Zirconia Ceramic Modular Heads (K992235)
 - Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412)
7. Device Description:

BIOLOX delta material is an aluminum oxide / zirconia ceramic composite composed of approximately 75% aluminum oxide and approximately 25% zirconia.

The Corin BIOLOX delta Modular Femoral Heads are available in 28mm and 32mm diameters. The 28mm heads are available with short (-3.5mm), medium (0mm) and long (+3.5mm) offsets. The 32mm heads are available with short (-4.0mm), medium (0mm), long (+4mm) and extra long (+7mm) offsets.

The Corin Biolox Delta heads are compatible with Corin titanium stems (i.e. Tri-Fit, Metafix and MiniHip femoral stems having a 12/14 taper trunnion) and the Trinity acetabular system.

8. Intended Use / Indications:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity and
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

9. Summary of Technologies/Substantial Equivalence:

The Corin Biolox Delta modular femoral heads have the same types of indications and intended uses as the predicates. The technological characteristics are the same as the predicates. Based on the materials, geometry, mechanical testing and indications for use, the Biolox Delta heads are considered to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Nonclinical testing included burst strength testing on both the 28mm-12/14L and 32mm-12/14XL Biolox delta heads on the Corin titanium taper trunnion to determine the worst case construct. Subsequently, fatigue, post-fatigue burst and pull-off testing were then performed on the worst case construct. The results of the ceramic head testing meet the suggested values in the "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems." The results of the preclinical data provided indicate that the subject system is within the range of legally marketed predicates.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin BIOLOX delta Modular Femoral Heads and the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Corin USA
% Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
10500 University Center Drive
Suite 190
Tampa, Florida 33612

FEB 28 2011

Re: K103120

Trade/Device Name: BioloX Delta Modular 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: February 09, 2011

Received: February 10, 2011

Dear Ms. Gerber:

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

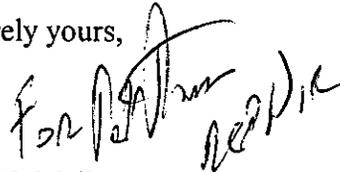
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K103120

Device Name: Corin BIOLOX delta Modular Femoral Heads

Indications for Use:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

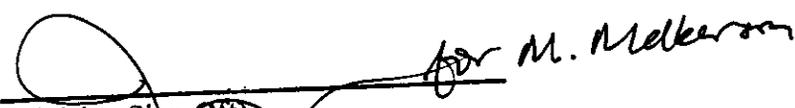
- o Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- o Rheumatoid arthritis
- o Correction of functional deformity and
- o Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

Page 1 of 1

510(k) Number K103120



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Corin USA
% Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
10500 University Center Drive
Suite 190
Tampa, Florida 33612

FEB 28 2011

Re: K103120

Trade/Device Name: Biolox Delta Modular 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: February 09, 2011

Received: February 10, 2011

Dear Ms. Gerber:

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

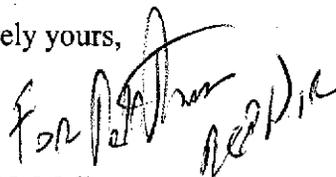
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Sincerely yours,



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

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K103120

Device Name: Corin BIOLOX delta Modular Femoral Heads

Indications for Use:

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- o Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- o Rheumatoid arthritis
- o Correction of functional deformity and
- o Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

Page 1 of 1

510(k) Number K103120



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

February 10, 2011

CORIN USA
10500 UNIVERSITY CENTER DRIVE SUITE 190
TAMPA, FLORIDA 33612
UNITED STATES
ATTN: LUCINDA GERBER

510k Number: K103120

Product: CORIN BIOLOX DELTA FEMORAL

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 13, 2011

CORIN USA
10500 UNIVERSITY CENTER DRIVE SUITE 190
TAMPA, FLORIDA 33612
UNITED STATES
ATTN: LUCINDA GERBER

510k Number: K103120

Product: CORIN BIOLOX DELTA FEMORAL HEA

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 at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. 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 (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 30, 2010

CORIN USA
10500 UNIVERSITY CENTER DRIVE SUITE 190
TAMPA, FLORIDA 33612
UNITED STATES
ATTN: LUCINDA GERBER

510k Number: K103120

Product: CORIN BIOLOX DELTA FEMORAL

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Sincerely,

510(k) Staff

64

K103120



10500 UNIVERSITY CENTER DRIVE
SUITE 190 • TAMPA, FLORIDA 33612
TEL: 813/977-4469 FAX: 813/979-0042
www.coringroup.com

October 21, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

OCT 22 2010

Received

**RE: Traditional 510(k) Premarket Notification –
Biologics Delta Modular Femoral Heads**

Dear Madam/Sir:

Please find enclosed a Traditional 510(k) Premarket Notification for the Biologics Delta Modular Femoral Heads. The official cover letter is enclosed in the submitted documentation.

The original document and one copy are submitted for FDA review. The enclosed CD provides an electronic version of the submission in PDF format. The Medical Device User Fee has been submitted with payment identification number MD6052308-956733.

If there are any questions on this information please contact me by email at Lucinda.gerber@coringroup.com or by phone at 813-977-4469.

Best regards,



Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate



10500 UNIVERSITY CENTER DRIVE
SUITE 190 • TAMPA, FLORIDA 33612
TEL: 813/977-4469 FAX: 813/979-0042
www.coringroup.com

October 21, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**RE: Traditional 510(k) Premarket Notification –
Biolog Delta Modular Femoral Heads**

Dear Madam/Sir:

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Best regards,

Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate

Form Approved: OMB No 0910-511 Expiration Date: January 31, 2010 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) CORIN USA 10500 UNIVERSITY CENTER DRIVE TAMPA FL 33612 US		2. CONTACT NAME Kathy Trier 2.1 E-MAIL ADDRESS kathy.trier@coringroup.com 2.2 TELEPHONE NUMBER (include Area code) 813-977-4469 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 813-979-0042
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)		
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)		
Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <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 4.1 If Yes, please enter your Small Business Decision Number:		<input checked="" type="checkbox"/> NO, I am not a small business
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?		
<input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)		
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		15-Oct-2010

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

Corin

TRADITIONAL 510(K)
PREMARKET
NOTIFICATION

CORIN
BIOLOX[®] DELTA
MODULAR FEMORAL HEADS

10500 UNIVERSITY CENTER DRIVE
SUITE 190
TAMPA, FL 33612

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1. 510(K) COVER LETTER

October 21, 2010

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

RE: Traditional 510(k) Premarket Notification – Corin BIOLOX[®] delta Modular Femoral Heads

Dear Madam/Sir:

Corin submits the enclosed information as a Traditional 510(k) Premarket Notification for the Corin BIOLOX delta Modular Femoral Heads. The basis for this submission is that this is a new material for an existing device design. The following regulation, product codes and classification are recommended for this device:

Recommended Classification Regulation: 21CFR 888.3353: Hip joint
metal/ceramic/polymer semi-constrained
cemented or nonporous uncemented
prosthesis

Recommended Class: II

Panel: 87 - Orthopedics

Product Code: LZ0

The following table briefly describes the design and use of the proposed device:

TABLE 1.1: DESIGN AND USE OF THE DEVICES

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? [^]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? [^]		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

[^] A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

Pursuant to 21 CFR 807.95(b)(1), Corin, considers this 510(k) submission to be confidential commercial information and requests that FDA treats it as such. Corin has taken precautions to protect the confidentiality of the intent to market these devices.

If there are any questions on this information please contact me by e-mail at Lucinda.gerber@coringroup.com or by phone at 813-977-4469.

Sincerely,



Lucinda Gerber BA (Hons)
Regulatory Affairs Associate
Corin USA

2. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Corin BIOLOX delta Modular Femoral Heads

Indications for Use:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity and
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.:
2. Contact Person: Lucinda Gerber BA (Hons)
Regulatory Affairs Associate
Corin USA
813-977-4469
Lucinda.gerber@coringroup.com
3. Proprietary Name: Corin BIOLOX delta Modular Femoral Heads
4. Common Name: Femoral Head
5. Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)
6. Legally Marketed Devices to which Substantial Equivalence is claimed:
 - Zyranox Zirconia Ceramic Modular Heads (K992235)
 - Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412)

7. Device Description:

BIOLOX delta material is an aluminum oxide / zirconia ceramic composite. composed of approximately 75% aluminum oxide and approximately 25% zirconia.

The Corin BIOLOX delta Modular Femoral Heads are available in 28mm and 32mm diameters. The 28mm heads are available with short (-3.5mm), medium (0mm) and long (+3.5mm) offsets. The 32mm heads are available with short (-4.0mm), medium (0mm), long (+4mm) and extra long (+7mm) offsets.

8. Intended Use / Indications:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity and
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

9. Summary of Technologies/Substantial Equivalence:

The Corin BIOLOX delta Modular Femoral Heads have similar intended uses, indications, designs and specifications as the predicate devices. The Biolox delta material is the same material used in the Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412). Based on these similarities, the Corin BIOLOX delta Modular Femoral Heads are believed to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Static compression burst strength and post-fatigue burst strength testing indicate that the Corin BIOLOX delta Modular Femoral Heads meet FDA's requirements. Axial pull-off testing from worst case femoral stem tapers indicate that the Corin BIOLOX delta Modular Femoral Heads are expected to be safe and effective for the proposed indications.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin BIOLOX delta Modular Femoral Heads and the predicate devices.

4. TRUTHFUL AND ACCURACY STATEMENT

In accordance with 21 CFR 807.87 (k), I certify that, in my capacity as Regulatory Affairs Associate for Corin USA, 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.



Lucinda Gerber
Regulatory Affairs Associate
Corin USA

21 - Oct - 10

Date

5. CLASS III SUMMARY AND CERTIFICATION

N/A. This is a Class II device.

6. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

N/A. Clinical data are not included in this submission.

7. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

N/A. This is a Traditional and not an Abbreviated 510(k) notification submission.

8. EXECUTIVE SUMMARY

Device Description:

BIOLOX delta material is an aluminum oxide / zirconia ceramic composite. composed of approximately 75% aluminum oxide and approximately 25% zirconia.

The Corin BIOLOX delta Modular Femoral Heads are available in 28mm and 32mm diameters. The 28mm heads are available with short (-3.5mm), medium (0mm) and long (+3.5mm) offsets. The 32mm heads are available with short (-4.0mm), medium (0mm), long (+4mm) and extra long (+7mm) offsets.

Intended Use / Indications:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity and
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

Predicate Devices:

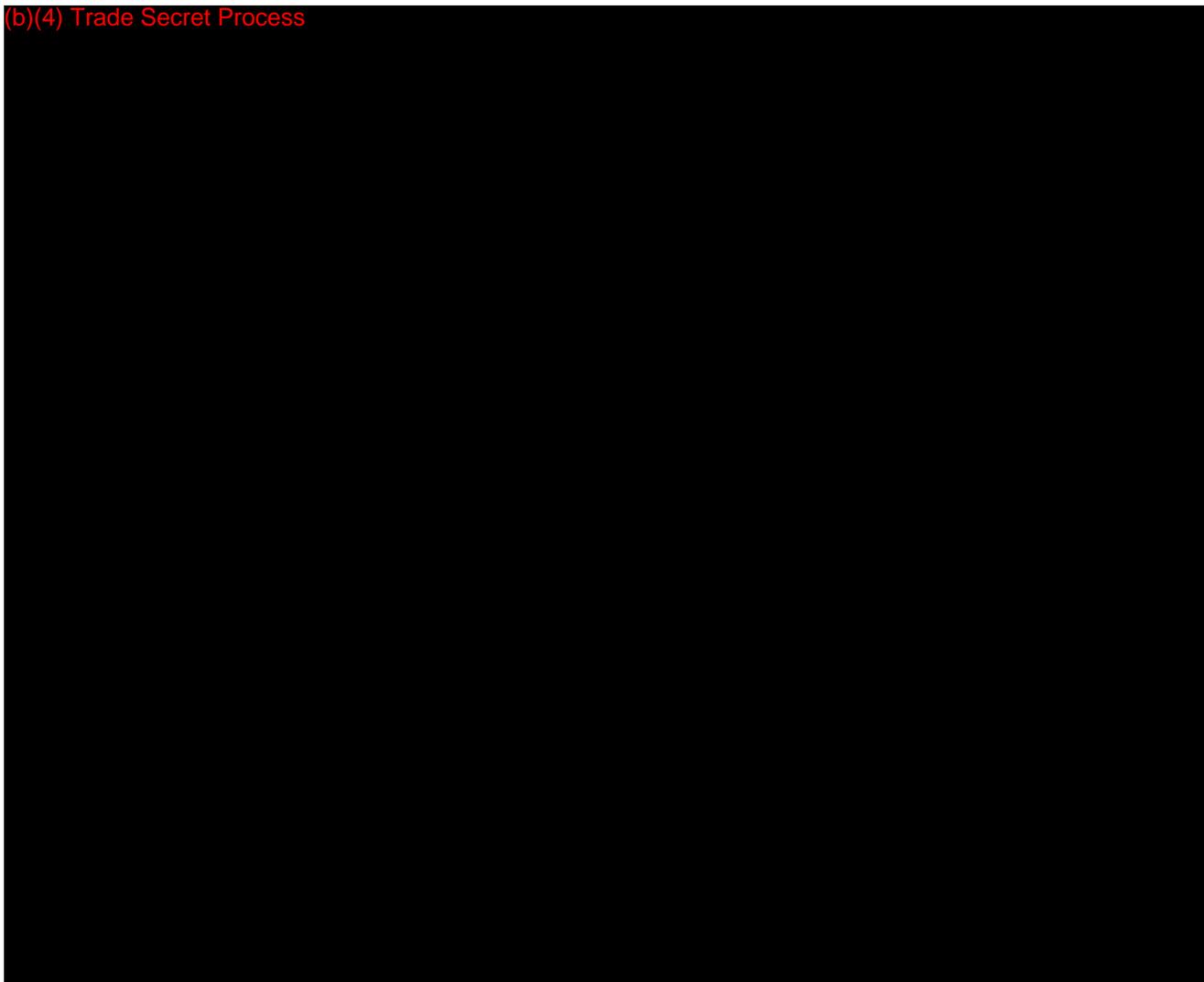
- Zyranox Zirconia Ceramic Modular Heads (K992235)

- Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412)

The Corin BIOLOX delta Modular Femoral Heads have similar intended uses, indications and designs as the predicate devices. The Biolox delta material is the same material used in the Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412). Mechanical testing indicates that the Corin BIOLOX delta Modular Femoral Heads meet FDA's requirements for static compression burst strength and post-fatigue burst strength and that axial pull-off loads from the taper of the femoral stem are sufficient for the femoral heads' intended use. The results of this testing show that the Corin BIOLOX delta Modular Femoral Heads are expected to be safe and effective for the proposed indications and are substantially equivalent to the predicate devices.

9. DEVICE DESCRIPTION

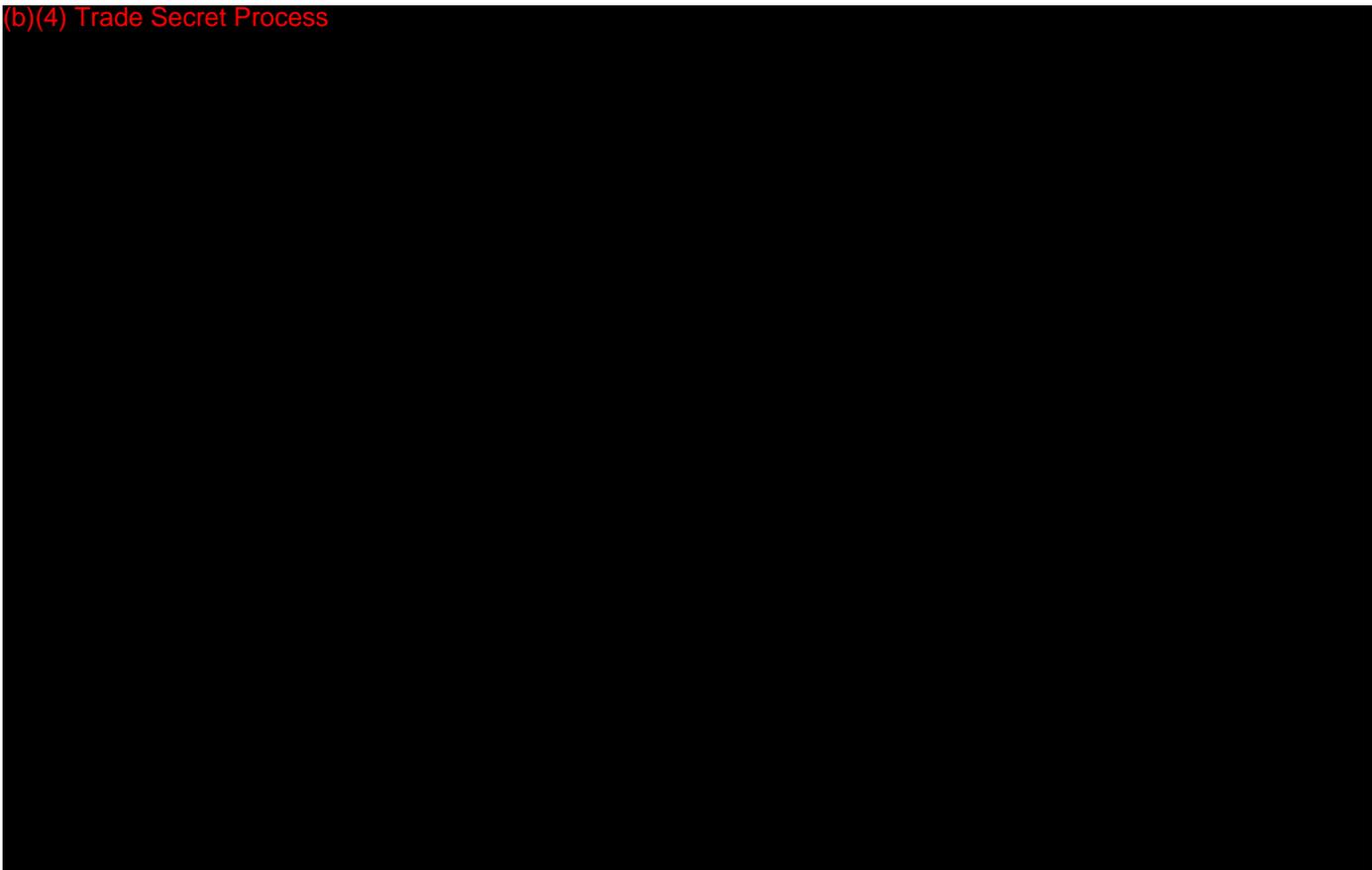
(b)(4) Trade Secret Process



surface changes (e.g. phases) and defects (e.g. cracks, pits) in and around the engraving are described in the Report from 2004.04.26. A description of the engraving process and the point in the manufacturing process where the engraving is made are provided in Folder 1 of MAF-197, Page 11/34 in the Summary Document as well as in the Appendix 14 pages 4 and 7. See Appendix B for summary page.

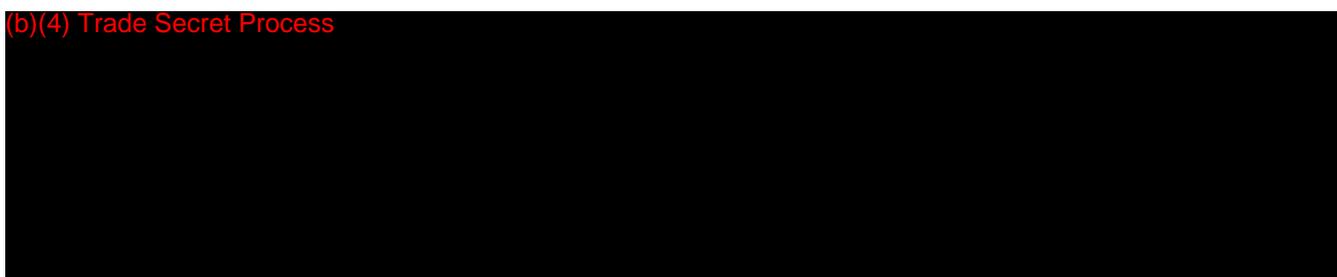
Specifications for the BIOLOX delta heads are provided on the engineering prints included in Appendix B. The specifications required by FDA's "Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems" are also provided below in Table 2.

(b)(4) Trade Secret Process



The Corin BIOLOX delta Modular Femoral Heads are designed to mate with Corin femoral stems having a 12/14 taper. Specifications for the femoral stem taper are provided on the engineering print (E000.020) included Appendix B and below in Table 3.

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Descriptions, part numbers and representative engineering prints for the Corin BioloX delta Modular Femoral Heads and compatible stem tapers are located in Appendix B. A list of compatible modular femoral stems and acetabular cup systems is provided in Appendix C. An instrument listing for the BioloX delta Modular Femoral Heads is provided in Appendix D.

10. SUBSTANTIAL EQUIVALENCE DISCUSSION

PREDICATE DEVICES:

- Zyranox Zirconia Ceramic Modular Heads (K992235)
- Smith & Nephew BioloX Delta Ceramic Femoral Heads (K100412)

Clearance letters for the predicate devices are provided in Appendix E.

SUBSTANTIAL EQUIVALENCE COMPARISON:

Comparisons of the Corin BIOLOX delta Modular Femoral Heads with the predicate devices are provided in Tables 4 and 5.

Table 4: Comparison of the Corin BIOLOX delta Modular Femoral Heads with the Corin Zirconia Ceramic Modular Heads (Predicate #1)

	Subject Device	(b)(4) Trade Secret Process
Company Name	Corin	(b)(4) Trade Secret Process
Device Name	BioloX delta Modular Femoral Head	
510(k) Number	N/A – New Submission	
Regulation	21 CFR 888.3353	
Product Code(s)	LZO	
Intended Use / Indications	<p>The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stem and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:</p> <ul style="list-style-type: none"> ○ Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis ○ Rheumatoid arthritis ○ Correction of functional deformity and ○ Developmental / congenital dysplasia of the hip (DDH / CDH) <p>The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.</p>	
Material	BioloX delta aluminum oxide / zirconia composite ceramic	
Design	<p>12/14 taper</p> <p>28mm diameter</p> <p>Short (-3.5mm)</p> <p>Medium (0mm)</p> <p>Long (+3.5mm) offsets</p>	

	Subject Device	Predicate #1
	32mm diameter Short (-4.0mm) Medium (0mm) Long (+4.0mm) Extra long (+7.0mm) offsets	(b)(4) Trade Secret Process

Table 5: Comparison of the Corin BIOLOX delta Modular Femoral Heads with the Smith & Nephew BIOLOX delta Ceramic Femoral Heads (Predicate #2)

	Subject Device	Predicate #2
Company Name	Corin	Smith & Nephew
Device Name	BioloX delta Modular Femoral Heads	BioloX Delta Ceramic Femoral Heads
510(k) Number	N/A – New Submission	K100412
Regulation	21 CFR 888.3353	21 CFR 888.3353
Product Code(s)	LZO	LZO
Intended Use / Indications	<p>The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:</p> <ul style="list-style-type: none"> ○ Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis ○ Rheumatoid arthritis ○ Correction of functional deformity and ○ Developmental / congenital dysplasia of the hip (DDH / CDH) <p>The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.</p>	<p>Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.</p> <p>The BioloX Delta Ceramic femoral heads are for single use only.</p>
Material	BioloX delta aluminum oxide / zirconia composite ceramic	BioloX delta aluminum oxide / zirconia composite ceramic

Design	Subject Device	Predicate #2
	12/14 taper 28mm diameter Short (-3.5mm) Medium (0mm) Long (+3.5mm) offsets 32mm diameter Short (-4.0mm) Medium (0mm) Long (+4.0mm) Extra long (+7.0mm) offsets	12/14 taper 28mm diameter 32mm diameter Offsets unknown

11. PROPOSED LABELING

Draft labels, a draft package insert and a draft surgical technique for the proposed devices are provided in Appendix F.

12. STERILIZATION AND SHELF LIFE

Corin Biolox delta Modular Femoral Heads are sterilized by gamma irradiation delivered from a cobalt₆₀ source.

After manufacture, the implants are transferred to a clean room operating to the level of Class 7 as defined by BS EN ISO 14644-1:1999 *Clean Rooms and Associated Controlled Environments Part 1: Classification of Air Cleanliness*. Here the devices are subjected to a cleaning process following which they are packaged. Sterility is preserved by packing into a special packaging system designed to comply with the requirements of EN 868 Part 1.

[REDACTED] (b)
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(b)(4) Trade Secret Process
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

The implants are sterilized by a contract sterilizer using a dose in the range 25 to 42 kGy.

The sterilization process has been validated to achieve a routine sterility assurance level (SAL) of 10^{-6} at a minimum dose of 25kGy. The process is validated in accordance with the requirements of ISO 11137:1995 *Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization*. The method used to validate the irradiation process is in accordance with AAMI TIR27:2001 – *Sterilization of health care products – Radiation*

sterilization – Substantiation of 25 kGy as a sterilization dose – Method VD_{max} . Dose audits are performed on a quarterly basis to ensure the ongoing validity of the irradiation sterilization process.

13. BIOCOMPATIBILITY

Biocompatibility testing was not conducted, because the material used in this device has been used in other implant devices that have been cleared for the same intended uses and indications (see Substantial Equivalence Discussion).

14. SOFTWARE

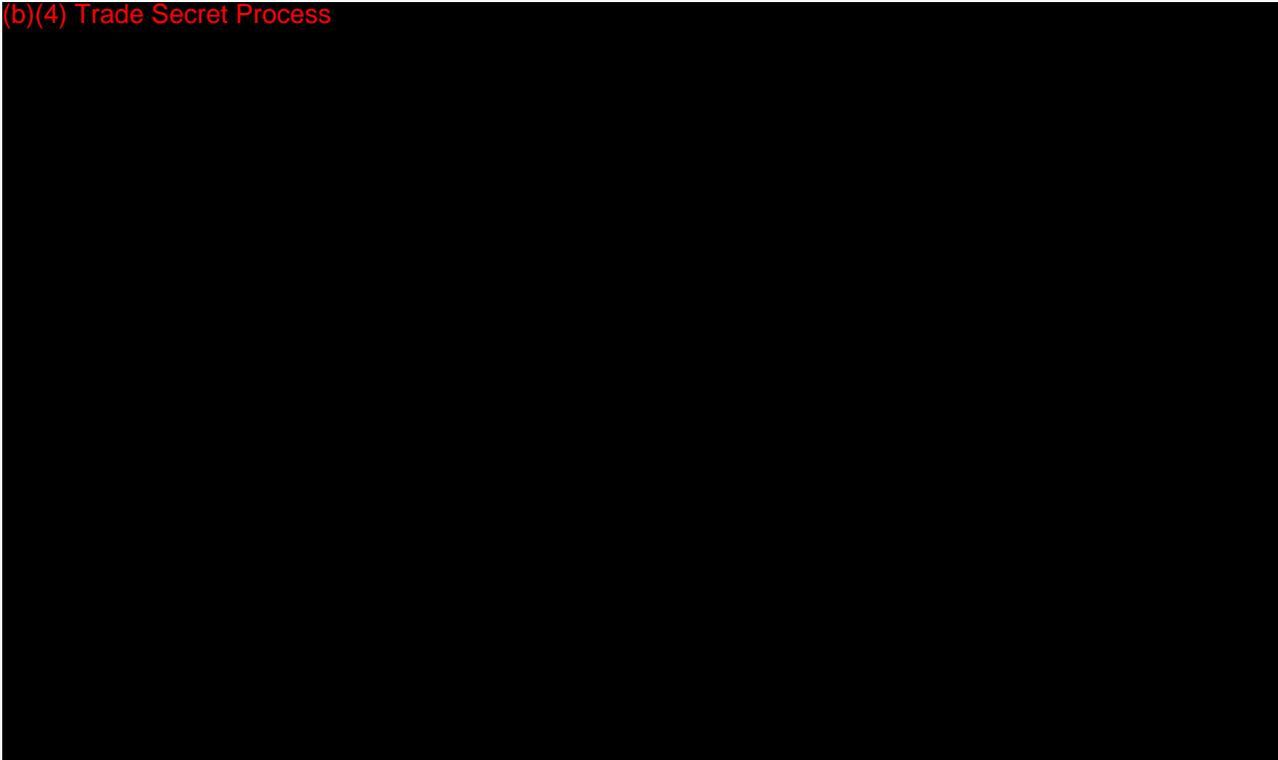
N/A. There is no software contained in this medical device.

15. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

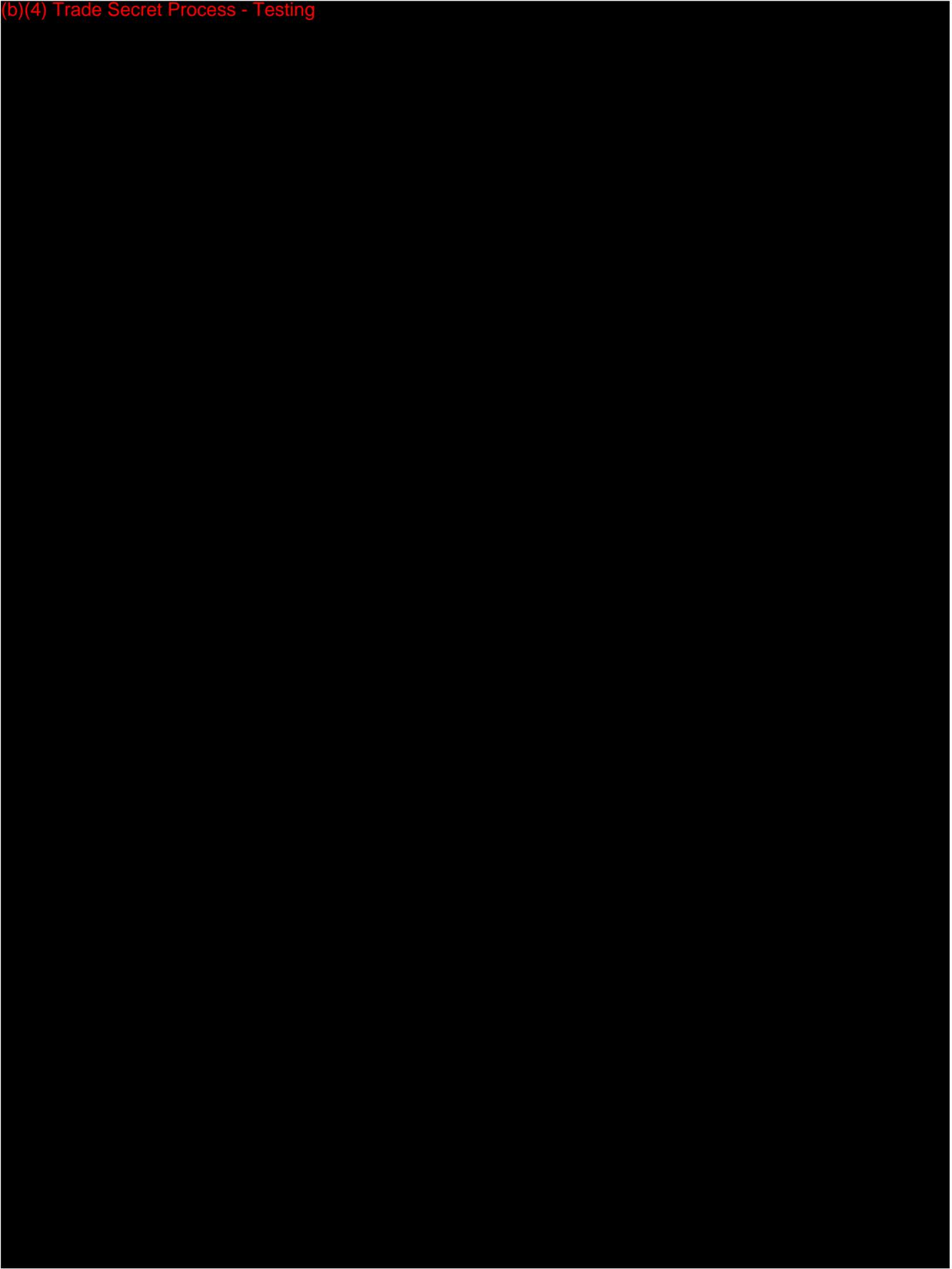
N/A. This device contains no electronic components.

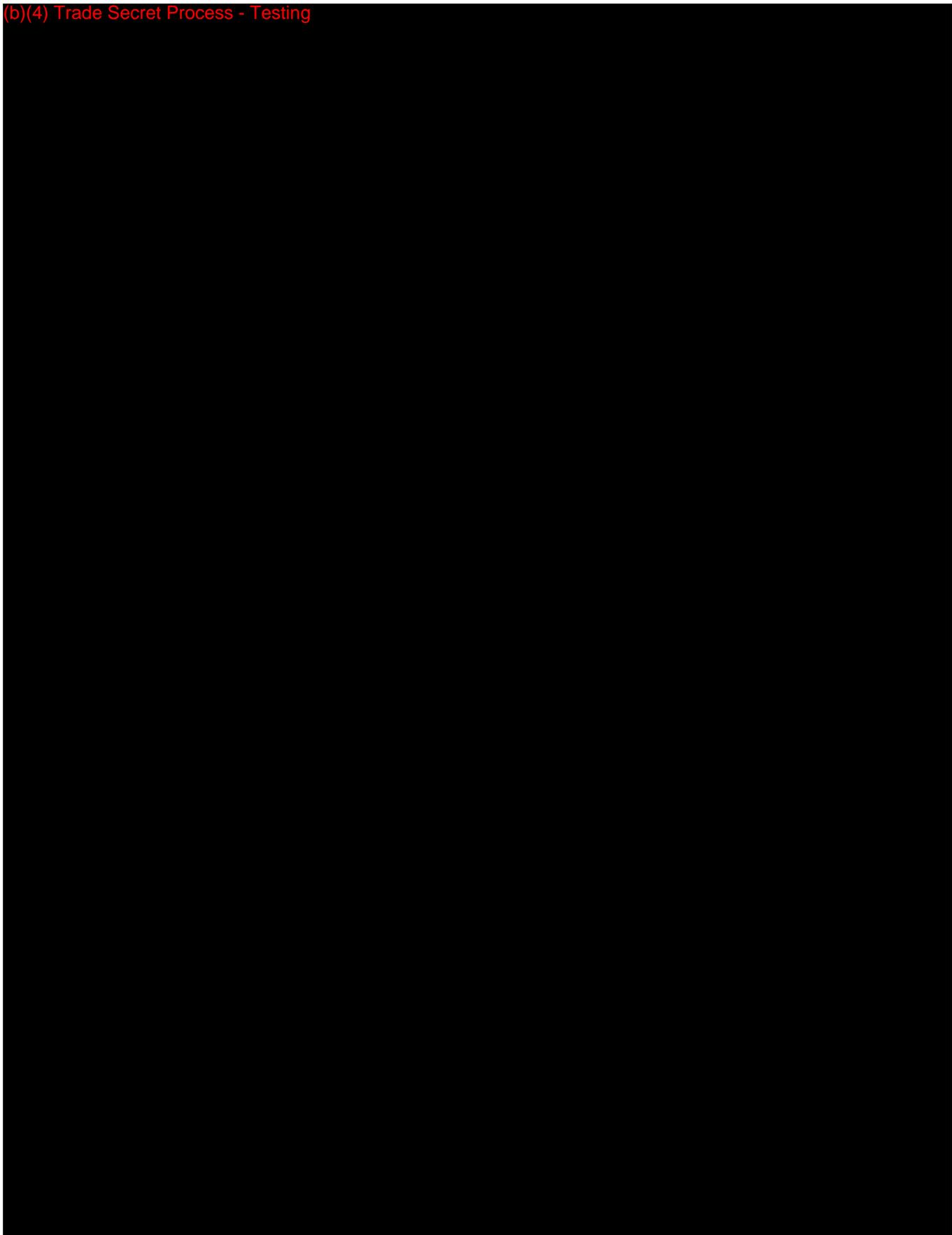
16. PERFORMANCE TESTING – BENCH

(b)(4) Trade Secret Process



(b)(4) Trade Secret Process - Testing





17. PERFORMANCE TESTING – ANIMAL

Animal testing was not performed. Substantial equivalence of this device to the predicate devices was demonstrated through a comparison of intended use, indications, materials, design and bench testing.

18. PERFORMANCE TESTING – CLINICAL

Clinical testing was not performed. Substantial equivalence of this device to the predicate devices was demonstrated through a comparison of intended use, indications, materials, design and bench testing.

APPENDIX A:

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



APPENDIX B:

**DESCRIPTIONS, PART NUMBERS AND REPRESENTATIVE
ENGINEERING DRAWINGS**

CORIN BIOLOX DELTA MODULAR FEMORAL HEADS

BIOLOX DELTA MODULAR HEADS

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



APPENDIX C:
COMPATIBLE FEMORAL HIP STEMS
AND ACETABULAR CUP SYSTEMS

CORIN METAFIX HIP STEMS

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



CORIN MINIHIP STEMS

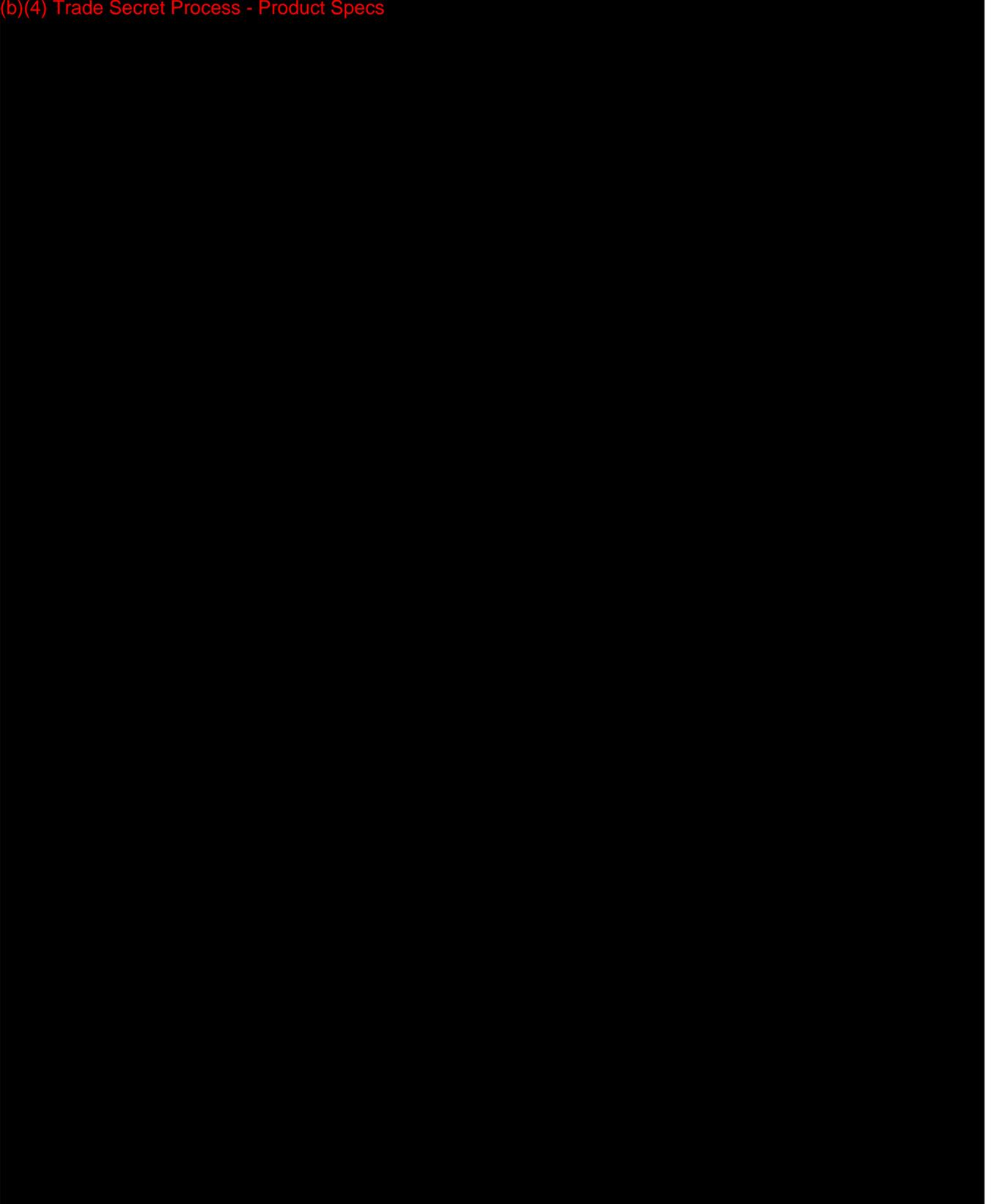
(b)(4) Trade Secret Process - Product Specs



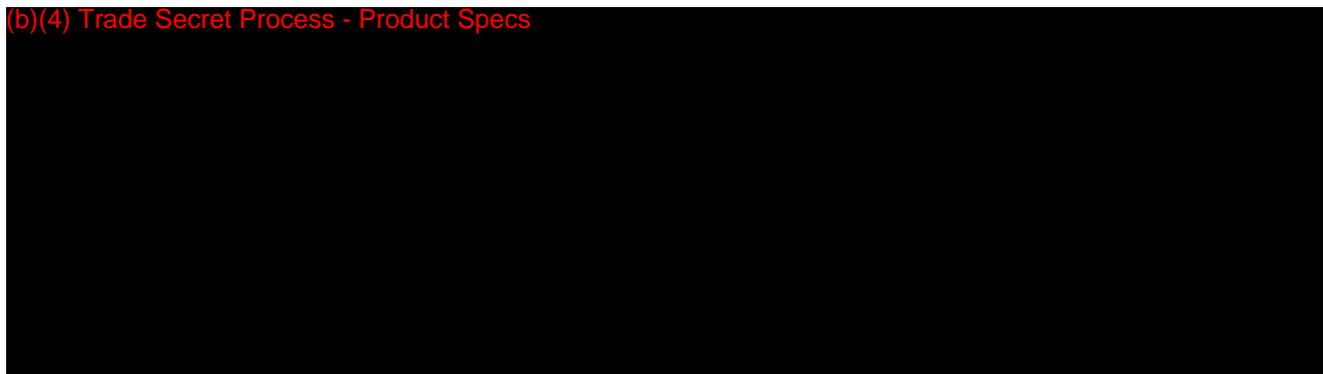
CORIN TRINITY ACETABULAR CUP SYSTEM

K093472 (currently under review)

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



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

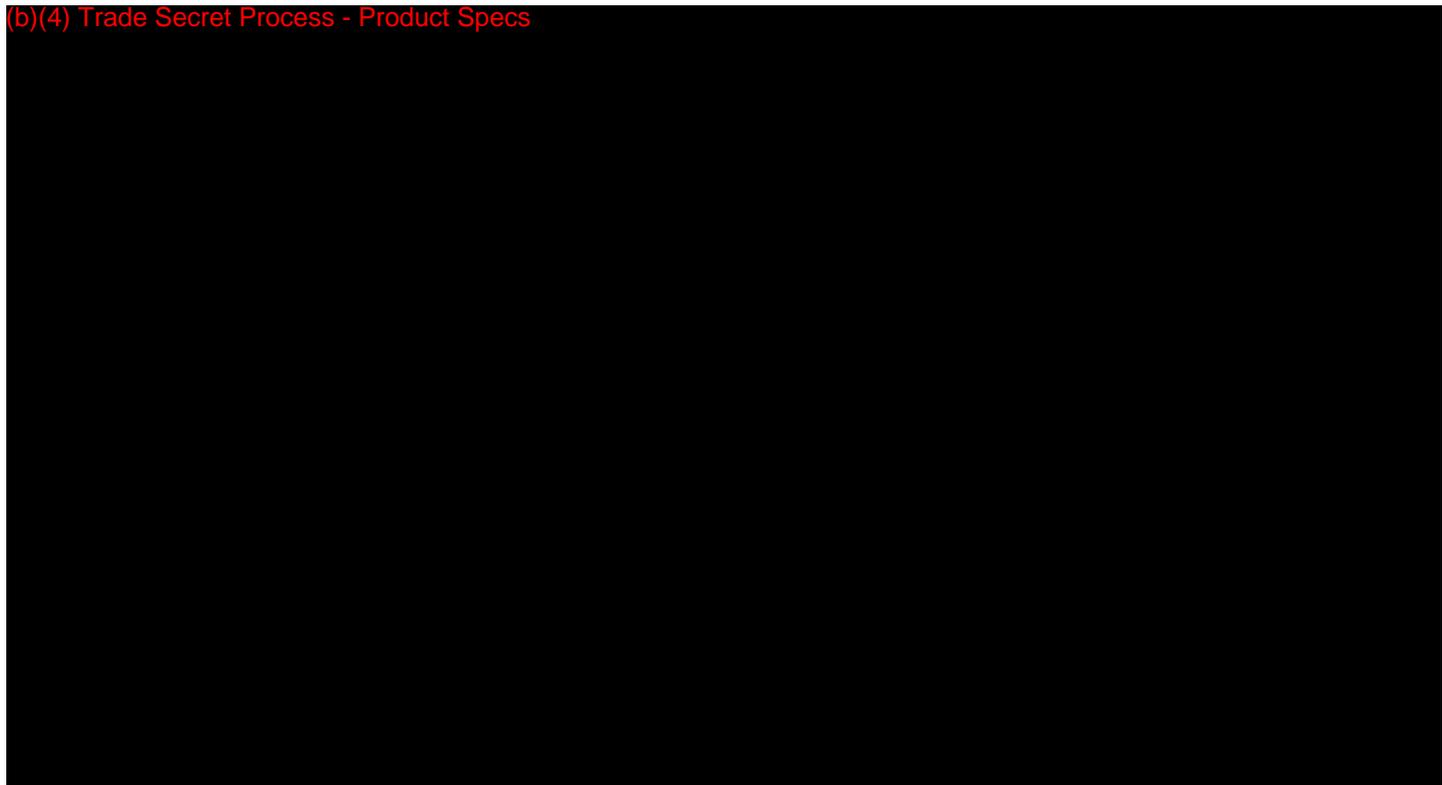


APPENDIX D:
INSTRUMENT LIST

Biolog Delta Modular Heads

Instruments used to implant heads

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



APPENDIX E:
PREDICATE DEVICE CLEARANCE LETTERS

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[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#)

New Search

Device Classification Name	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Po
510(K) Number	K992235
Device Name	ZYRANOX ZIRCONIA CERAMIC FEMORAL HEADS CORIN U.S.A.
Applicant	10500 University Center Dr., Suite 190 Tampa, FL 33612
Contact	Craig Corrance
Regulation Number	888.3353
Classification Product Code	LZO
Date Received	07/02/1999
Decision Date	11/23/1999
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

NOV 23 1999

K 992235

510(k) SUMMARY

Name of Company: Corin Medical
The Corinium Centre
Cirencester
Gloucestershire
GL7 1YJ
England

Name of Device: Zyranox Zirconia Ceramic Modular Heads

Device Description:

A Modular Femoral Head, manufactured from high purity 3 mol% Ytria Stabilized Zirconia Polycrystals (Y-TZP), used in total hip replacement surgery.

These Zirconia Ceramic Modular Heads are available in standard Corin trunnion and Eurocone trunnion options. The devices are available in short, standard and long neck and 28mm and 32mm outside diameters.

The bore of the Modular Head is designed so as to ensure compatibility with the cone (trunnion) of the Femoral Stem, and hence locking of the components in situ.

The Corin Medical Zirconia ceramic modular heads incorporate a female trunnion (taper). The modular head is applied to the male trunnion of a Corin Medical femoral stem.

The Zirconia ceramic modular heads are designed to articulate with ultra high molecular weight polyethylene (UHMWPE) acetabular cups or acetabular cup liners to reinstate function following the degenerative effects of osteo or rheumatoid arthritis, post-trauma disease effects, avascular necrosis and septic or aseptic total hip revision.

Zirconia ceramic modular heads offer an ultra smooth surface in order to decrease torque and reduce stresses normally associated with the articulation of cobalt chromium alloy femoral heads with ultra high molecular weight polyethylene (UHMWPE) acetabular components.

Zirconia ceramic modular heads are more resistant to third body wear from cement particles than cobalt chromium alloy modular heads. This, in conjunction with their low friction and decreased torque, significantly reduces polyethylene wear related total hip prostheses problems such as osteolysis.

The use of zirconia ceramic modular heads also eliminates the release of metallic corrosion particulates into the joint space, which can be found when cobalt chromium alloy heads are mounted onto cobalt chromium alloy femoral stems. These ceramic modular heads are designed for use with cobalt chromium alloy femoral hip stems manufactured by Corin Medical.

Sub-contract manufacture of Corin Medical's Zirconia Ceramic Modular Heads is performed by Morgan Matroc Ltd, St Peter's Road, Rugby, Warwickshire, CV21 3QR, England.

Morgan Matroc Ltd's master file held by the FDA is reference number MAF-343.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 23 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Craig Corrance
President
Corin U.S.A.
10500 University Center Drive, Suite 190
Tampa, Florida 33612

Re: K992235
Trade Name: Zyranox™ Zirconia Ceramic Femoral Heads
Regulatory Class: II
Product Code: LZO
Dated: September 15, 1999
Received: September 24, 1999

Dear Mr. Corrance:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Craig Corrance

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992235

Device Name: Zyranox Zirconia Ceramic Femoral Heads

INDICATIONS FOR USE

The Zirconia Ceramic Modular Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cups or acetabular cup liners to reinstate function following the degenerative effects of osteo or rheumatoid arthritis, post-trauma disease effects, avascular necrosis and septic or aseptic total hip revision.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992235

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)

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New Search

Device Classification Name	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Po
510(K) Number	K100412
Device Name	BIOLOX DELTA CERAMIC FEMORAL HEADS
Applicant	SMITH & NEPHEW, INC. 1450 Brooks Road Memphis, TN 38116
Contact	Megan Bevill
Regulation Number	888.3353
Classification Product Code	LZO
Date Received	02/16/2010
Decision Date	05/05/2010
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Summary of Safety and Effectiveness
Bilox Delta Ceramic Femoral Heads
Smith & Nephew, Inc.

Contact Person and Address

Megan Bevill
 Regulatory Affairs Specialist
 Smith & Nephew, Inc.
 Orthopaedic Division
 1450 Brooks Road
 Memphis, Tennessee 38116
 T (901) 399-5340

Date of Summary: April 27, 2010

MAY - 5 2010

Name of Device: BioloX Delta Ceramic Femoral Heads

Common Name: Femoral Heads

Device Classification Name and Reference: 21 CFR 888.3353 Hip joint metal/ceramic/polymer
 semi-constrained cemented or nonporous uncemented prosthesis

Device Class: Class II

Panel Code: Orthopaedics/87 LZO

Device Description

Subject of this Traditional Premarket Notification are BioloX Delta Ceramic Femoral Head line additions. The subject devices are ceramic femoral head components which are intended to be used in conjunction with existing Smith & Nephew 12/14 taper hip stems, and they are intended to articulate against appropriately sized, existing XLPE acetabular liners. The BioloX Delta Ceramic Femoral Heads are manufactured from BioloX delta ceramic material and will be offered in sizes 40 and 44mm with offsets of 0, +4, and +8mm.

BioloX Delta Ceramic Femoral Heads in smaller sizes (28, 32, and 36mm) have previously been cleared for market via premarket notification K083762. The only difference between the subject BioloX Delta Ceramic Femoral Heads and those cleared via K083762 is the size offering: the subject devices are offered with a larger diameter than the predicate devices. All other design features, including material choice, taper design, and articular surface finish, are identical. Additionally, BioloX Delta Ceramic Femoral Heads in the same size range have previously been cleared for market via K082844.

Intended Use

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip, and correction of deformity.

Summary of Safety and Effectiveness
BioloX Delta Ceramic Femoral Heads
Smith & Nephew, Inc.

Performance Data

Performance testing has been conducted for the subject devices in accordance with the guidance titled "Draft Guidance Document for Testing Non-articulating, 'Mechanically Locked,' Modular Implant Components," dated May 1, 1995, "Guidance Document for Testing Acetabular Cup Prostheses," dated May 1995, and "Draft Guidance for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems", dated January 10, 1995. Range of motion, femoral head burst, femoral head fatigue, wear performance, assembly/disassembly strength, and head/stem construct fatigue have been evaluated. A review of the testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject devices.

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The subject BioloX Delta Ceramic Femoral Heads are substantially equivalent to the predicate devices listed in the table below. Giving consideration to the device modifications described in the Device Description section, no changes have been made to the overall design philosophy, intended use, and material choices when compared to the predicate femoral heads.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	BioloX Delta Ceramic Femoral Heads	K083762	3/11/09
Zimmer, Inc.	BioloX Delta Ceramic Femoral Heads	K071535	11/19/07
Encore Medical, LP	BioloX Delta Ceramic Femoral Heads	K082844	11/25/08

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the BioloX Delta Ceramic Femoral Heads. Based on the similarities to the predicate devices and a review of the testing, the devices are substantially equivalent to femoral head components currently marketed under K083762, K071535, and K082844.



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

Smith & Nephew, Inc.
% Ms. Megan Bevill
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

MAY - 5 2010

Re: K100412

Trade/Device Name: BioloX Delta 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: II
Product Code: LZO
Dated: February 11, 2010
Received: February 16, 2010

Dear Ms. Bevill:

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

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

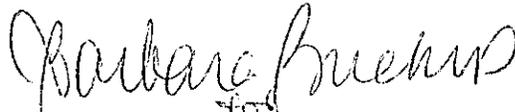
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic,
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100412

Device Name: BioloX Delta Ceramic Femoral Heads

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

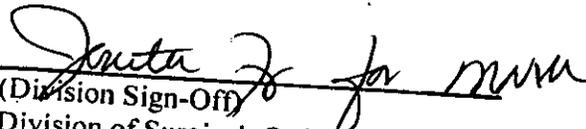
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

510(k) Number K100 412

APPENDIX F:
DRAFT LABELING –
LABELS, PACKAGE INSERT, SURGICAL TECHNIQUE

APPENDIX G:
BENCH TESTING

APPENDIX G1:
MECHANICAL TESTING – RESISTANCE TO TORQUE

APPENDIX G2:
MECHANICAL TESTING – AXIAL PULL-OFF

APPENDIX G3:

**MECHANICAL TESTING – RESISTANCE TO STATIC LOAD/
COMPRESSION TESTING**

APPENDIX G4:

MECHANICAL TESTING – FATIGUE/ POST FATIGUE TESTING

APPENDIX H:
STANDARDS FORMS

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹ ASTM F 2009-00 (reapproved 2005) Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # Not Available

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

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

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹ ASTM F 2345-03 Standard Test Method for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # Not Available

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹ ISO 7206-9:1994 Implants for Surgery- Partial and Total Hip Joint Prostheses - Part 9: Determination of Resistance to Torque of Head Fixation of Stemmed Femoral Components.

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # Not Available

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹ ISO 7206-10 Implants for Surgery - Partial and Total hip-joint prostheses - Part 10: Determination of resistance to static load of modular heads

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # Not Available

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COVER SHEET MEMORANDUM

From: Reviewer Name Gantenberg
Subject: 510(k) Number K103120/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/0_5631/Screening%20Checklist%207%202%2007.doc)
- 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 Original ecopy p.7/131	<i>Attach IFU</i>	X	
510(k) Summary /510(k) Statement – S2 ecopy p.41/42	<i>Attach Summary</i>	X	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	X	
Is the device Class III? If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
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)? N Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of Clinical Trials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X

Nanotechnology		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 **Class*** **Product Code**

 21 CFR 888.3353 II(87 Panel) LZO
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ *DEJDB* *2/28/2011*
 (Branch Chief) (Branch Code) (Date)

Final Review: _____
 (Division Director) _____ (Date)
Mr. P. R.
2/28/11



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

Premarket Notification [510(k)] Review
Traditional

K103120/S2

Date: 2/24/11

To: The Record

Office: ODE

From: Gantenberg

Division/Branch: DSORD/OJDB

510(k) Holder: Corin USA (Tampa, FL)

Device Name: Biolox Delta Modular Femoral Heads

Official Contact: Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
10500 University Center Drive
Suite 190
Tampa, Florida 33612

Phone: 813-977-4469 / Email: Lucinda.gerber@coringroup.com

Handwritten signature and date: 2/28/11

Product Code: LZO (21 CFR 888.3353)

I. Purpose

The 510(k) holder would like to introduce the Biolox Delta Modular Femoral Heads into interstate commerce. I received S2 copy on 2/9/11. My review began on 2/24/11. Based on the similarities of the device materials, geometry and mechanical testing to predicates, I recommend the device be found substantially equivalent.

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

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.

Reviewer Comment: Effective Dec. 26, 2007 and later

Table with 4 columns: Requirement, Yes, No, N/A. Row: Certificate of Compliance of Clinical Trials - Form FDA 3674 Original.

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)? No for implants, Yes for instruments Are "cleaning" instructions included for the end user?		X	

Device Description Summary

A predicate comparison table was provided in Original, p.15/131.

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



BIOLOX delta head sizes	Neck length offsets (mm)
-------------------------	--------------------------

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



Reviewer Comment: 32mm(+7) was worst case per S2 testing.

The BIOLOX delta heads are engraved with diameter, taper size, offset, year of manufacture, manufacturer, a delta sign (symbolizing the BIOLOX delta material) and a sequential manufacturing number on the rim of the head (see Engineering Prints included in Appendix B). Magnified photographs of the femoral head engravings, an evaluation of any surface changes (e.g. phases) and defects (e.g. cracks, pits) in and around the engraving are described in the Report from 2004.04.26. A description of the engraving process and the point in the manufacturing process where the engraving is made are provided in Folder 1 of MAF-197, Page 11/34 in the Summary Document as well as in the Appendix 14 pages 4 and 7. See Appendix B for summary page.

The following data is derived from Original, p.13/131:

Table 2: Corin BIOLOX delta Modular Femoral Head Specifications

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



Per Drawings:

Head size	Bore Axial Length (mm)	Bore Diameter Top (mm)	Bore diameter Bottom (mm)	Gage diameter (mm)/Overlap %
-----------	------------------------	------------------------	---------------------------	------------------------------

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

The stem magnified taper trunnion drawing was provided on p.47/131:

Stem Taper Material	Axial Taper Length inch	Cone Angle	Cone Angle Tolerance	Diameter (gage) (mm)	Diameter at bottom of taper (inch)	Straightness	Sphericity	Surface Roughness
---------------------	-------------------------	------------	----------------------	----------------------	------------------------------------	--------------	------------	-------------------

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

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

Mechanical drawings for the subject device are found in Original, App.B, p.31/131.

Catalogue listing of subject components are found below and in Original App.C, p.49/131.

Part Number	Description
(b)(4) Trade Secret Process - Product Specs	

Instruments -- Original, p.53/131

Compatible Components (Original App.C, p.50/131): Titanium Stems --K010243, K082525 and K083312 and Trinity Acetabular Cup System (K093472).

Reviewer Comment: Note that K010243, K082525 and K083312 are the only titanium stems on the market by Corin at present and were all cleared previously for use with the K992235 Zirconia heads. All 3 titanium stems are being evaluated for use with the BioloX delta heads in this 510(k).

