

Summary of Safety and Effectiveness

Date: September 25, 2008

Contact Person:

NOV 25 2008

Manufacturer:

DJO Surgical (legally Encore Medical, L.P.)
9800 Metric Blvd
Austin, TX 78758

Teffany Hutto

Manager, Regulatory Affairs

Phone: (512) 834-6255

Fax: (512) 834-6313

Email: teffany.hutto@djosurgical.com

Product	510(k) Number, Clearance Date/ Classification	Product Code
Bilox® Ceramic Femoral Head	K955563 – August 9, 1996 / Class II	LZO

Product Code	Regulation and Classification Name
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353

Description: The modification consists of a new material used in the manufacture of the BioloX Ceramic Femoral Heads. The femoral heads, manufactured from BioloX® *delta** material, are fabricated from an alumina matrix composite. The standard femoral head will mate with a femoral stem through a taper fit. The Option femoral head includes a sleeve that is inserted into the head and attached to the femoral stem through a taper fit. The heads will be available in sizes 22, 28, 32, 36, 40 and 44mm.

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

These devices may also be indicated in the salvage of previously failed surgical attempts.

Intended Use: DJO Surgical hip devices are intended for treatment of patients who are candidates for total hip arthroplasty per the indications for use. While hip replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

Predicate Devices:

- Zimmer BioloX® *delta* Ceramic Femoral Head – K071535, Cleared November 19, 2007
- Biomet BioloX *delta* Ceramic Head – K042091, Cleared March 25, 2005, K051411, Cleared June 29, 2005, K061312, Cleared June 6, 2006
- DePuy Delta Ceramic Femoral Head – K062748, Cleared November 30, 2006
- Stryker Howmedica Osteonics V40™ BioloX *delta* Ceramic Femoral Head – K052781, Cleared October 27, 2005
- Stryker Howmedica Osteonics V40™/C-Taper Adapter Sleeve – K003379, Cleared November 30, 2000

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same indications, materials, sterilization, and intended use.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: None provided.

*Trademark of CeramTec AG



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Encore Medical, L.P.
% Ms. Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Blvd.
Austin, Texas 78758

NOV 25 2008

Re: K082844

Trade/Device Name: Biolox *delta* Ceramic Femoral Head
Biolox *delta* Ceramic Femoral Head Offset Sleeve
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: October 30, 2008
Received: October 31, 2008

Dear Ms. Hutto:

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

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

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

Page 2 – Ms. Teffany Hutto

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

510(k) Number (if known): K082844 (pg 1/1)

Device Name: Ceramic Femoral Head

Indications for Use:

**BioloX® delta Ceramic Femoral Head
Indications for Use**

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

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 General, Restorative,
and Neurological Devices

510(k) Number K082844



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Encore Medical, L.P.
% Ms. Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Blvd.
Austin, Texas 78758

NOV 25 2008

Re: K082844

Trade/Device Name: Biolog *delta* Ceramic Femoral Head
Biolog *delta* Ceramic Femoral Head Offset Sleeve

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: October 30, 2008

Received: October 31, 2008

Dear Ms. Hutto:

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

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

510(k) Number (if known): K082844 (pg 1/1)

Device Name: Ceramic Femoral Head

Indications for Use:

**BioloX® delta Ceramic Femoral Head
Indications for Use**

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

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 General, Restorative,
and Neurological Devices

510(k) Number K082844



October 22, 2008

ENCORE MEDICAL, L.P.
9800 METRIC BLVD.
AUSTIN, TEXAS 78758
UNITED STATES
ATTN: TEFFANY HUTTO

510k Number: K082844

Product: BIOLOX DELTA CERAMIC FEMORAL H

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

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

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

Sincerely yours,

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



September 29, 2008

ENCORE MEDICAL, L.P.
9800 METRIC BLVD.
AUSTIN, TEXAS 78758
UNITED STATES
ATTN: TEFFANY HUTTO

510k Number: K082844

Received: 9/26/2008

Product: BIOLOX DELTA CERAMIC

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

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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



K082844

DJO Surgical
9800 Metric Boulevard
Austin, TX 78758-5445
T 800.456.9696
djosurgical.com

September 25, 2008

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FDA CDRH DMC

SEP 26 2008

Received

Re: **Special 510(k) Notification**

K955563 – Foundation® Stems with BioloX® Heads

Dear Sir/Madam:

DJO Surgical hereby submits two copies of a **Special 510(k): Device Modification** to request clearance for the use of a new material for our current BioloX® ceramic femoral heads. We are also adding an option that consists of a sleeve that inserted into the femoral head. We believe this modification is eligible for the Special 510(k) process since the fundamental scientific technology and intended use has not changed from the previously approved devices and because the ceramic material is currently being used in other legally marketed predicate devices.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (512) 834-6255 or by email at teffany.hutto@djosurgical.com.

Sincerely,

Teffany Hutto
Manager, Regulatory Affairs

Enclosures (as stated)

K31

9H

DJOglobal.com

K082844

Special 510(k)
BioloX® delta Ceramic Femoral Head
September 25, 2008

FDA CDRH DMC

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SEP 26 2008

Received

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Attachments

Labeling.....	Attachment A
Device Drawings.....	Attachment B
Predicate Device Information.....	Attachment C
Analysis of Modification and Risk Analysis.....	Attachment D
Indications for Use.....	Attachment E
Declaration of Conformity.....	Attachment F
Summary of Safety and Effectiveness.....	Attachment G
Truthful and Accurate Statement.....	Attachment H

1. **Manufacturer Information**

Legal Company Name: Encore Medical, L.P.
Trade Name: DJO Surgical
9800 Metric Boulevard
Austin, TX 78758

Establishment Registration Number: 1644408

Contact Person:

Teffany Hutto
Manager, Regulatory Affairs
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: teffany.hutto@djosurgical.com

2. **Device Information**

The following device has been affected by the modifications outlined in this Special 510(k):

510(k) Number	K955563 – Cleared August 9, 1996
Classification Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
Common/Usual Name	Femoral Head
Trade/Proprietary Name	Bilox® Ceramic Femoral Head
Device Classification	Class II
Indications for Use	Total hip replacement is indicated for patients suffering from disability due to: <ul style="list-style-type: none">• noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;• rheumatoid arthritis;• correction of functional deformity;• femoral fracture. This device may also be indicated in the salvage of previously failed surgical attempts.

3. **Labeling**

Labeling and IFU's are included as **Attachment A**. Updates to the cleared IFU are noted in blue.

4. **Packaging and Sterilization**

There have been no changes to the method of packaging or sterilization.

5. **Device Description**

The BioloX® *delta* Ceramic Femoral Head is an alumina matrix composite manufactured by CeramTec AG and is currently cleared for use with predicate devices (See Section 6 below).

As with the currently approved BioloX® Ceramic Femoral Head (K955563), the standard *delta* head will be mated with a femoral stem through a CERASIV taper fit.

The BioloX® Option *delta* Ceramic Femoral Head is used with a sleeve made of Ti-6Al-4V that is inserted into the head. The sleeve is available in 4 different neck lengths including: -3 mm, 0 (neutral), 4 mm, and 7 mm. The head with sleeve is mated with a femoral stem through a

CERASIV taper fit. This is similar in design the V-40/C Taper Adapter Sleeve (K003379) manufactured by Stryker Howmedica.

Sizes for the femoral heads will be offered in 22, 28, 32, 36, 40 and 44mm. They will be used with acetabular liners manufactured from standard ultra high molecular weight polyethylene (K973119, K974093, and K974095) or highly cross-linked polyethylene (K072154).

The *delta* Ceramic Femoral Heads and *delta* Option Femoral Heads will be mated with the following femoral stems:

Product	510(k) Number, Clearance Date
CLP™ I	K930963 – January 7, 1994
Foundation® Cemented	K935449 – March 30, 1995
Vitality® Hip Stem	K962560 – September 19, 1996
Foundation® Press-Fit Hip Stem	K973302 – December 2, 1997
Revelation® Hip Stem (Standard & V2)	K973685 – December 19, 1997
Foundation® Fracture Hip Stem	K973809 – January 2, 1998
Linear® Hip Stem	K974294 – January 12, 1998
Stamina® Hip Stem	K980473 – April 16, 1998
ALFA™ II	K984227 – November 24, 1998
Keystone® Modular Hip Stem	K000521 – May 10, 2000
R120™	K011774 – September 5, 2001
R120™ PC	K021822 – July 23, 2002
CLP-R™	K052320 – December 30, 2005
CLP™ Offset (Revision)	K052320 – December 30, 2005

All hip stems have the same Morse type taper, taper finish, and cross-section geometry. There will be no changes to the taper feature from the cleared ceramic femoral head (K955563). Additionally, the taper of the *delta* Option femoral head is the same as the cleared ceramic femoral head (K955563).

Device drawings are provided as **Attachment B**.

6. Substantial Equivalence

Predicate device information for the following devices is provided as **Attachment C**.

Device	Clearance Information
Zimmer Biologx® <i>delta</i> Ceramic Femoral Head	K071535, Cleared November 19, 2007
Biomet Biologx <i>delta</i> Ceramic Head	K042091, Cleared March 25, 2005 K051411, Cleared June 29, 2005 K061312, Cleared June 6, 2006
DePuy Delta Ceramic Femoral Head	K062748, Cleared November 30, 2006
Stryker Howmedica Osteonics V40™ Biologx <i>delta</i> Ceramic Femoral Head	K052781, Cleared October 27, 2005
Stryker Howmedica V40™/C-Taper Adapter Sleeve	K003379, Cleared November 30, 2000

7. **Design Control Activities**

Testing performed by the manufacturer of the Biolox *delta* material, CeramTec AG, is provided as **Attachment D**. Additionally, a risk assessment (FMEA) is also provided as **Attachment D**.

8. **Indications for Use**

The Indications for Use are provided as **Attachment E**.

9. **Declaration of Conformity**

A Declaration of Conformity is provided as **Attachment F**.

10. **Summary of Safety and Effectiveness**

A Summary of Safety and Effectiveness is included as **Attachment G**.

11. **Truthful and Accuracy Statement**

A Truthful and Accuracy Statement is provided as **Attachment H**.

BILOX[®] DELTA CERAMIC FEMORAL HEADS

Femoral Head, Ceramic



REF 400-03-281

LOT SAMPLE

28mm Dia.
-3.5mm

MATERIAL: Alumina Matrix Composite

Qty. 01

STERILE R



09-2013

AVCA

REF 400-03-281

LOT SAMPLE

STERILE R

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

28mm Dia.
-3.5mm



09-2013

Qty. 01

AVCA

REF 400-03-281

LOT SAMPLE

09-2013

28mm Dia.
Femoral Head, Ceramic

-3.5mm



AVCA

BILOX[®]

BILOX[®] DELTA CERAMIC FEMORAL HEADS

Femoral Head, Ceramic



REF 400-03-281

LOT SAMPLE

28mm Dia.
-3.5mm

MATERIAL: Alumina Matrix Composite

Qty. 01



09-2013

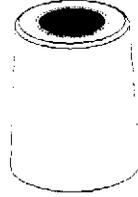
STERILE R

AVCA

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BIOLOX[®] DELTA CERAMIC FEMORAL HEADS

Offset Sleeve



REF 400-05-007

LOT SAMPLE

+ 7.0mm

MATERIAL: Ti6Al4V

Qty. 01

STERILE R



+H972400050071/SS8010914SAMPLE



09-2014

AVCA

REF 400-05-007

LOT SAMPLE

STERILE R

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

+ 7.0mm



09-2014

Qty. 01

AVCA

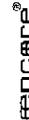
REF 400-05-007

LOT SAMPLE

09-2014

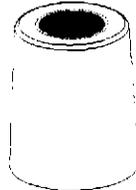
+ 7.0mm
Offset Sleeve

AVCA



BIOLOX[®] DELTA CERAMIC FEMORAL HEADS

Offset Sleeve



REF 400-05-007

LOT SAMPLE

+ 7.0mm

MATERIAL: Ti6Al4V

Qty. 01



09-2014

STERILE R

AVCA

DRAFT

 Do Not Re-use  See "Instructions for Use"  Keep Dry

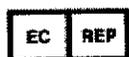
 Manufacturer  Quantity of Items in Package  Sterilized using Hydrogen Peroxide Gas Plasma (H₂O₂)

 LOT number /Batch Code  Expiration Date ("Use By")  REF Catalog Number

 Store in a cool place: Do not store in environments with the potential for extreme heat or direct sun light



9800 Metric Boulevard
 Austin, TX 78758 USA
 1+512 832 9500



MDSS GmbH
 Schiffgraben 41
 30175 Hannover, Germany

0400-0104 N

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1. Product Handling

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage which may compromise sterility. If packaging has been opened or damaged, please refer to Section 8 entitled, "Sterilization" for instructions. You may also contact the manufacturer's representative. When unpacking the implant, verify the labeling for correct Ref. No. and size. When removing the implant from its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects which may damage the surface finish. Inspect each implant prior to use for visual damage. This implant is part of a system and should be used only in combination with other original DJO Surgical Product belonging to the same system.

2. Product Description and Implant Materials

Hip Stem	Fixation Method	Material	Applicable Standard
Linear®	Cementless	Ti6Al4V alloy and CP Ti porous coating where applicable	ASTM F67, ASTM F136, ASTM F620, ISO 5832/3
Foundation® Press-fit	Cementless	Ti6Al4V alloy and CP Ti porous coating where applicable	ASTM F67, ASTM F1185
Keystone® Modular	Cementless	Ti6Al4V alloy and Hydroxyapatite, where applicable	ASTM 1580
Revelation®	Cementless	Ti6Al4V alloy and CP Ti Plasma coating where applicable	ASTM F136, ASTM F1108, ASTM F67
Revelation® V2	Cementless	Ti6Al4V alloy and CP Ti Plasma coating where applicable	ASTM F136, ASTM F1108, ASTM F67
Vitality®	Cemented	CoCr	ASTM F799, ISO 5832/4
Foundation® Cemented	Cemented		
Foundation® Fracture	Cementless	Ti6Al4V alloy	ASTM F136, ISO 5832/3
Stamina®	Cementless		
CLP™ I	Cementless	Ti6Al7Nb Niobium Alloy	ASTM F1295, ISO 5832/11
CLP™ Offset	Cementless		
R120™ / R120PC™	Cemented or Cementless	Cast CoCrMo	ASTM F75, ISO 5832/4
ALFA™ II	Cemented or Cementless	CoCrMo Porous Coating where applicable	ASTM F75
CLP-R™	Cemented or Cementless	CP Ti Plasma coating where applicable	ASTM F1580

DJO Surgical hip stems can be used with any DJO Surgical femoral heads for total joint replacement. DJO Surgical Hip Systems are for total hip replacement except for Bipolar and Unipolar which are for hemi arthroplasty applications. The CLP Offset, CLP-R, Vitality and Stamina hip systems are for either total or hemi applications.

Component	Fixation Method	Material	Applicable Standard
All Poly Acetabular Cup	Cemented	Medical grade UltraHigh Molecular Weight Polyethylene and PMMA Ti6Al4V alloy	ASTM F648, ISO 5834/1+2 PMMA
Femoral Heads	Cementless Cementless ¹ Cementless ³	CoCr Ceramic Al ₂ O ₃ ¹ BioloX® delta Ceramic ³	ASTM F799/F1537, ISO 5832/4 ISO 6474
BioloX® Option delta Ceramic Femoral Head with Titanium Sleeve	Cementless ³	BioloX® delta Ceramic ³ Ti6Al4V alloy	ASTM F799/F1537, ISO 5832/4 ISO 6474, ASTM F136, ISO 5832/3
Modular Femoral Neck	Cemented	CoCrMo	ASTM F1537, ISO 5832/4
Acetabular Shells	Cementless	Ti6Al4V alloy and CP Ti porous coating where applicable	ASTM F136, ISO 5832/3 ASTM F67, F1580
Polyethylene Acetabular Liners	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene	ASTM F648, ISO 5834/1+2
Constrained Acetabular Liners	Cemented or Cementless	Medical grade UltraHigh Molecular Weight Polyethylene Ti6Al4V alloy	ASTM F648, ISO 5834/1+2 ASTM F136, ASTM F620, ISO 5832/3
X-all™ Highly Cross-Linked Polyethylene Acetabular Liner ²	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene (Highly Cross-Linked)	ASTM F648
Metal/Metal Acetabular Liners	Cementless	Medical grade UltraHigh Molecular Weight Polyethylene CoCr	ASTM F648, ISO 5834/1+2 ASTM F799, ISO 5832/4
Metal/Metal Monoblock Acetabular System	Cementless	CoCrMo	ASTM F1537
Bipolar/Unipolar/Sleeves	Cemented or Cementless	CoCr Ti6Al4V alloy Medical grade Ultra High Molecular Weight Polyethylene	ASTM F799, ISO 5832/4 ASTM F648, ISO 5834/1+2
Distal Centralizers	N/A	PMMA	PMMA
Screws	N/A	Ti6Al4V alloy	ASTM F136, ISO 5832/3

¹For Ceramic-on-Ceramic applications please refer to the Keramos Total Hip System IFU. NOTE: Keramos® is an Encore Medical Registered Trademark for CeramTec's BioloX forte™ Alumina Ceramic femoral heads.

²X-all™ Highly Cross Linked Polyethylene Liners are for use with CoCr and BioloX® delta and BioloX® Option delta Ceramic femoral heads only.

³BioloX® delta and BioloX® Option delta Ceramic Femoral Heads are not approved for use with the Ceramic-on-Ceramic applications

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3. Indications

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture.

This device may also be indicated in the salvage of previously failed surgical attempts.

The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for who all other options to constrained acetabular components have been considered.

4. Intended Use

DJO Surgical hip devices are intended for treatment of patients who are candidates for total hip arthroplasty per the indications for use. While hip replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

*For Ceramic-on-Ceramic applications, please refer to the Keramos Total Hip System IFU.

5. Contraindications*

Joint replacement is contraindicated where there is:

- infection or sepsis;
- insufficient bone quality which may affect the stability of the implant;
- muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- skeletally immature patients and cases where there is a loss of abductor musculature, poor bone stock, poor skin coverage around hip joint which would make the procedure unjustifiable;
- osteomyelitis;
- rapid joint destruction or bone absorption apparent on roentgenogram;
- pathological conditions of the acetabulum, which would prevent achieving proper range of motion, appropriate head stability, and/or a well-seated and supported smooth articulation of the head within the acetabulum;
- alcoholism or other addictions;
- materials sensitivity;
- loss of ligamentous structures;
- high levels of physical activity (e.g. competitive sports, heavy physical labor);
- pregnancy (contraindicated for Metal on Metal applications only)

*For Ceramic-on-Ceramic applications, please refer to the Keramos Total Hip System IFU.

6. Precautions and Warnings*

- 1) An implant should never be reused. Although the implant may appear undamaged, previous stresses could create imperfections that may lead to mechanical failure. It is advised to utilize new prostheses of current design.
- 2) Familiarity with, and attention to the surgical technique recommended for this device is imperative for best results. The correct selection as well as the correct seating/placement of the prosthetic implant is extremely important. Use of the largest stem possible is recommended. Only DJO Surgical Hip System implants, instruments, and trial prostheses should be used.
- 3) Care must be taken to protect mating surfaces (i.e. tapers) and polished bearing surfaces from nicks and scratches which could become the focal point for failure. Contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load. An implant must not be tampered with, as tampering will adversely affect the performance of the implant.
- 4) Do not implant HA (Hydroxyapatite) coated implants with bone cement.
- 5) To determine the use of the hip stem with the correct femoral head (CoCr or Ceramic), please refer to Section 2. Product Description and Implant Materials.
- 6) Ceramic femoral heads are only available in sizes 28 and 32 and are to be used with hip stems having a Morse Type Taper. See Section 2. Product Description and Materials for a listing of hip stems that are cleared for use with the ceramic femoral head.
- 7) Ceramic femoral heads are only indicated for use with stems during total hip replacement.

Precautions and Warnings Specific to the Constrained Acetabular Liner

Precautions:

- 1) In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.
- 2) To correctly position the metallic locking ring, surgeons should consult the manufacturer's instructions for appropriate device assembly.
- 3) Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.
- 4) Regarding component malposition above, recommendation is to caution physician regarding the malpositioned acetabular components cup and the potential for impingement, premature dislocation and revision.

Warnings

- 1) Closed reduction of this device is not possible. Patients should be made aware that treatment of device dislocation will require additional surgery.
- 2) There may be a failure of the retaining ring.
- 3) A retaining ring that is placed incorrectly may have a reduced life.
- 4) Retaining ring failure, which may be due to impingement, fatigue, and/or wear, increases the probability of dislocation.
- 5) Failure or migration of the retaining ring may require additional surgery.

*For Ceramic-on-Ceramic applications, please refer to the Keramos Total Hip System IFU.
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

7. Preoperative Planning and Postoperative Care

Preoperative planning provides essential information regarding the appropriate prosthesis and likely combinations of components. Use instrument trial components for fit verification (where applicable) and extra implant components for backup. X-ray templates for all sizes of the DJO Surgical Hip system are available upon request.

Accepted surgical practices should be followed for postoperative care. The patient should be made aware of the limitation of total joint reconstruction. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture, and/or wear of the prosthetic implants. The patient should be cautioned to govern his/her activities accordingly as the risk of implant failure increases with weight and activity levels of the patient.

Patient Counseling Information Specific to the Constrained Acetabular Liner

- 1) The prosthesis will not restore function to the level expected with a normal healthy joint, and the patient should be instructed as to the limitations of the device.
- 2) The range of motion achievable with a constrained liner is less than the range of motion of a normal joint, and less than with a semi-constrained prosthesis.
- 3) The patient should be told that, although the constrained hip liner provides resistance to dislocation, it can dislocate if subjected to excessive loading.
- 4) Once dislocated, additional surgery will be required to reduce the joint.
- 5) Patients should be instructed that significant reduction in the range of motion is inherent to the design characteristic of a constrained acetabular liner, and activities that may force the joint to exceed those range of motion limits should be avoided.

8. Adverse Effects*

- 1) Accelerated wear of the polyethylene articulating surfaces have been reported following total hip replacement. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prosthesis, and leads to early revision surgery to replace the worn prosthetic components.
- 2) Metallosis and osteolysis may be implicated from wear debris associated with the use of orthopedic implants.
- 3) Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly the result of surgical trauma.
- 4) Metal sensitivity reactions in patients following joint replacement have been rarely reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the healing process. In some cases, wear debris can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening of the implant.
- 5) Dislocation and subluxation of implant components can result from improper positioning of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
- 6) Ring fracture could lead to increased risk of dislocation.
- 7) Implants can loosen or migrate due to trauma or loss of fixation.
- 8) Infection can lead to failure of the joint replacement.
- 9) While rare, fatigue fracture of the implant can occur as a result of strenuous activity, improper alignment, or duration of service.
- 10) Fracture of the femur can occur while press-fitting (seating) the femoral stem into the prepared femoral canal.
- 11) Allergic reactions.

Intraoperative and early postoperative complications can include:

- 1) acetabular perforation, or fracture;
- 2) femoral fracture can occur while seating the device;
- 3) damage to blood vessels;
- 4) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
- 5) undesirable shortening or lengthening of the limb;
- 6) traumatic arthrosis of the hip from intraoperative positioning of the extremity;
- 7) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- 8) hematoma;
- 9) delayed wound healing; and,
- 10) infection.