Deficiencies Addressed:

- For your subject components, please provide the purpose of the subject design components and whether or not the components are addressing any adverse events seen in your legally marketed predicates. See deficiency item #1a. Although not provided in original submission, in S1 response dated 12/28/10, in item #1a, sponsor states that the heads do not represent design modification to legally marketed predicates to address any adverse events. Adequate.
- Please clarify the purpose of p.129 (ecopy p.131/131) in your submission regarding the Orthoplastics Medical Grade Polyoxymethylene Copolymer (POM). Please clarify if this material is an instrument material and whether or not this material has been cleared (identify submission number) previously. See deficiency item #1b.

Although not provided in original submission, in S1 response dated 12/28/10, in item #1a, sponsor stated that the POM material is used for the head trials. The Certificate of Conformity documents the vendor's compliance with applicable FDA regulation.

Review: Adequate. The material is for a head trial instrument and not an implant. JNG reviewed the certificate again in original submission. The material is also known as POM C, polyacetal copolymer, and acetal copolymer. Acetal copolymers appear to be used in numerous 510(k)s as noted in the Image search. The FDA regulations identified are 21 CFR 177.2470 and the colorant used conforms to 21 CFR 178.3297:

The material supplied has been manufactured to the requirements specified on the purchase order received

The Extruded material manufactured from Polyoxymethylene is supplied in compliance with FDA regulation 21CFR177.2470.

All Colourants used during the manufacture of the extruded product are in compliance with FDA regulation 21 CFR Part 73 or 21 CFR 178.3297

[Redacted text block]

JNG took this information to Joint Team Hip subgroup. This information is sufficient as FDA has seen numerous submissions with trials made of the acetal copolymer. No additional biocompatibility information is needed.

[Redacted text block]

- We did not locate FDA Form 3674 with your submission. Section 402(j)(5)(B) of the Public Health Service Act, as amended by Title VIII of the Food and Drug Administration Amendments of 2007 (FDAAA), requires that certifications be submitted with certain applications/submissions to FDA. Please complete and submit this Certification Form. When submitting the Certification Form, please reference the submission the form should have accompanied. Form 3674 may be found at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf>. See deficiency item #1d. Although not provided in original submission, in S1 response dated 12/28/10, in item #1d, sponsor provided the form. Adequate.
- 510(k) Summary advisory provided in original deficiency list that modifications to summary will be needed once all testing is finalized. FDA will work interactively with sponsor upon submitting response. See S1 deficiency item #3. Although not provided in original submission, in S2 submission dated 2/9/11, in item #3, sponsor provided revised summary as requested. Adequate.

IV. Indications for Use (ecopy Original, p.7/131)

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- o Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- o Rheumatoid arthritis
- o Correction of functional deformity and
- o Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

Review: Adequate.

V. Predicate Device Comparison

A predicate comparison table was provided in Original submission (ecopy, p.15/131).

Sponsor's information in support of SE determination as provided in S1 Response:

Zyranox Zirconia Ceramic Modular Heads (K992235)

Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412)

Review of other 510(k)s for SE determination:

K041940 (Howmedica Osteonics) Zirconia Toughened Alumina (BioloX delta) heads

K071535 (Zimmer) BIOLOX® delta Ceramic Femoral Head

Reviewer Note: K071535 cleared with the following head sizes and offsets:

BIOLOX delta head sizes	Neck length offsets (mm)			
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

VI. Labeling (Original, App. F, p.67/131)

Package label, package insert, and STM provided.

Package Label – (Original, ecopy p.75/131)

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

Outer package label (A2 dated 12/1/10) – legend with text and symbols defined. Corin has provided a copy of an additional label that contains a legend defining the symbols used on the outer box label.

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

[REDACTED]

Review: Appears adequate.

Package Insert – A draft package insert was provided – (Revised and adequate in S2, App.B (ecopy p.24/42), Previously provided in S1 App.C, Original, ecopy p.75/131)

History:

Original insert:

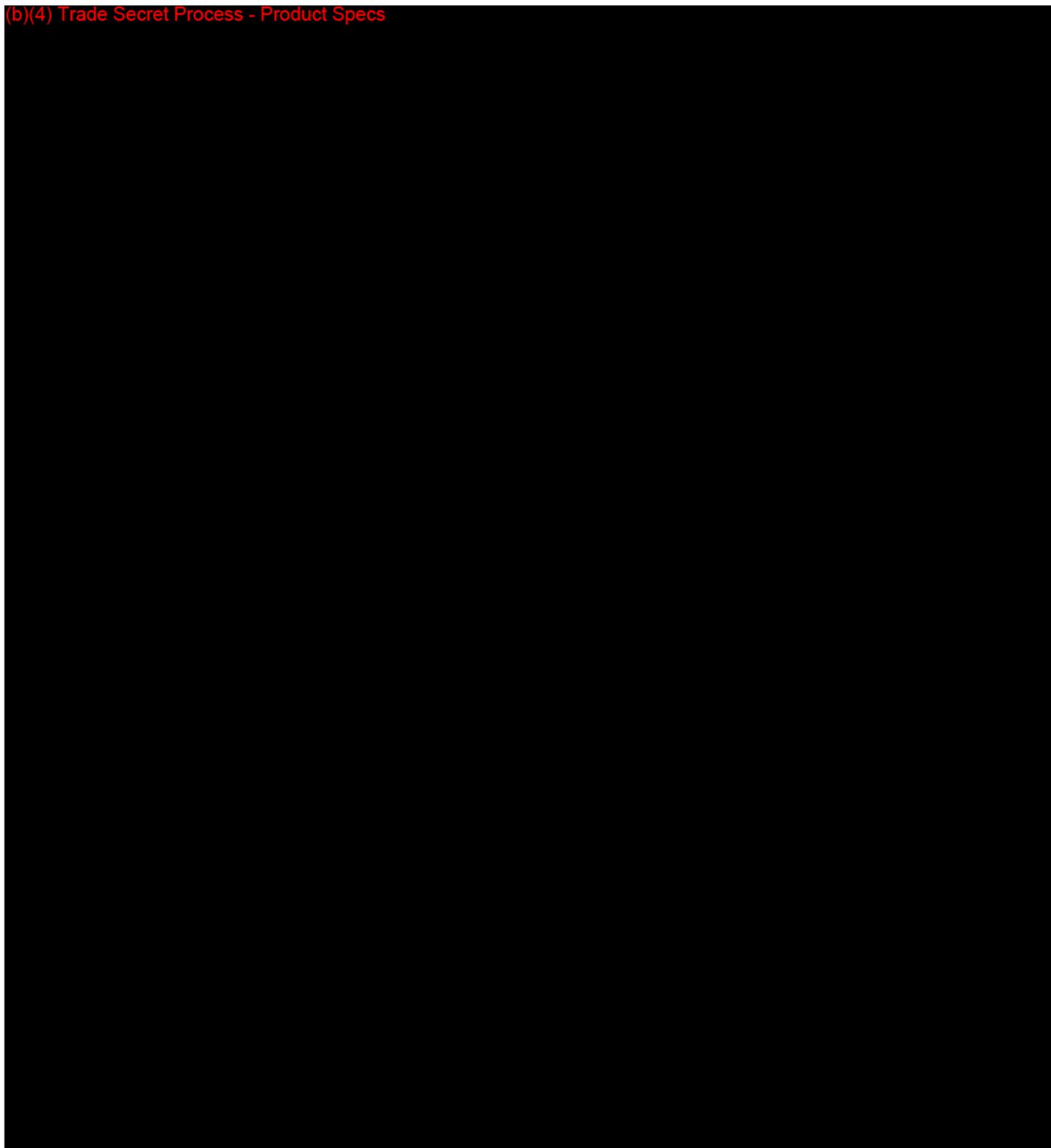
1. System name? No, for incorporation with Trinity Acetabular System
2. Specific intended uses and indications? Yes
3. List of contraindications, warnings, precautions and potential risks, adverse effects provided. Deficient
4. "Sterile" notation provided? Yes.

Nonsterile Recommended process parameters: N/A for implants.

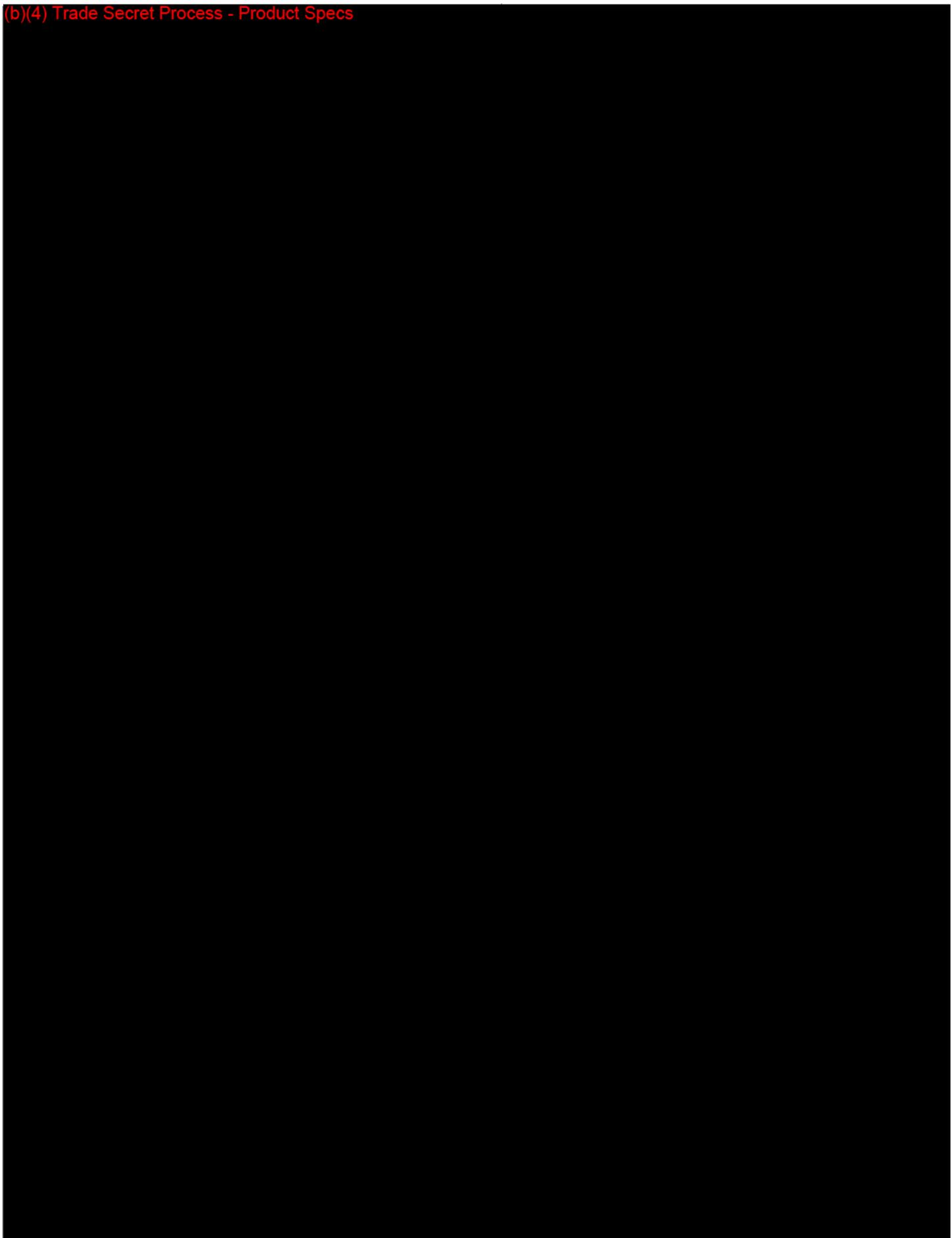
Instruments are to be resterilized. Instructions based on validated sterilization are provided.

- Method: Moist-Heat Sterilization
- Cycle: Pre-Vacuum (Pre-Vac)
- Temperature: 270 F (132 C)
- Exposure Time: 4 minutes
- Pressure: 2-15 PSIA
- Dry-Time: 30 minutes (minimum, in chamber)
- Cool-Time: 60 minutes (minimum, at room temperature)

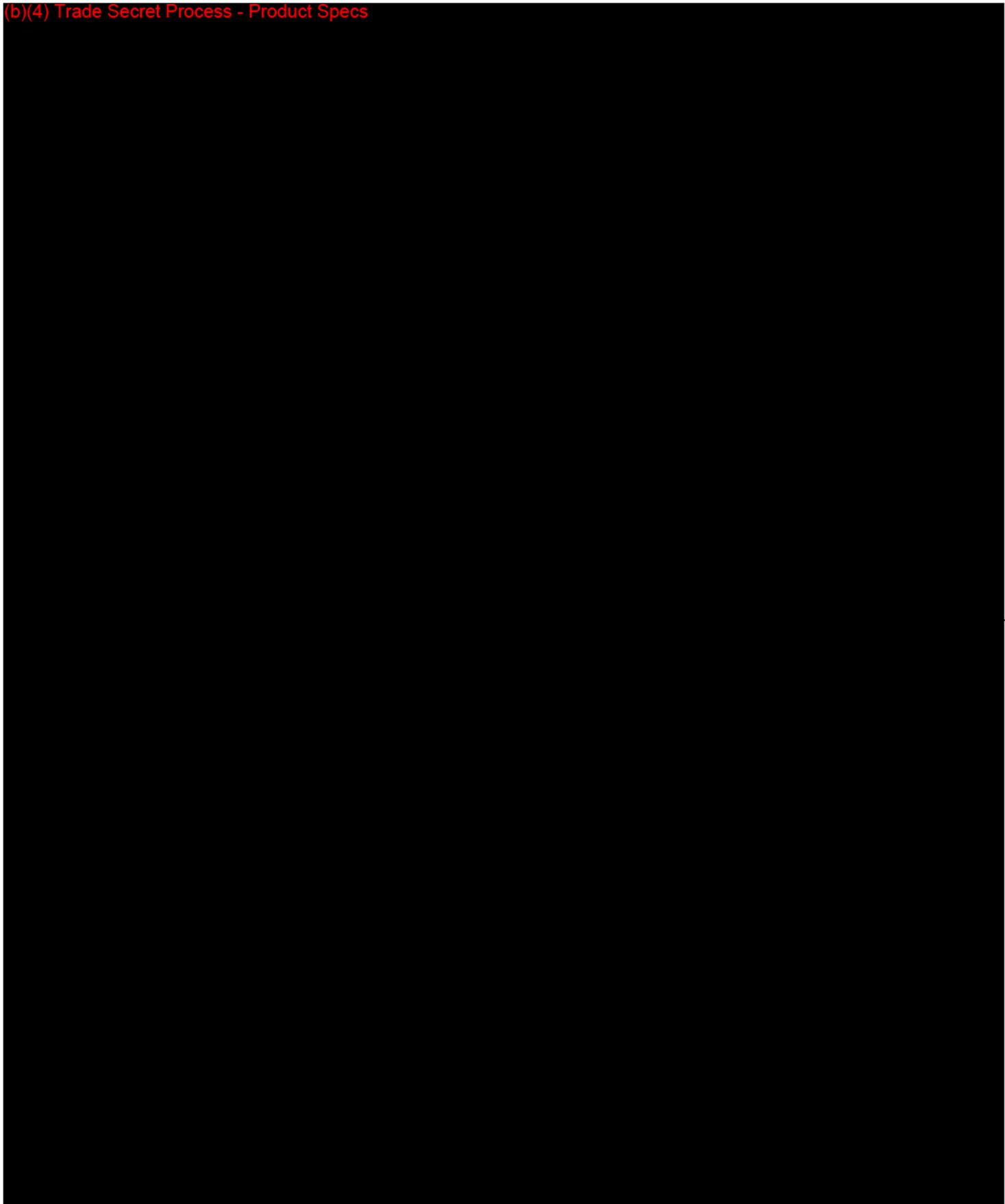
(b)(4) Trade Secret Process - Product Specs



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



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



VII. Sterilization/Shelf Life/Reuse (A1, dated 10/28/10)

Single use for implants.

Shelf-life- 5 years

1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam, EtO, Radiation):	Gamma radiation from Co60	
b. Dose , for radiation (e.g., 25 – 40 kGy):	25-35 kGy	
c. Sterilant residuals remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	N/A	X
2. A description of the Validation Method for the sterilization cycle (not data): (e.g., Overkill/1/1alf-cycle method, bioburden method, combination method)	validated per ISO 11137:2006 Sterilization of Health Care Products- Part 1 - Requirements for Validation and Routine Control - Radiation sterilization using Method V _{Dmax.25} as described in ISO 11137-3:2007 Sterilization of Health Care Products – Radiation-Part 2: Establishing the sterilization Dose.	
3. Sterility assurance level (SAL): (e.g., 10 ⁻⁶ for all devices (except 10 ⁻³ for devices that contact intact skin))	10 ⁻⁶	
4. Is it labeled "Pyrogen Free"?		X
If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amebocyte Lysate test))	N/A	
5. A description of the packaging (p.25/605) (not including package integrity test data):	(b)(4) Trade Secret Process - Product Specs	

VIII. **Biocompatibility** (Original, ecopy p.19/131)

On p.30/131, CeramTec provides references for the biocompatibility and hydrothermal stability (adequate). The implant materials have a long history of use in the orthopedic industry.

IX. **Software**

N/A

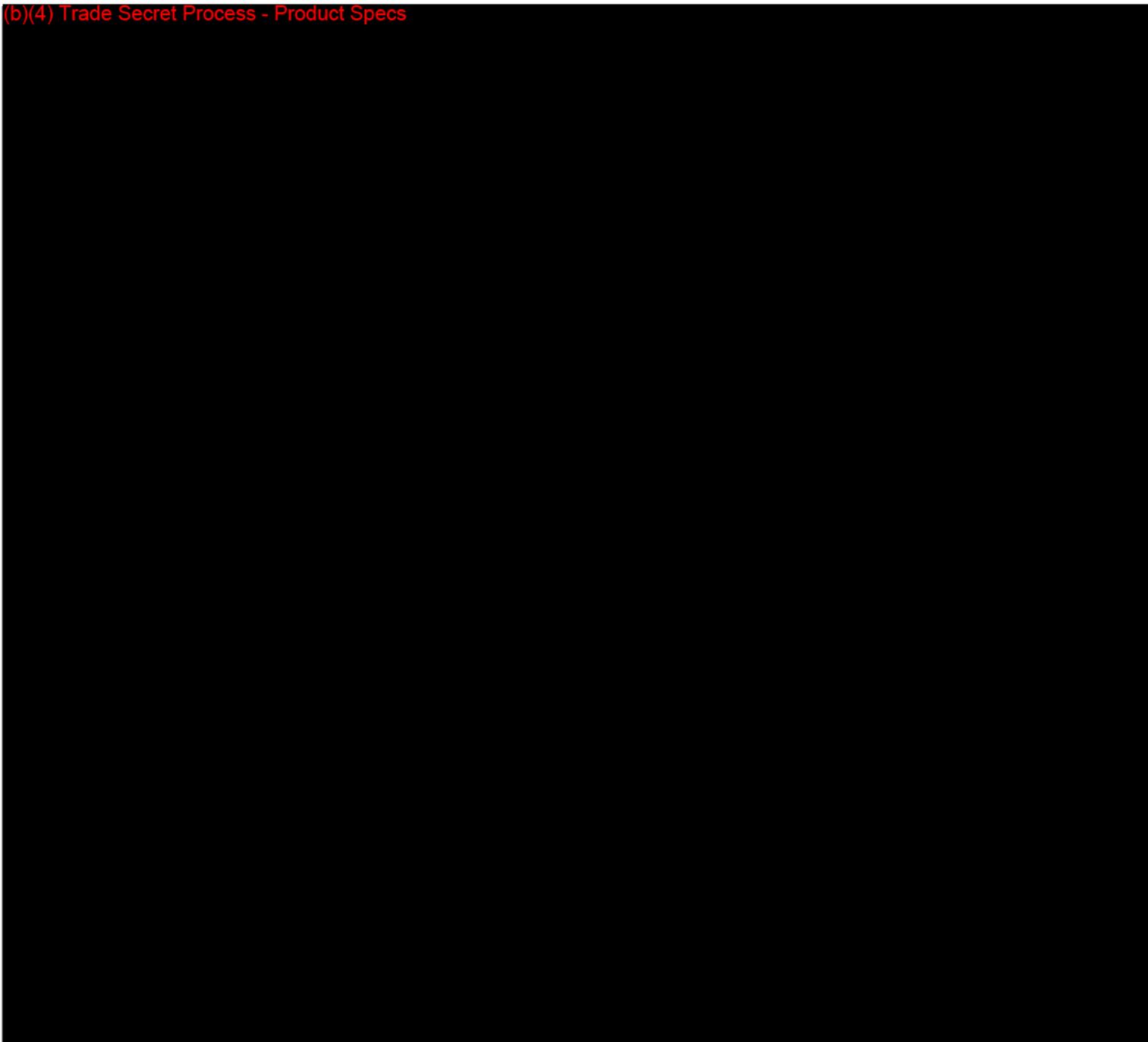
X. **Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

MR language is addressed in the IFU.

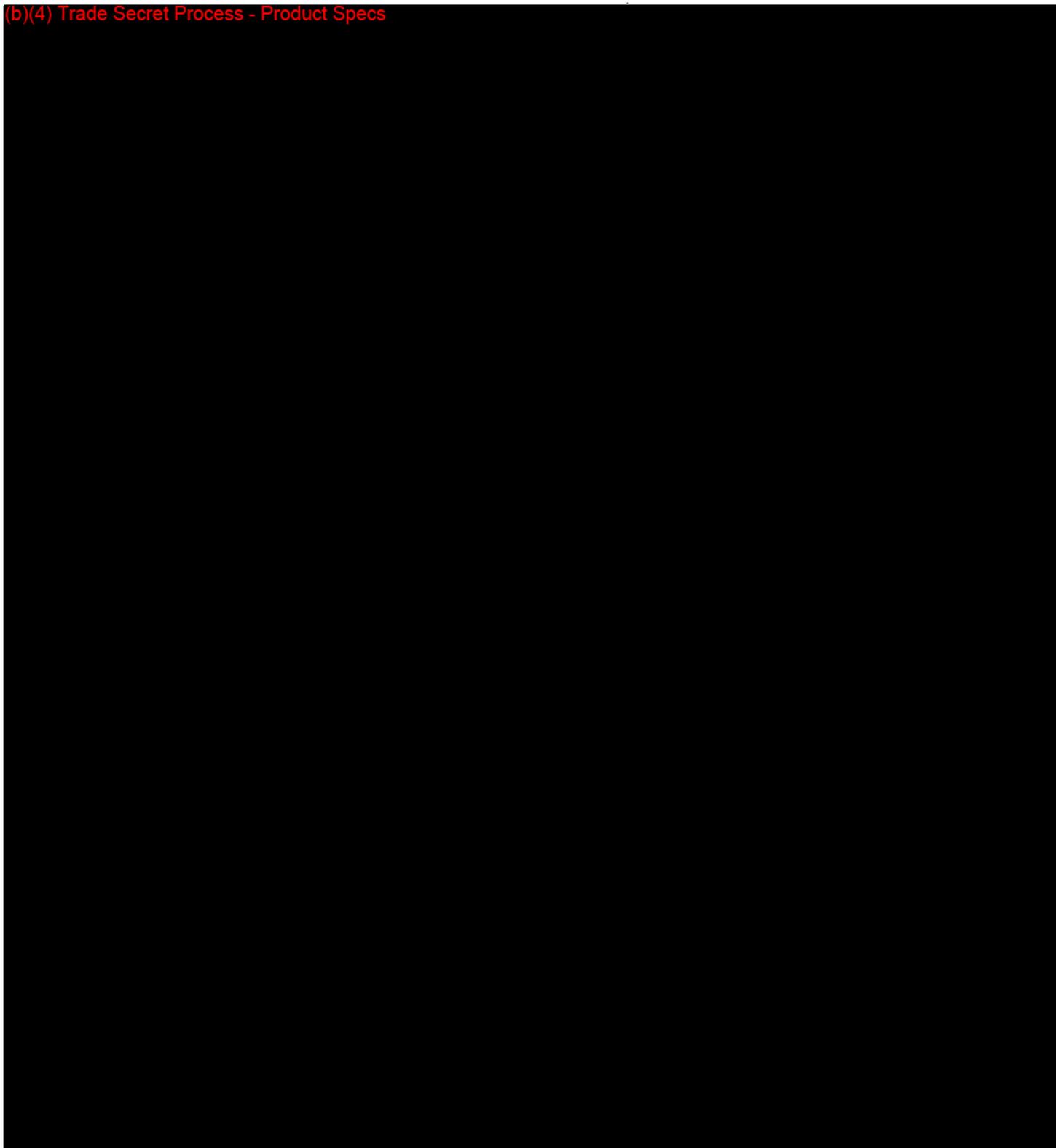
XI. **Performance Testing – Bench-** (Original p.20/131)

1. **Torque to Resistance Testing** (Original, p.91/131) Test date 10/20/10

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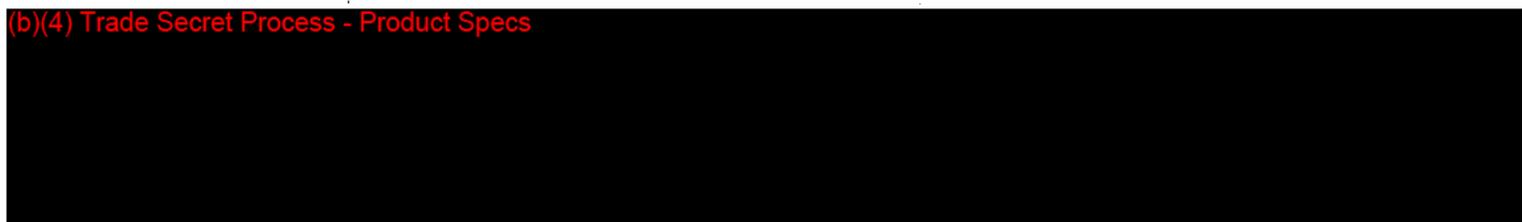


(b)(4) Trade Secret Process - Product Specs

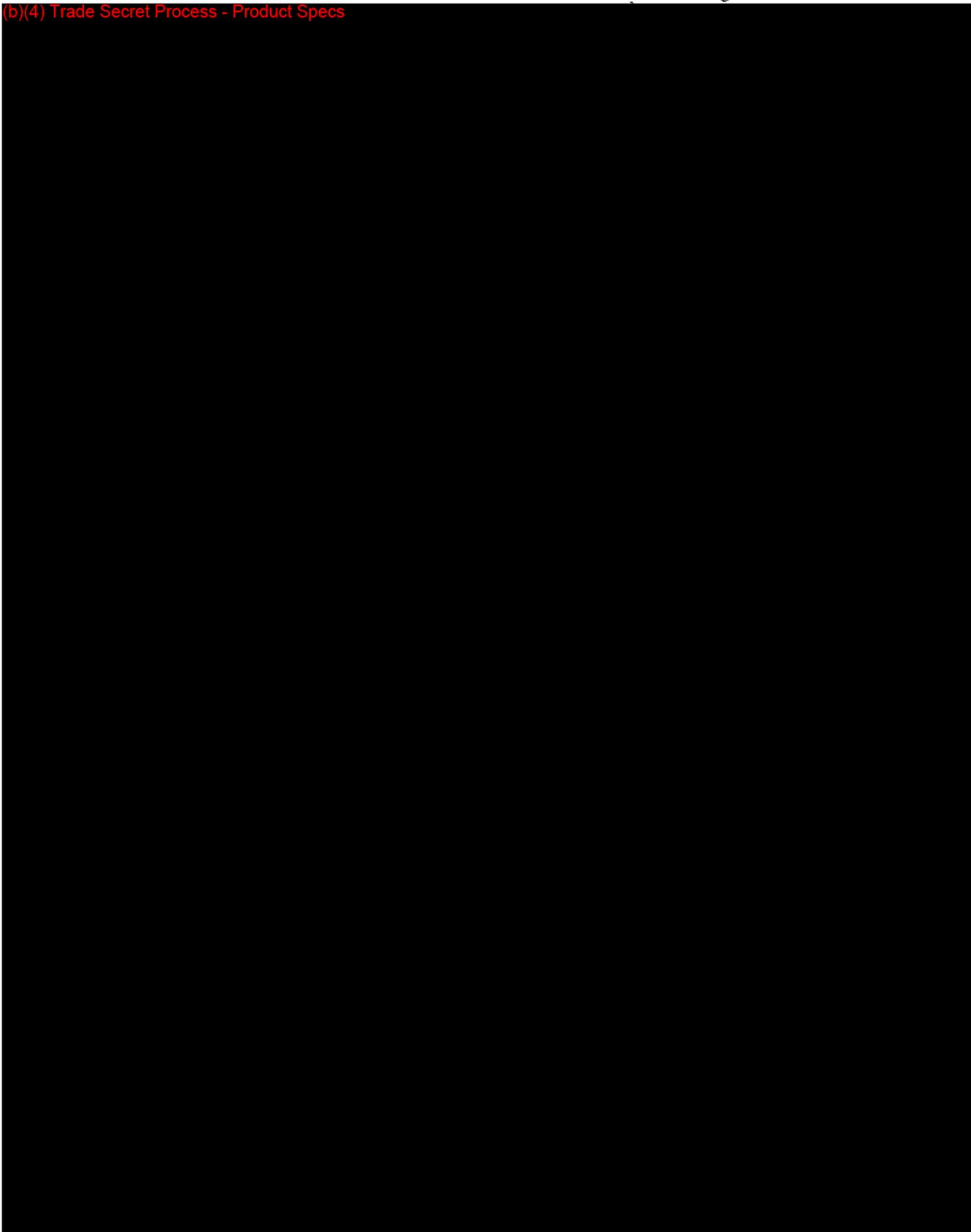


3. Burst Testing (Original, p.106/131): Test date 10/20/10

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



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

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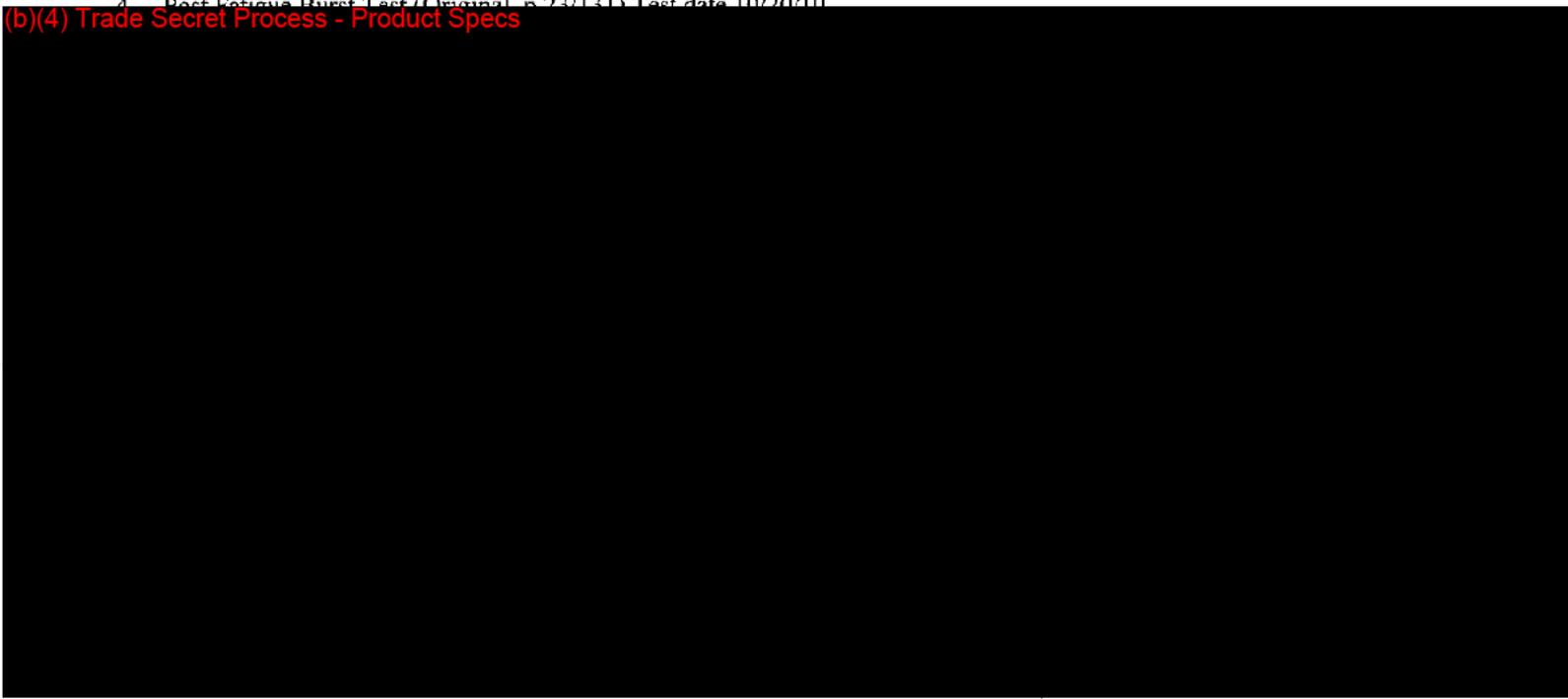
3. Fatigue Testing (Original, p.111/131): Test date 10/18/10 by CeramTec

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

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

4. Post-Fatigue Burst Test (Original, p.23/131): Test date 10/20/10

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

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

XII. Performance Testing – Animal

None.