Late postoperative complications can include:

- 1) avulsion as a result of excess muscular weakening;
- 2) non-union due to inadequate reattachment and/or early weight bearing;
- 3) aggravated problems of other joints of the affected limb or muscle deficiencies;
- 4) femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- 5) periparticular calcification or ossification, with or without impediment to joint mobility;
- 6) inadequate range of motion due to improper selection or positioning of components, by impingement, and calcification.

*For Ceramic-on-Ceramic applications, please refer to the Keramos Total Hip System IFU.

9. Sterilization

Unless opened or damaged, DJO Surgical implants are supplied sterile in multiple pouches or barrier blister trays. Upon receipt, check all packaging for punctures or other damage. If during inspection, packaging is found opened or damaged, contact manufacturer or manufacturer's representative for instructions.

Sterilization of implants other than the Highly Cross-Linked Polyethylene Acetabular Liner is performed by gamma radiation at the minimum dose of 25 kGy to achieve a Sterility Assurance Level (SAL) of 10^{-6} . Implants are single-use devices. Trials and other instruments are used to determine sizing before the sterile package needs to be opened. Should the integrity of the original sterile package be lost by being opened, punctured, or torn before implantation in the surgical field, the metallic devices may be resterilized prior to use following the guidelines listed below.

Sterilization of the Highly Cross-Linked Polyethylene Acetabular Liner is performed by hydrogen peroxide gas plasma to achieve a Sterility Assurance Level (SAL) of 10^{-6} . These liners are single-use devices and CANNOT be resterilized by a healthcare facility. Liner trials and other instruments are used to determine sizing before the sterile package needs to be opened.

Do not sterilize an implant or component that has been opened outside of the surgical field or in contact with or contaminated by blood or other substances. Do not try to clean an implant since standard procedures cannot be relied upon to remove contamination from the implant or component and storage of the implant or component should be avoided.

Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines found in the DJO Surgical Instrumentation Instructions for Use.

User Resterilization Guidelines for Implants:

Porous coated or non-coated metallic implants or components, which have not been previously used or implanted, or contaminated with blood or other bodily substances, can be resterilized using the following steam sterilization cycle. All devices should be disassembled prior to resterilization and care should be taken to protect implant or component from mechanical damage.

<u>Steam Resterilization</u> for metallic implants and components ONLY!	Remove from supplied packaging and wrap in protective sterilization wrap according to AAMI / AORN guidelines or place into appropriate case configuration.
	Pre-Vacuum Autoclave (HI-VAC): 270-272° F (132-134° C), 6-minute exposure time, with 4 pulses and a 5-minute dry time shall achieve a SAL of 10^{-6} . Gravity Displacement Autoclave: 270-272° F (132-134° C), 30-minute exposure time, with a 5-minute dry time shall achieve a SAL of 10^{-6} .

WARNING: DO NOT resterilize any hip prosthesis distributed by DJO Surgical (Encore Medical, L.P.) if sterile packaging is opened or damaged. Return the implant with respective packaging to DJO Surgical for inspection and disposition.

WARNING: Protect all porous coated and polished surfaces. Standard cleaning procedures can not be relied upon to remove contamination from the implant or component.

WARNING: DO NOT resterilize UHMWPE (ultra-high molecular weight polyethylene) implants, PMMA (polymethylmethacrylate) spacers, HA (Hydroxyapatite) coated implants, and ceramic implants.

WARNING: Highly Cross-Linked Polyethylene CANNOT be resterilized by a healthcare facility.

DJO Surgical has validated the above steam sterilization cycles and has data on file. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques. Proper validation of the autoclave is essential to ensure proper sterilization temperatures and cycle times. **NOTE: DJO Surgical does not recommend Flash or Chemical Sterilization.**

10. Trademarks and patents

FOUNDATION®, LINEAR®, KEYSTONE®, VITALITY® are registered trademarks of Encore Medical, L.P., Austin, TX 78758 USA or its affiliates.



NOV 19 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

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

Dear Ms. Jenks:

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

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

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

Page 2 –

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

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K071535

Summary of Safety and Effectiveness

NOV 19 2007

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

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

Date: June 4, 2007

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

Common Name: Ceramic Femoral Head Prosthesis

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

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

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

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

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

* Trademark of CeramTec AG

Intended Use:

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

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

Comparison to Predicate Device(s):

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

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

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

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

K071535

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX* *delta** Ceramic Femoral Head

Indications for Use:

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

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

Prescription Use X
(Part 21 CFR 80) Subpart D)

AND/OR

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

(Please do not write below this line—Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Fruchip
(Division Sign-off)

Division of General, Restorative,
and Neurological Devices

*Trademark of CeramTec AG

Page 1 of 1

510(k) Number K071535



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

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

Re: K042091

Trade/Device Name: Biolox[®] *delta* Ceramic Heads
Regulation Numbers: 21 CFR 888.3353
Regulation Names: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: II
Product Codes: LZO
Dated: January 27, 2005
Received: January 28, 2005

Dear Ms. Beres:

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

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

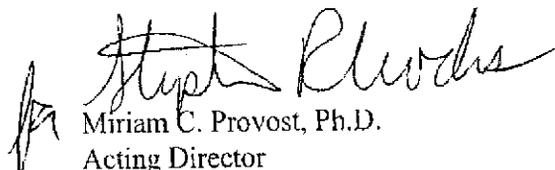
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Patricia Sandborn Beres

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

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost". The signature is written in a cursive style and is positioned to the right of a small, stylized initial "M".

Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices

and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042091

Device Name: BioloX® delta Ceramic Heads

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

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

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

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

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K042091

K042091

1/2

MAR 25 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: BioloX® *delta* Ceramic Heads

Common or Usual Name: Ceramic Modular Head

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

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Biomet Zirconia Ceramic Modular Heads cleared through 510(k) K943586, K925345 and K905687 and DePuy Ceramic Femoral Heads cleared through K031803.

Device Description: BioloX® *delta* Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. This submission covers 28mm diameter heads with neck lengths of -3, 0, +3 and +5 and 32mm diameter heads with neck lengths of -3, 0, +3 and +6.

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

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

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

Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrosis.

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K042091

2/2

510(k) Summary
BioloX[®] delta Ceramic Heads
Biomet Manufacturing Corp.
Page 2

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

Summary of Technologies: The BioloX[®] delta Ceramic Heads are technologically similar to the predicate devices.

Non-Clinical Testing: All parameters of the "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" were met for the devices contained in this 510(k).

Clinical Testing: None provided



JUN 29 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tracy Bickel Johnson
Manager of Regulatory Affairs
Biomet Incorporated
P.O. Box 587
Warsaw, Indiana 46582

Re: K051411

Trade/Device Name: ArComXL™ Acetabular Liners and BioloX® *delta* Ceramic Heads

Regulation Number: 21 CFR 888.3353

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

Regulatory Class: II

Product Code: LZ0

Dated: May 27, 2005

Received: May 31, 2005

Dear Ms. Johnson:

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

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

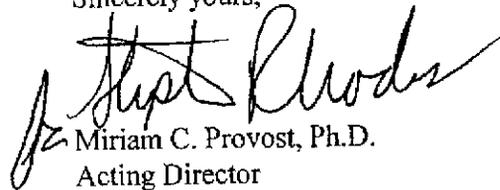
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms.Tracy Bickel Johnson

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

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

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ArComXL™ Acetabular Liners and BioloX® *delta* Ceramic Heads

Indications For Use:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- 2) Rheumatoid arthritis.
- 3) Correction of functional deformity.
- 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
- 5) Revision of previously failed total hip arthroplasty.

Intended for cemented and uncemented applications

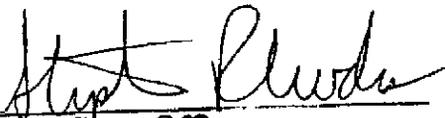
Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K051411

K051411 p/1

JUN 29 2005

510(K) SUMMARY

Sponsor: Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy Bickel Johnson, RAC

Proprietary Name: ArComXL™ Acetabular Liners and BioloX® delta Ceramic Heads

Common Name: Acetabular liners and ceramic heads

Classification Name: LZO- hip joint/ceramic/polymer, semi-constrained, cemented or non-cemented prosthesis (888.3353)

Substantially Equivalent Devices: ArComXL™ Acetabular Liners (K042051)
BioloX® delta Ceramic Heads (K042091)

Device Description: The ArComXL™ polyethylene liners are manufactured from highly cross-linked polyethylene conforming to ASTM F648 that was previously cleared in K042051. ArComXL™ is available in three designs: MaxRom, Hi-Wall, and 10°.

BioloX® *delta* Ceramic Heads (K042091) are composed of Transition-Toughened-Platelet-Alumina (TTPA). The highly polished spherical surface articulates with the ArComXL™ polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper.

Indications for Use: 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, 2) Rheumatoid arthritis, 3) Correction of functional deformity 4) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques, 5) Revision of previously failed total hip arthroplasty.

Intended for cemented and uncemented applications

Summary of Technologies: The design, sizes, intended use, indications, contraindications, and design specifications of the subject components remain identical to their predicate component counterparts. This submission allows the ArComXL™ Acetabular Liners and the BioloX® *delta* Ceramic Heads to be used together.

Non-Clinical Testing: Volumetric wear testing was performed on ArComXL™ Acetabular Liners and the BioloX® delta Ceramic Liners showing less wear.

Clinical Testing: None provided as a basis for substantial equivalence.

All trademarks are property of Biomet, Inc.

JHB



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

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

Re: K061312

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

Regulation Number: 21 CFR 888.3353

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

Regulatory Class: Class II

Product Code: LZO

Dated: May 9, 2006

Received: May 10, 2006

Dear Ms. Beres:

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

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

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

JH7

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


for Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known): K061312

Device Name: 36mm BioloX® delta Ceramic Heads

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

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

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

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

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K061312

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K061312

JUN -6 2006



510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: 36mm BioloX® *delta* Ceramic Heads

Common or Usual Name: Ceramic Modular Head

Classification Name: Hip joint/ceramic/polymer semiconstrained cemented or non-cemented prosthesis

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
BioloX® *delta* Ceramic Heads – K042091 & K051411

Device Description: BioloX® *delta* Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. This submission covers 36mm diameter heads with neck lengths of -3, 0, +3 and +6.

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

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

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

Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrosis.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

510(k) Summary
36mm Bioloc® *delta* Ceramic Heads
Biomet Manufacturing Corp.
Page 2

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

Summary of Technologies: The 36mm Bioloc® *delta* Ceramic Heads are technologically similar to the predicate devices.

Non-Clinical Testing: All parameters of the "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" were met for the devices contained in this 510(k).

Clinical Testing: None provided

Bioloc is a trademark of CeramTec AG



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 30 2006

Re: K062748

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

Dear Ms. Schuler:

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

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

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

Page 2 – Ms. Anne M. Schuler

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K062748
Device Name: DePuy Delta Ceramic Femoral Head

Indications for Use:

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

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

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janet Kuehn
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K062748

510(k) Summary of Safety and Effectiveness**K062748**

NAME OF FIRM: DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT: Anne M. Schuler
Sr. Regulatory Affairs Associate

DATE PREPARED: September 13, 2006

TRADE NAME: DePuy Delta Ceramic Femoral Head

COMMON NAME: Ceramic Femoral Ball Prosthesis

CLASSIFICATION: 888.3353: Hip joint femoral metal/ceramic/polymer, semi-constrained cemented or nonporous, uncemented prosthesis;

DEVICE PRODUCT CODE: 87 LZO

SUBSTANTIALLY EQUIVALENT DEVICE: DePuy Ceramic Femoral Heads, K031803
DePuy Ceramic Heads, K040644

DEVICE DESCRIPTION:

The DePuy Delta Ceramic Femoral Head is composed of an alumina composite material and is available in a 36mm head diameter with +9 and +12 offset options. The internal bore of the ceramic femoral head taper is available in an 11/13 S-ROM option.

The Delta Ceramic head is designed to mate with DePuy femoral hip stems with a corresponding taper design. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction, and articulates with a polyethylene acetabular component.

INDICATIONS FOR USE AND INTENDED USE:**Indications for Use**

The DePuy Ceramic Femoral Head is indicated for use as the femoral head component in total hip arthroplasty procedures. Total hip arthroplasty is intended to provide increased patient mobility and to reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

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

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Intended Use

The DePuy Ceramic Femoral Head is intended for use in total hip arthroplasty applications to replace the articular surface of the femoral head.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The modified DePuy Delta Ceramic femoral heads have a similar design and the same intended use, indications, manufacturing method, sterilization and packaging as the Ceramic Femoral heads cleared in K031803 and in K040644. Based on this DePuy believes that the subject Delta Ceramic femoral heads are substantially equivalent to the previously cleared Ceramic femoral heads.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

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

Re: K052718
Trade/Device Name: V40™ BioloX® delta Ceramic Femoral Heads (Line Extension to the Alumina V40™ Ceramic Femoral Heads)
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: September 28, 2005
Received: September 29, 2005

Dear Ms. Ariemma:

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

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

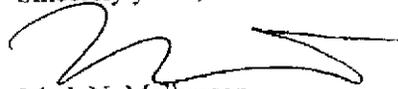
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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

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

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

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K052718

Device Name: Biolog[®] delta V40[™] Ceramic Femoral Heads

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

For Use as a Total Hip Replacement:

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

For Use as a Bipolar Hip Replacement

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

Other Considerations:

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

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

(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



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052718

OCT 27 2005

510(k) Summary of Safety and Effectiveness
Line Extension to the Alumina V40™ Ceramic Femoral Heads

Proprietary Name: V40™ Biolox® delta Ceramic Femoral Heads
Common Name: Artificial femoral head component
Proposed Regulatory Class: Class II
Classification: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353.
Device Product Code: 87 LZO: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented.
For Information contact: Karen Ariemma, Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Telephone: (201) 831-5718
Fax: (201) 831-6038
Email: karen.ariemma@stryker.com
Date Summary Prepared: September 28, 2005

Device Description

The subject V40™ Biolox® delta Ceramic Femoral Heads mate with Howmedica Osteonics' V40™ taper femoral stems fabricated from Titanium, CoCr or stainless steel alloys. The V40™ Biolox® delta Ceramic Femoral Heads are available in 28, 32 and 36 mm diameters and a variety of neck offsets.

Device Modification

This submission modifies the material of the Alumina V40™ Ceramic Femoral Heads from alumina to Zirconia Toughened Alumina (ZTA) and adds additional offsets of 28 and 36mm diameter heads.

Indications for Use

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

For Use as a Total Hip Replacement:

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

For Use as a Bipolar Hip Replacement

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

Other Considerations:

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

Substantial Equivalence

The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of the new components to the predicate devices in regards to mechanical strength. In addition, the intended use, manufacturing methods, packaging, and sterilization of the predicate and new components are identical.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 30 2000

Ms. Elizabeth A. Staub
Vice President, Quality Assurance/ Regulatory Compliance/ Clinical Research
Stryker Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K003379
Trade Name: V40™/C-Taper Adapter Sleeve
Regulatory Class: II
Product Code: LZO
Dated: October 30, 2000
Received: October 31, 2000

Dear Ms. Staub:

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 control provisions of the Act. The general control 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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 premarket 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.

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.

Page 2 - Ms. Elizabeth A. Staub

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,

for 

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

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K003379

Device Name: V40™/C-Taper Adapter Sleeve

Indications For Use:

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' adapter sleeves is as follows:

For Use as a Total Hip Replacement:

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

For Use as a Bipolar Hip Replacement

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

Other Considerations:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkus

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003379

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K003379

NOV 3 0 2000

**Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the
V-40™/C-Taper Adapter Sleeve**

Submission Information

Name and Address of the Sponsor Of the 510(k) Submission	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	October 19, 2000

Device Identification:

Proprietary Name:	V-40™/C-Taper Adapter Sleeve
Common Name:	Adapter Sleeve for Femoral Head
Classification Name and Reference	Hip Joint, Metal/Ceramic/Polymer, Semi- Constrained, Cemented or Nonporous Uncemented Prosthesis, 21 CFR §888.3353

Predicate Device Identification

The V-40™/C-Taper Adapter Sleeve is substantially equivalent to the Osteonics® Titanium Adapter Sleeve which was determined substantially equivalent via 510(k) 885102.

Device Description

The Osteonics® Titanium Adapter Sleeve is a tapered sleeve component with a female Morse taper to provide locking with a Howmedica Osteonics' femoral stem with a Morse taper. In addition, the sleeve has a tapered male exterior surface that provides locking with an Osteonics® C-Taper Alumina Ceramic Head. The V40™/C-Taper Adapter Sleeve is a modification of the predicate Osteonics® Titanium Adapter Sleeve. The modification involves changing the inner taper diameter from a Morse taper to a V40™ taper and removing the cap of the sleeve. This modification is designed to allow both Osteonics® Alumina C-Taper Heads and Zirconia C-Taper Ceramic Heads to mate with Howmedica Osteonics' femoral stems with a V40™ taper. The modified sleeve is identical to the unmodified sleeve in every aspect with the exception of the female taper angle. The subject and predicate devices are fabricated from the same material.

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Intended Use

The intended use of the V40™/C-Taper Adapter Sleeve is identical to that of the predicate Osteonics® Titanium Adapter Sleeve. The V40™/C-Taper Adapter Sleeve is intended to allow either an Osteonics® C-Taper Alumina Head or an Osteonics® C-Taper Zirconia Ceramic Head to mate with any Howmedica Osteonics' femoral stem with a V40™ taper. The V40™/C-Taper Adapter Sleeve is a single-use device.

Indications for Use**For Use as a Total Hip Replacement:**

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

For Use as a Bipolar Hip Replacement

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

Other Considerations:

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

Statement of Technological Comparison

The subject V40™/C-Taper Adapter Sleeve share the same material, intended use, and basic design concepts as the predicate Osteonics® Titanium Adapter Sleeve.

510(k) Number (if known): _____

Device Name: Ceramic Femoral Head

Indications for Use:

**BioloX® *delta* Ceramic Femoral Head
Indications for Use**

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

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)

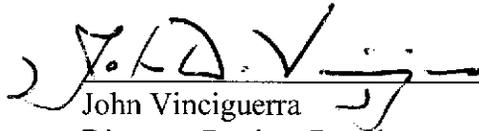


DJO Surgical
9800 Metric Boulevard
Austin, TX 78758-5445
T 800.456.9696
djosurgical.com

Declaration of Conformity with Design Controls

**Verification
Activities**

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



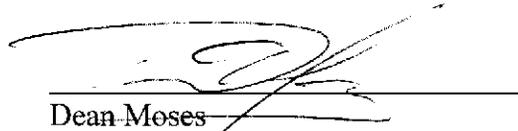
John Vinciguerra
Director, Product Development
DJO Surgical

9-5-08

Date

**Manufacturing
Facility**

The manufacturing facility, DJO Surgical is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.



Dean Moses
Director, Manufacturing
DJO Surgical

9-4-08

Date

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Summary of Safety and Effectiveness

Date: September 25, 2008

Manufacturer:

DJO Surgical (legally Encore Medical, L.P.)
9800 Metric Blvd
Austin, TX 78758

Contact Person:

Teffany Hutto
Manager, Regulatory Affairs
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: teffany.hutto@djosurgical.com

Product	510(k) Number, Clearance Date/ Classification	Product Code
BioloX® Ceramic Femoral Head	K955563 – August 9, 1996 / Class II	LZO

Product Code	Regulation and Classification Name
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353

Description: The modification consists of a new material used in the manufacture of the BioloX Ceramic Femoral Heads. The femoral heads, manufactured from BioloX® *delta** material, are fabricated from an alumina matrix composite. The standard femoral head will mate with a femoral stem through a taper fit. The Option femoral head includes a sleeve that is inserted into the head and attached to the femoral stem through a taper fit. The heads will be available in sizes 22, 28, 32, 36, 40 and 44mm.

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

These devices may also be indicated in the salvage of previously failed surgical attempts.

Intended Use: DJO Surgical hip devices are intended for treatment of patients who are candidates for total hip arthroplasty per the indications for use. While hip replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

Predicate Devices:

- Zimmer BioloX® *delta* Ceramic Femoral Head – K071535, Cleared November 19, 2007
- Biomet BioloX *delta* Ceramic Head – K042091, Cleared March 25, 2005, K051411, Cleared June 29, 2005, K061312, Cleared June 6, 2006
- DePuy Delta Ceramic Femoral Head – K062748, Cleared November 30, 2006
- Stryker Howmedica Osteonics V40™ BioloX *delta* Ceramic Femoral Head – K052781, Cleared October 27, 2005
- Stryker Howmedica Osteonics V40™/C-Taper Adapter Sleeve – K003379, Cleared November 30, 2000

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same indications, materials, sterilization, and intended use.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: None provided.

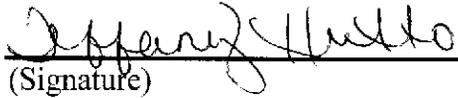
*Trademark of CeramTec AG

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*

(As Required by 21 CFR 807.87 (j))

Pursuant to 21 CFR 807.87(j), I, Teffany Hutto, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Manager, Regulatory Affairs of DJO Surgical and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.



(Signature)

Teffany Hutto

(Typed Name)

September 25, 2008

(Dated)

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission
 September 25, 2008

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

FDA Submission Document Number (if known)

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

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Encore Medical, L.P.		Establishment Registration Number (if known) 1644408	
Division Name (if applicable)		Phone Number (including area code) (512) 834-6255	
Street Address 9800 Metric Blvd.		FAX Number (including area code) (512) 834-6313	
City Austin	State / Province TX	ZIP/Postal Code 78758	Country USA
Contact Name Teffany Hutto			
Contact Title Manager, Regulatory Affairs		Contact E-mail Address Teffany_Hutto@encoremed.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

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SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

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

- Location change:
 - Manufacturer
 - Sterilizer
 - Packager

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

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

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

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (specify):

SECTION D2

REASON FOR APPLICATION - IDE

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
 - Correspondent / Applicant
 - Design / Device
 - Informed Consent
 - Manufacturer
 - Manufacturing Process
 - Protocol - Feasibility
 - Protocol - Other
 - Sponsor

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

- Reponse to FDA Letter Concerning:
 - Conditional Approval
 - Deemed Approved
 - Deficient Final Report
 - Deficient Progress Report
 - Deficient Investigator Report
 - Disapproval
 - Request Extension of Time to Respond to FDA
 - Request Meeting
 - Request Hearing

- Other Reason (specify):

SECTION D3

REASON FOR SUBMISSION - 510(k)

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (specify):
New femoral head material

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

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

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K955563	1 Foundation Stems with Biolox Heads	1 Encore Medical, L.P.
2 K071535	2 Biolox® delta Ceramic Femoral Head	2 Zimmer
3 K042091	3 Biolox delta Ceramic Head	3 Biomet
4 K062748	4 Delta Ceramic Femoral Head	4 DePuy
5 K052781	5 V40™ Biolox delta Ceramic Femoral Head	5 Stryker Howmedica Osteonics
6 K003379	6 V40™/C-Taper Adapter Sleeve	6 Stryker Howmedica Osteonics

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Ceramic Femoral Head

Trade or Proprietary or Model Name for This Device	Model Number
1 Biolox® delta Ceramic Femoral Head	1 400-03; 400-04
2 Biolox® delta Ceramic Femoral Head Offset Sleeve	2 400-05
3	3
4	4

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

1 K955563	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LPH	C.F.R. Section (if applicable) 21 CFR 888.3358	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedic		

Indications (from labeling)
 Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

These devices may also be indicated in the salvage of previously failed surgical attempts

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

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 1644408	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Encore Medical, L.P.		Establishment Registration Number 1644408	
Division Name (if applicable)		Phone Number (including area code) (512) 832-9500	
Street Address 9800 Metric Blvd.		FAX Number (including area code) (512) 834-6313	
City Austin		State / Province TX	ZIP/Postal Code 78758
Country USA			
Contact Name Albert E. Alonso	Contact Title V.P., QA/RA/CA	Contact E-mail Address Al_Alonso@encoremed.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code
Country			
Contact Name	Contact Title	Contact E-mail Address	

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SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

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

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

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

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.		
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/cover sheet.html				
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ENCORE MEDICAL L P 9800 Metric Blvd. Austin TX 78758 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 650572565	2. CONTACT NAME Teffany Hutto 2.1 E-MAIL ADDRESS Teffany_Hutto@encoremed.com 2.2 TELEPHONE NUMBER (include Area code) 512-834-6255 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 512-834-6313			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <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 </td> <td style="vertical-align: top;"> 3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>			<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 one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
<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 one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:				
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>			<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)		28-Jul-2008		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER DJO Surgical	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 09/25/2008
3. ADDRESS (Number, Street, State, and ZIP Code) 9800 Metric Blvd. Austin, TX 78758	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) (512) 834-6255 (Fax) (512) 834-6313

PRODUCT INFORMATION

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

BioloX delta Ceramic Femoral Heads, Class II, Models 400-03,
400-04

BioloX delta Ceramic Femoral Head Offset Sleeve, Class II, Model
400-05

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

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

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

CERTIFICATION STATEMENT / INFORMATION

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

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

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

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

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

NCT Number(s): _____

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Teffany Hutto (Title) Manager, Regulatory Affairs	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 9800 Metric Blvd. Austin, TX 78758	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) (512) 834-6255 (Fax) (512) 834-6313	15. DATE OF CERTIFICATION 09/25/2008

Instructions for Completion of Form FDA 3674

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

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

Paperwork Reduction Act Statement

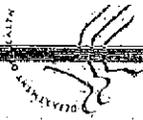
Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

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



COVER SHEET MEMORANDUM

From: Reviewer Name Taxa Shepherd
Subject: 510(k) Number K082844/SI
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/ScreeningChecklist>)
 - Hold (Additional Information or Telephone Hold)
 - Final Decision (SE SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATEDSTANDARDSDATAFORM.DOC)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____ see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-08).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

Additional Product Codes: _____

Review: Jourte (Branch Chief) WDB (Branch Code) 11/21/08 (Date)

Final Review: Mark A. Melanson (Division Director) 11/24/08 (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

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

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		YES	NO
1.	Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		✓
2.	Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		✓
3.	Does this device type require a PMA by regulation? (Please see management.)		✓
Questions 4-8 are intended to help you start your review:		YES	NO
4.	Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)		✓
5.	a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		✓
6.	To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device? Please list document number and/or date, here:		✓
7.	To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)? Please list document number, here:		✓
8.	Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		✓

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER

K082844 S001

Date: November 21, 2008

From: Tara Shepherd, Biomedical Engineer (HFZ-410)

Division: DGRND/OJDB

TNS 11/21/08

Device Name: BioloX Delta Ceramic Femoral Head

Classification: 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; LZO

Company: Encore Medical

Contact: Teffany Hutto

Manager, Regulatory Affairs

9800 Metric Blvd.

Austin, TX 78758

Phone: (512) 834 – 6255; Fax: (512) 834 – 6313; Email: teffany.hutto@djosurgical.com

Recommendation: I recommend the BioloX *delta* Ceramic Femoral head be found **Substantially Equivalent (SE)**.

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
 - Foundation Stems with BioloX Heads (K955563)

Reviewer's Comments: Sponsor has also listed the following additional predicate devices:

- BioloX *delta* Ceramic Femoral Heads – Zimmer (K071535)
- BioloX *delta* Ceramic Head – Biomet (K042091)
- Delta Ceramic Femoral Head – DePuy (K062748)
- V40 BioloX *delta* Ceramic Femoral Head – Stryker Howmedica (K052781)
- V40/C Taper Adapter Sleeve – Stryker Howmedica (K003379)

*These predicate devices were identified to support the addition of BioloX *delta* ceramic femoral heads to the product line. This is acceptable. Spoke with OJDB at October 15, 2008 branch meeting and listing these as predicate devices in the 510(k) Summary is also acceptable since the modification is a material change.*

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

Joint replacement is indicated for patients suffering from disability due to:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head
- Rheumatoid arthritis

- Correction of functional deformity
- Femoral fracture

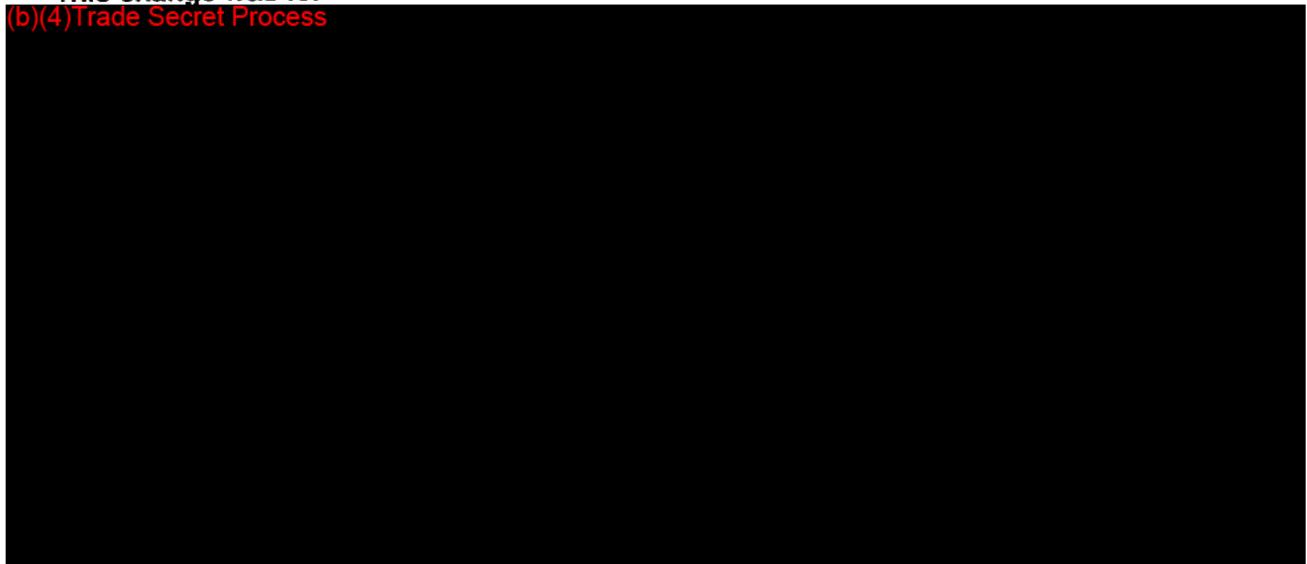
This device may also be indicated in the salvage of previously failed surgical attempts.

Reviewer's Comments: Indications are similar to predicate device. Sponsor has reworded some of the indications. For example, predicate states "revision surgery" and proposed states "salvage of previously failed surgical attempts". This is acceptable.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

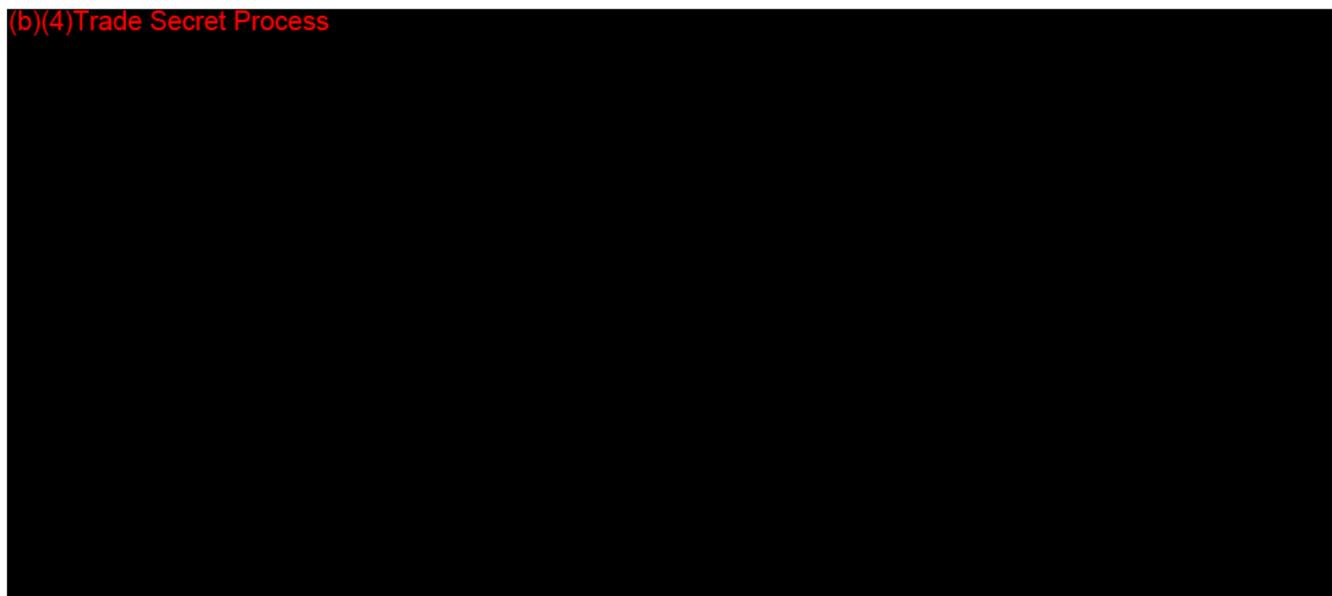
This change was for

(b)(4)Trade Secret Process



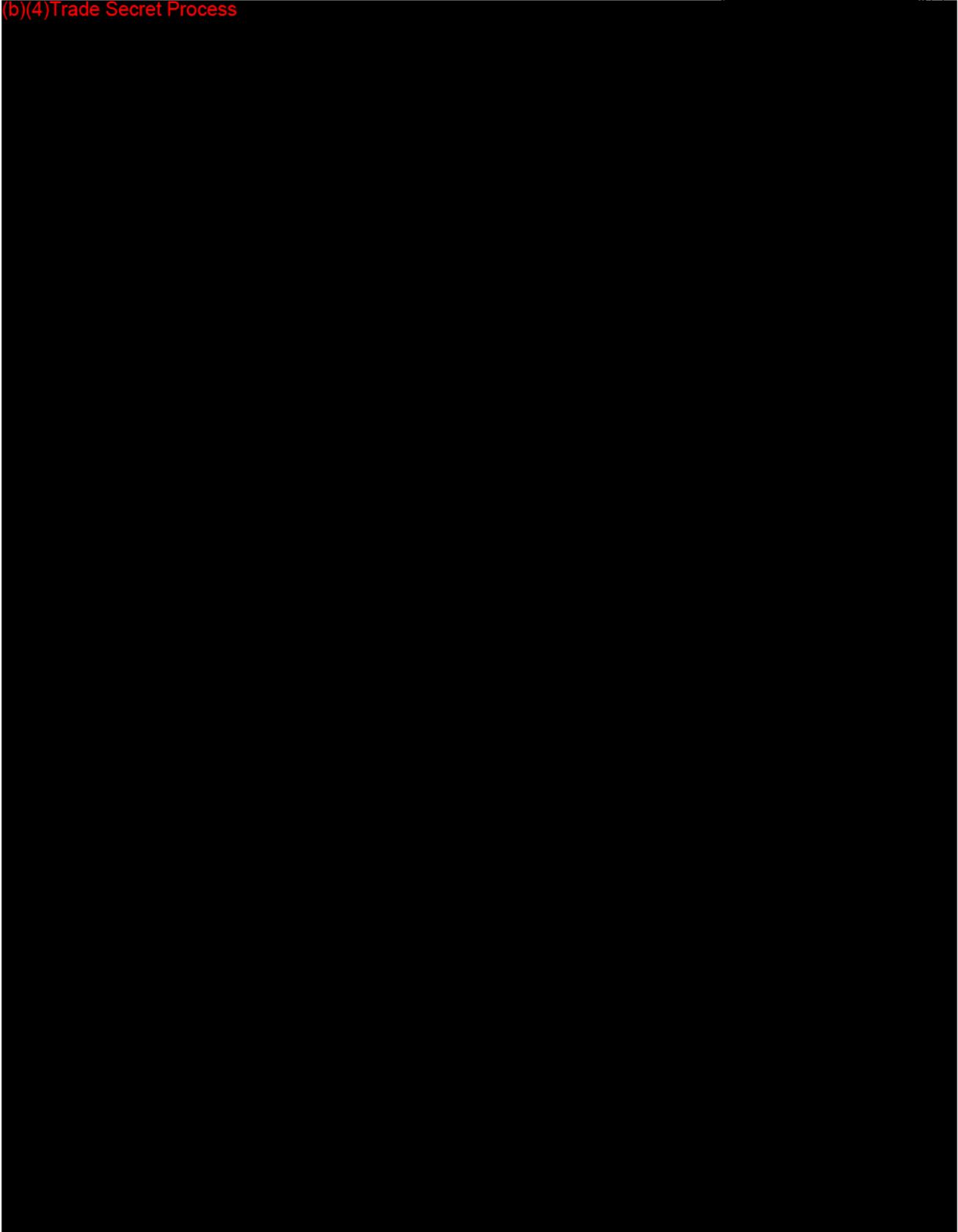
Comparison Information (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

(b)(4)Trade Secret Process

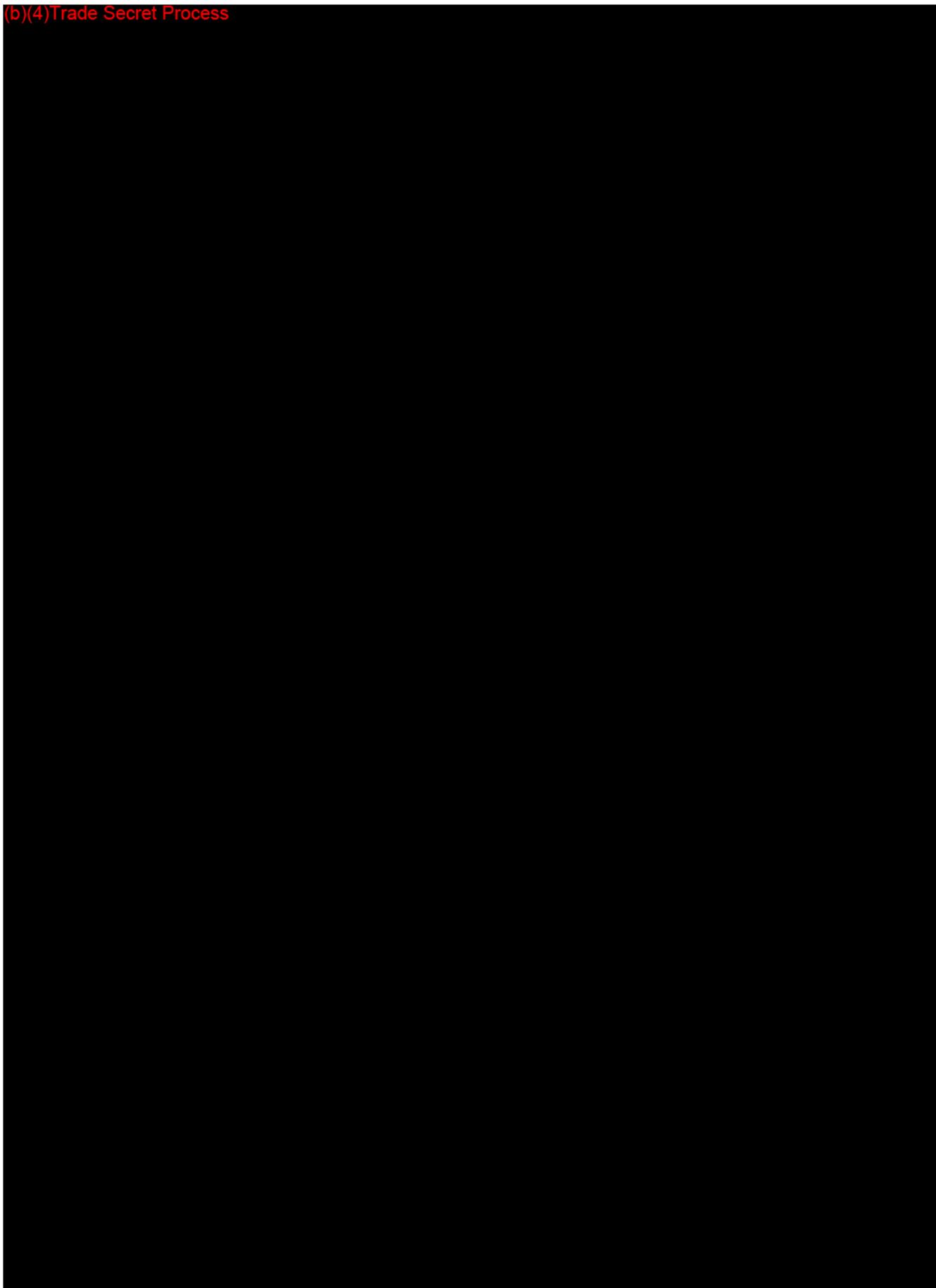


The *delta* Ceramic Femoral Heads and *delta* Option Femoral Heads will be mated with the following components:

(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



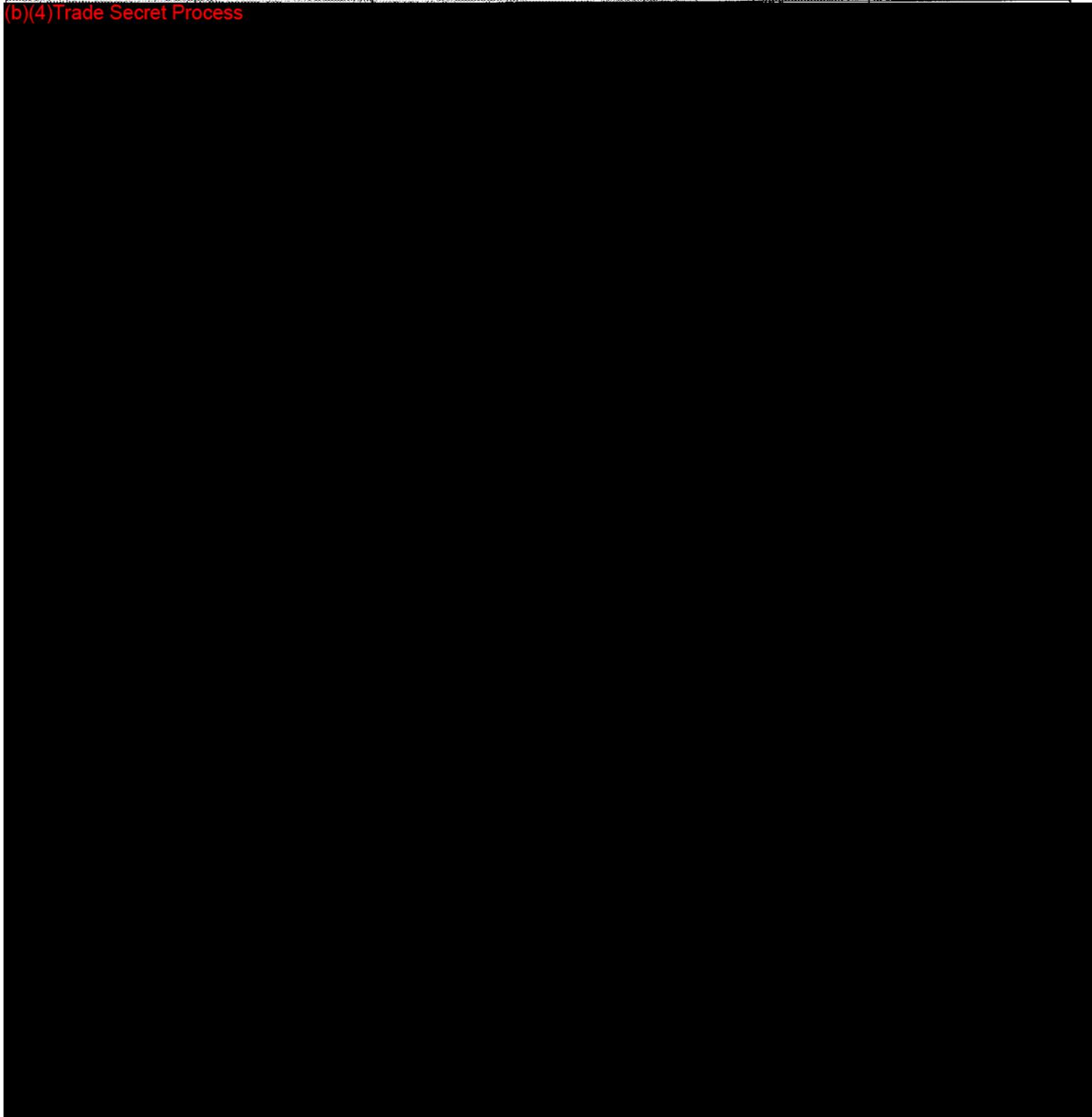
- A summary of how the results of the verification activities met the acceptance criteria.

For your reference I have enclosed a sample Design Control Activities Summary.