XIII. Performance Testing – Clinical

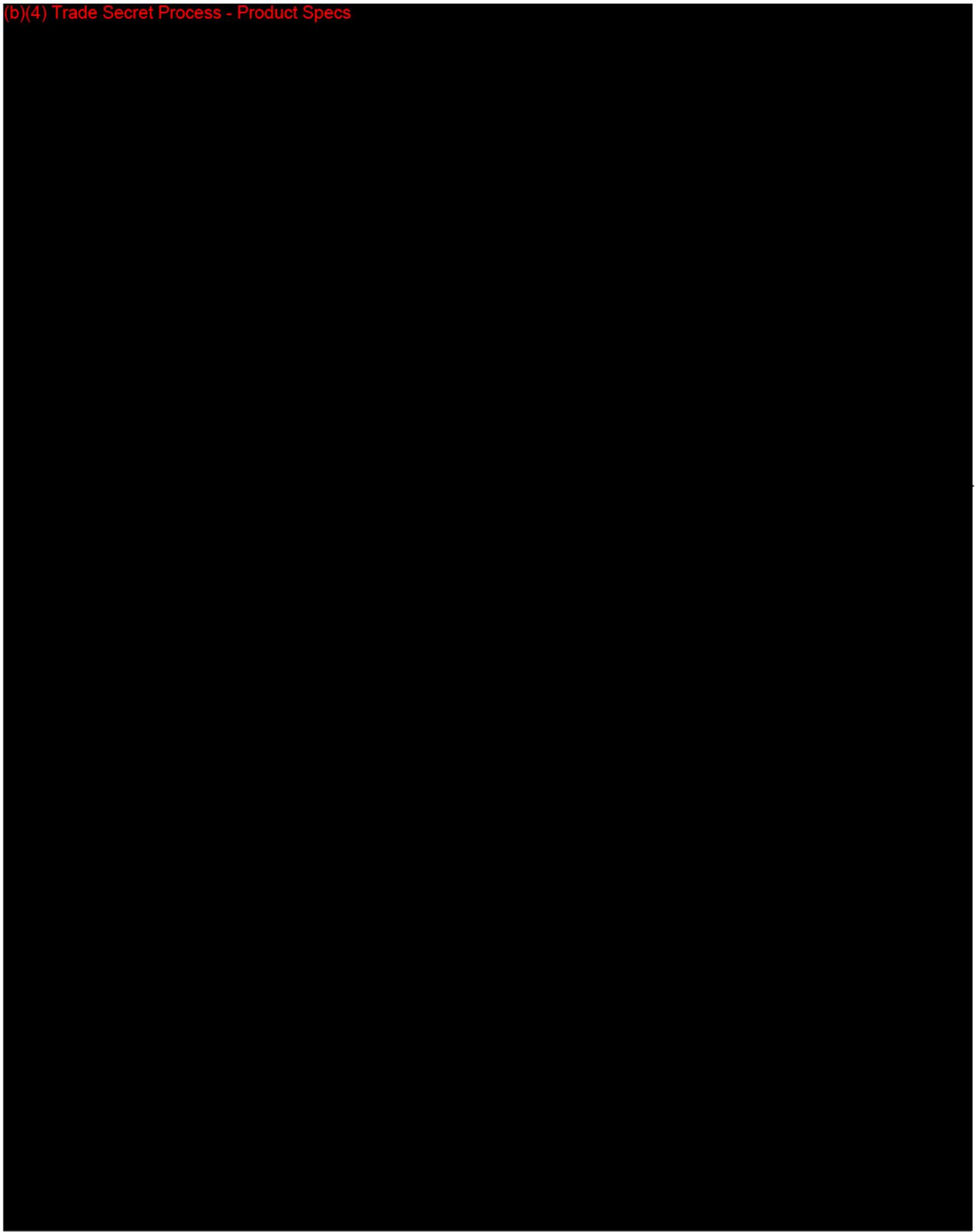
None.

XIV. Substantial Equivalence Discussion

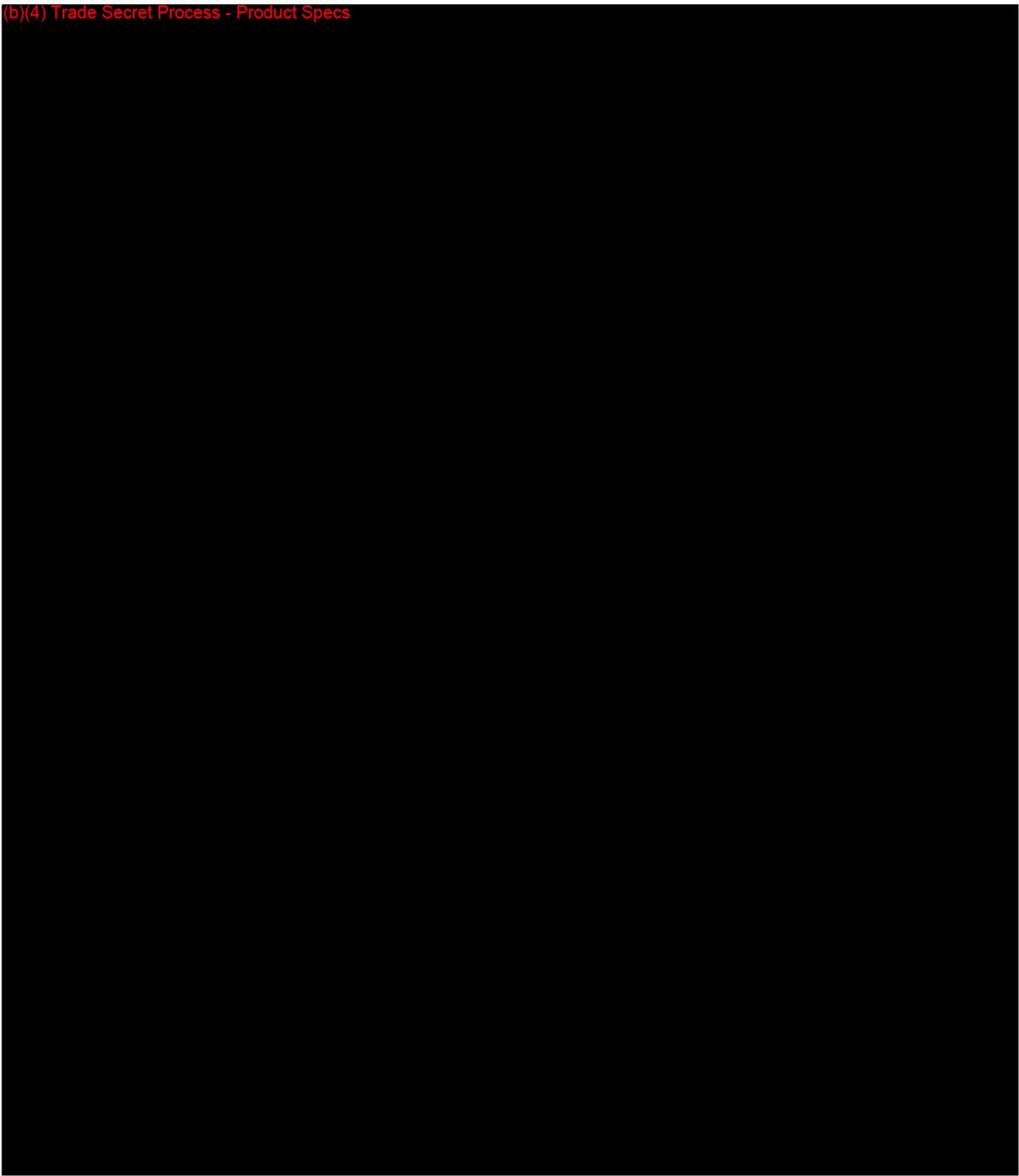
	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To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

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
 (b)(4) Trade Secret Process - Product Specs
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

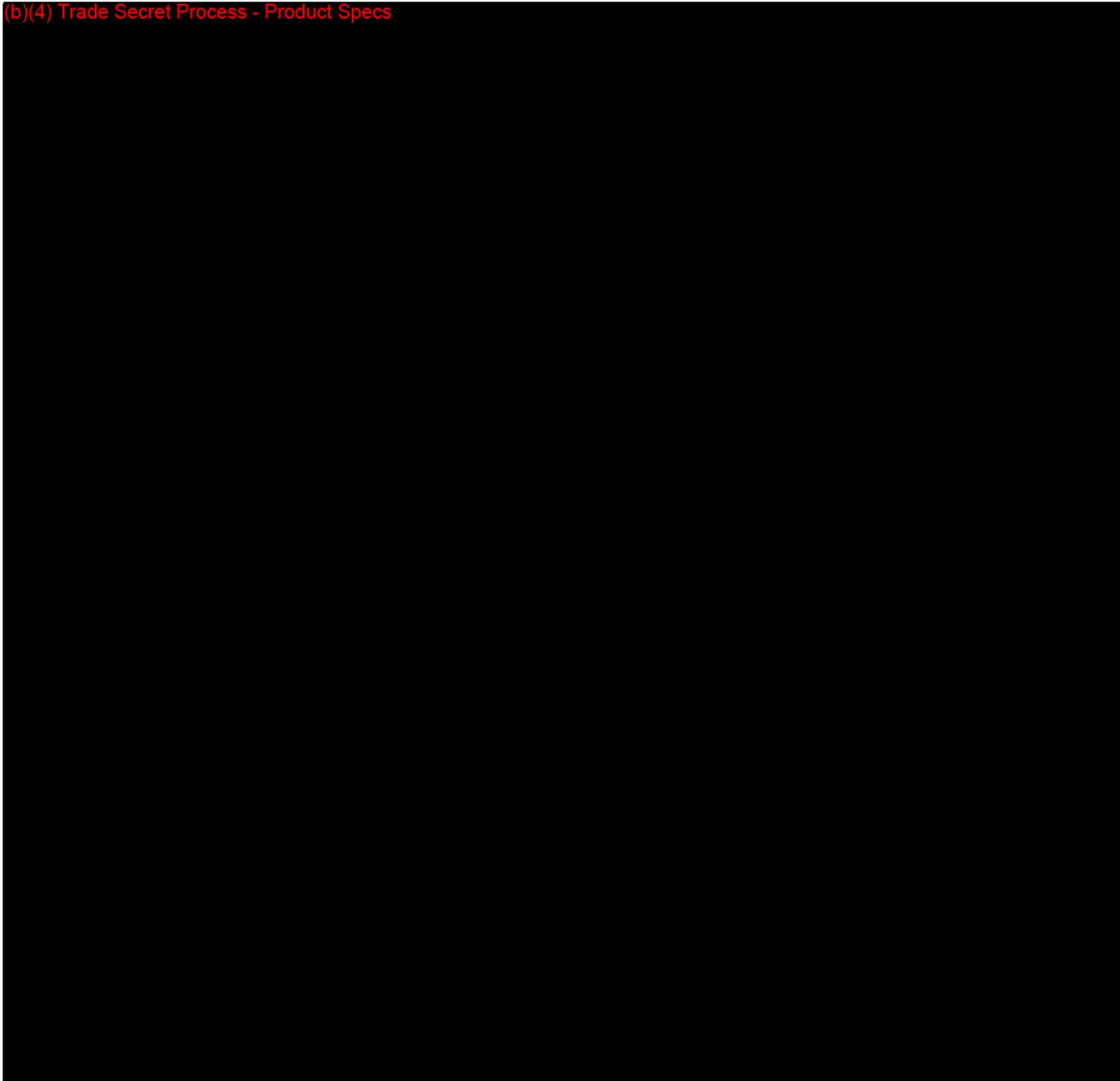
(b)(4) Trade Secret Process - Product Specs



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

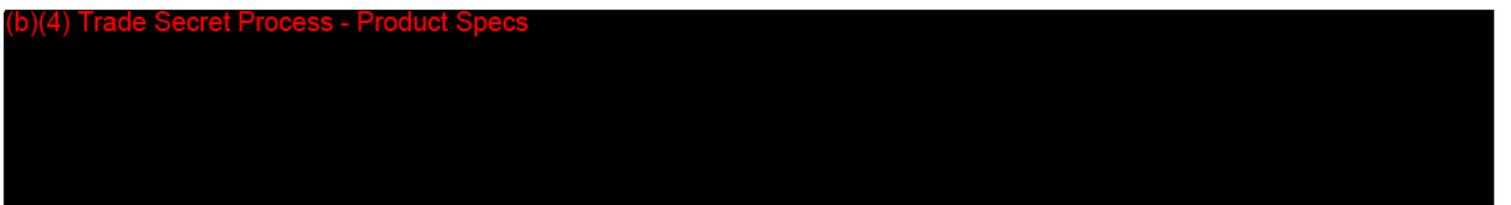


(b)(4) Trade Secret Process - Product Specs



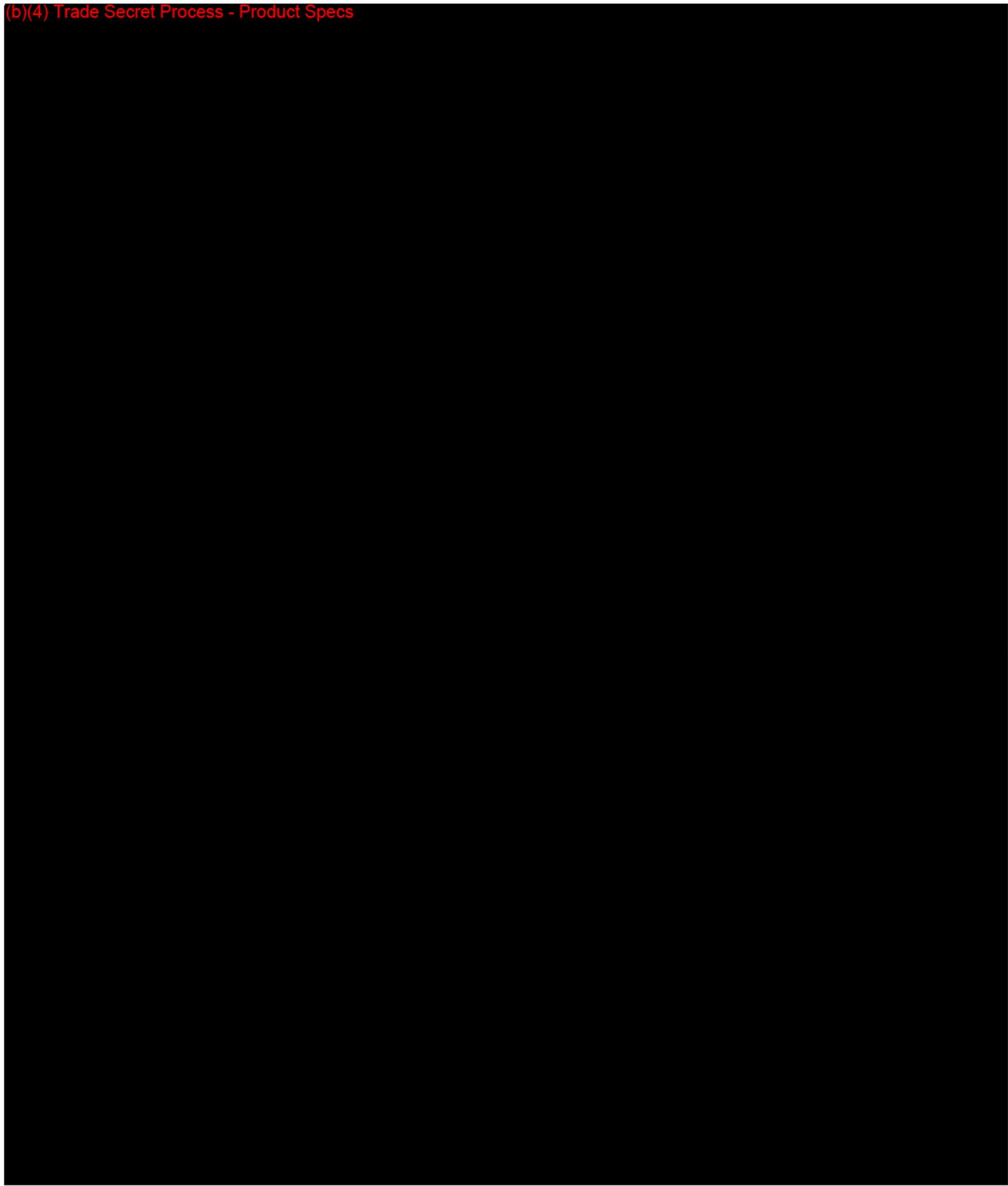
Sincerely,
Julie B. Gantenberg, M.S.
Biomedical Engineer
FDA Reviewer for DSORD/OJDB

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

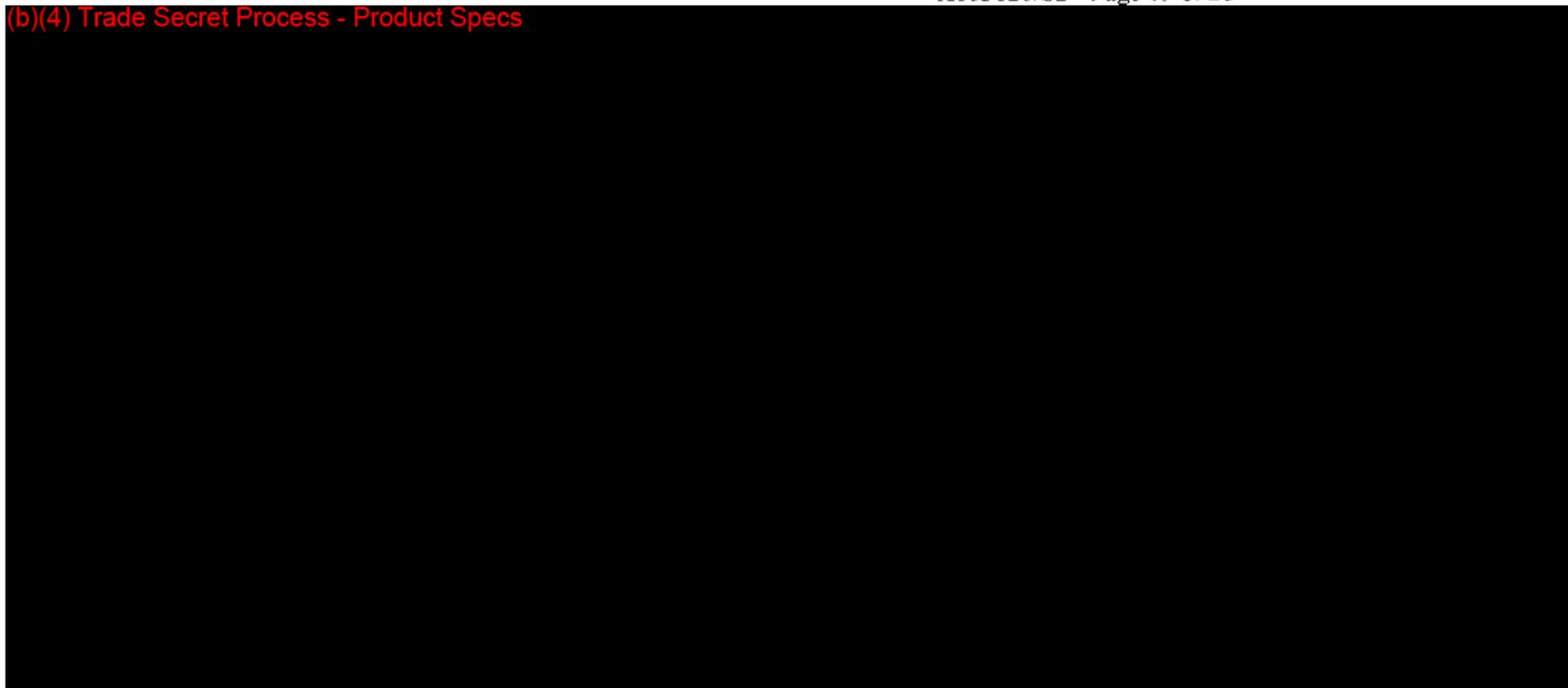


23

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



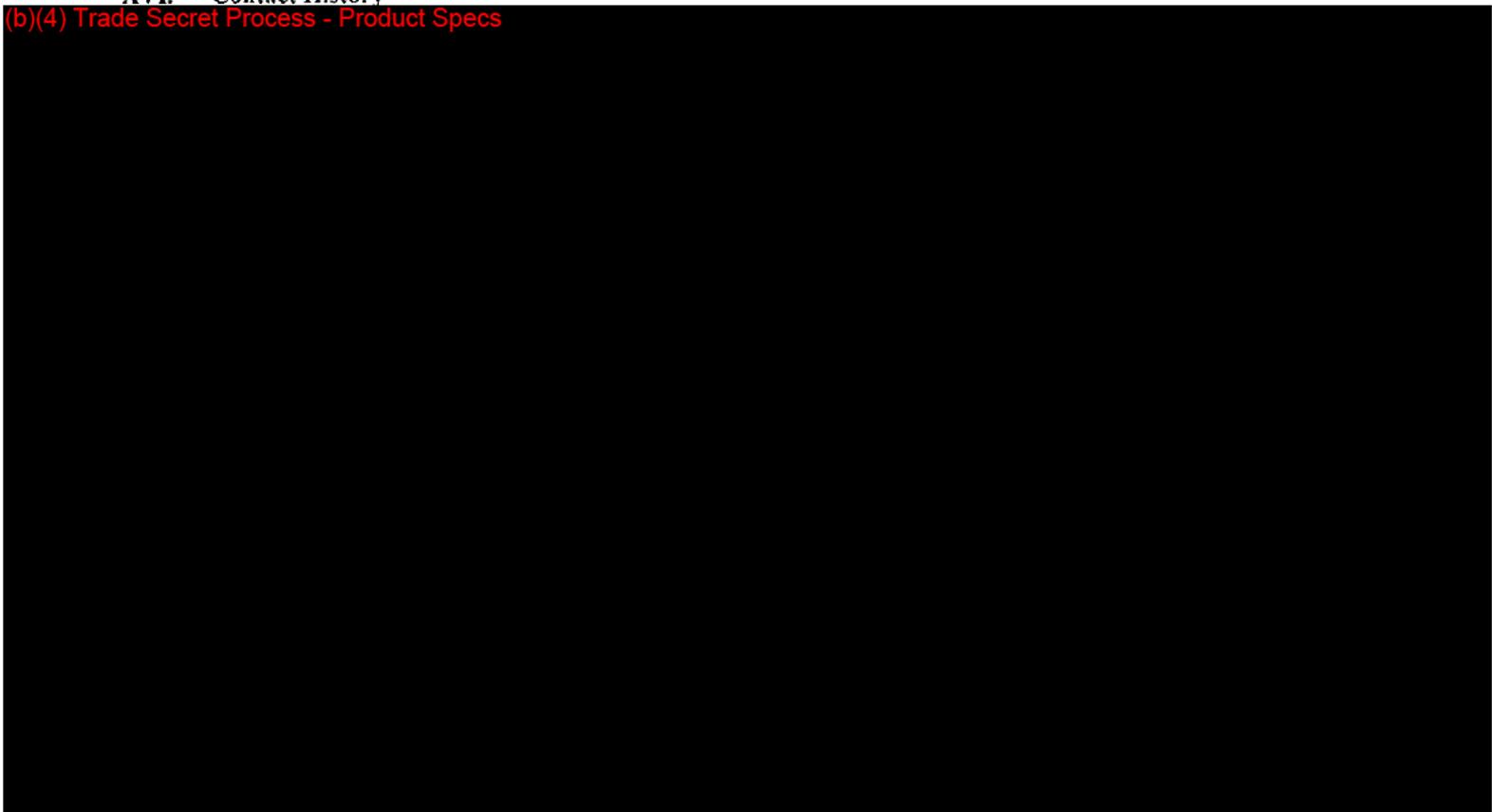
(b)(4) Trade Secret Process - Product Specs



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

XVI. Contact History

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



Best regards,
Kathy

25

Kathy Trier
VP Clinical and Regulatory Affairs

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042 | Mobile: 1 (813) 766-2112
Email: Kathy.Trier@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie * [mailto:Julie.Gantenberg@fda.hhs.gov]
Sent: Monday, November 29, 2010 3:48 PM
To: Kathy Trier
Cc: Foy, Jonette; Lucinda Gerber; Richard Sharp; Gantenberg, Julie *
Subject: RE: K093472 Trinity Acetabular System and K103120 BioloX Delta heads

Dear Kathy,

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

Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Kathy Trier [mailto:Kathy.Trier@coringroup.com]
Sent: Monday, November 29, 2010 5:22 PM
To: Gantenberg, Julie *
Cc: Foy, Jonette; Lucinda Gerber; Richard Sharp
Subject: RE: K093472 Trinity Acetabular System and K103120 BioloX Delta heads

Dear Julie,

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

We appreciate your guidance.
Best regards,
Kathy

Kathy Trier
VP Clinical and Regulatory Affairs

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042 | Mobile: 1 (813) 766-2112

Email: Kathy.Trier@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Thursday, December 02, 2010 12:54 PM
To: Gantenberg, Julie *
Cc: Kathy Trier
Subject: Biolox Delta K103120 Add to File
Importance: High

Hi Julie,

Please find attached an electronic copy of the "add to file" I sent to you yesterday for our Biolox Delta 510K, K103120.

If you need anything else from me please let me know.

Many thanks,
Lucinda



Add to File 1Dec10
LG.pdf (570...

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042
Email: lucinda.gerber@coringroup.com

www.coringroup.com

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CORIN LIMITED
Registered Office: The Corinium Centre, Cirencester, Gloucestershire, GL7 1YJ
Registered in England: Number 01910453

From: Gantenberg, Julie *
Sent: Wednesday, December 08, 2010 11:22 AM
To: 'Lucinda Gerber'
Cc: Kathy Trier; Dang, Jiyoung M; Gantenberg, Julie *
Subject: K103120 deficiencies
Importance: High

Dear Lucinda,

To complete our review of your 510(k) entitled, "Biolox Delta Modular Heads," K103120, we will need to place your document on hold until we receive the information presented in the attachment. Please send in your response in duplicate to the Document Mail Center via standard mail.

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If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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 additional information request.

Please note that I copied Dr. Jiyoung Dang on this email. She is now acting OJDB branch chief while Dr. Foy is on a detail position.

PLEASE EMAIL ME TO VERIFY RECEIPT OF THIS REQUEST.