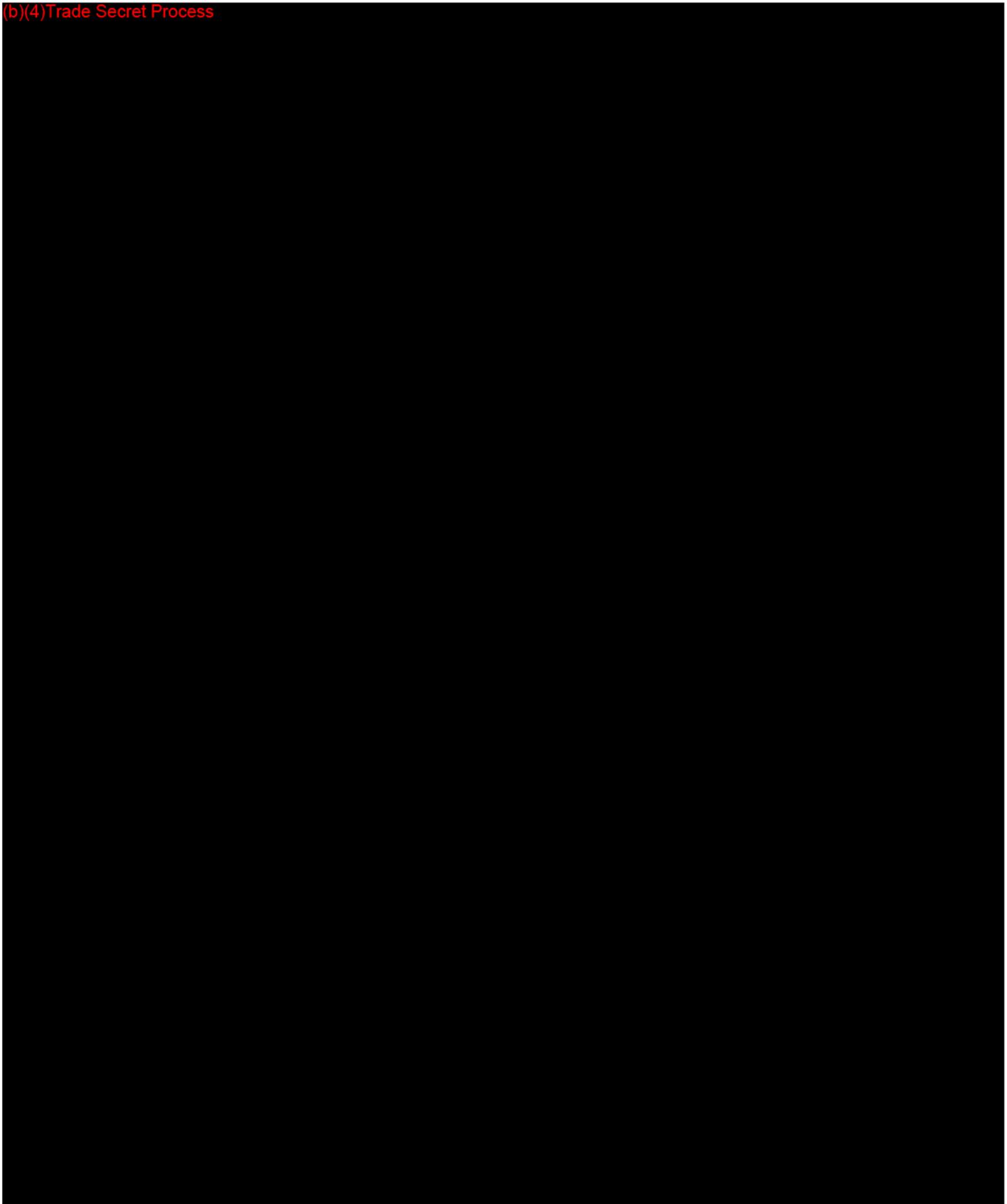
Sponsor's Response:

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
---------------------	------	-----------------------	---------------------	-------------------------

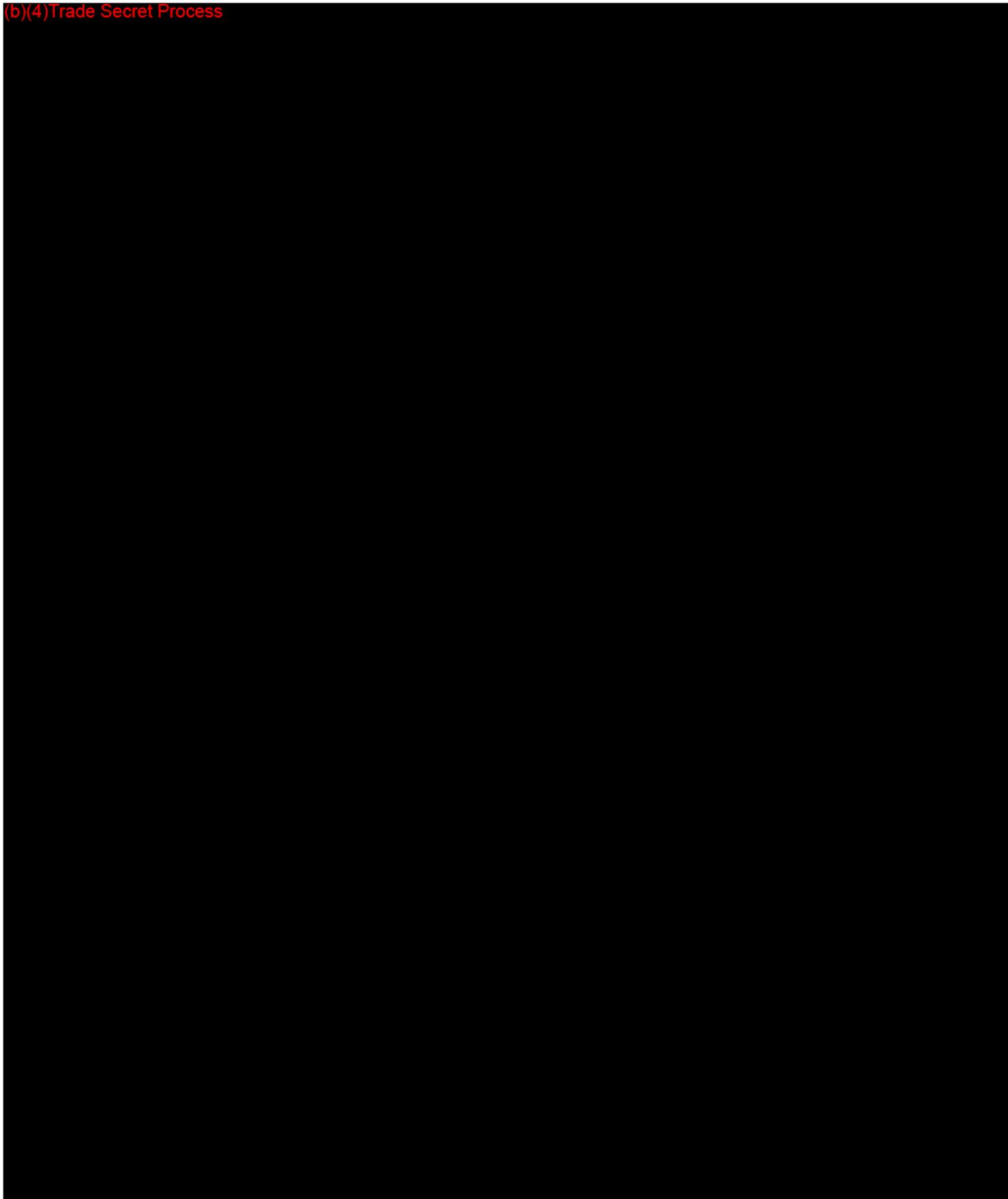
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

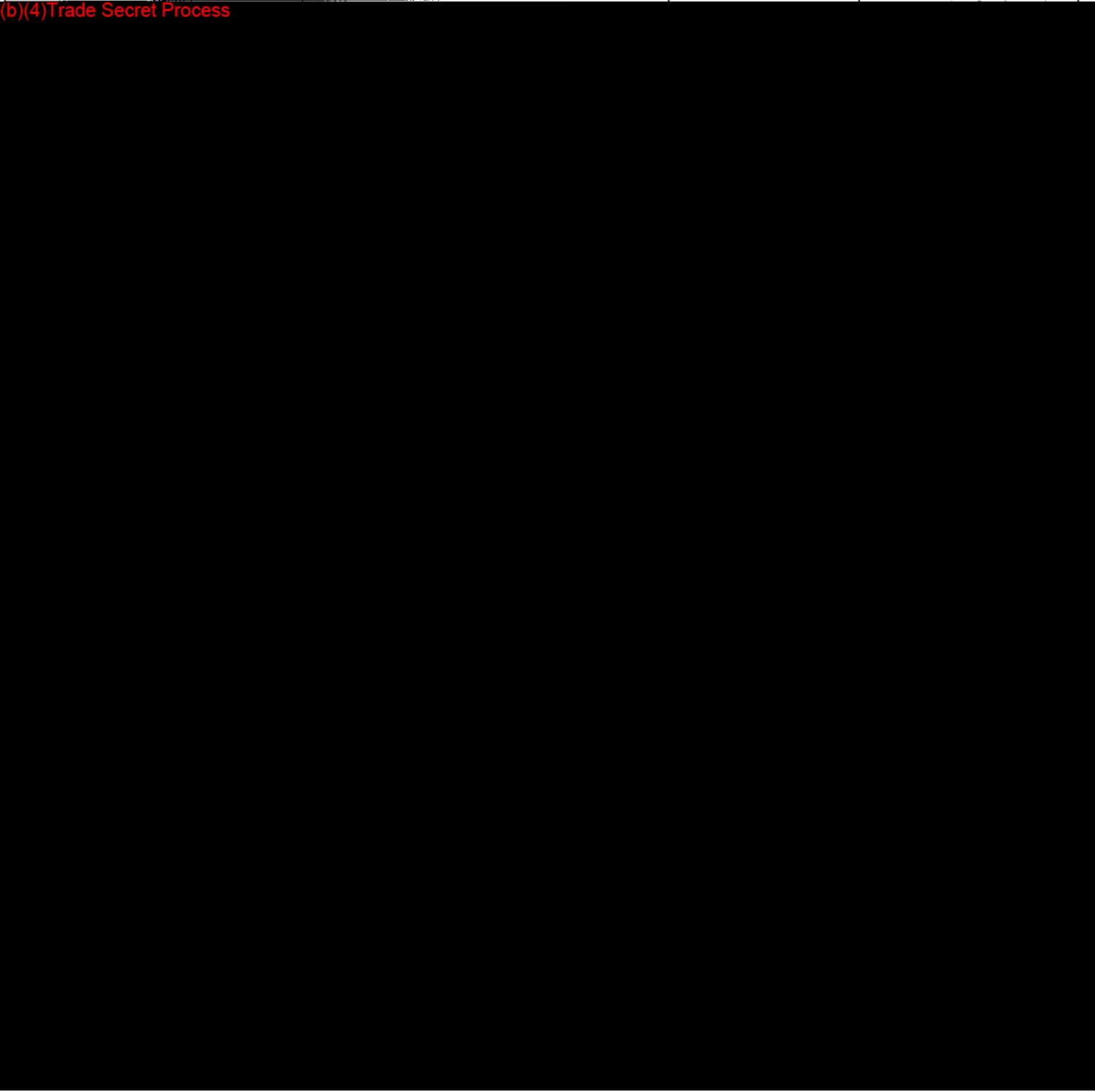


Therefore, it is unclear that all risks related to the BioloX Option delta femoral heads were mitigated. Please update your Design Control Activities Summary accordingly to demonstrate that you have mitigated these risks.

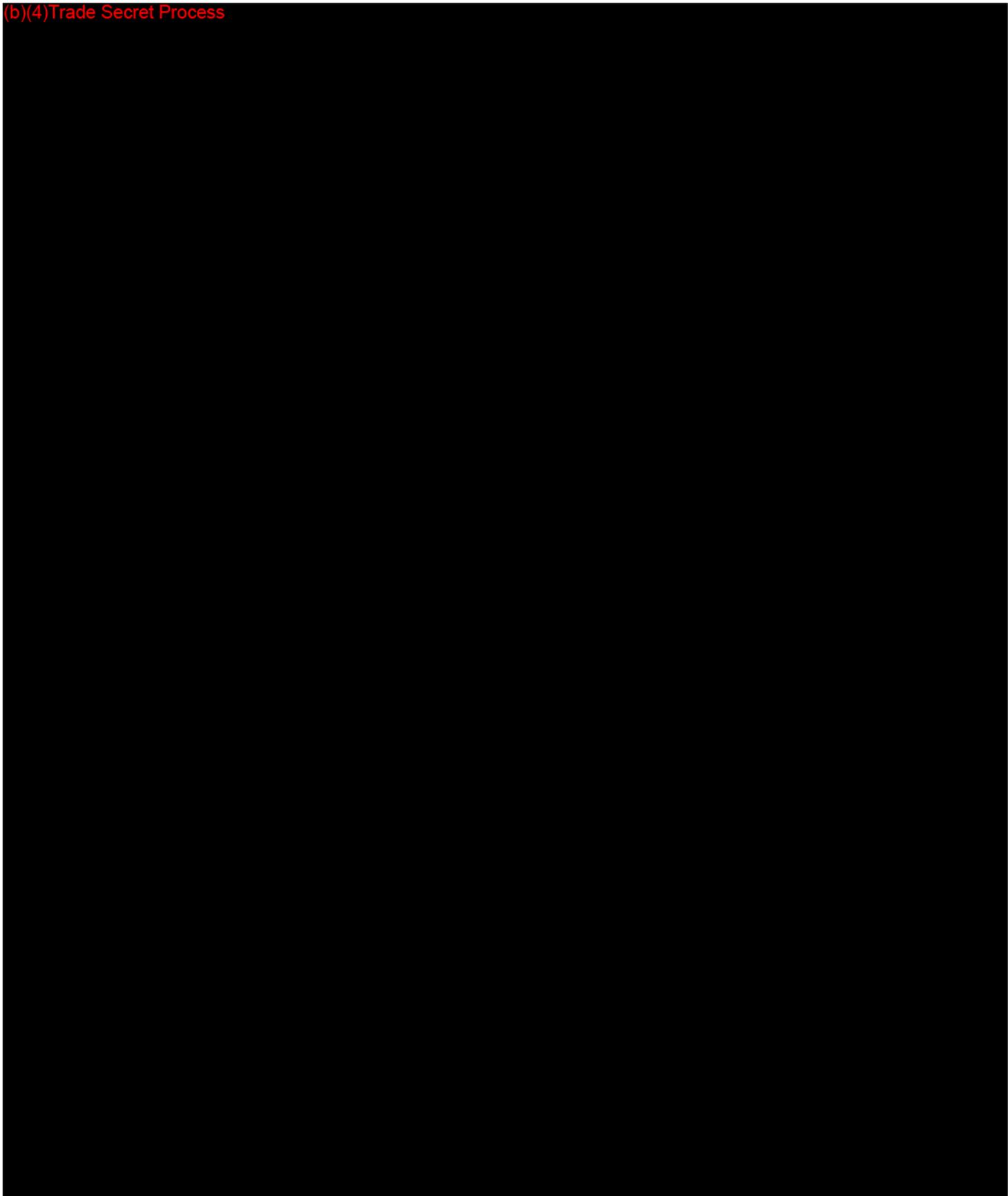
Sponsor's Response:

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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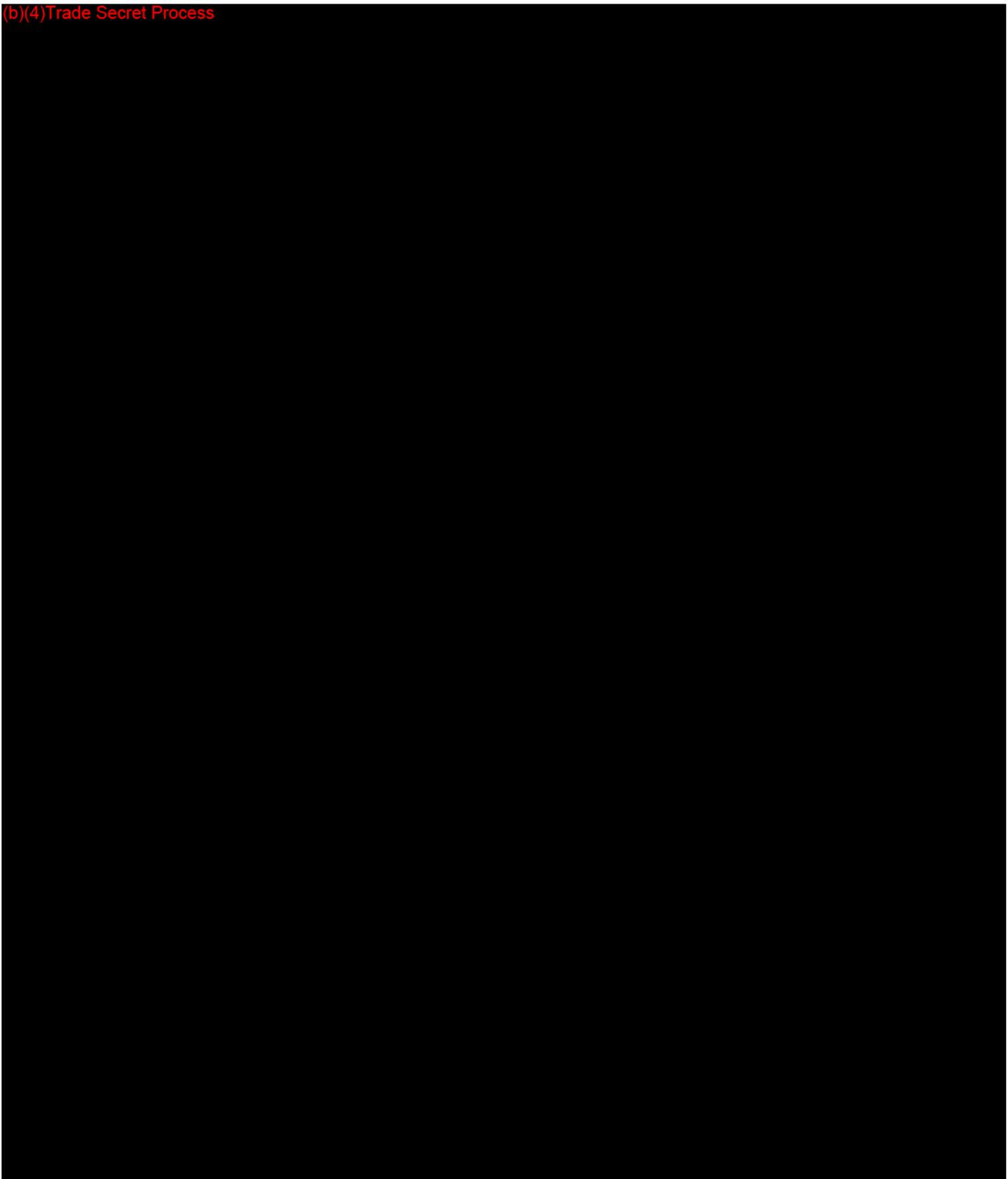
(b)(4)Trade Secret Process



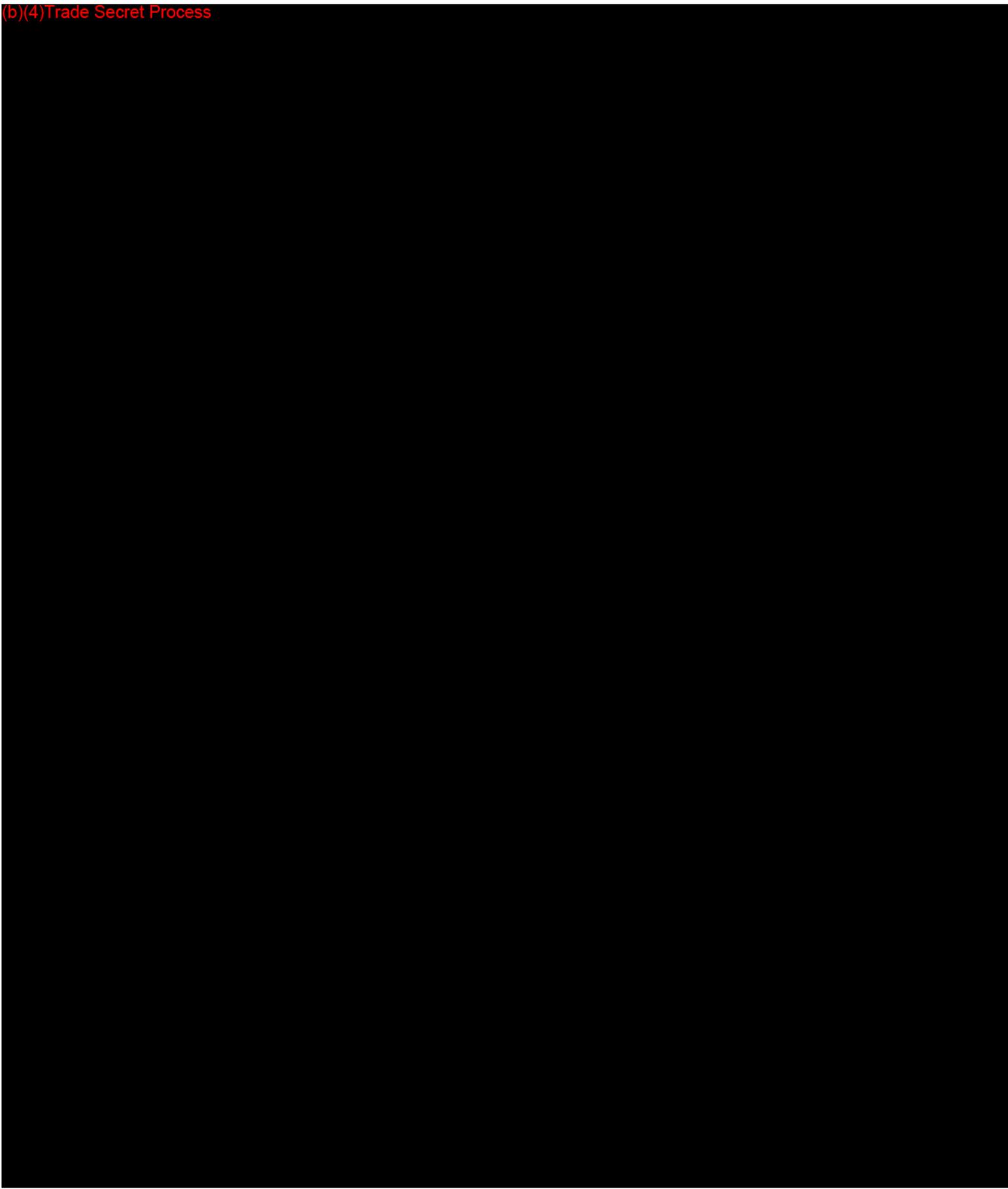
(b)(4)Trade Secret Process



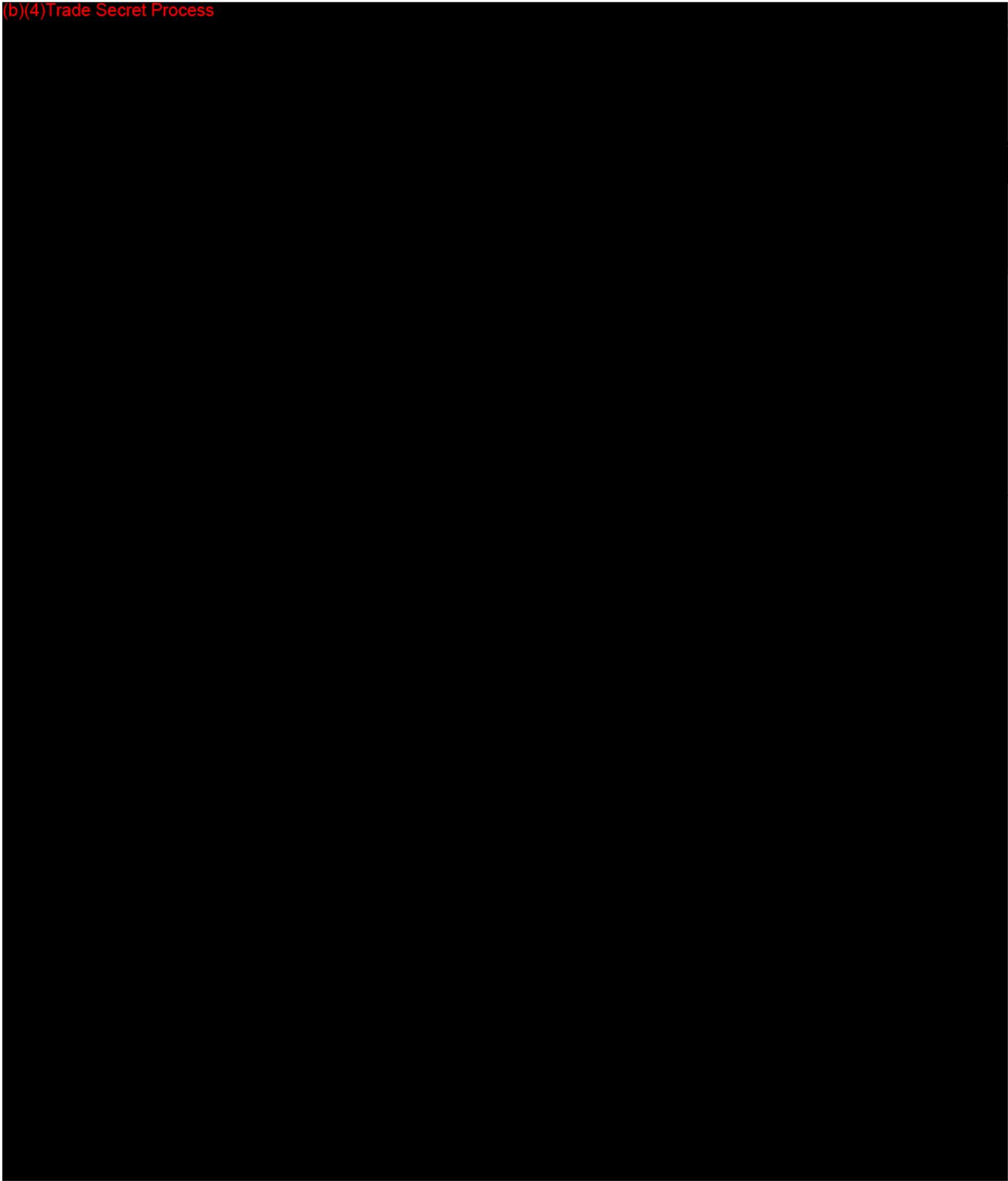
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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: SE

5. Explain how descriptive characteristics are not precise enough:
Performance testing necessary
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
Performance testing demonstrates that device will perform as well as or better than predicate device

Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Friday, November 21, 2008 11:03 AM
To: Shepherd, Tara N
Subject: RE: Conference Call Follow-Up
Attachments: Design Control Activities Summary_21NOV08.doc

Dear Ms. Shepherd,

(b)(4)Trade Secret Process

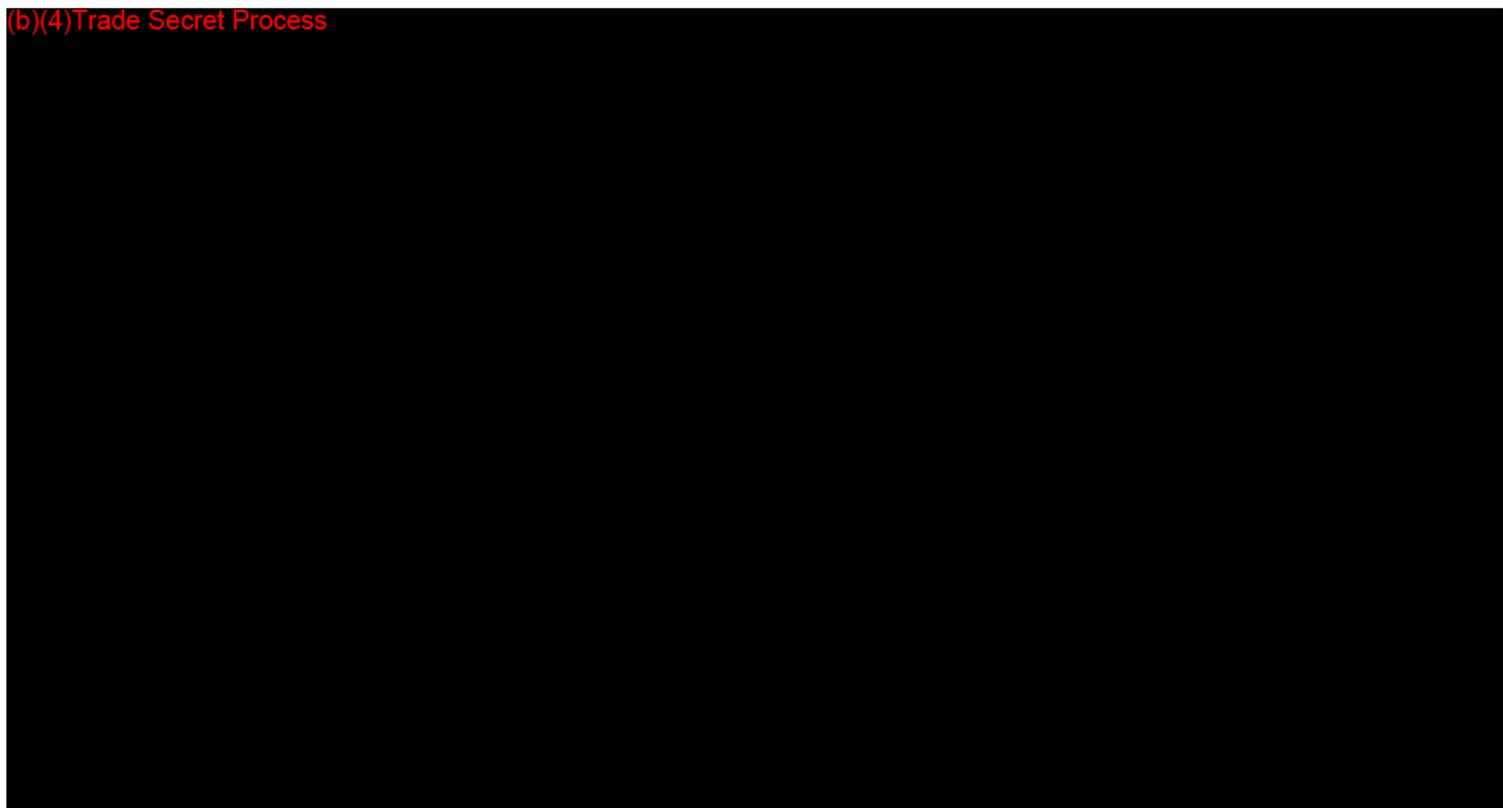


Have a nice weekend,
Teffany

From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Thursday, November 20, 2008 11:35 AM
To: Hutto, Teffany
Subject: RE: Conference Call Follow-Up

Teffany,

(b)(4)Trade Secret Process



Tara N. Shepherd, M.S.

11/21/2008

19

Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

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11/21/2008

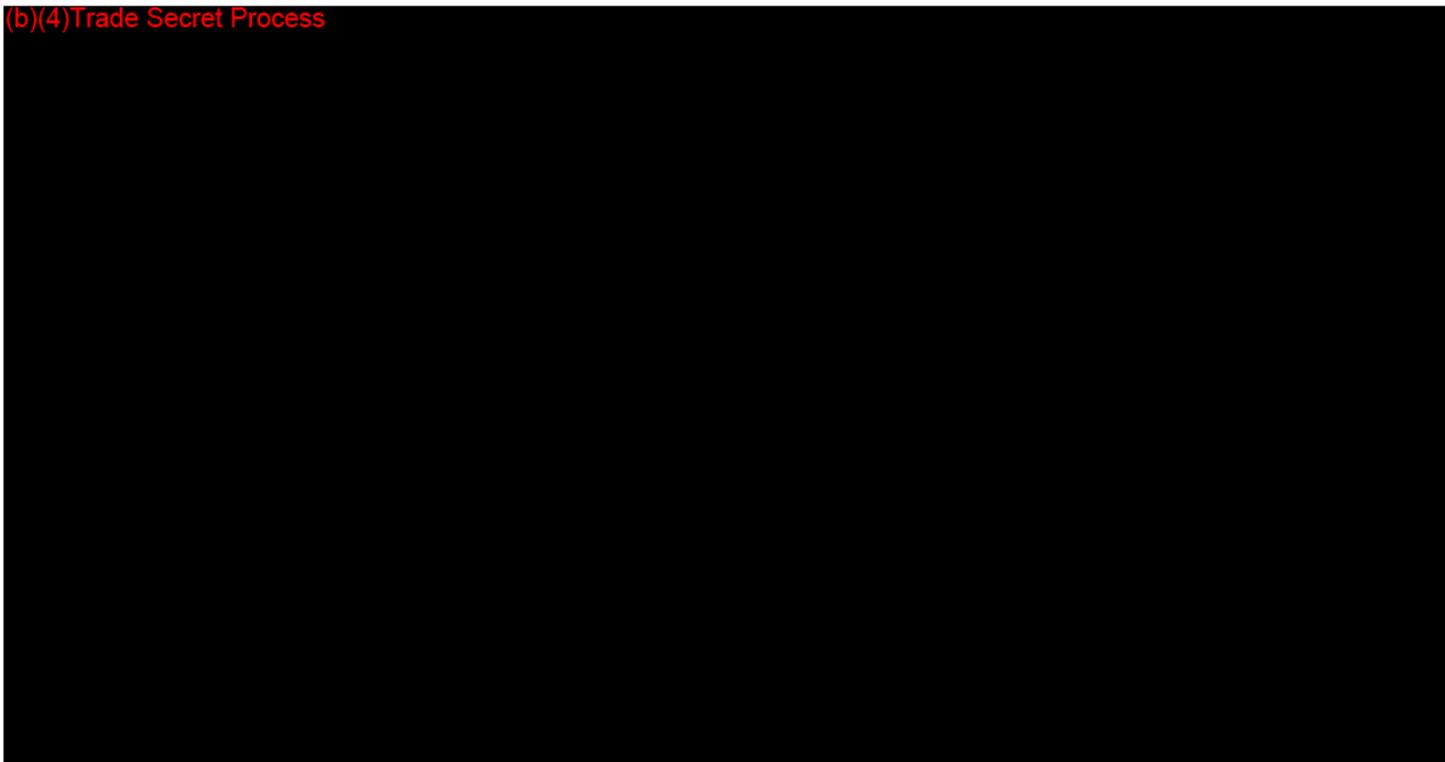
20

Shepherd, Tara N

From: Shepherd, Tara N
Sent: Thursday, November 20, 2008 12:35 PM
To: 'Hutto, Teffany'
Subject: RE: Conference Call Follow-Up

Teffany,

(b)(4)Trade Secret Process



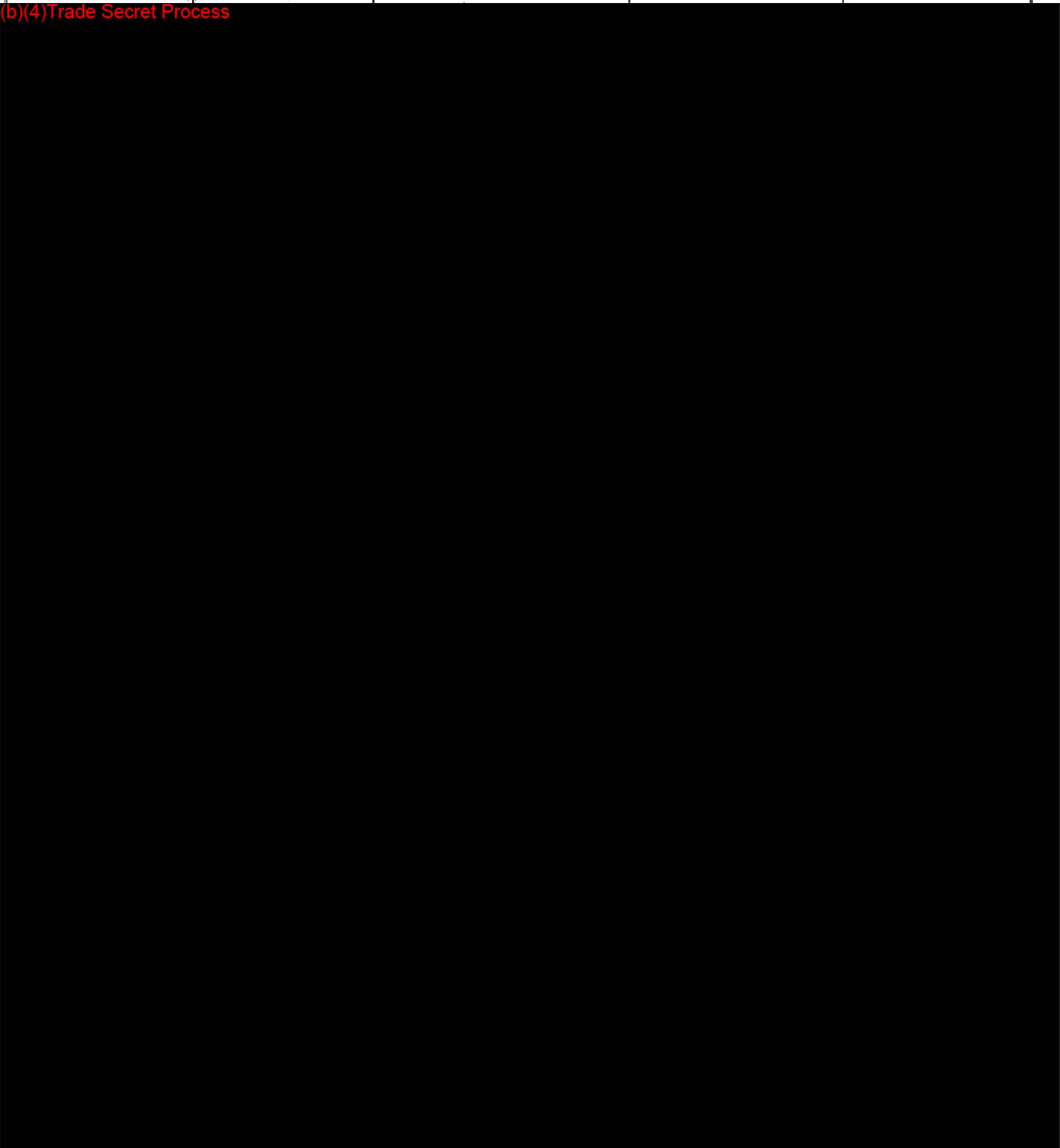
Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

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Encore Medical BioloX *delta* Ceramic and *delta* Option Femoral Heads
"Design Control Activities Summary"
November 21, 2008

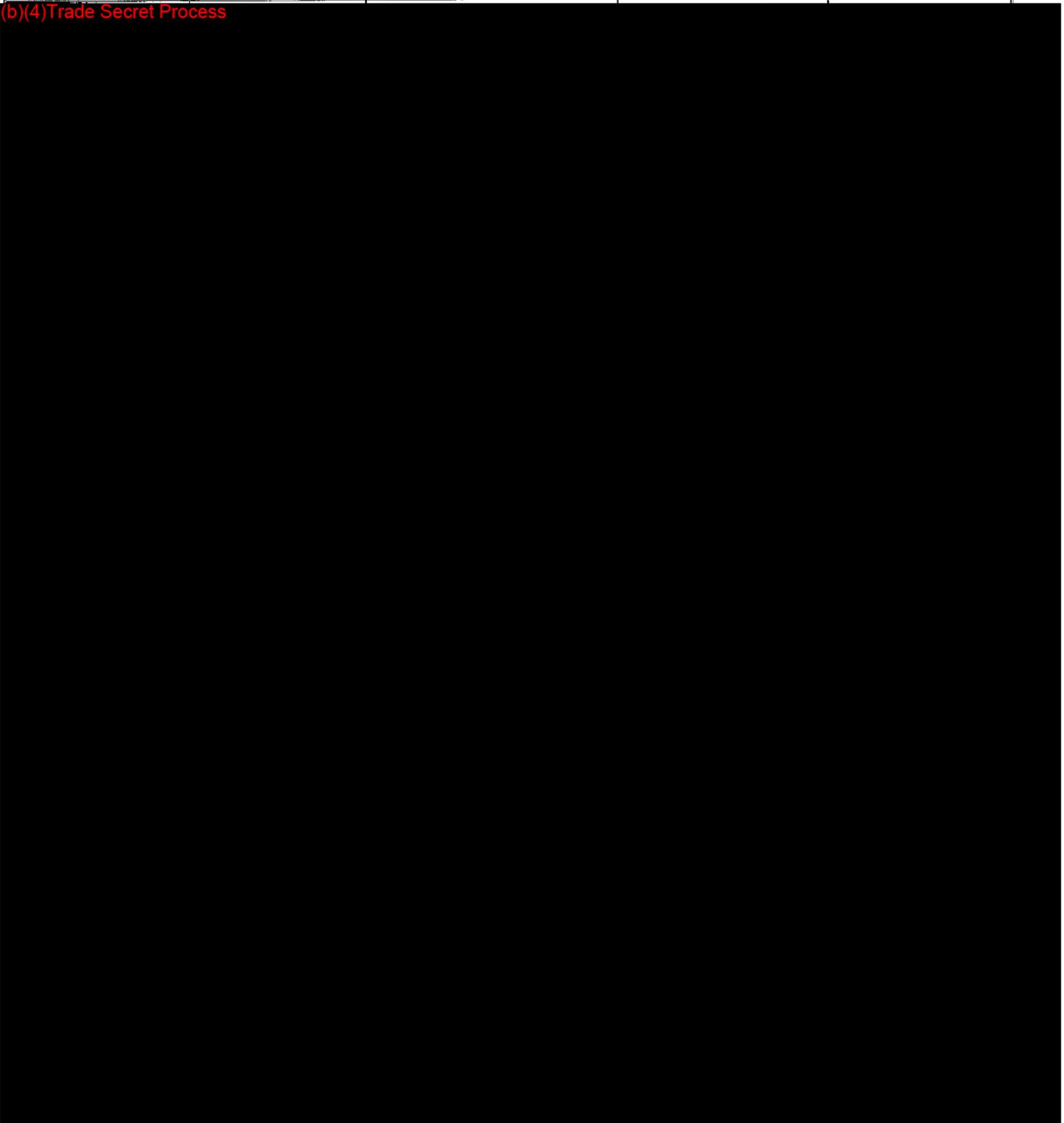
Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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(b)(4) Trade Secret Process



Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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(b)(4) Trade Secret Process

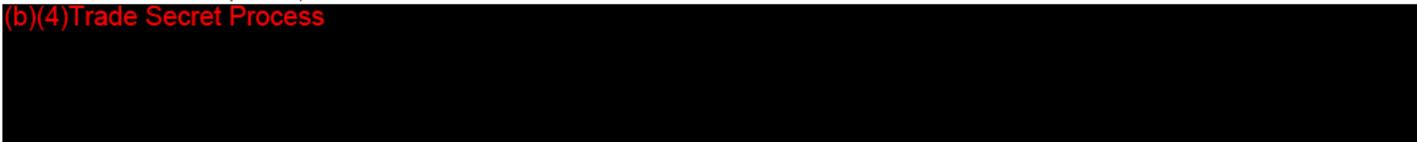


Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Thursday, November 20, 2008 10:12 AM
To: Shepherd, Tara N
Subject: RE: Conference Call Follow-Up
Attachments: 510k K082844 - Response to BioloX Option Heads.docx

Dear Ms. Shepherd,

(b)(4)Trade Secret Process

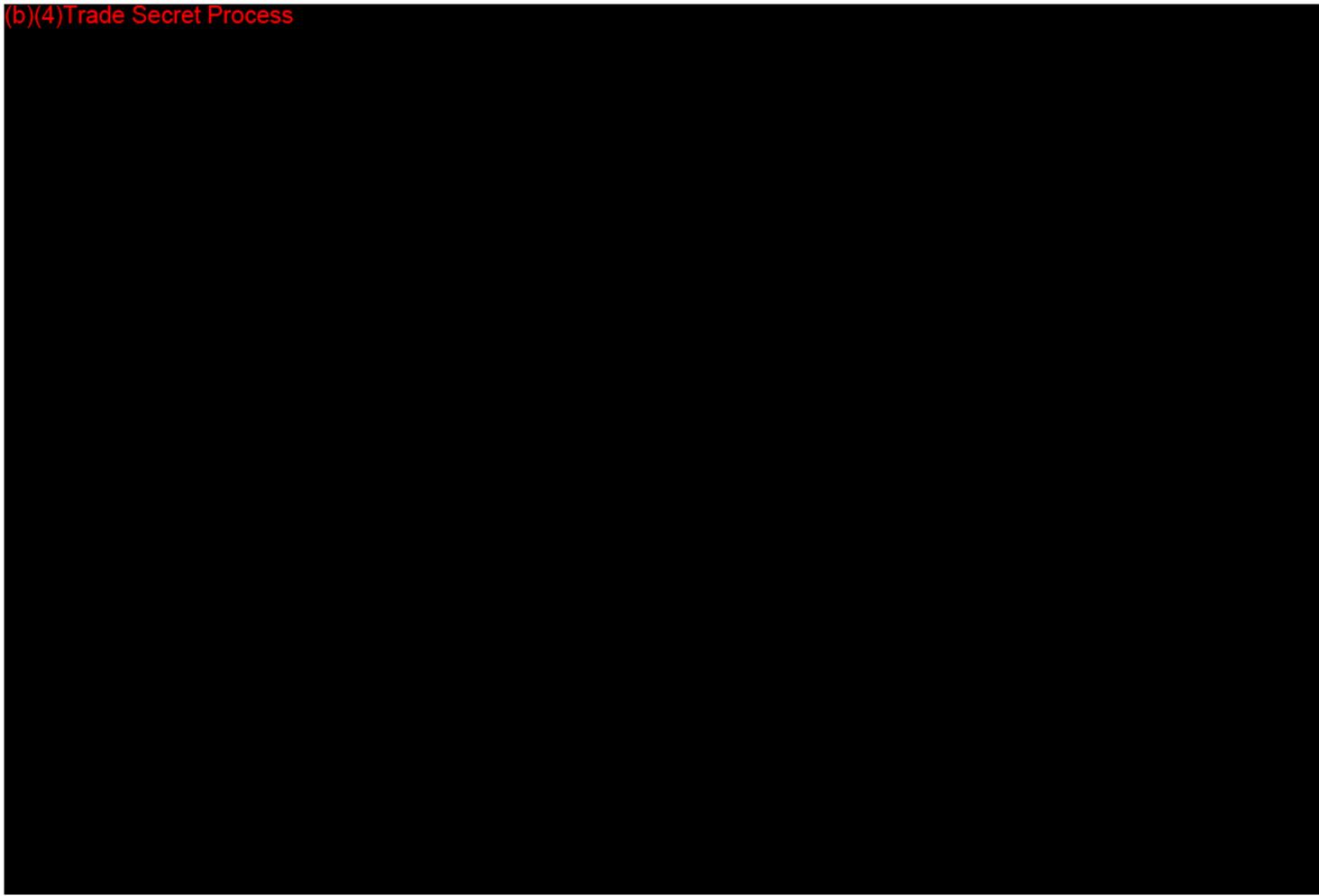


Best regards,
Teffany

From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Wednesday, November 19, 2008 4:03 PM
To: Hutto, Teffany
Subject: Conference Call Follow-Up