If you need to contact me, please email me at julie.gantenberg@fda.hhs.gov.

Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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See Original deficiency attachment in Deficiency section.

From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Wednesday, December 08, 2010 11:29 AM
To: Gantenberg, Julie *
Cc: Kathy Trier; Dang, Jiyoung M
Subject: RE: K103120 deficiencies

Dear Julie,
Thank you I received your e-mail request for further information. I will get the requested information back to you as soon I can.
Kind Regards,
Lucinda

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I
Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042
Email: lucinda.gerber@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie *
Sent: Thursday, December 30, 2010 3:50 PM
To: 'Lucinda Gerber'
Cc: Kathy Trier; Dang, Jiyoung M
Subject: RE: K103120 deficiencies

Dear Lucinda,
Could you please provide me an ecopy of your S1 response to facilitate our review?
Thanks,
Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch

U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Thursday, December 30, 2010 5:34 PM
To: Gantenberg, Julie *
Cc: Kathy Trier; Dang, Jiyoung M
Subject: RE: K103120 deficiencies

Dear Julie,

Please find attached a copy of our S1 response as per your request.

Many Thanks,
Lucinda
Sponsor emailed ecopy of response.

From: Gantenberg, Julie *
Sent: Monday, January 03, 2011 6:30 AM
To: 'Lucinda Gerber'
Cc: Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Hi Lucinda,

I was unable to open your attachment due to an "error." Could you please check and then resend the ecopy of S1?

Thanks,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Monday, January 03, 2011 8:17 AM
To: Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Hi Julie,

I'm sorry about that, please find the deficiency response attached. Please let me know if you can not open this and I will send it to you in a different format.

Many Thanks,
Lucinda

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042

Email: lucinda.gerber@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie *
Sent: Monday, January 03, 2011 8:33 AM
To: 'Lucinda Gerber'
Cc: Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Lucinda,
Thanks for resending the attachment. I was able to open this one.
Sincerely,

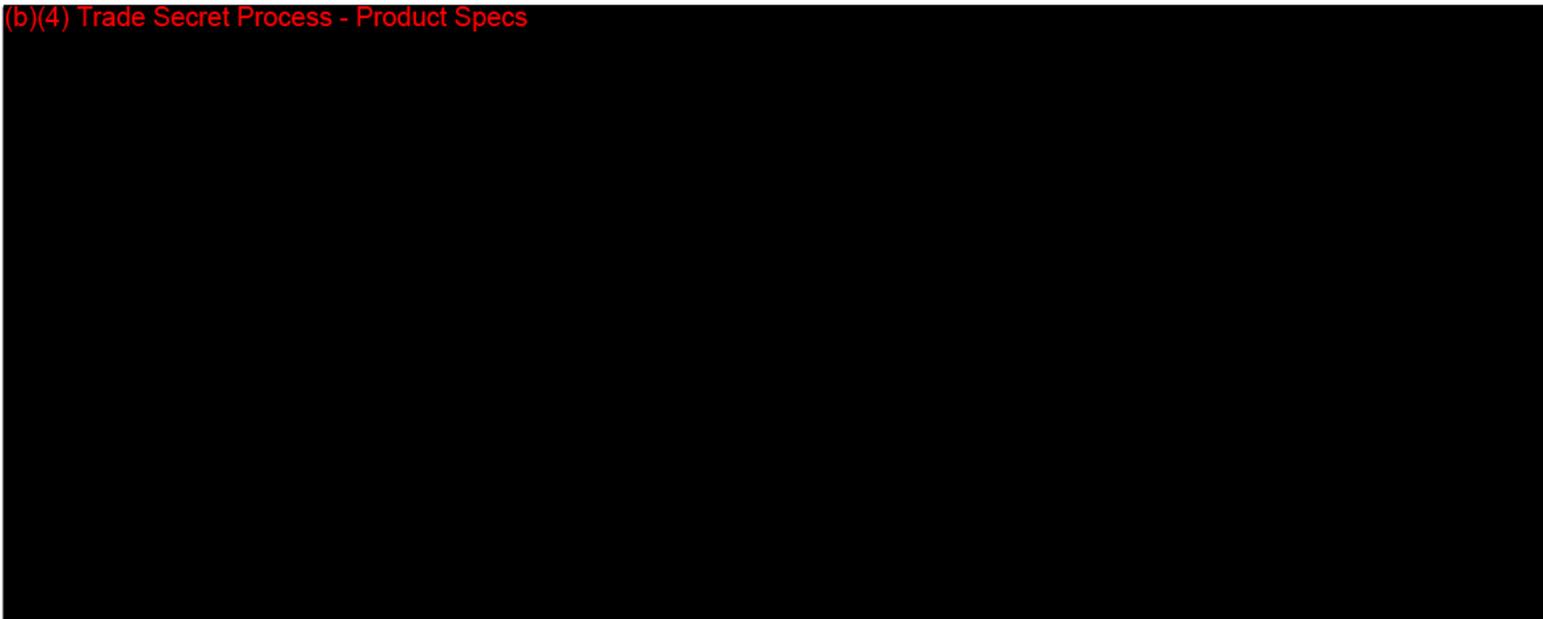
Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Gantenberg, Julie *
Sent: Wednesday, January 12, 2011 12:17 PM
To: 'Lucinda Gerber'
Cc: Dang, Jiyoung M; Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Dear Lucinda,

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



Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch

30

U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

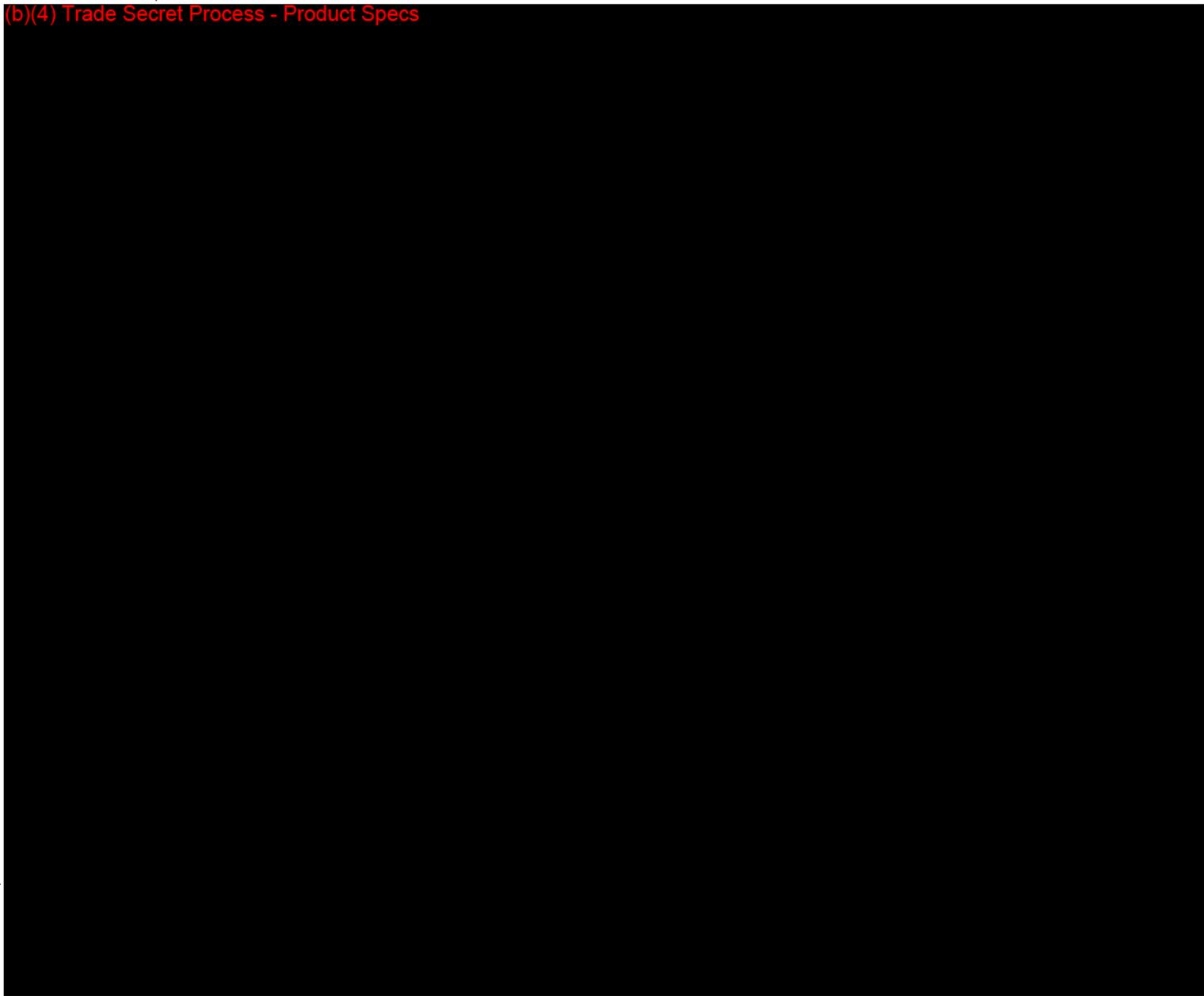
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See S1 attachment in deficiency section.

From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Tuesday, January 25, 2011 11:45 AM
To: Gantenberg, Julie *
Cc: Dang, Jiyoung M; Kathy Trier
Subject: RE: K103120 deficiencies

Dear Julie,

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



Best regards,
Lucinda Gerber

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042
Email: lucinda.gerber@coringroup.com

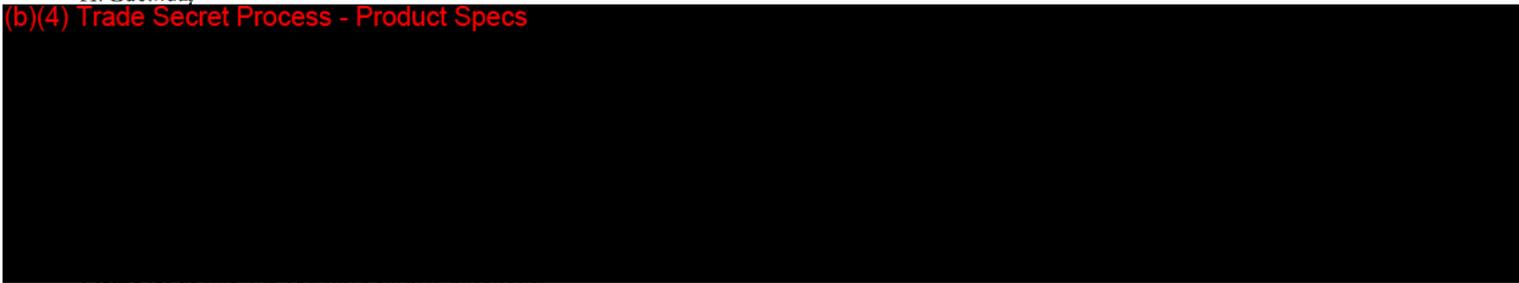
www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie *
Sent: Wednesday, January 26, 2011 8:51 AM
To: 'Lucinda Gerber'
Cc: Dang, Jiyoun M; Kathy Trier; Shepherd, Tara N; Gantenberg, Julie *
Subject: RE: K103120S1 deficiencies

Hi Lucinda,

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



Sincerely,

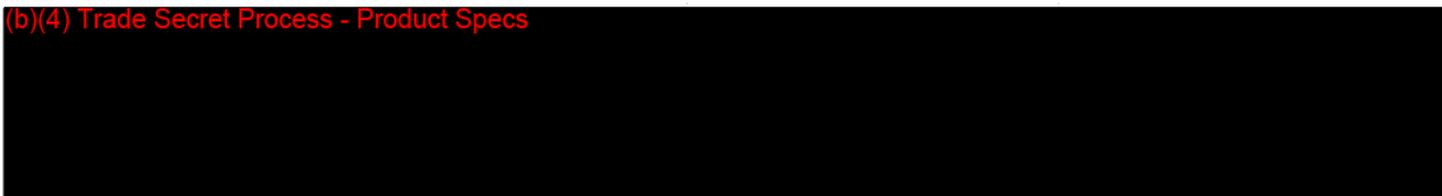
Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Lucinda Gerber [<mailto:Lucinda.Gerber@coringroup.com>]
Sent: Wednesday, February 09, 2011 1:38 PM
To: Gantenberg, Julie *
Cc: Dang, Jiyoun M; Kathy Trier
Subject: RE: K103120 deficiencies

Dear Julie,

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



Kind Regards,
Lucinda

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA

Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042
Email: lucinda.gerber@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie *
Sent: Thursday, February 10, 2011 8:08 AM
To: 'Lucinda Gerber'
Cc: Dang, Jiyoung M; Gantenberg, Julie *
Subject: RE: K103120 deficiencies- ecopy received

Dear Lucinda,

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

Sincerely,
Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Kathy Trier [<mailto:Kathy.Trier@coringroup.com>]
Sent: Friday, February 11, 2011 3:53 PM
To: Gantenberg, Julie *
Cc: Lucinda Gerber
Subject: FW: K103120 deficiencies- ecopy received

Dear Julie

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

Best regards,
Kathy

Kathy Trier
VP Clinical and Regulatory Affairs

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042 | Mobile: 1 (813) 766-2112
Email: Kathy.Trier@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie *
Sent: Monday, February 14, 2011 10:03 AM
To: 'Kathy Trier'
Cc: Lucinda Gerber; Dang, Jiyoung M; Shepherd, Tara N; Gantenberg, Julie *
Subject: RE: K103120 deficiencies- ecopy received

Dear Kathy,

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

Sincerely,
Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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-----Original Message-----

From: Kathy Trier [mailto:Kathy.Trier@coringroup.com]
Sent: Monday, February 14, 2011 11:46 AM
To: Gantenberg, Julie *
Cc: Lucinda Gerber; Dang, Jiyoung M; Shepherd, Tara N
Subject: RE: K103120 deficiencies- ecopy received

Dear Julie,

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

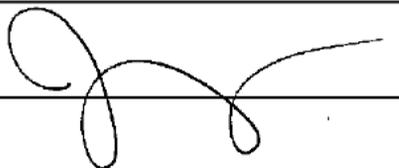
Best regards,
Kathy

XVII. Recommendation

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

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
Other Product Codes for system: N/A

Gantenberg
Reviewer



Branch Chief

2/24/11
Date

2/28/2011
Date



COVER SHEET MEMORANDUM

From: Reviewer Name Gantenberg

Subject: 510(k) Number K103120/S1

To: The Record

Please list CTS decision code AC

Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRH3PremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

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 Original ecopy p.7/131	Attach IFU	X	
<u>510(k) Summary /510(k) Statement – Original ecopy p.8/131</u>	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
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://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRH3PremarketNotification510kProgram/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)? N Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X

Nanotechnology		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 **Class*** **Product Code**

 21 CFR 888.3353 II(87 Panel) LZO
 (*if unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____ *DJDB* *1/12/2012*
 (Branch Chief) (Branch Code) (Date)

Final Review: _____
[Signature] (Division Director) (Date)



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

Premarket Notification [510(k)] Review
Traditional

K103120/S1

Date: 1/12/11

To: The Record

From: Gantenberg

510(k) Holder: Corin USA (Tampa, FL)

Device Name: Biolox Delta Modular Femoral Heads

Office: ODE

Division/Branch: DSORD/OJDB

Official Contact: Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Phone: 813-977-4469 / Email: Lucinda.gerber@coringroup.com

Product Code: LZO (21 CFR 888.3353)

I. Purpose

The 510(k) holder would like to introduce the Biolox Delta Modular Femoral Heads into interstate commerce. I received S1 Image ecopy on 1/6/11. My review began on 1/6/11. I recommend telephone hold.

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

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 Statement, and Standards Form.

Reviewer Comment: Effective Dec. 26, 2007 and later

Table with 4 columns: Requirement, Yes, No, N/A. Row: Certificate of Compliance of Clinical Trials - Form FDA 3674 Original

40

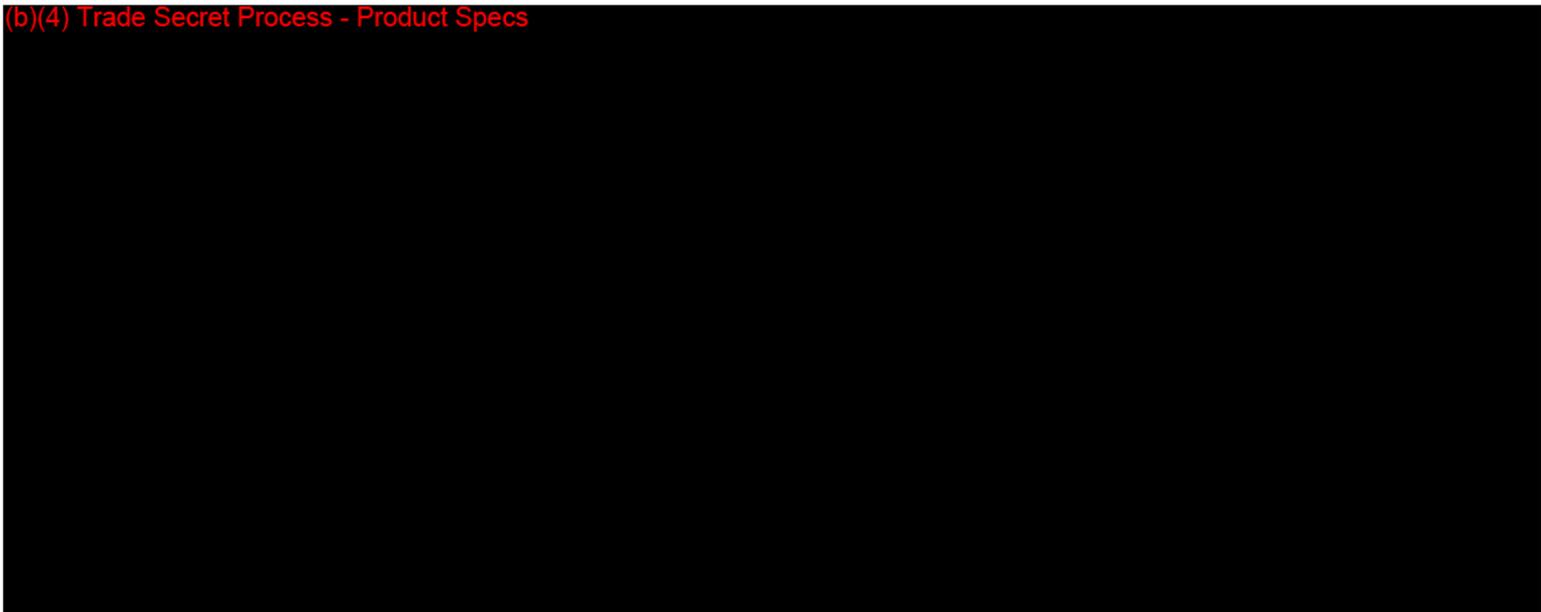
III. Device Description (Executive summary and Premarket Notification Sections)

	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)? No for implants, Yes for instruments Are "cleaning" instructions included for the end user?		X	

Device Description Summary

A predicate comparison table was provided in Original, p.15/131.

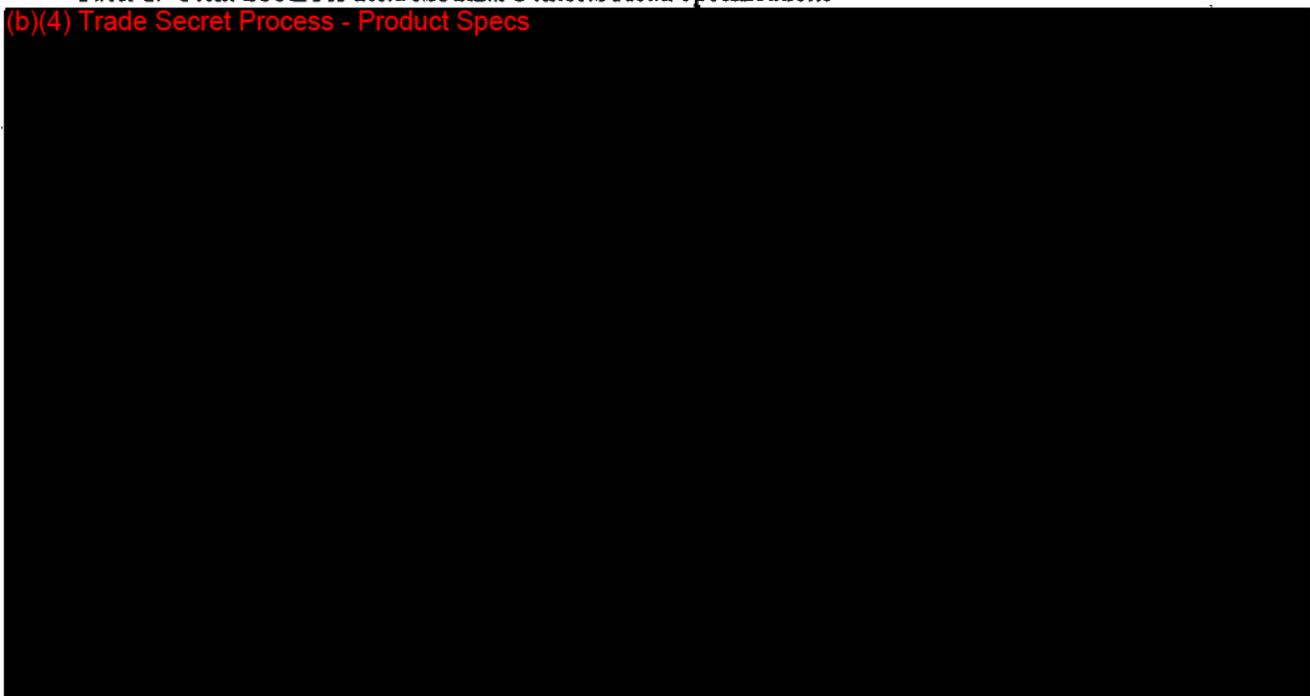
(b)(4) Trade Secret Process - Product Specs



The following data is derived from Original, p.13/131:

Table 2: Corin BIOLOX delta Modular Femoral Head Specifications

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



(b)(4)

Per Drawings:

Head size	Bore Axial Length (mm)	Bore Diameter Top (mm)	Bore diameter Bottom (mm)	Gage diameter (mm)/Overlap %
-----------	------------------------	------------------------	---------------------------	------------------------------

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

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
------------	------------	------------	------------	------------

The stem magnified taper trunnion drawing was provided on p.47/131:

Stem Taper-Material	Axial Taper Length inch	Cone Angle	Cone Angle Tolerance	Diameter (gage) (mm)	Diameter at bottom of taper (inch)	Straightness	Sphericity	Surface Roughness
---------------------	-------------------------	------------	----------------------	----------------------	------------------------------------	--------------	------------	-------------------

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

[REDACTED]								
------------	------------	------------	------------	------------	------------	------------	------------	------------

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

[REDACTED]

Mechanical drawings for the subject device are found in Original, App.B, p.31/131.

Catalogue listing of subject components are found below and in Original App.C, p.49/131.

Part Number	Description
-------------	-------------

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

[REDACTED]	[REDACTED]
------------	------------

Instruments - Original, p.53/131

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

[REDACTED]

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

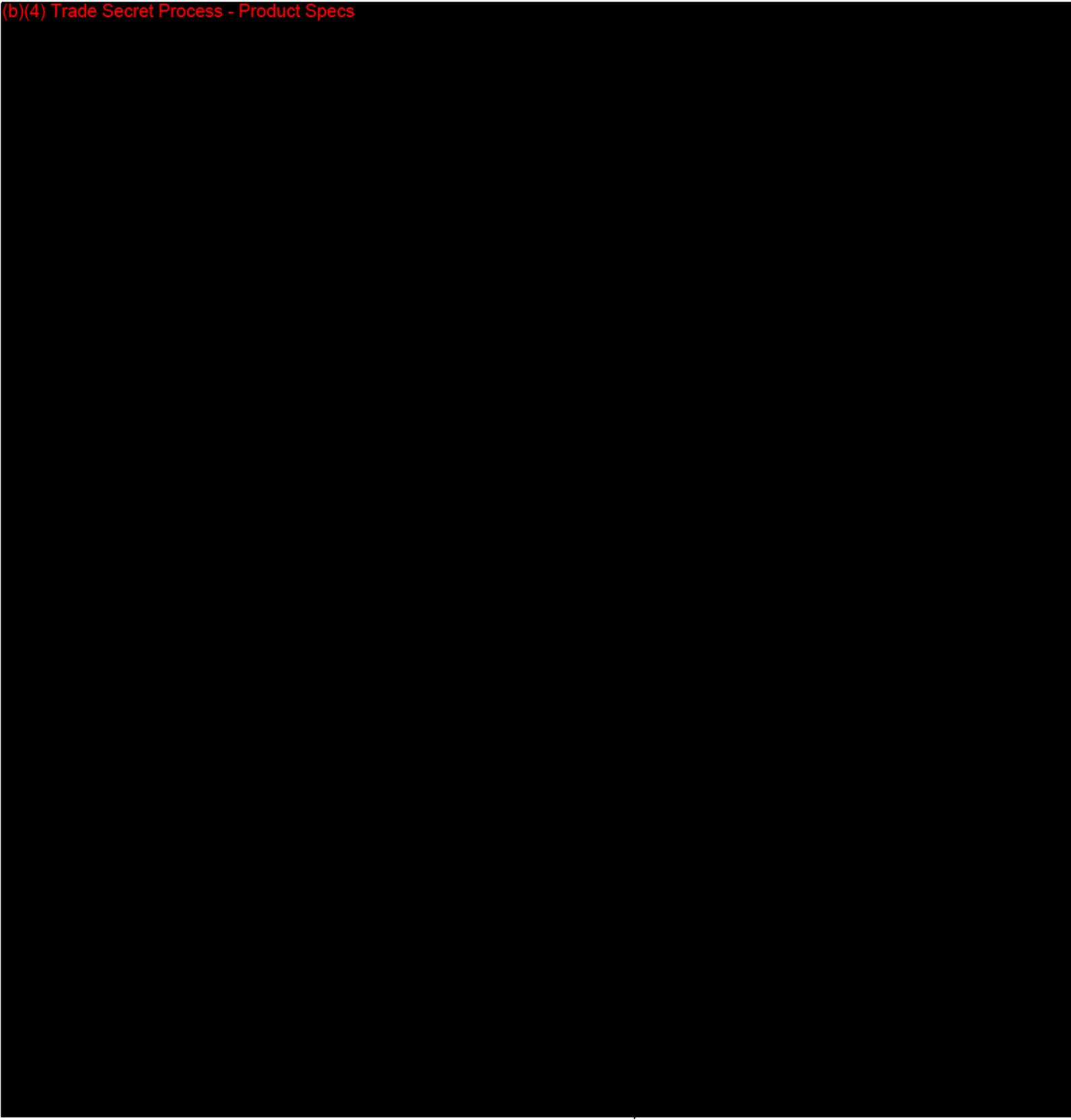
[REDACTED]

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

[REDACTED]

42

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



IV. Indications for Use (ecopy p.7/131)

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

43

- o Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- o Rheumatoid arthritis
- o Correction of functional deformity and
- o Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

Review: Adequate.

V. Predicate Device Comparison

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



VI. Labeling (Original, App. F, p.67/131)

Package label, package insert, and STM provided.