Teffany,

(b)(4)Trade Secret Process



(b)(4) Trade
Secret

Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

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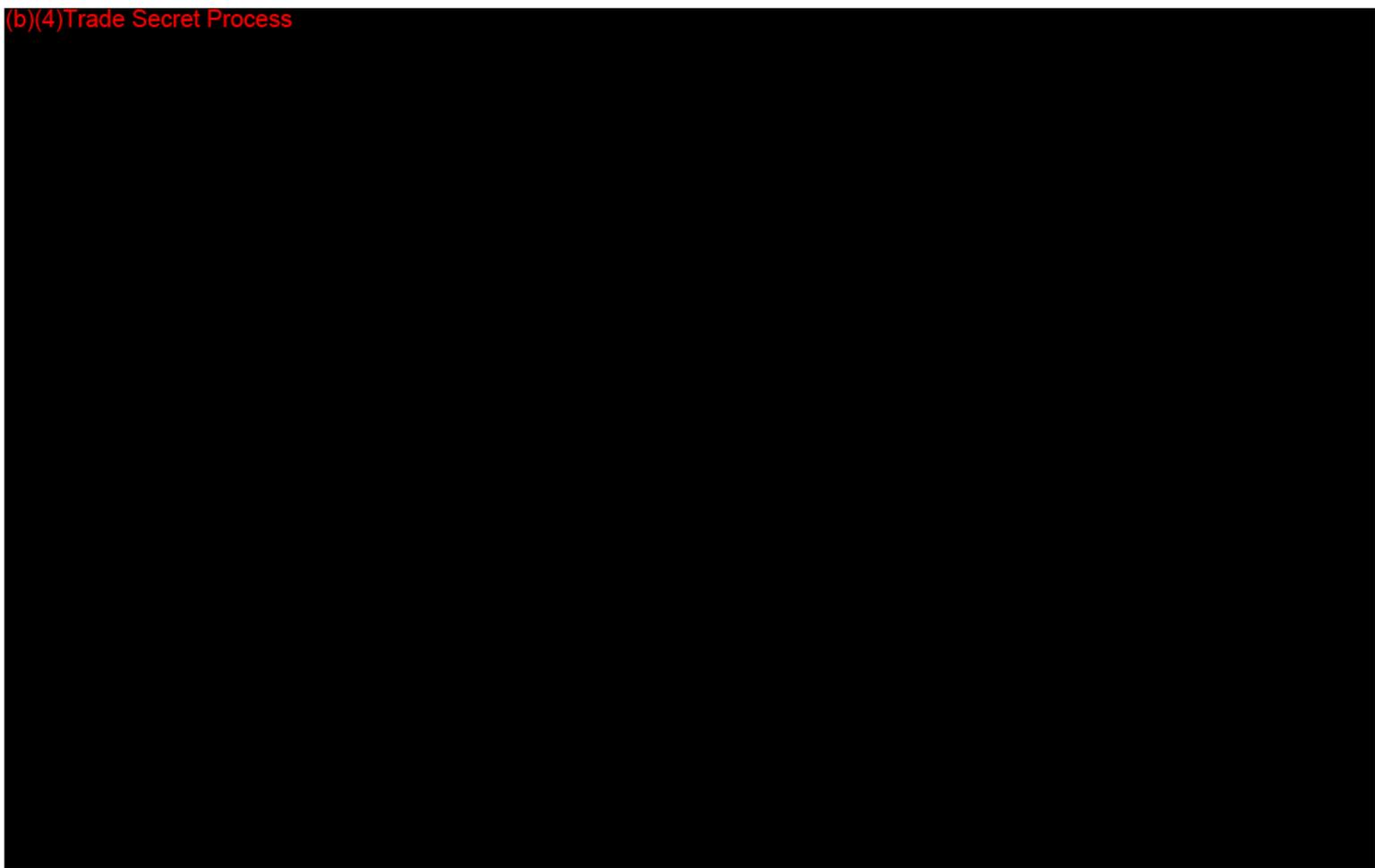
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MEMORANDUM

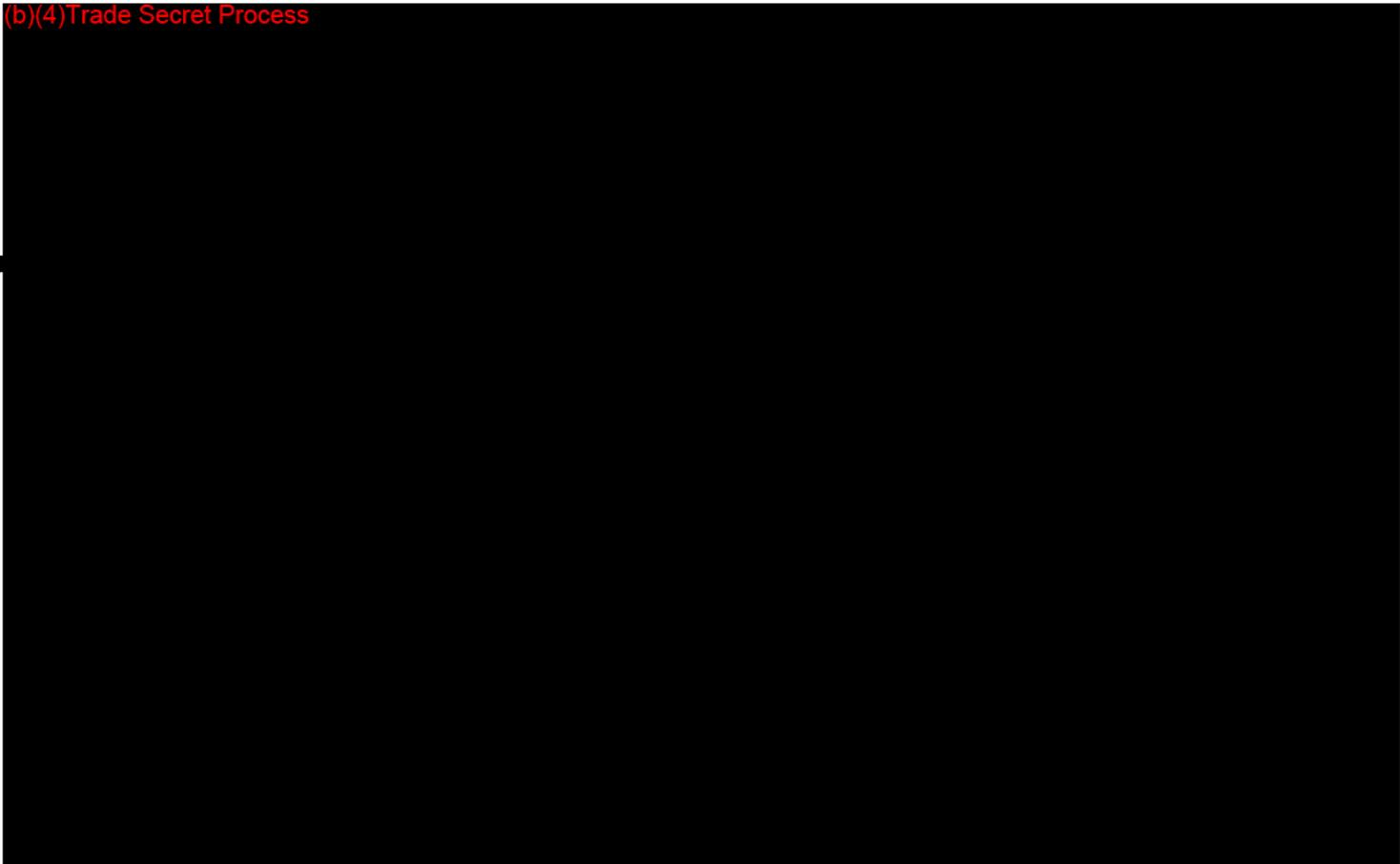
To: FDA, DHF-HIP-034
From: John Vinciguerra – Director, Product Development
Date: November 20, 2008
Subject: 510(k) K082844 - Response to Questions Regarding BioloX®
Option Heads

(b)(4) Trade Secret Process





(b)(4)Trade Secret Process

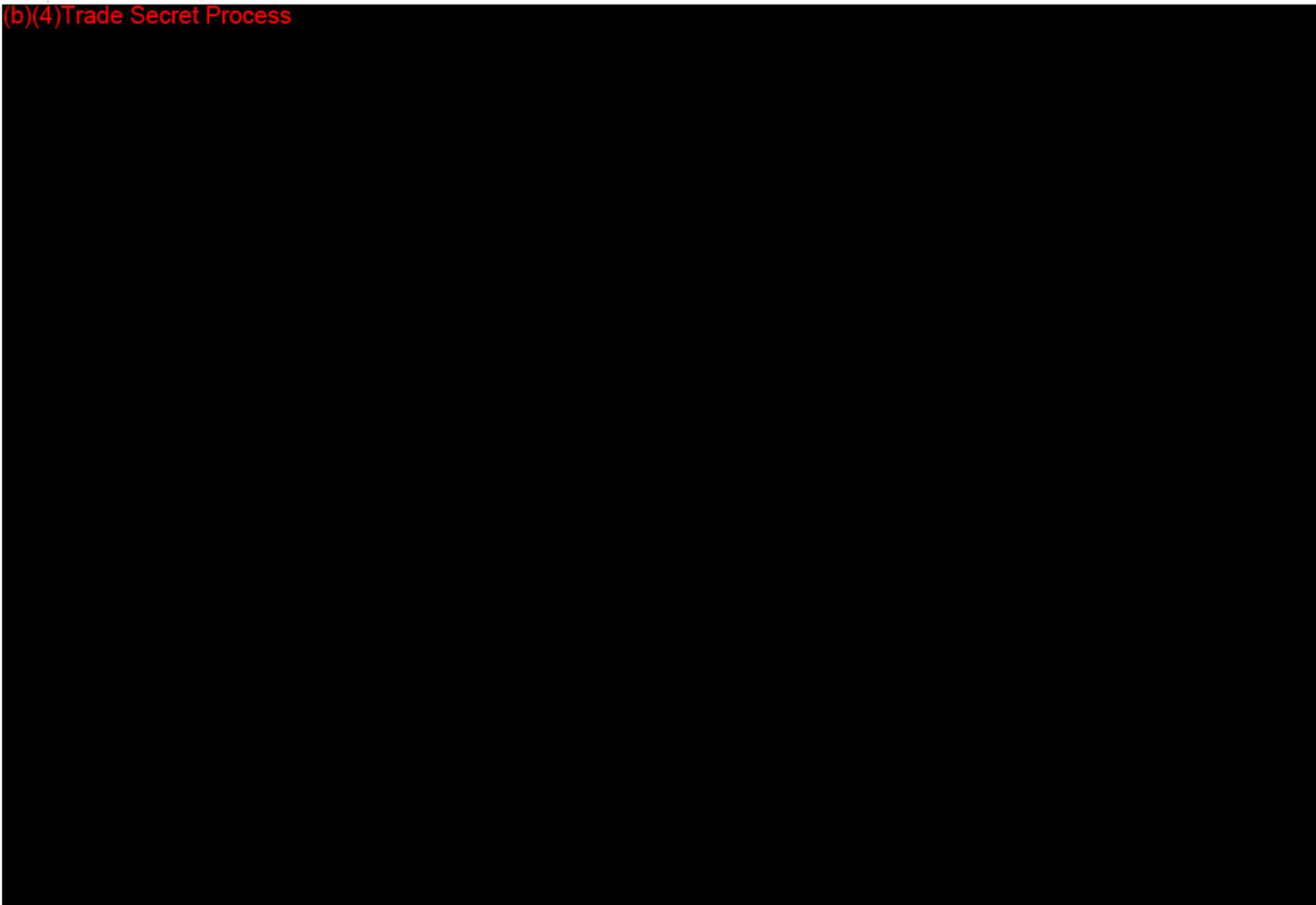
A large black rectangular redaction box covers the majority of the page content, starting below the logo and extending nearly to the bottom of the page.

Shepherd, Tara N

From: Shepherd, Tara N
Sent: Wednesday, November 19, 2008 5:03 PM
To: 'Hutto, Teffany'
Subject: Conference Call Follow-Up

Teffany,

(b)(4)Trade Secret Process



Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
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Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Wednesday, November 19, 2008 3:03 PM
To: Shepherd, Tara N
Subject: Conference Call Topic
Attachments: Experience with BioloX Option Revision Heads.pdf; Zimmer GMBH Delta Option Approval.pdf

Tara,

(b)(4)Trade Secret Process



Manager, Regulatory Affairs

DJO Surgical
9800 Metric Boulevard
Austin, TX 78758-5445 U.S.A
D 512-834-6255
F 512-834-6313
Teffany.Hutto@djosurgical.com
DJOglobal.com

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K073567

Summary of Safety and Effectiveness

MAR 13 2008

Submitter: Zimmer GmbH
Sulzer Allee 8
Winterthur, Switzerland CH - 8404

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

Alternate Contact: Natalie Heck
Sr. Manager, Regulatory Affairs
Telephone: (574) 372-4219
Fax: (574) 372-4605

Date: March 4, 2008

Trade Name: *BIOLOX[®] OPTION** Ceramic Femoral Head System

Common Name: Ceramic Femoral Head Prosthesis

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

Predicate Device(s): DePuy Delta TS (Taper Sleeve) Ceramic Femoral Head, manufactured by DePuy Orthopaedics, Inc., K071830, cleared September 28, 2007

Device Description: The *BIOLOX OPTION* Ceramic Femoral Head System consist of a ceramic head fabricated from an alumina matrix composite available in diameters of 28, 32, 36, and 40 mm and a titanium adapter for the femoral stem cone with a range of offsets to accommodate various patient anatomies. The system serves as an alternative to both metal and alumina ceramic femoral heads and is for use in both primary and revision total hip arthroplasty.

Intended Use: The *BIOLOX OPTION* Ceramic Femoral Head System is comprised of modular components

* Trademark of CeramTec AG

used in primary or revision total hip arthroplasty and indicated for the following:

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

Comparison to Predicate Device(s):

The *BIOLOX OPTION* Ceramic Femoral Head System is substantially equivalent to the femoral head system listed above as the predicate device. Both the proposed and predicate designs are intended to function as a modular ceramic femoral head component in total hip arthroplasty and are manufactured by CeramTec AG from the same materials.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing was performed and results indicate that the *BIOLOX OPTION* Ceramic Femoral Head System is equivalent to devices currently legally marketed, is compatible with Zimmer 12/14 femoral stems and capable of withstanding *in vivo* loading.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer GmbH
c/o Ms. Natalie Heck
Senior Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

MAR 13 2008

Re: K073567
Trade/Device Name: BIOLOX OPTION Ceramic Femoral Head System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained
cemented or non porous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: February 19, 2008
Received: February 21, 2008

Dear Ms. Heck:

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

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

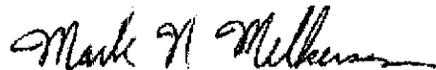
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Natalie Heck

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

K073567

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX[®] OPTION* Ceramic Femoral Head System

Indications for Use:

The BIOLOX OPTION Ceramic Femoral Head System is comprised of modular components used in primary or revision total hip arthroplasty and indicated for the following:

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)

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

*Trademark of CeramTec AG

Page 1 of 1

510(k) Number K073567

Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Wednesday, November 19, 2008 10:28 AM
To: Shepherd, Tara N
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

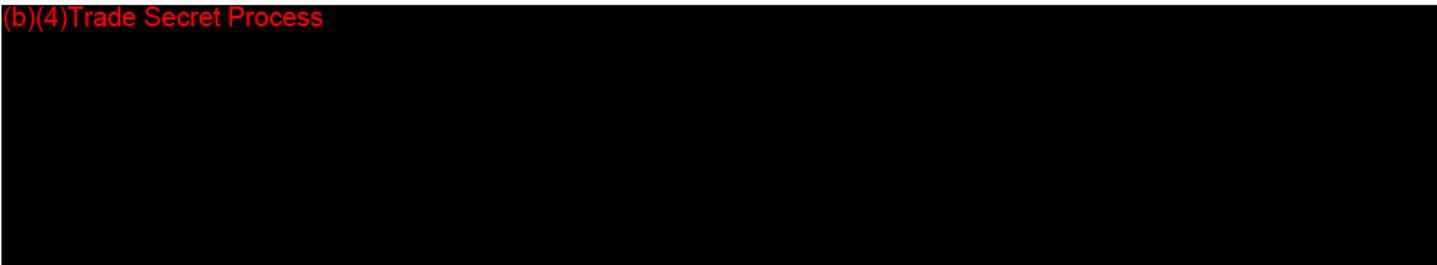
(b)(4)Trade Secret Process



From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Wednesday, November 19, 2008 9:21 AM
To: Hutto, Teffany
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Teffany,

(b)(4)Trade Secret Process



Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
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240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

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From: Hutto, Teffany [mailto:Teffany.Hutto@djosurgical.com]
Sent: Wednesday, November 19, 2008 10:10 AM
To: Shepherd, Tara N

11/20/2008

42

Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Ms. Shepherd,

(b)(4)Trade Secret Process

From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Tuesday, November 18, 2008 5:03 PM
To: Hutto, Teffany
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Teffany,

(b)(4)Trade Secret Process

Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

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From: Hutto, Teffany [mailto:Teffany.Hutto@djosurgical.com]
Sent: Tuesday, November 18, 2008 5:49 PM
To: Shepherd, Tara N
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