Package Label – (Original, ecopy p.75/131)

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

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



Package Insert (

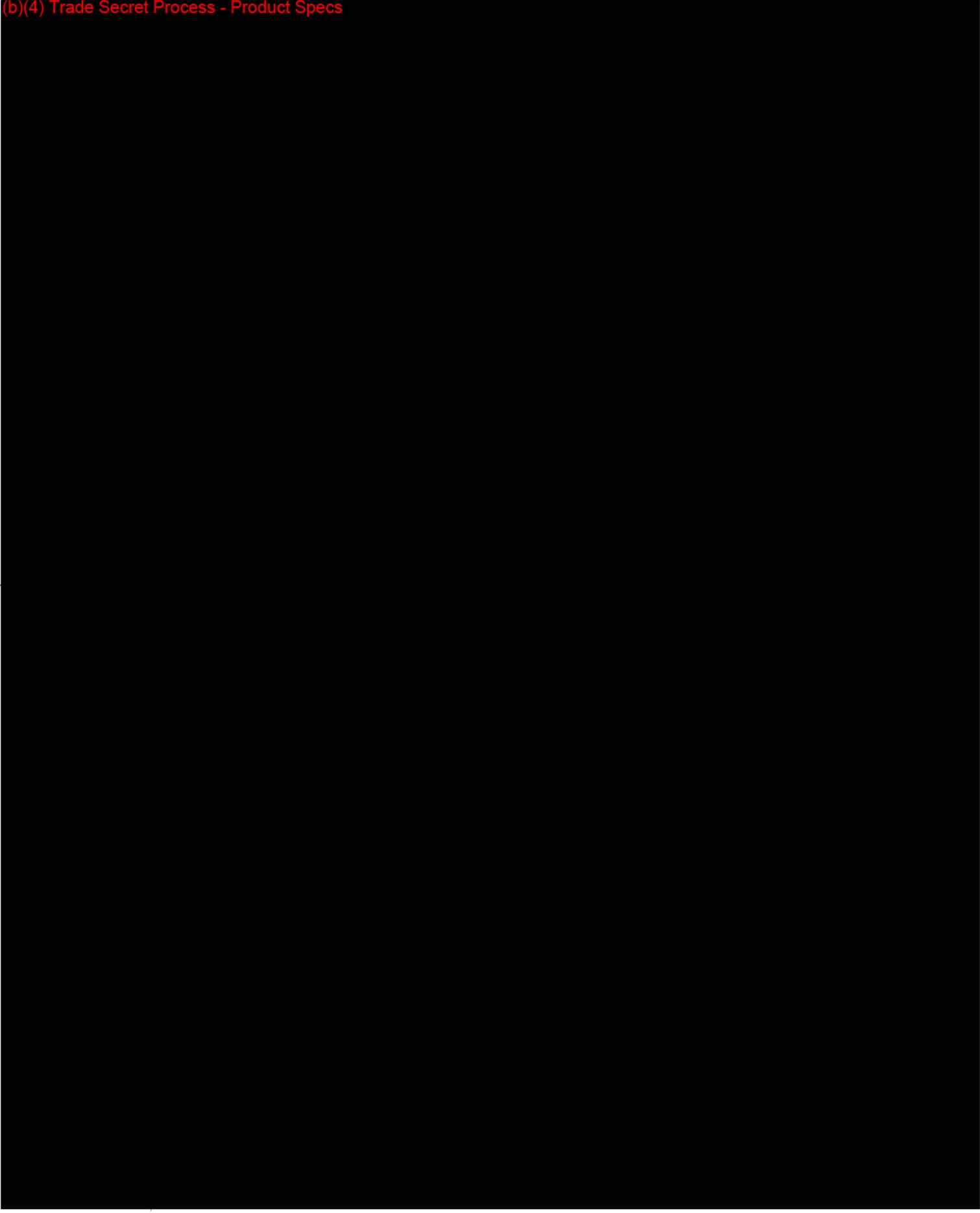
b

)

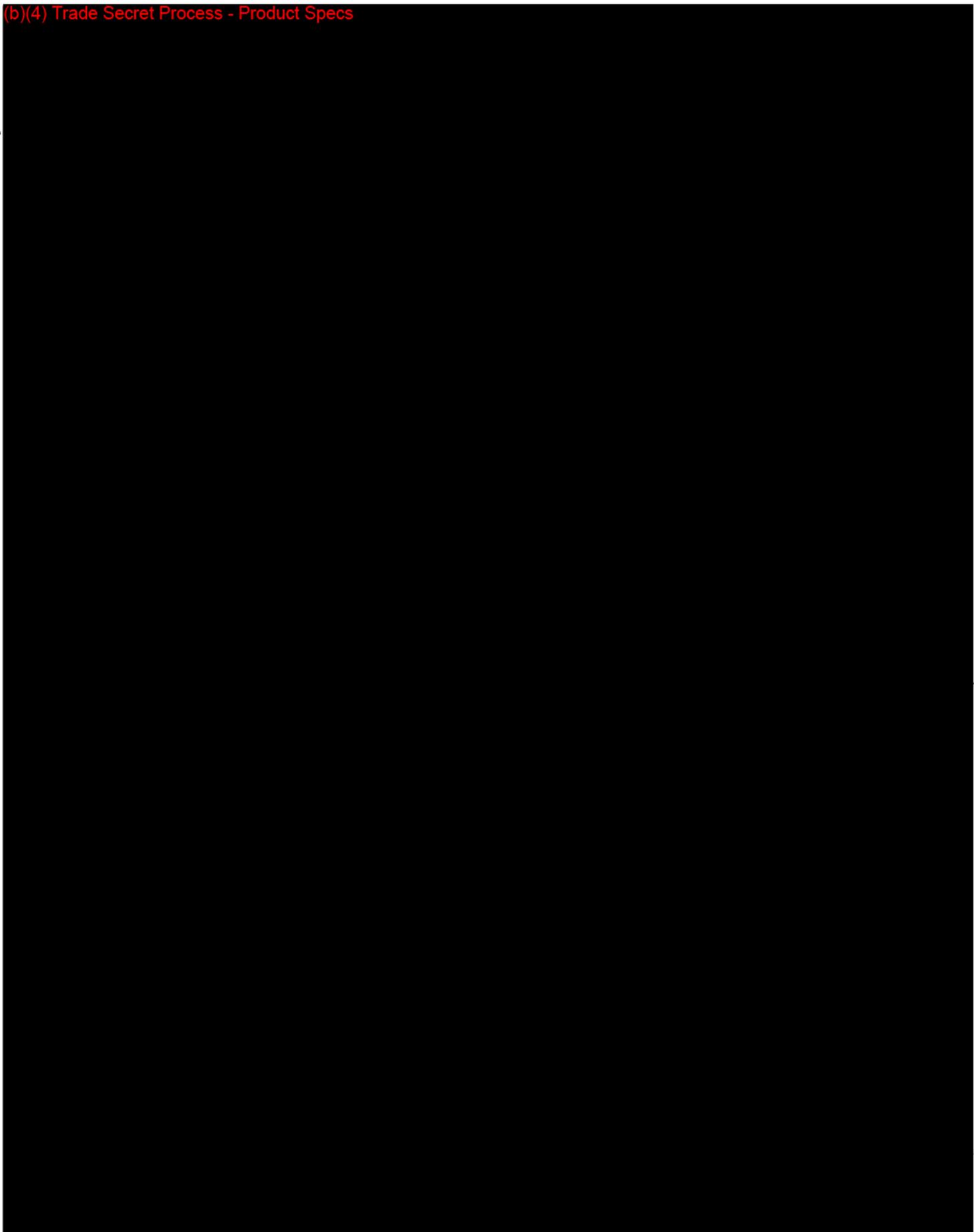
(

4

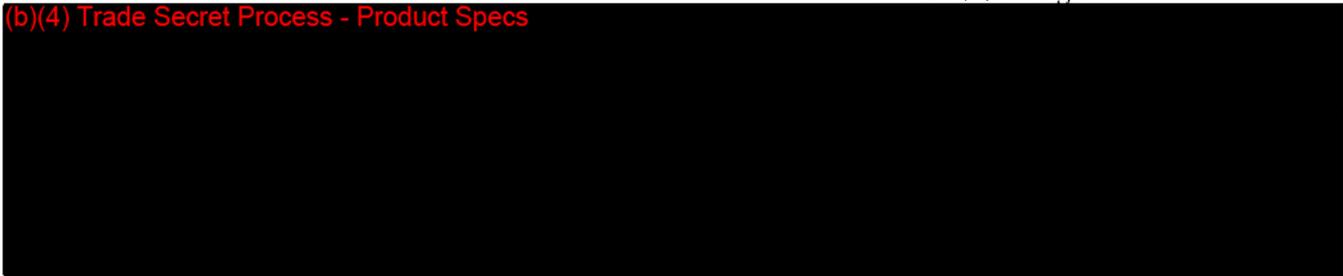
(b)(4) Trade Secret Process - Product Specs



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



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



Surgical Technique Manual (STM) (b)(4) Trade Secret Process - Product Specs

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



VII. Sterilization/Shelf Life/Reuse (b)(4)

Single use for implants.

(b)(4) Trade

I. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam, EtO, Radiation):	Gamma radiation from Co60	
b. Dose, for radiation (e.g., 25 – 40 kGy):	25-35 kGy	
c. Sterilant residuals remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals):	N/A	X
2. A description of the Validation Method for the sterilization cycle (not data): (e.g., Overkill/Half-cycle method, bioburden method, combination method)	validated per ISO 11137:2006 Sterilization of Health Care Products- Part 1 - Requirements for Validation and Routine Control - Radiation sterilization using Method V _{Dmax.25} as described in ISO 11137-3:2007 Sterilization of Health Care Products – Radiation-Part 2: Establishing the sterilization Dose.	
3. Sterility assurance level (SAL): (e.g., 10 ⁻⁶ for all devices (except 10 ⁻³ for devices that contact intact skin))	10 ⁻⁶	
4. Is it labeled "Pyrogen Free"?		X
If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amoebocyte Lysate test))	N/A	

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5. A description of the packaging (p.25/605)
(not including package integrity test data):

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

VIII. Biocompatibility (Original, ecopy p.19/131)

(b)
(4)

IX. Software
N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
MR language is addressed in the IFU.

XI. Performance Testing – Bench-(Original p.20/131)

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

XIII. Performance Testing – Clinical

None.

XIV. Substantial Equivalence Discussion

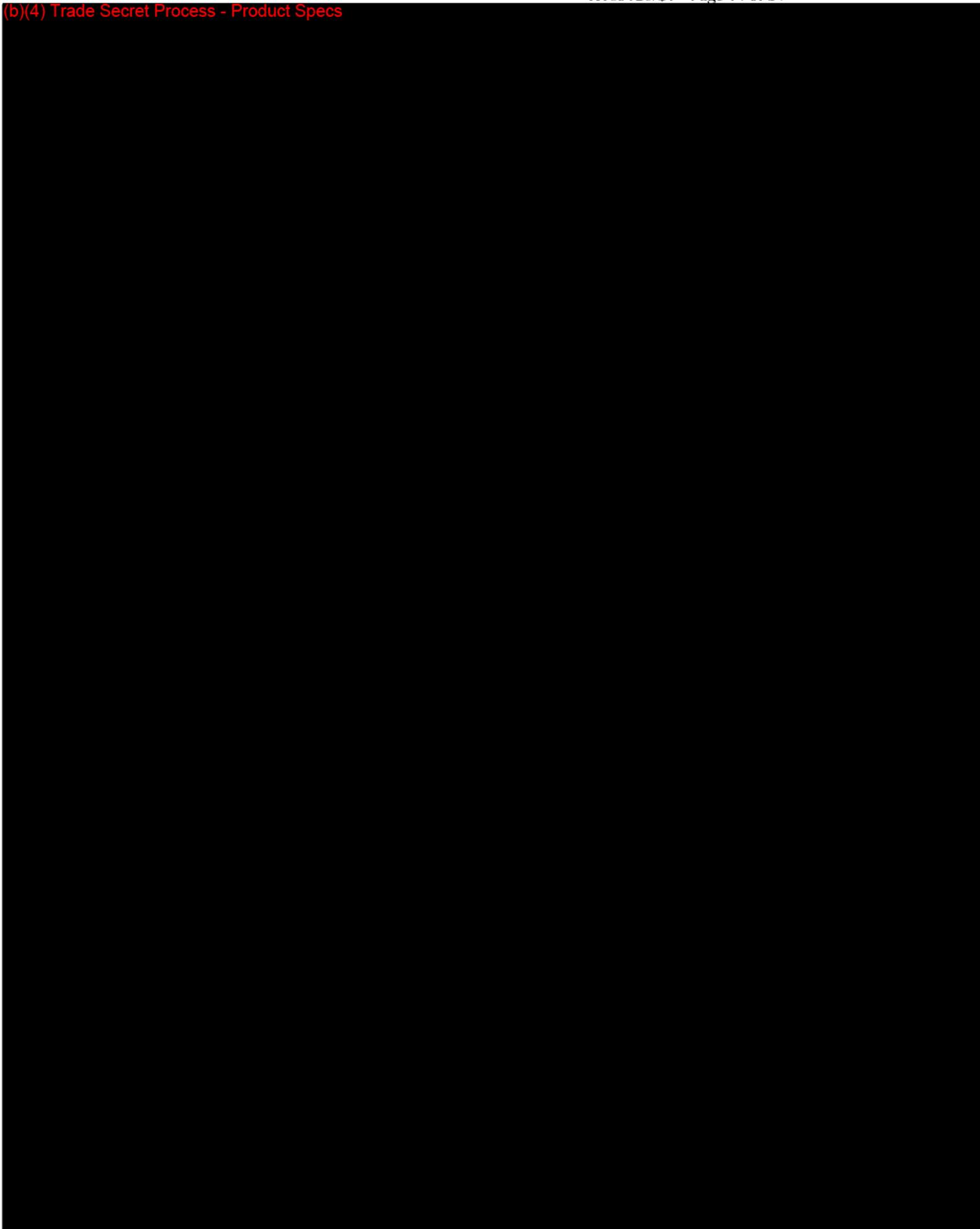
	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To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

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
(b)(4) Trade Secret Process - Testing
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
(b)(4) Trade Secret Process - Testing
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

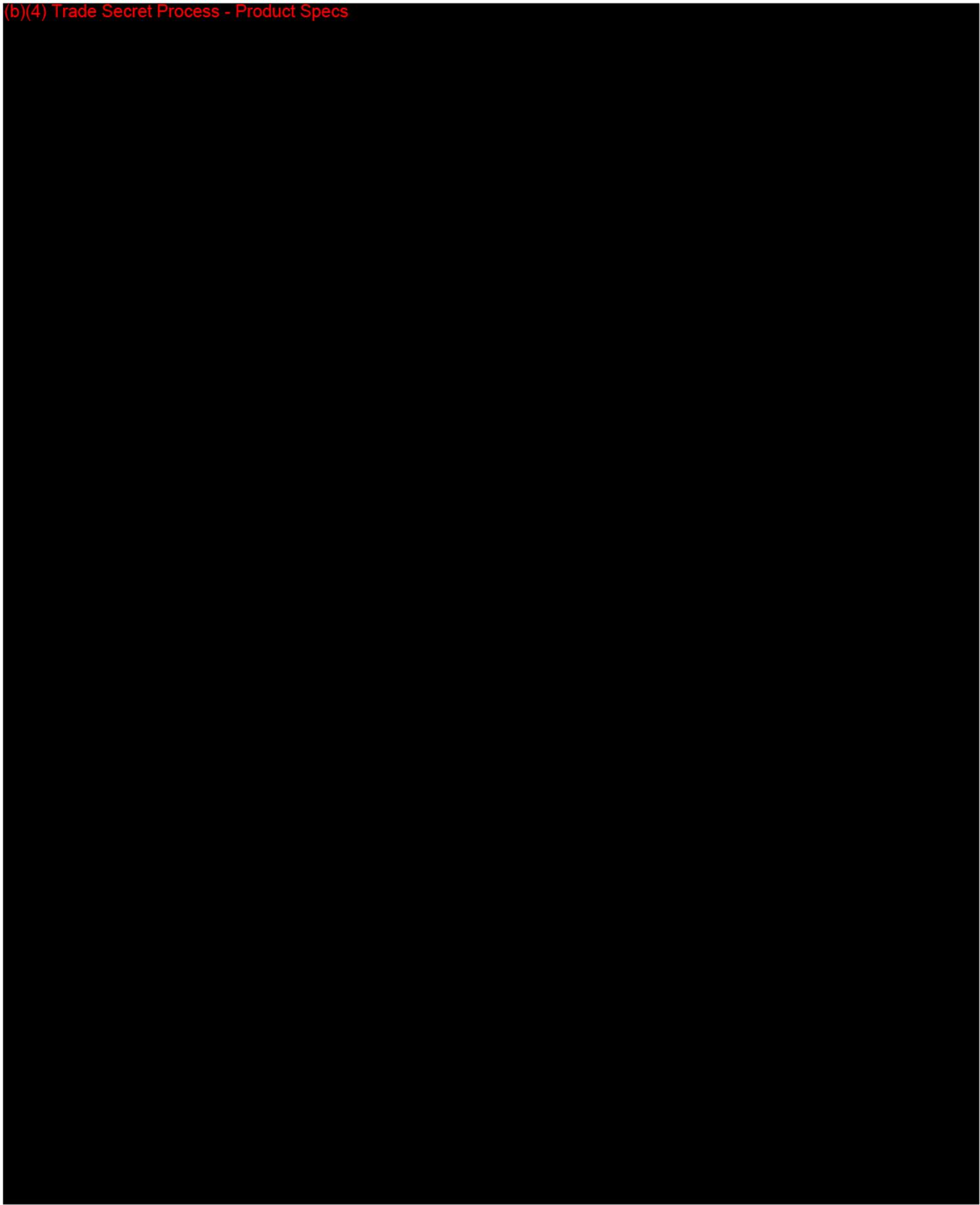
(b)(4) Trade Secret Process - Product Specs

32

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



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

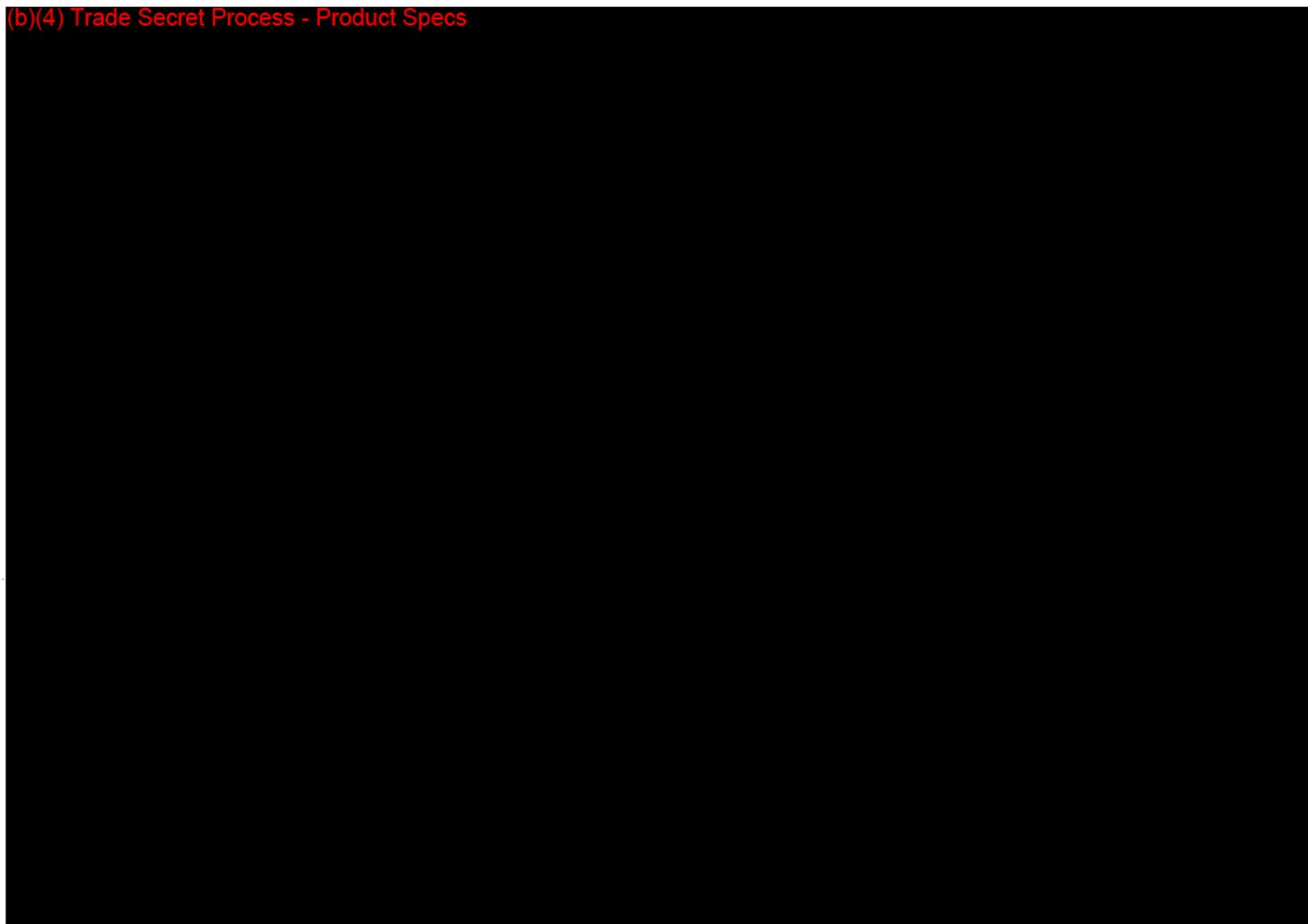


(b)(4) Trade Secret Process - Product Specs

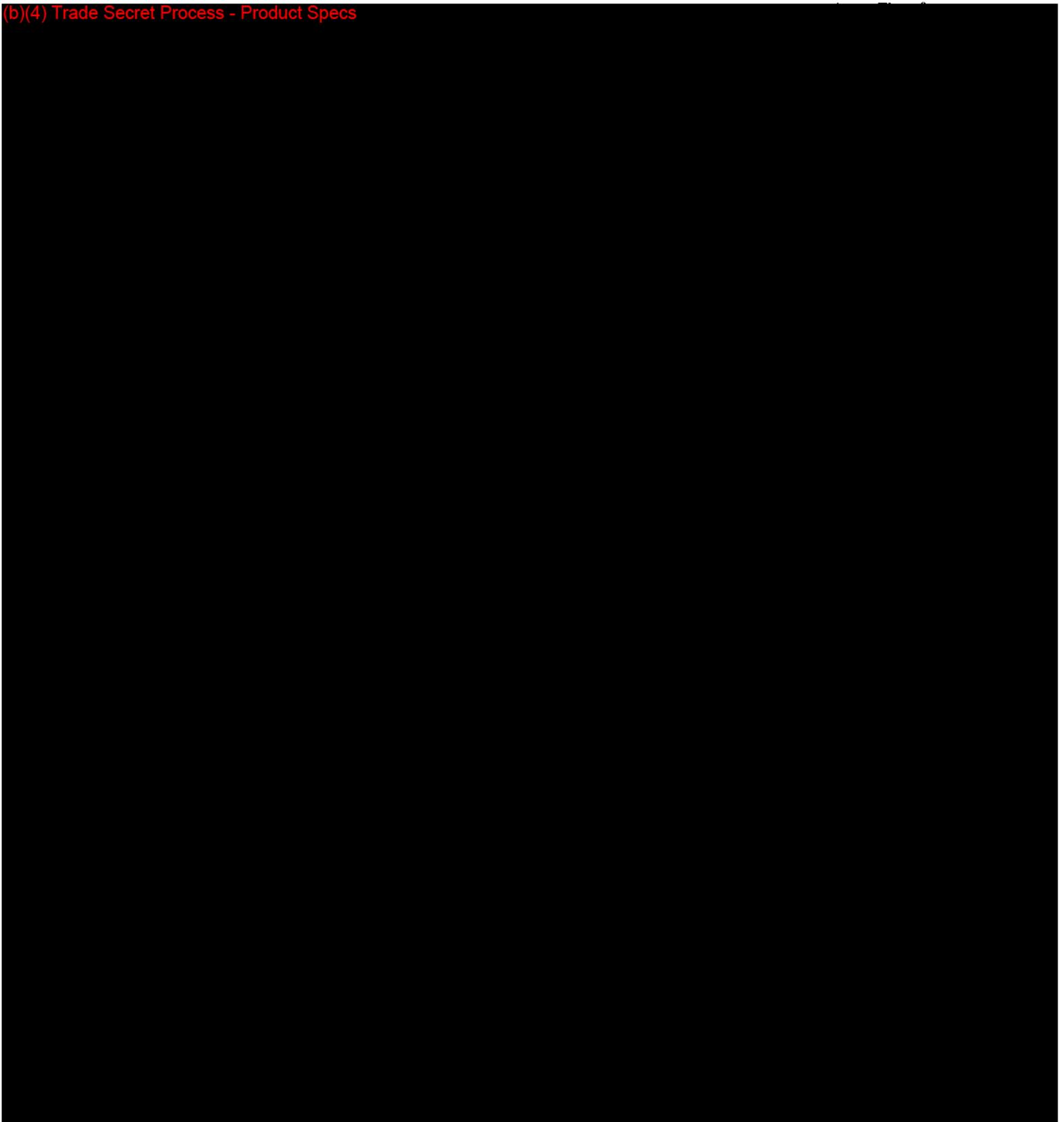


Sincerely,
Julie B. Gantenberg, M.S.
Biomedical Engineer
FDA Reviewer for DSORD/OJDB

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



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



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

SL

XVI. Contact History

From: Kathy Trier [mailto:Kathy.Trier@coringroup.com]
Sent: Monday, November 29, 2010 3:28 PM
To: Gantenberg, Julie *
Cc: Foy, Jonette; Lucinda Gerber; Richard Sharp
Subject: K093472 Trinity Acetabular System and K103120 BioloX Delta heads

Dear Julie,

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



Best regards,
Kathy

Kathy Trier
VP Clinical and Regulatory Affairs

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042 | Mobile: 1 (813) 766-2112
Email: Kathy.Trier@coringroup.com

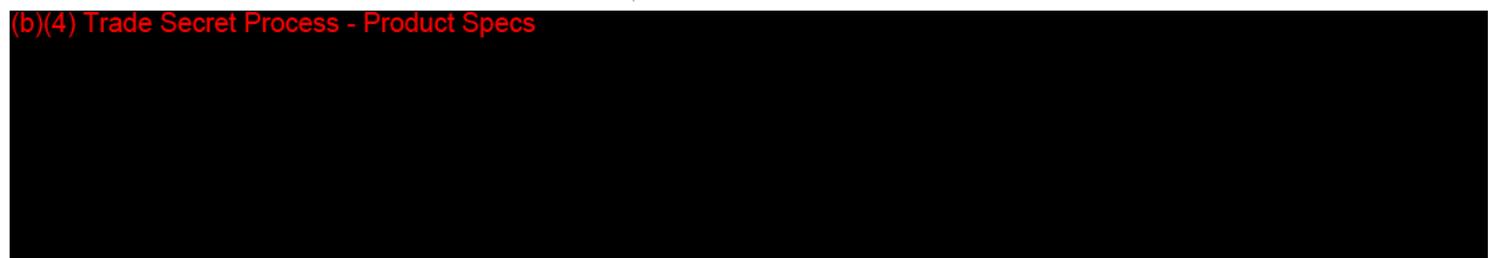
www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie * [mailto:Julie.Gantenberg@fda.hhs.gov]
Sent: Monday, November 29, 2010 3:48 PM
To: Kathy Trier
Cc: Foy, Jonette; Lucinda Gerber; Richard Sharp; Gantenberg, Julie *
Subject: RE: K093472 Trinity Acetabular System and K103120 BioloX Delta heads

Dear Kathy,

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



Sincerely,

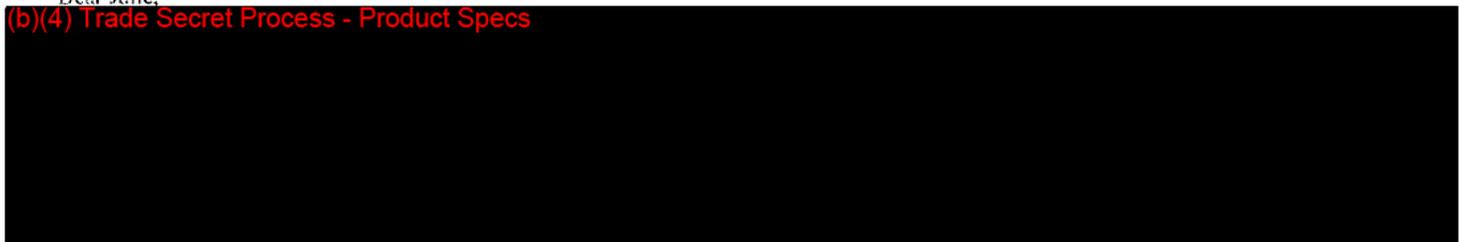
Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Kathy Trier [<mailto:Kathy.Trier@coringroup.com>]
Sent: Monday, November 29, 2010 5:22 PM
To: Gantenberg, Julie *
Cc: Foy, Jonette; Lucinda Gerber; Richard Sharp
Subject: RE: K093472 Trinity Acetabular System and K103120 Biolox Delta heads

Dear Julie,

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



Best regards,
Kathy

Kathy Trier
VP Clinical and Regulatory Affairs

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042 | Mobile: 1 (813) 766-2112
Email: Kathy.Trier@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Lucinda Gerber [<mailto:Lucinda.Gerber@coringroup.com>]
Sent: Thursday, December 02, 2010 12:54 PM
To: Gantenberg, Julie *
Cc: Kathy Trier
Subject: Biolox Delta K103120 Add to File
Importance: High

Hi Julie,

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



Many thanks,
Lucinda



Add to File 1Dec10
LG.pdf (570...

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042
Email: lucinda.gerber@coringroup.com

www.coringroup.com

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CORIN LIMITED
Registered Office: The Corinium Centre, Cirencester, Gloucestershire, GL7 1YJ
Registered in England: Number 01910453

From: Gantenberg, Julie *
Sent: Wednesday, December 08, 2010 11:22 AM
To: 'Lucinda Gerber'
Cc: Kathy Tric; Dang, Jiyoung M; Gantenberg, Julie *
Subject: K103120 deficiencies
Importance: High

Dear Lucinda,

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



Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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[REDACTED] (b)(4) [REDACTED]

From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Wednesday, December 08, 2010 11:29 AM
To: Gantenberg, Julie *
Cc: Kathy Trier; Dang, Jiyoun M
Subject: RE: K103120 deficiencies

Dear Julie,
Thank you I received your e-mail request for further information. I will get the requested information back to you as soon I can.
Kind Regards,
Lucinda

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I
Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: Fax: 1 (813) 979-0042
Email: lucinda.gerber@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie *
Sent: Thursday, December 30, 2010 3:50 PM
To: 'Lucinda Gerber'
Cc: Kathy Trier; Dang, Jiyoun M
Subject: RE: K103120 deficiencies

Dear Lucinda,

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

Thanks,
Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Thursday, December 30, 2010 5:34 PM
To: Gantenberg, Julie *
Cc: Kathy Trier; Dang, Jiyoun M
Subject: RE: K103120 deficiencies

Dear Julie,

[REDACTED]

Many Thanks,
Lucinda
Sponsor emailed ecopy of response.