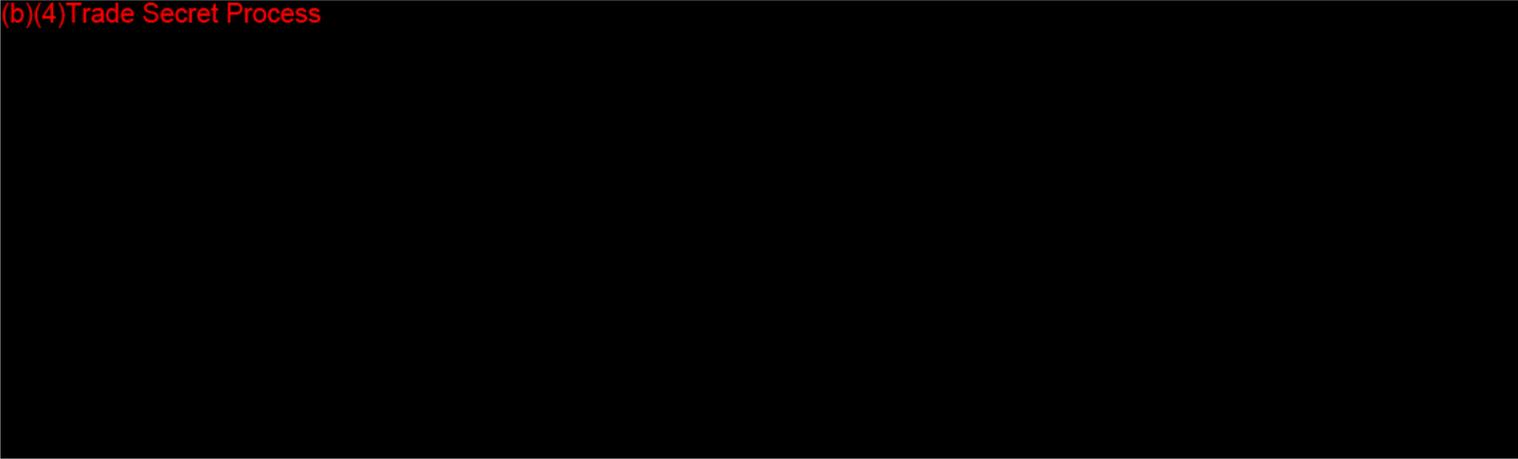
Dear Ms. Shepherd,

(b)(4)Trade Secret Process

11/20/2008

A3

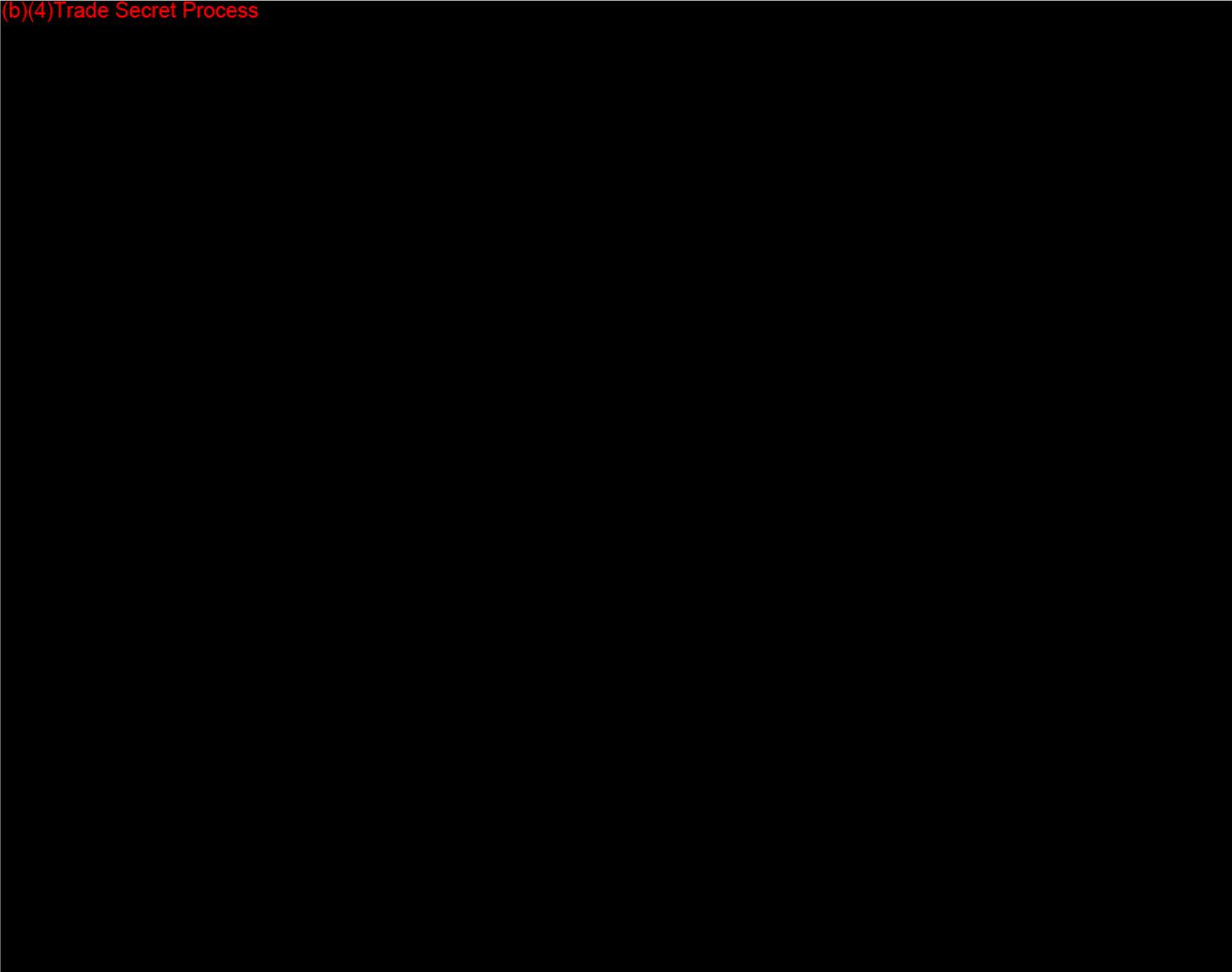
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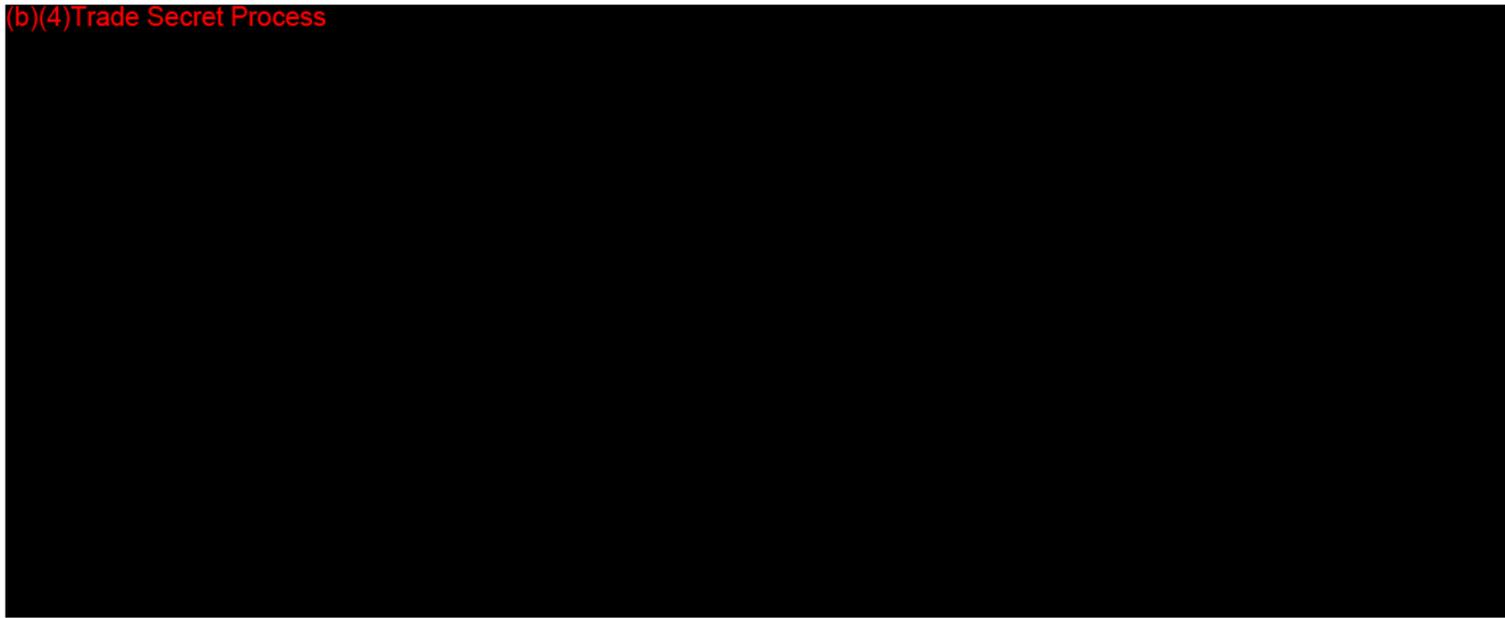
From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Thursday, November 13, 2008 2:09 PM
To: Hutto, Teffany
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Teffany,

(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



Tara N. Shepherd, M.S.
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240-276-3761 (fax)
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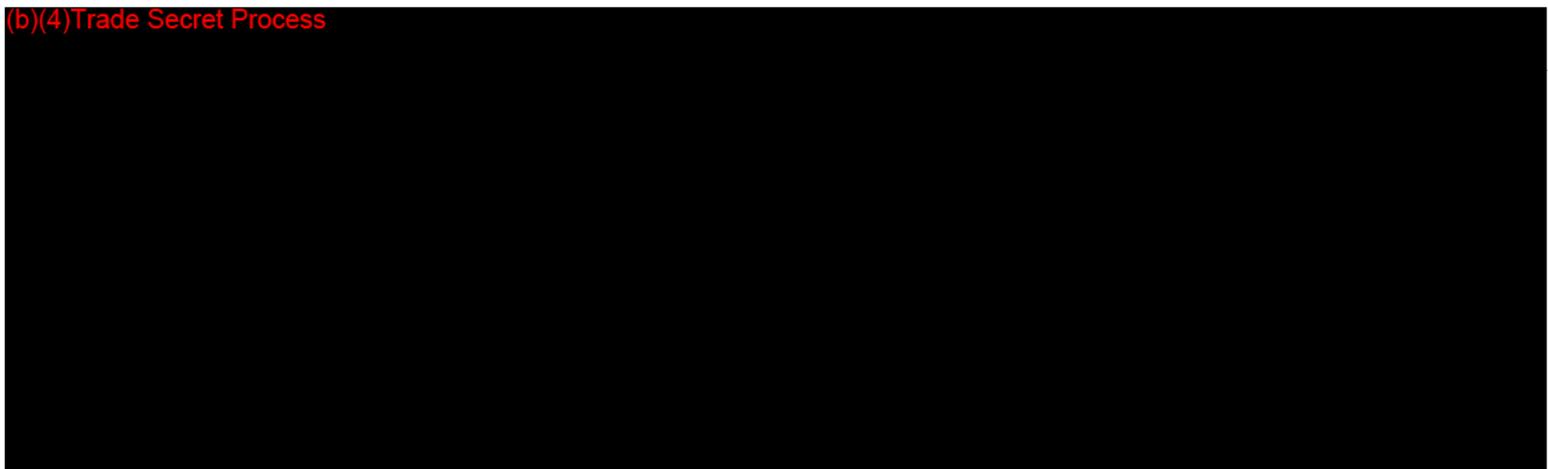
AS

Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Tuesday, November 18, 2008 5:49 PM
To: Shepherd, Tara N
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Dear Ms. Shepherd,

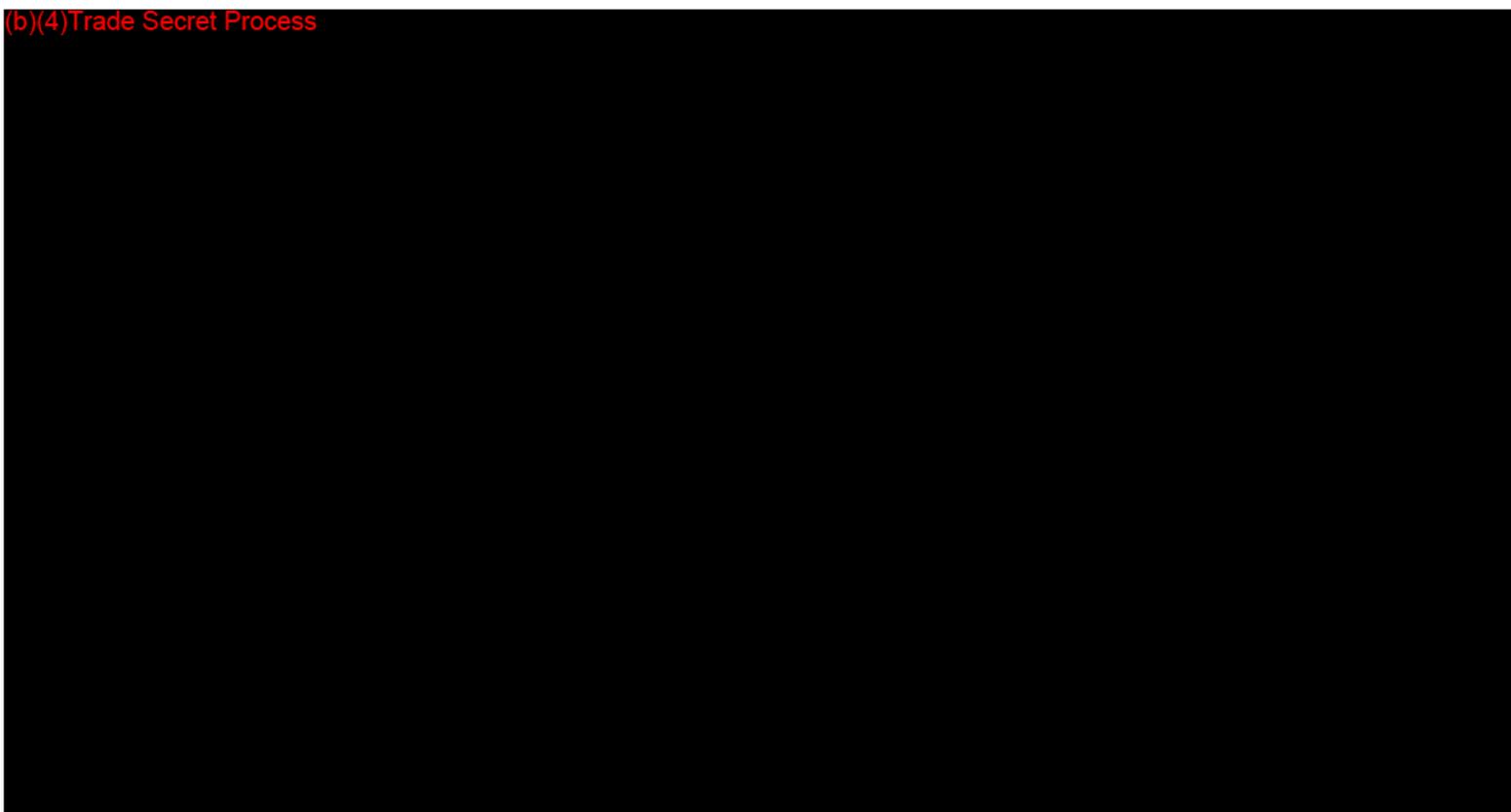
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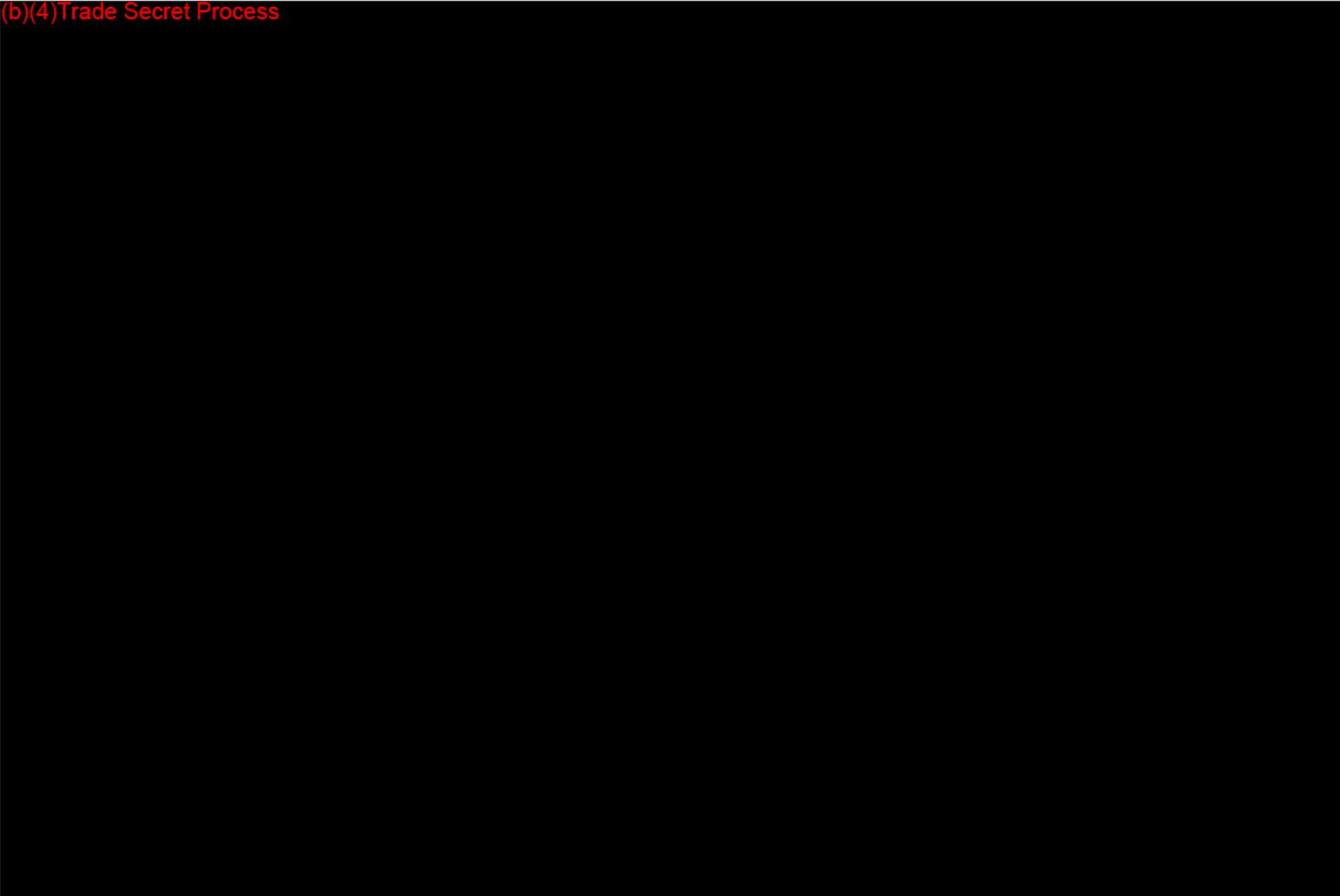
From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Thursday, November 13, 2008 2:09 PM
To: Hutto, Teffany
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Teffany,

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Tara N. Shepherd, M.S.
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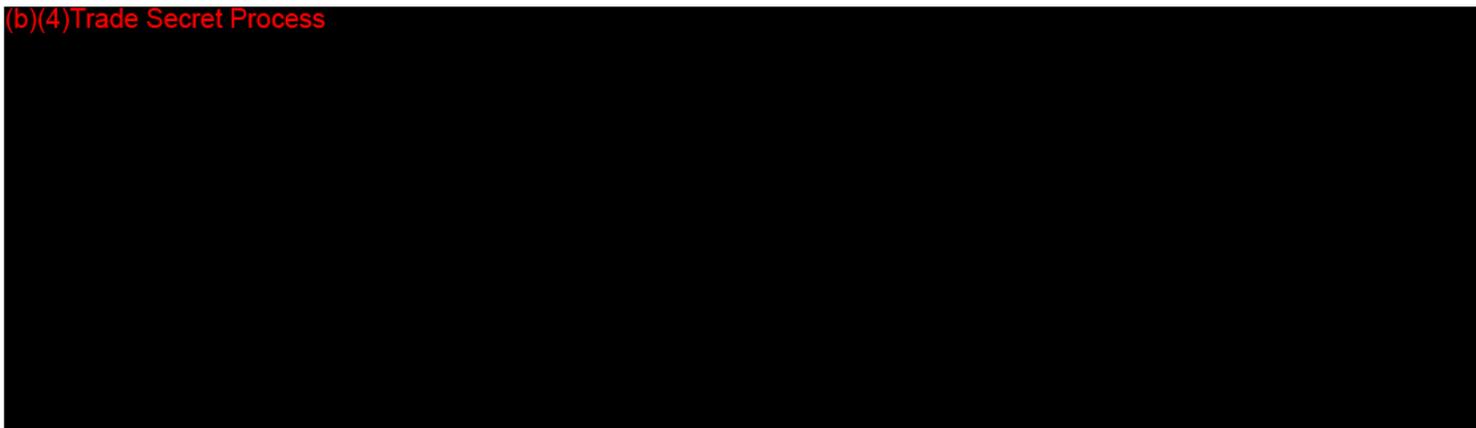
47

Shepherd, Tara N

From: Shepherd, Tara N
Sent: Tuesday, November 18, 2008 6:03 PM
To: 'Hutto, Teffany'
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Teffany,

(b)(4)Trade Secret Process



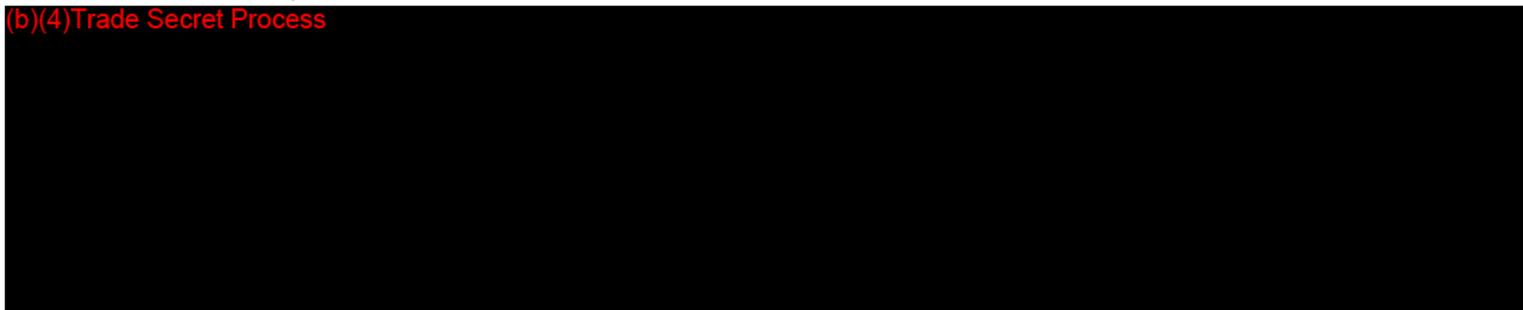
Tara N. Shepherd, M.S.
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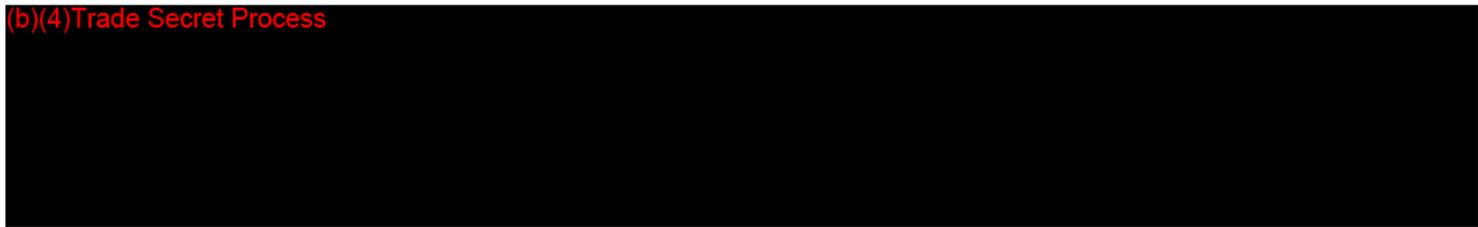
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To: Shepherd, Tara N
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Dear Ms. Shepherd,

(b)(4)Trade Secret Process



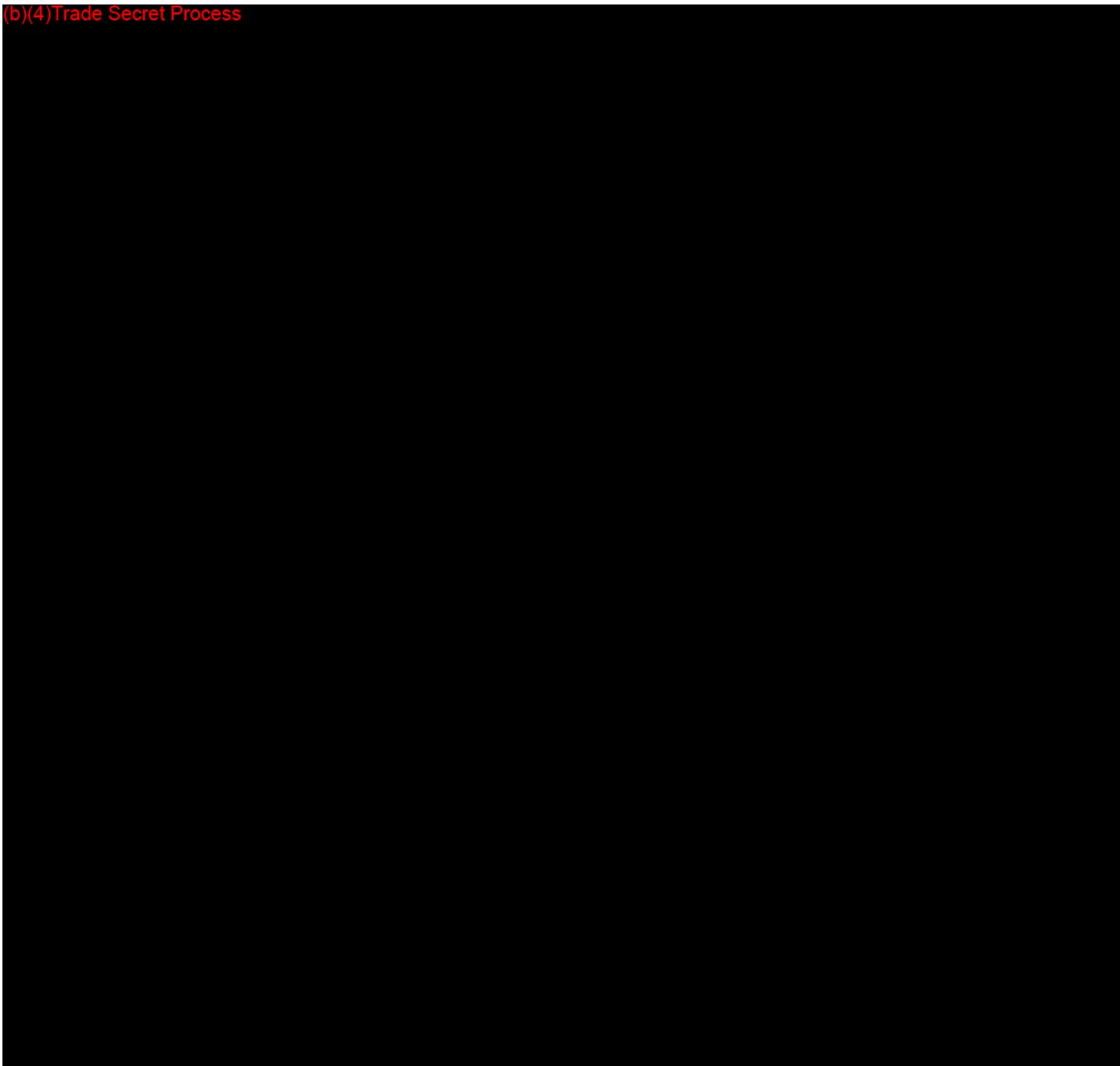
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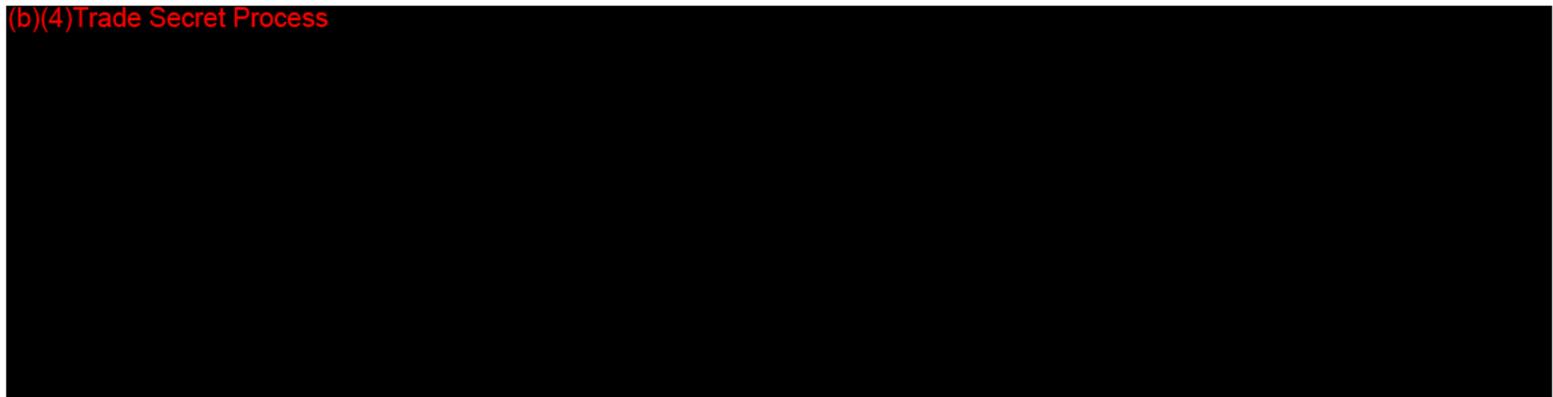
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Teffany,