From: Gantenberg, Julie *
Sent: Monday, January 03, 2011 6:30 AM
To: 'Lucinda Gerber'
Cc: Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Hi Lucinda,

[REDACTED] (b) (4)

Thanks,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Lucinda Gerber [mailto:Lucinda.Gerber@coringroup.com]
Sent: Monday, January 03, 2011 8:17 AM
To: Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Hi Julie,

[REDACTED] (b)(4) Trade

Many Thanks,
Lucinda

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate I

Corin USA Limited | 10500 University Center Drive | Suite 190 | Tampa | Florida 33612 | USA
Main: 1 (813) 977-4469 | Fax: 1 (813) 979-0042
Email: lucinda.gerber@coringroup.com

www.coringroup.com

Please consider the environment before printing this e-mail

From: Gantenberg, Julie *
Sent: Monday, January 03, 2011 8:33 AM
To: 'Lucinda Gerber'

Cc: Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Lucinda,

[REDACTED] b
Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910
Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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From: Gantenberg, Julie *
Sent: Wednesday, January 12, 2011 12:17 PM
To: 'Lucinda Gerber'
Cc: Dang, Jiyoung M; Gantenberg, Julie *
Subject: RE: K103120 deficiencies

Dear Lucinda,

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



Sincerely,

Julie B. Gantenberg, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
Phone: 301-796-6910

62

Fax: 301-847-8119
julie.gantenberg@fda.hhs.gov

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[Redacted]

XVII. Recommendation

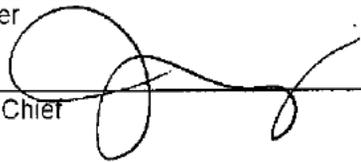
[Redacted] (b)(4) [Redacted]

T d

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
Other Product Codes for system: N/A

Gantenberg

Reviewer



Branch Chief

1/12/11

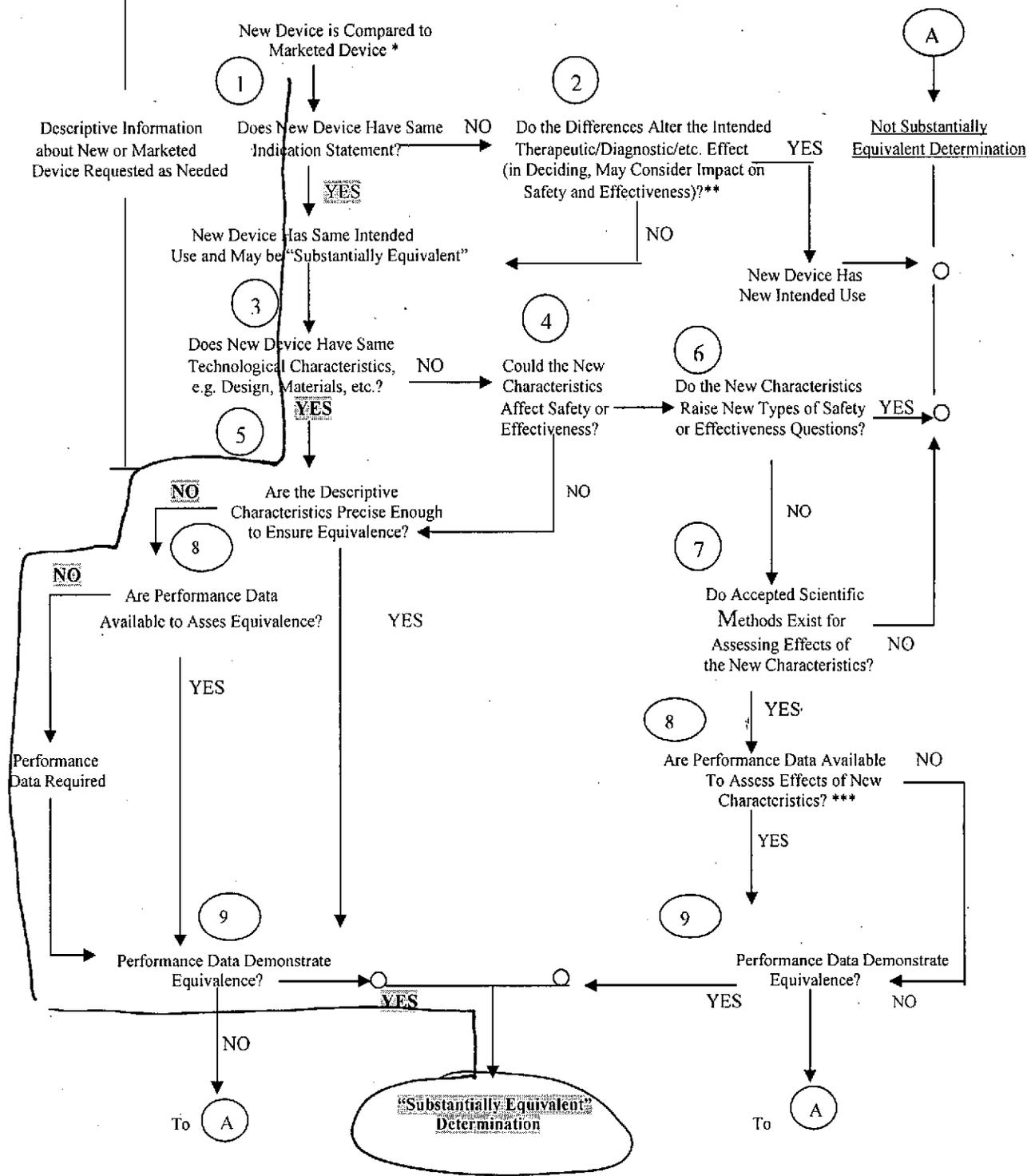
Date

1/12/2011

Date



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



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

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

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

Corin

K103120/S1

FDA CDRH DMC

DEC 29 2010

~~RECEIVED~~

K-77

December 28, 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Julie B. Gantenberg, M.S., Biomedical Engineer, FDA Reviewer for DSORD/OJDB

Re: **K103120 Corin BIOLOX delta Modular Heads
Response to December 8, 2010 Hold Letter**

Dear Ms. Gantenberg,

The purpose of this letter is to respond to the questions raised by FDA in the email dated December 8, 2010 regarding the review of the 510(k) submitted for the Corin BIOLOX delta Modular Heads (K103120).

Please find enclosed one (1) original printed copy of the submission and a CD with an electronic version of the document which is identical to the printed original.

Pursuant to 21 CFR 807.95(b)(1), Corin, considers this additional information for Corin's 510(k) submission (K093472) to be confidential commercial information and requests that FDA treat it as such. Corin has taken precautions to protect the confidentiality of the intent to market these devices.

If there are any questions on this information please contact me by e-mail at Lucinda.gerber@coringroup.com or by phone at 813-977-4469.

Sincerely,



Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
Corin USA

www.coringroup.com

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(813) 977-4469 | Fax: (813) 979-0042 | Email: usa@coringroup.com



December 28, 2010

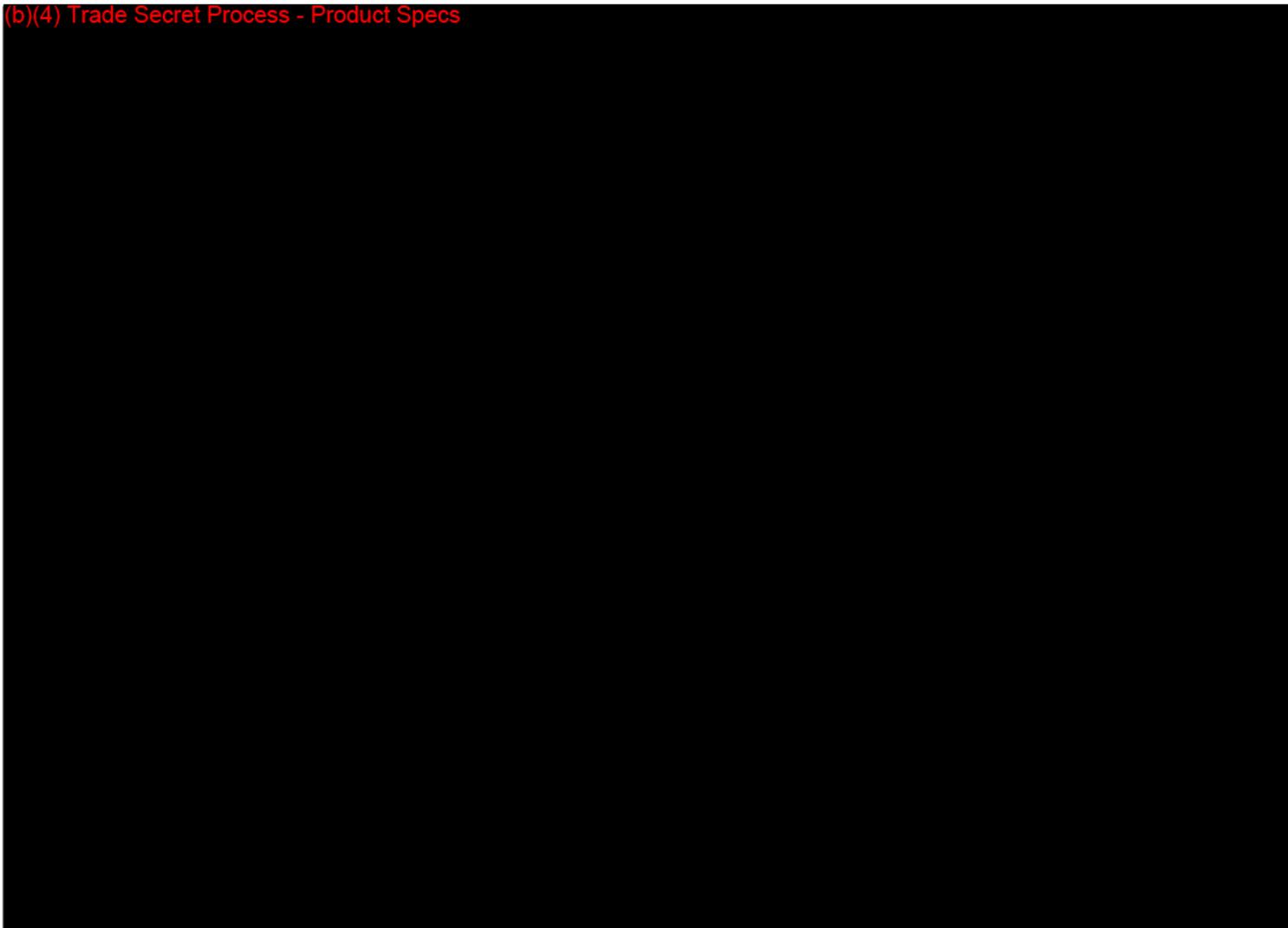
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Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Julie B. Gantenberg, M.S., Biomedical Engineer, FDA Reviewer for DSORD/OJDB

Re: **K103120 Corin BIOLOX delta Modular Heads**
Response to December 8, 2010 Hold Letter

Dear Ms. Gantenberg,

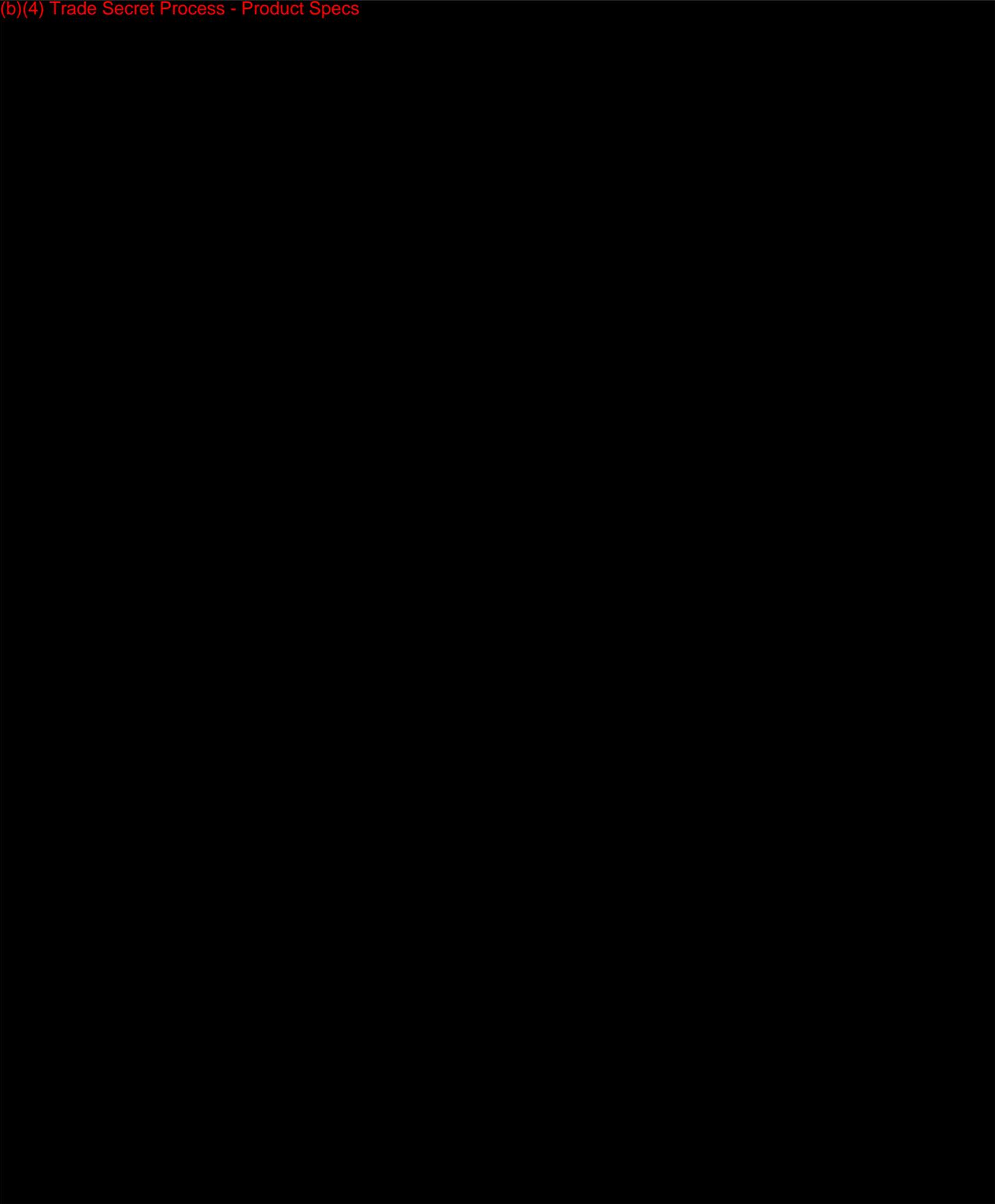
(b)(4) Trade Secret Process - Product Specs



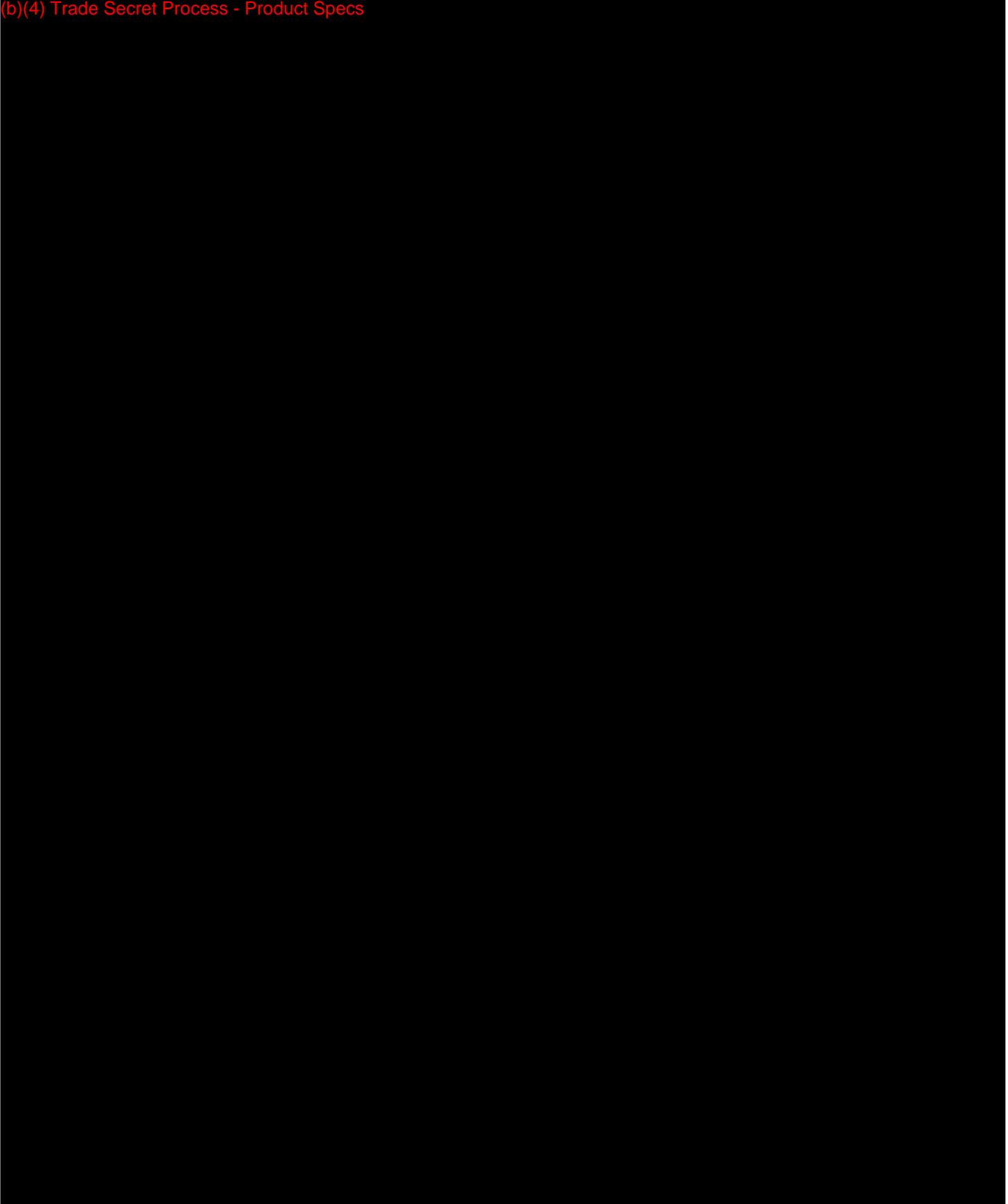
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(813) 977-4469 | Fax: (813) 979-0042 | Email: usa@coringroup.com

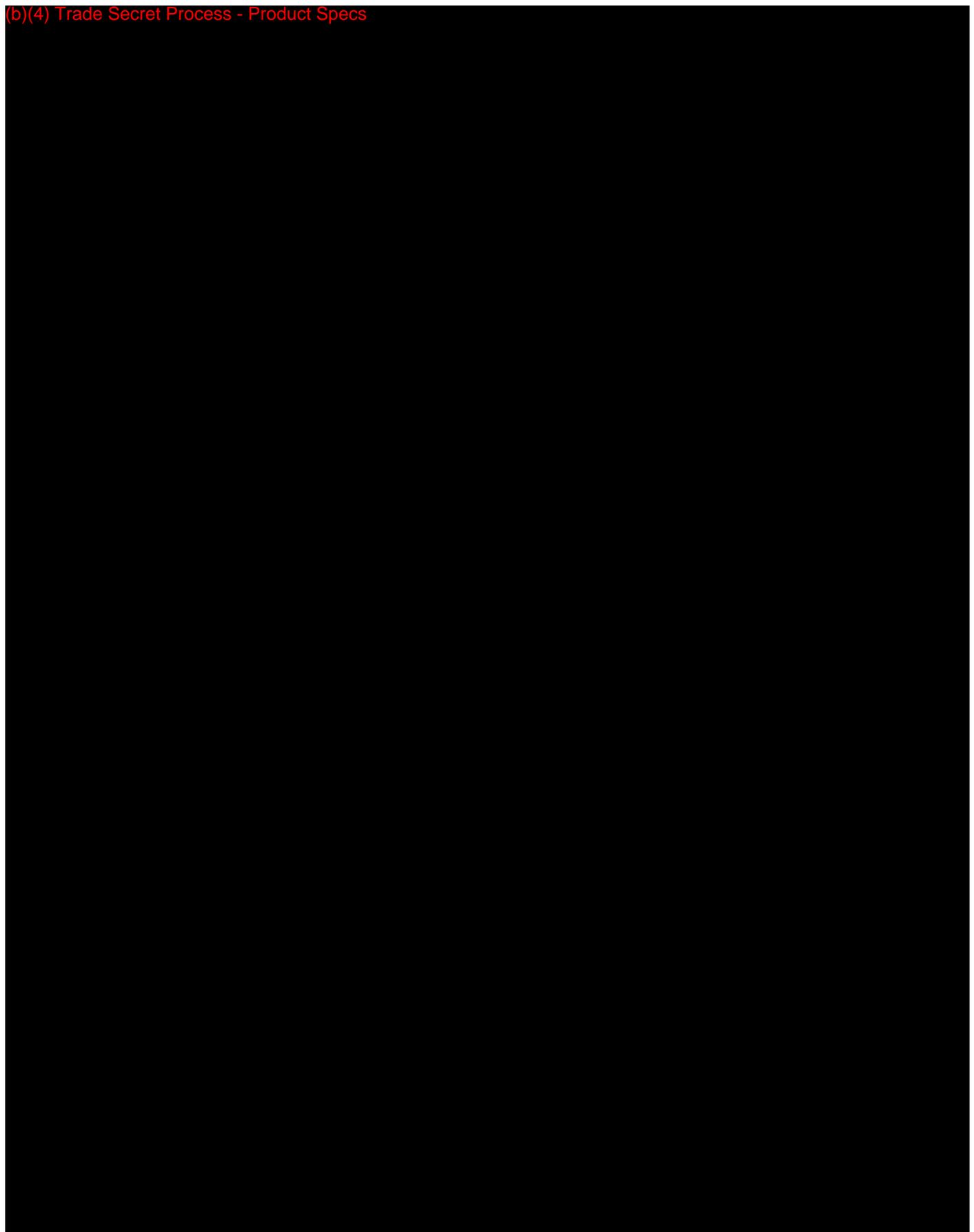
(b)(4) Trade Secret Process - Product Specs



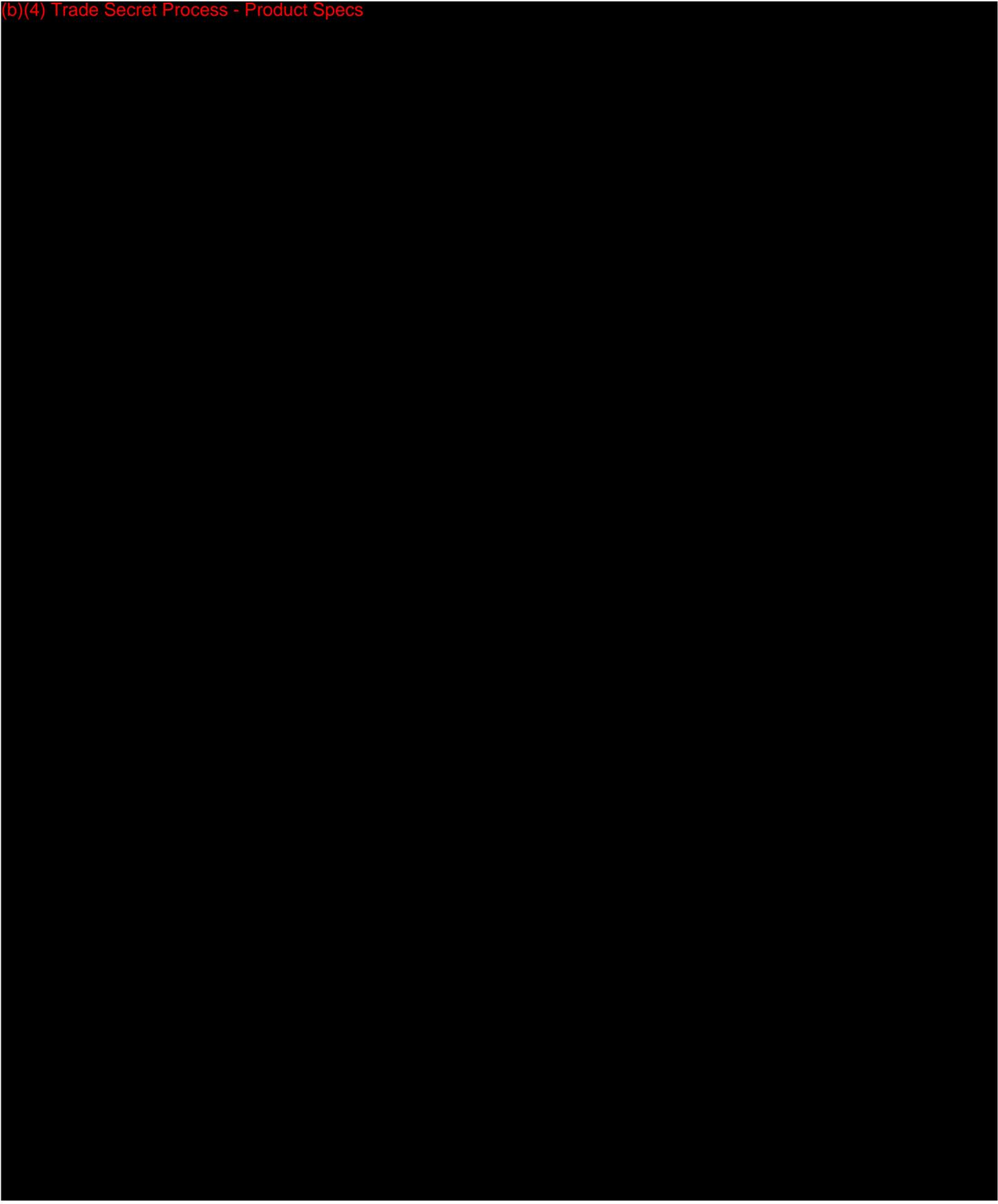
(b)(4) Trade Secret Process - Product Specs



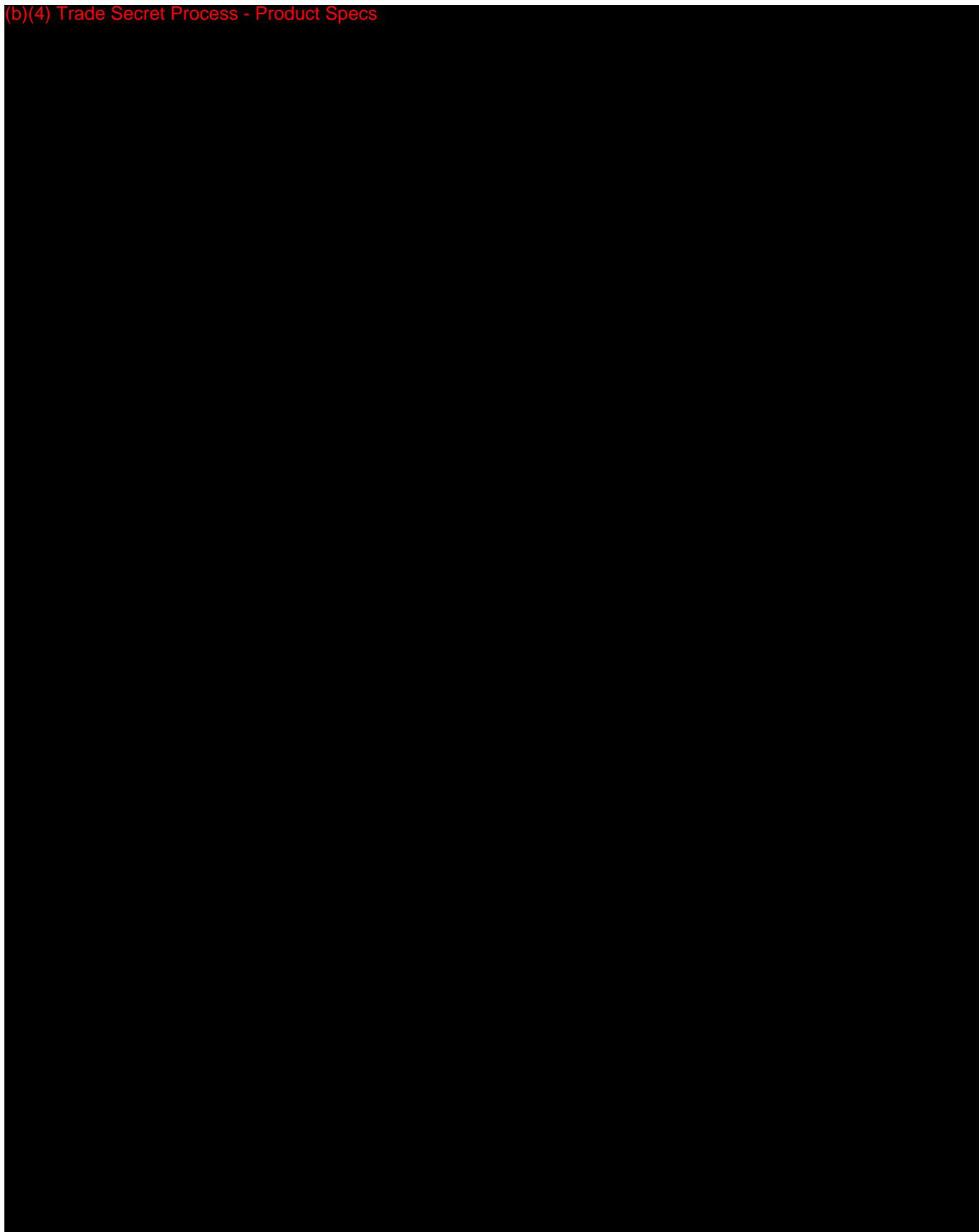
(b)(4) Trade Secret Process - Product Specs



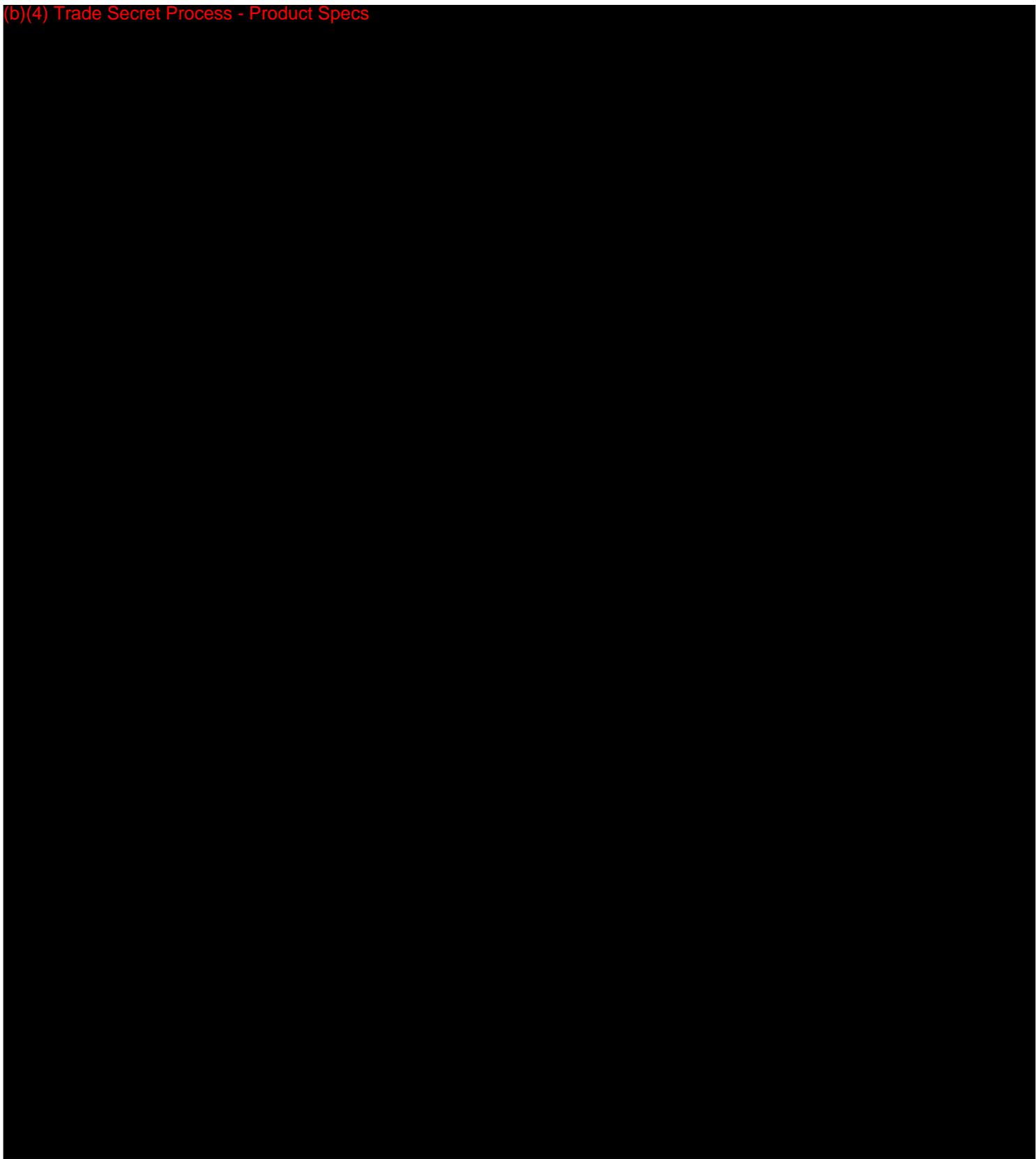
(b)(4) Trade Secret Process - Product Specs



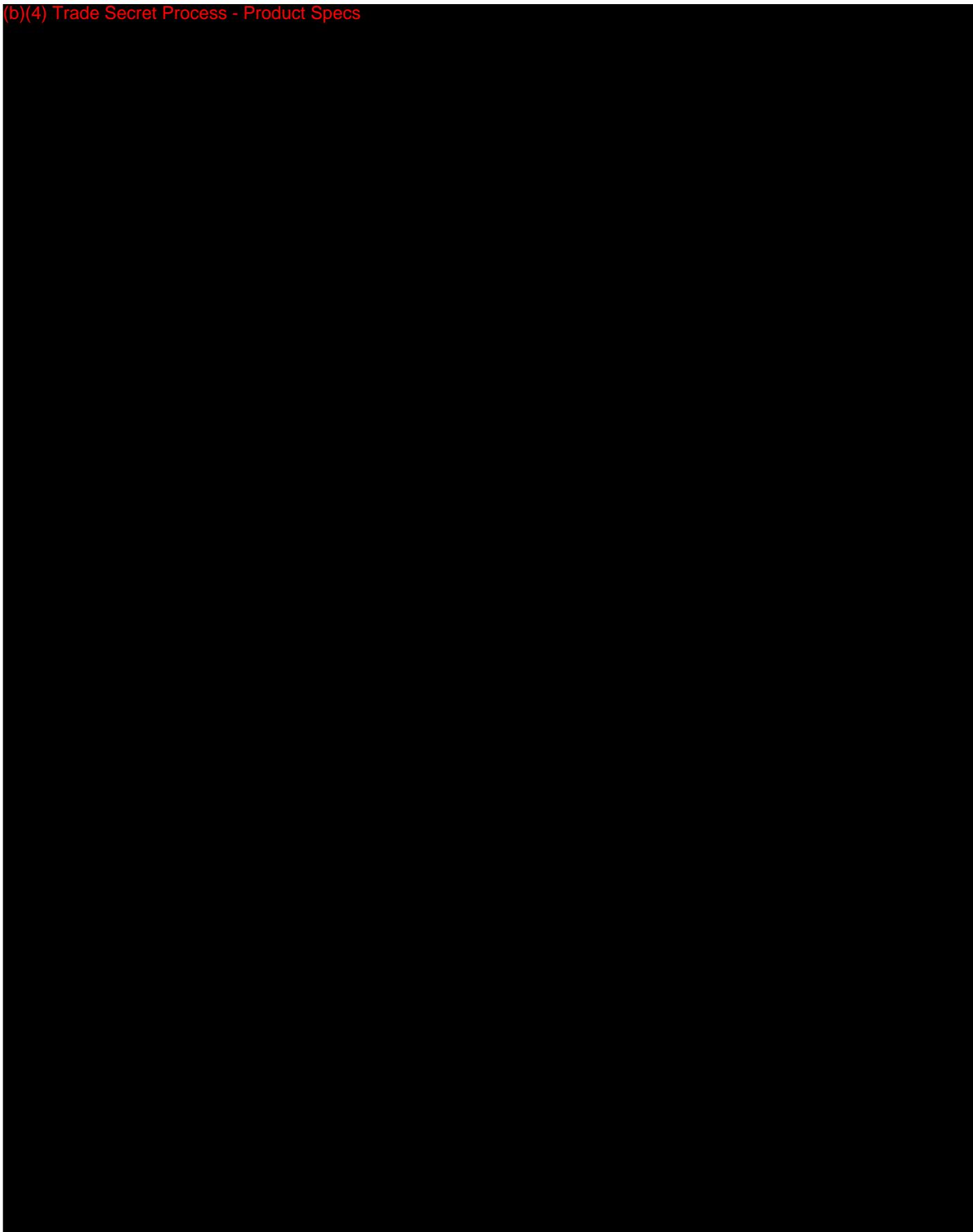
(b)(4) Trade Secret Process - Product Specs



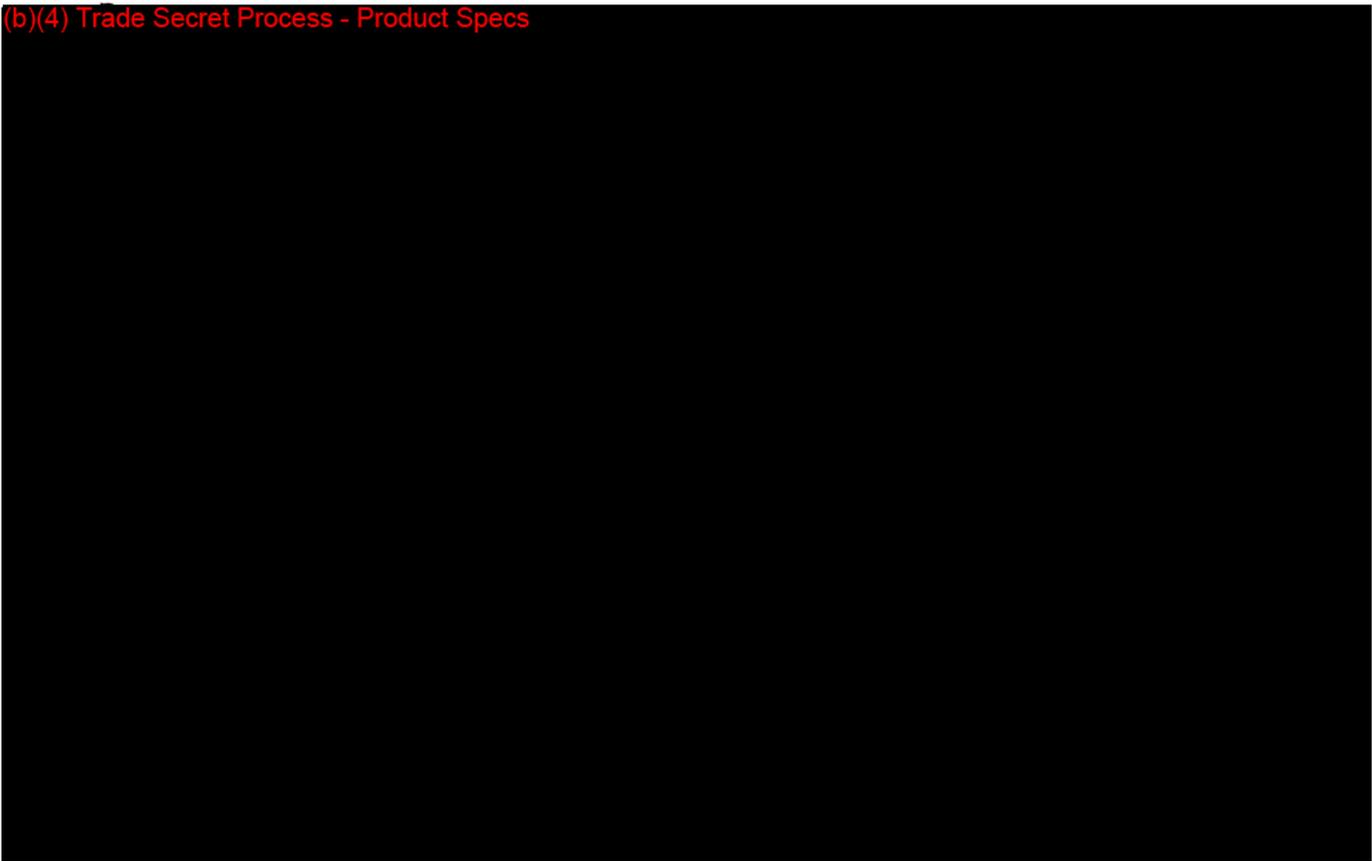
(b)(4) Trade Secret Process - Product Specs



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



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



Sincerely,

A handwritten signature in blue ink, appearing to read "L. Gerber", is written over the typed name.

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate
Corin USA

Appendix A
FDA Form 3674

Appendix B
Testing

(b)(4) Trade Secret Process - Testing



Appendix C
Draft package insert



Appendix D
Step-by-step cleaning instructions for instruments

Error - Couldn't merge file with following reason - PdfReader not opened with owner password
0900262180d1e3e2.pdf

System attempted to attach the file. Please look at attachments to open this file manually.

Corin

K103120/S2

FDA CDRH DMC
FEB 10 2011
Received K42

February 9, 2011

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Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Julie B. Gantenberg, M.S., Biomedical Engineer, FDA Reviewer for DSORD/OJDB

Re: **K103120 Corin BIOLOX delta Modular Heads**
Response to December January 12, 2011 Hold e-mail

Dear Ms. Gantenberg,

The purpose of this letter is to respond to the questions raised by FDA in the email dated January 12, 2011 regarding the review of the 510(k) submitted for the Corin BIOLOX delta Modular Heads (K103120).

Please find enclosed one (1) original printed copy of the submission and a CD with an electronic version of the document which is identical to the printed original.

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If there are any questions on this information please contact me by e-mail at Lucinda.gerber@coringroup.com or by phone at 813-977-4469.

Sincerely,



Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
Corin USA

www.coringroup.com

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(813) 977-4469 | Fax: (813) 979-0042 | Email: usa@coringroup.com



February 9, 2011

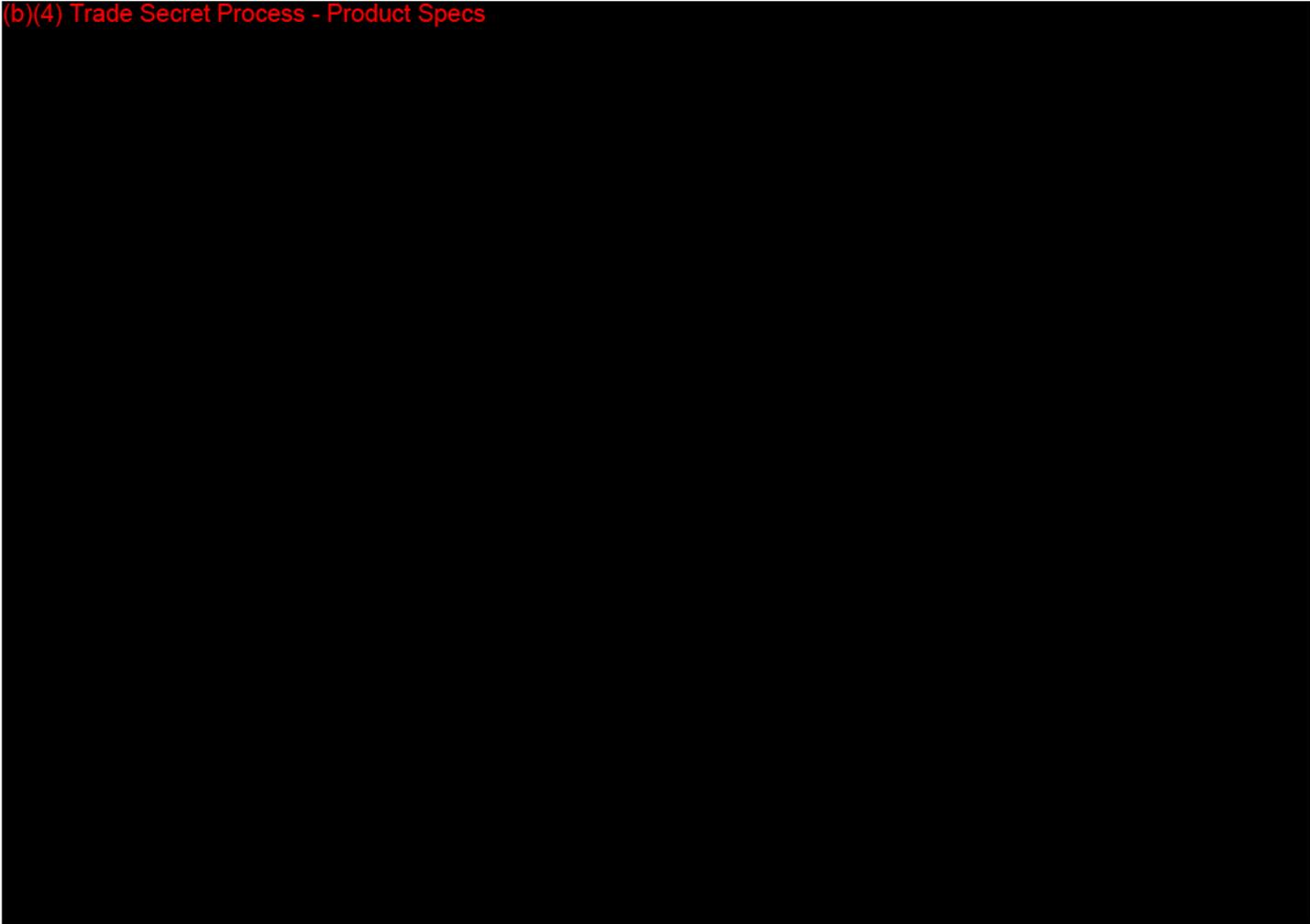
U.S. Food and Drug Administration
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10903 New Hampshire Avenue
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Attention: Julie B. Gantenberg, M.S., Biomedical Engineer, FDA Reviewer for DSORD/OJDB

Re: **K103120 Corin BIOLOX delta Modular Heads**
Response to January 12, 2011 Hold Letter

Dear Ms. Gantenberg,

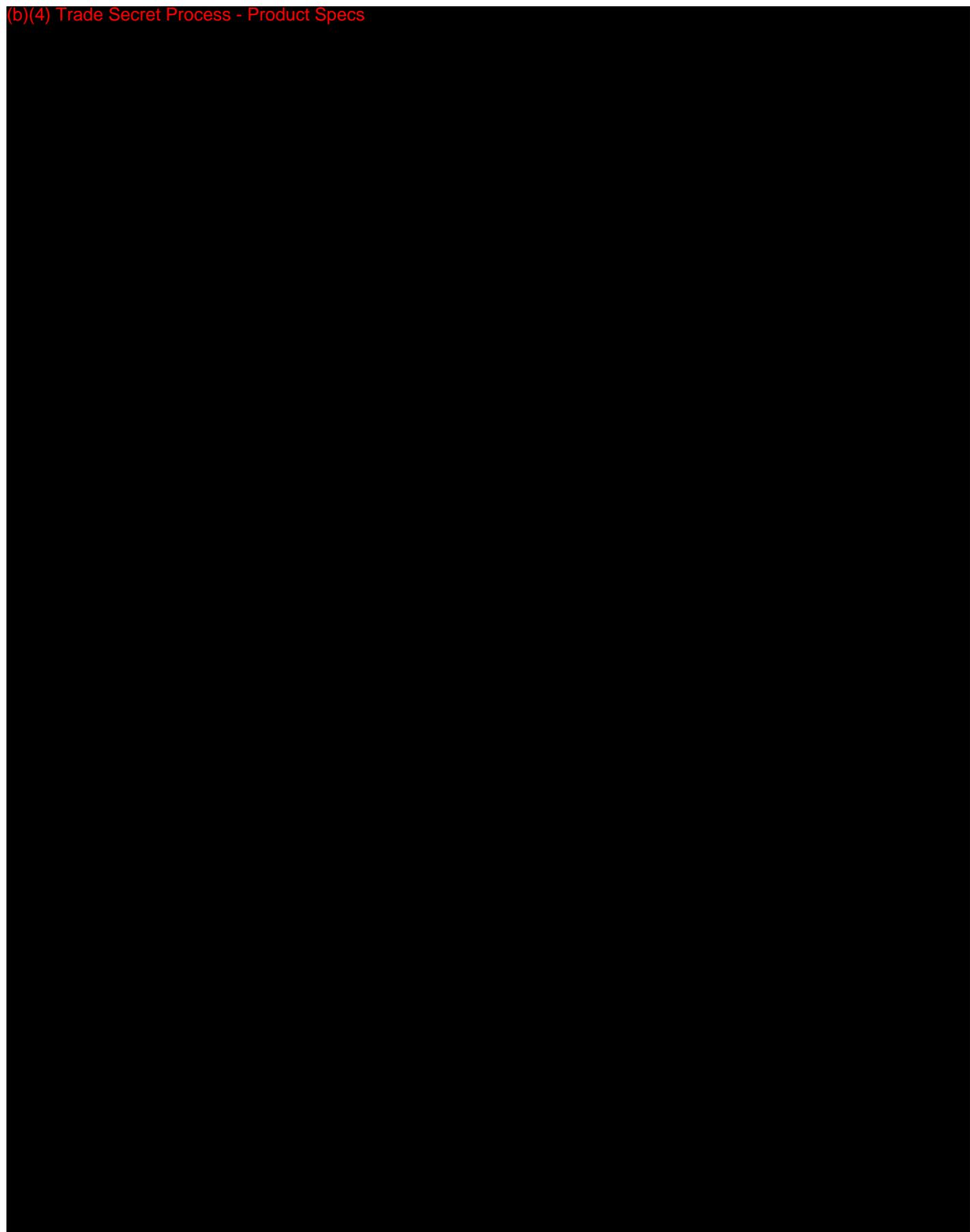
(b)(4) Trade Secret Process - Product Specs



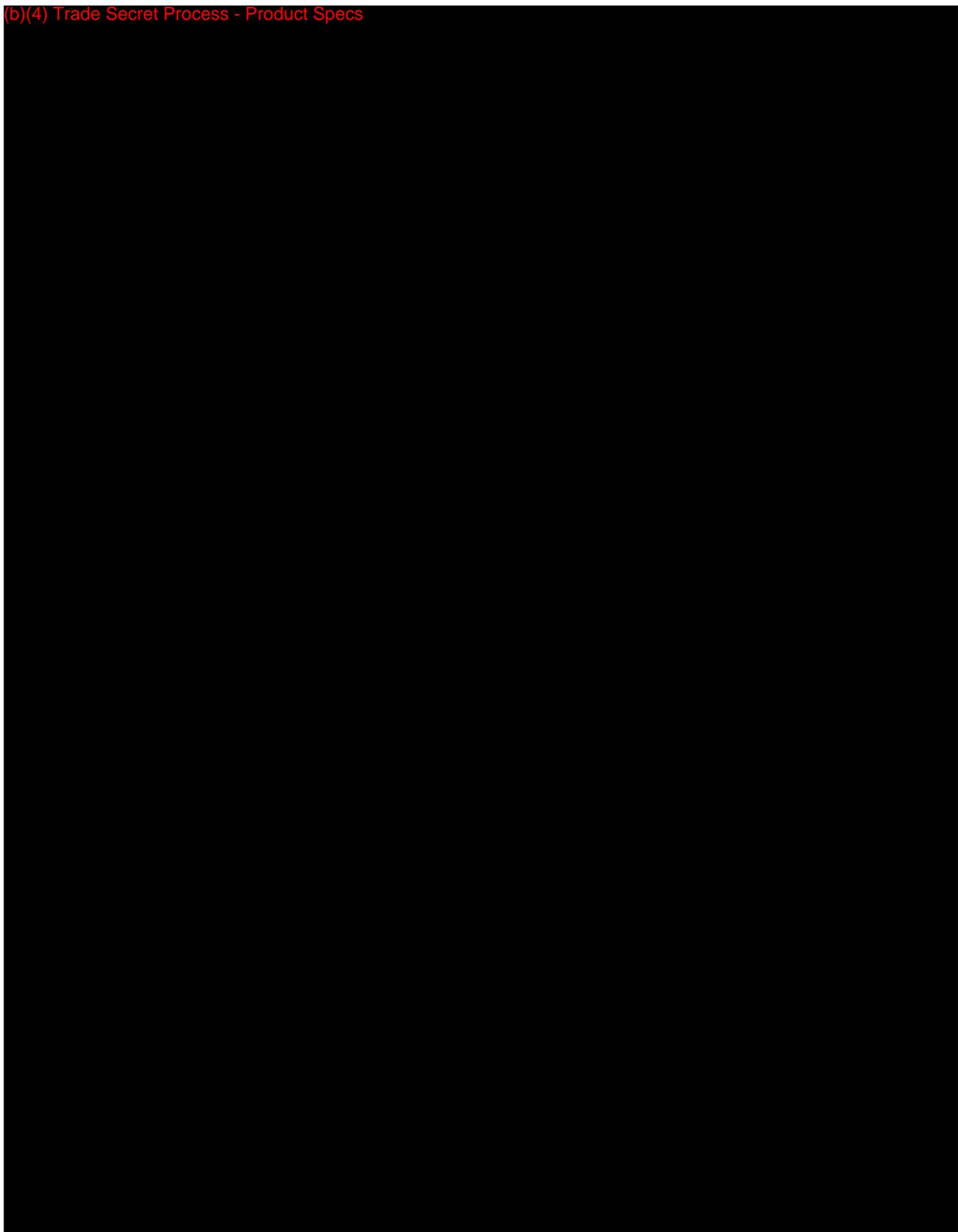
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(813) 977-4469 | Fax: (813) 979-0042 | Email: usa@coringroup.com

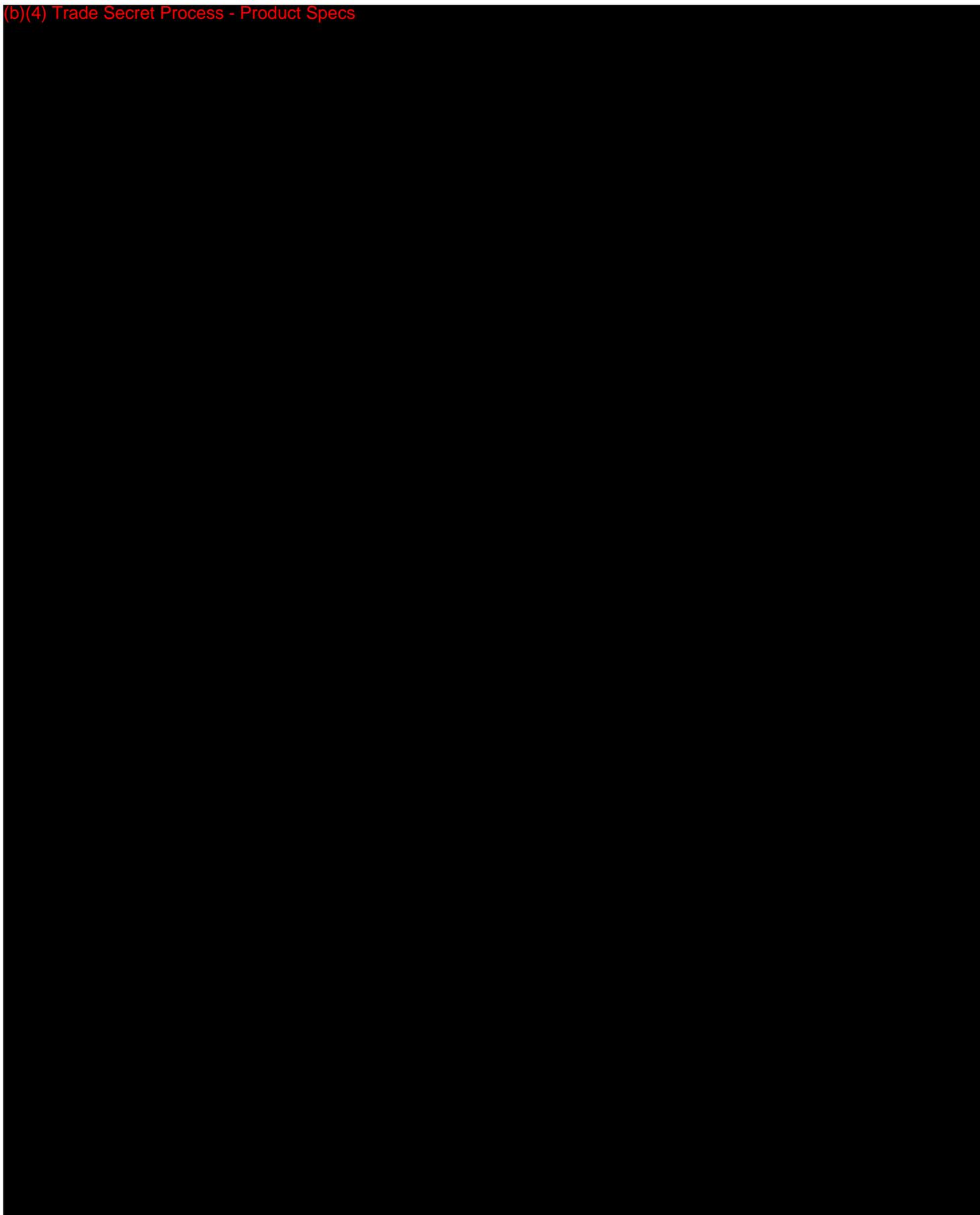
(b)(4) Trade Secret Process - Product Specs



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



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



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

Sincerely,

A handwritten signature in blue ink, appearing to read 'L. Gerber', with a long horizontal flourish extending to the right.

Lucinda Gerber BA (Hons)
Regulatory Affairs Associate
Corin USA

Appendix A

Test Reports

Appendix B
Package Insert

Appendix C
Operative Technique

Appendix D
510(k) Summary

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.:
2. Contact Person: Lucinda Gerber BA (Hons)
Regulatory Affairs Associate
Corin USA
813-977-4469
Lucinda.gerber@coringroup.com
3. Proprietary Name: Corin BIOLOX delta Modular Femoral Heads
4. Common Name: Femoral Head
5. Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)
6. Legally Marketed Devices to which Substantial Equivalence is claimed:
 - Zyranox Zirconia Ceramic Modular Heads (K992235)
 - Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412)
7. Device Description:

BIOLOX delta material is an aluminum oxide / zirconia ceramic composite composed of approximately 75% aluminum oxide and approximately 25% zirconia.

The Corin BIOLOX delta Modular Femoral Heads are available in 28mm and 32mm diameters. The 28mm heads are available with short (-3.5mm), medium (0mm) and long (+3.5mm) offsets. The 32mm heads are available with short (-4.0mm), medium (0mm), long (+4mm) and extra long (+7mm) offsets.

The Corin Biolox Delta heads are compatible with Corin titanium stems (i.e. Tri-Fit, Metafix and MiniHip femoral stems having a 12/14 taper trunnion) and the Trinity acetabular system.

8. Intended Use / Indications:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity and
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

9. Summary of Technologies/Substantial Equivalence:

The Corin Biolox Delta modular femoral heads have the same types of indications and intended uses as the predicates. The technological characteristics are the same as the predicates. Based on the materials, geometry, mechanical testing and indications for use, the Biolox Delta heads are considered to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Nonclinical testing included burst strength testing on both the 28mm-12/14L and 32mm-12/14XL Biolox delta heads on the Corin titanium taper trunnion to determine the worst case construct. Subsequently, fatigue, post-fatigue burst and pull-off testing were then performed on the worst case construct. The results of the ceramic head testing meet the suggested values in the “Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems.” The results of the preclinical data provided indicate that the subject system is within the range of legally marketed predicates.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin BIOLOX delta Modular Femoral Heads and the predicate devices.