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



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Shepherd, Tara N

From: Shepherd, Tara N
Sent: Thursday, November 13, 2008 3:09 PM
To: 'Hutto, Teffany'
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Teffany,

(b)(4)Trade Secret Process



(b)(4) Trade Secret
Process

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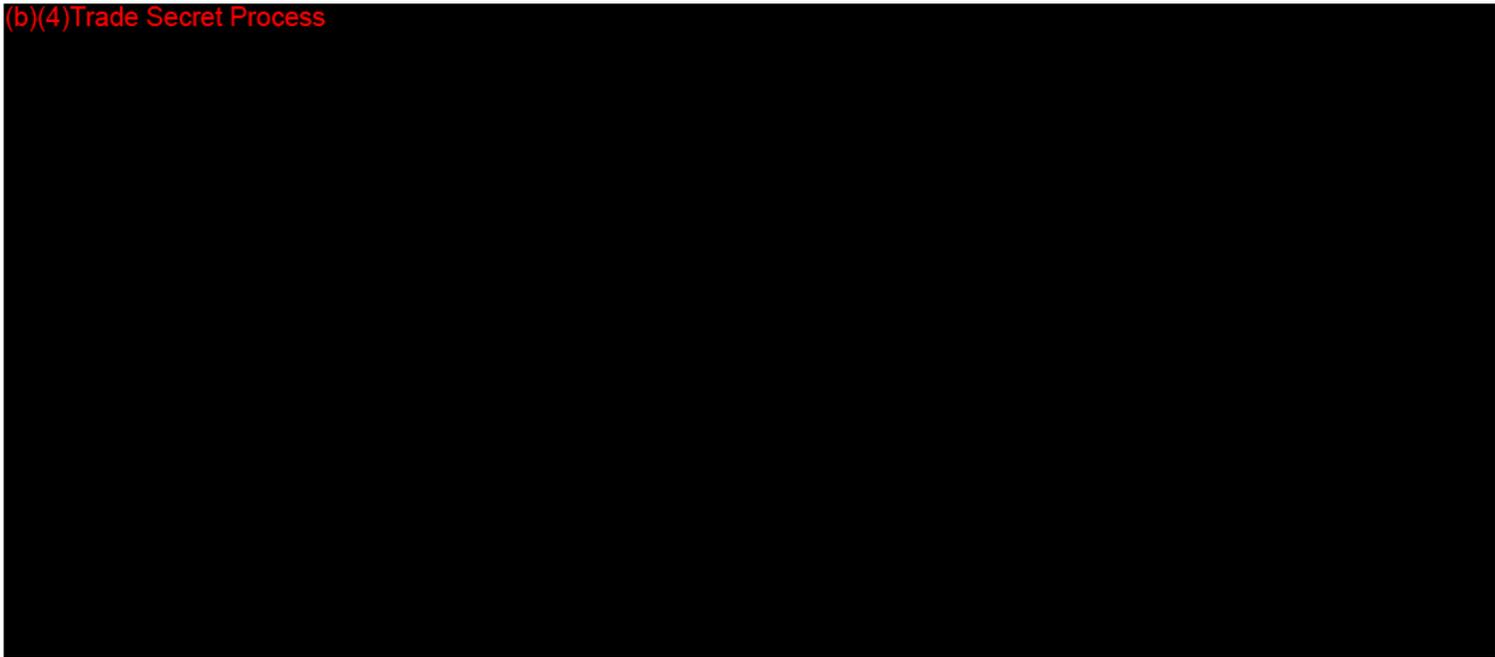
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Shepherd, Tara N

From: Shepherd, Tara N
Sent: Thursday, November 13, 2008 11:29 AM
To: 'Hutto, Teffany'
Subject: K082844 S001 - Biolog Delta Ceramic Femoral Head

Ms. Hutto,

(b)(4)Trade Secret Process



Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
lara.shepherd@fda.hhs.gov

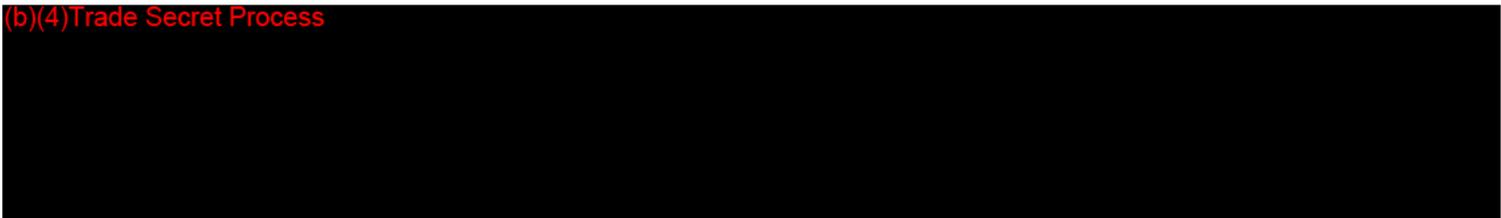
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Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Thursday, November 13, 2008 1:25 PM
To: Shepherd, Tara N
Subject: RE: K082844 S001 - BioloX Delta Ceramic Femoral Head

Dear Ms. Shepherd,

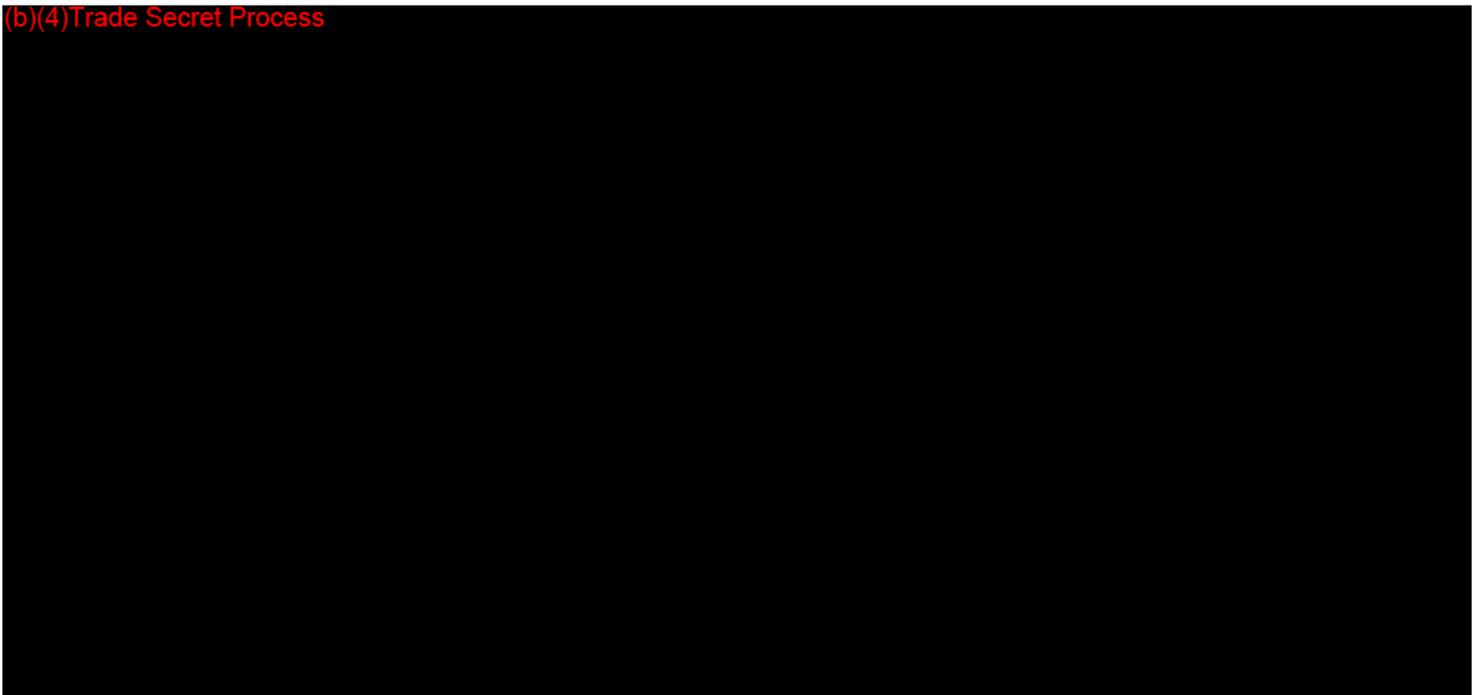
(b)(4)Trade Secret Process

A large black rectangular redaction box covers the main body of the email. The text "(b)(4)Trade Secret Process" is written in red at the top left corner of this redacted area.

From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Thursday, November 13, 2008 10:29 AM
To: Hutto, Teffany
Subject: K082844 S001 - BioloX Delta Ceramic Femoral Head

Ms. Hutto,

(b)(4)Trade Secret Process

A large black rectangular redaction box covers the main body of the email. The text "(b)(4)Trade Secret Process" is written in red at the top left corner of this redacted area.

Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

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11/20/2008

SH

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COVER SHEET MEMORANDUM

From: Reviewer Name

Taxa Shepherd

Subject: 510(k) Number

K082844

To: The Record

Please list CTS decision code TH

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%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	Attach IFU		
510(k) Summary / 510(k) Statement	Attach Summary		
Truthful and Accurate Statement	Must be present for a Final Decision		
Is the device Class III?			
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/opacdm/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____ see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
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/edrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of Clinical Trials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <= 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comr/guidance/169.html)	Contact OC.

Regulation Number Class* Product Code

288.3353

11

LZO

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

Additional Product Codes:

Review:

Jonata
(Branch Chief)

OTDB
(Branch Code)

10/21/08
(Date)

Final Review:

for Jonata
(Division Director)

10/21/08
(Date)

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER

K082844

Date: October 21, 2008

From: Tara Shepherd, Biomedical Engineer (HFZ-410) Division: DGRND/OJDB

TNS 10/21/08

Device Name: BioloX Delta Ceramic Femoral Head

Classification: 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; LZO

Company: Encore Medical

Contact: Teffany Hutto

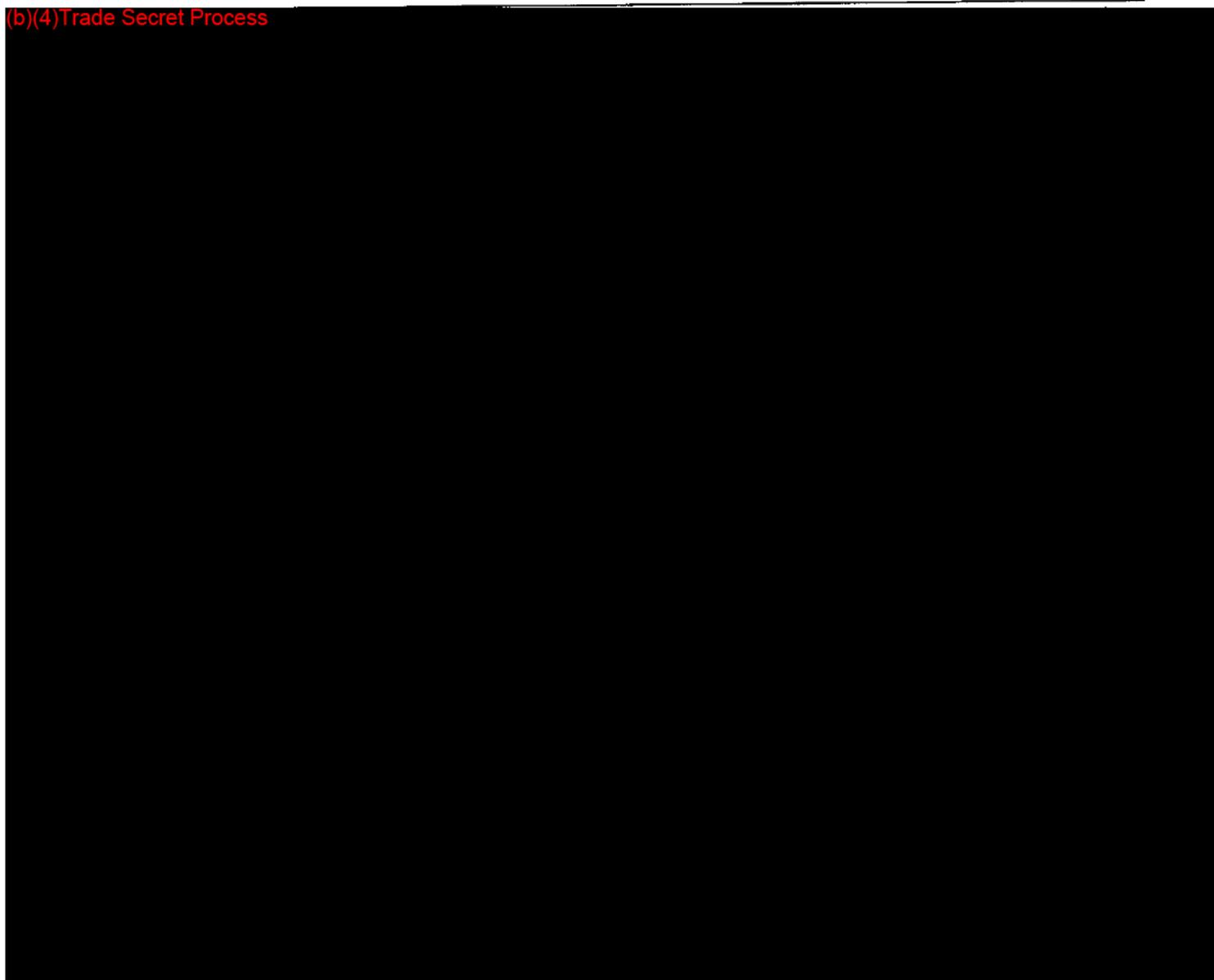
Manager, Regulatory Affairs

9800 Metric Blvd.

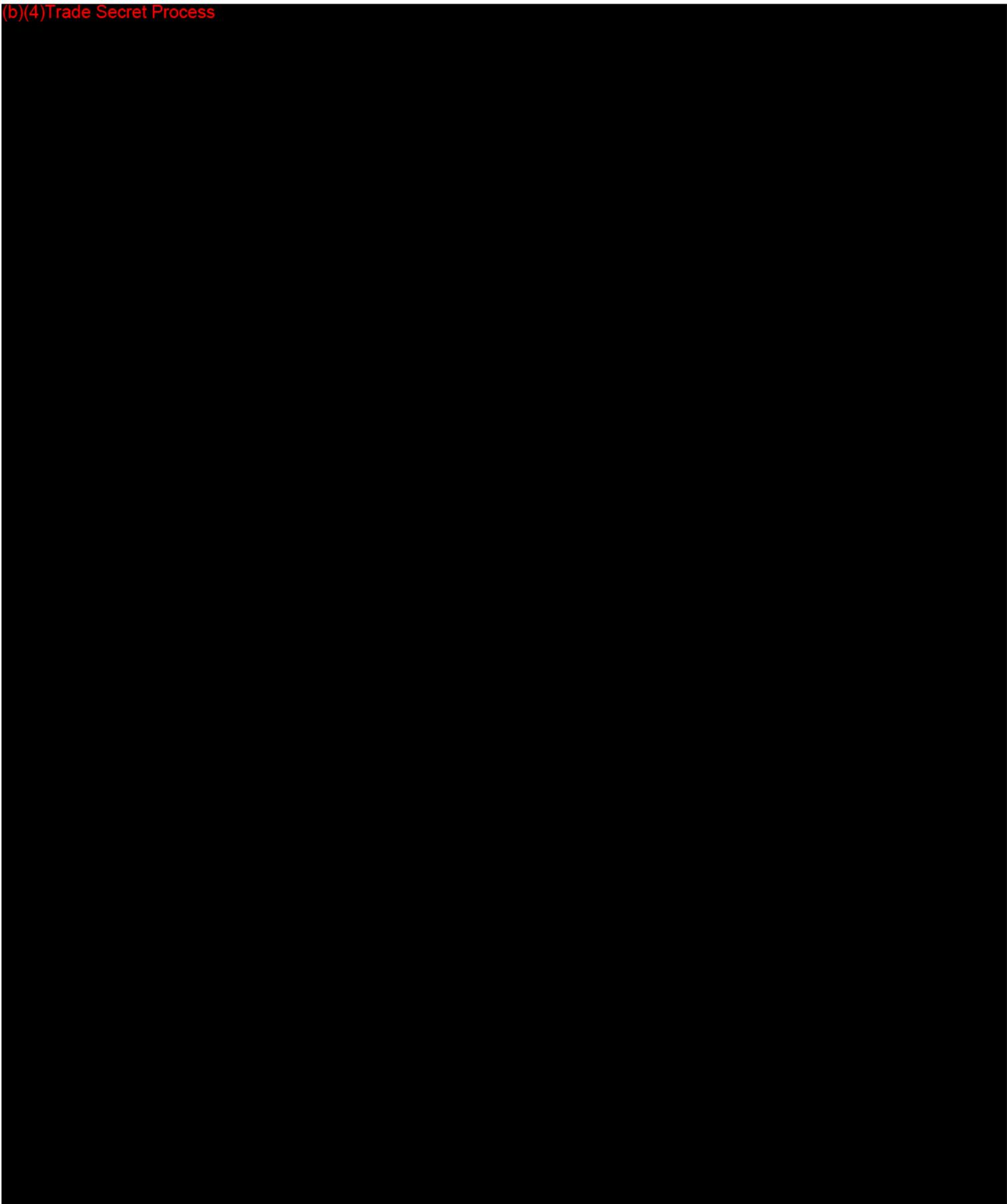
Austin, TX 78758

Phone: (512) 834 – 6255; Fax: (512) 834 – 6313; Email: teffany.hutto@diosurgical.com

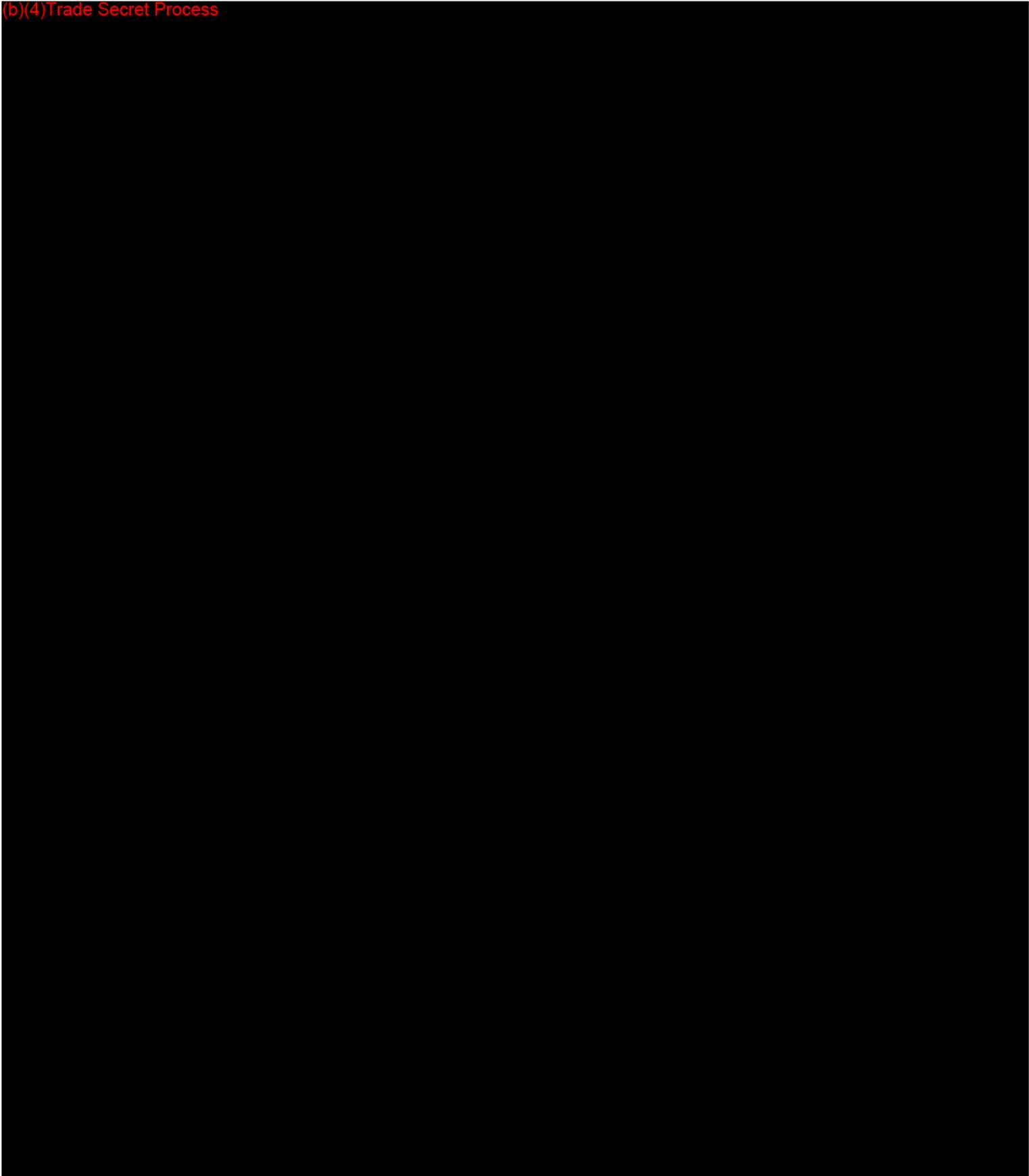
(b)(4) Trade Secret Process



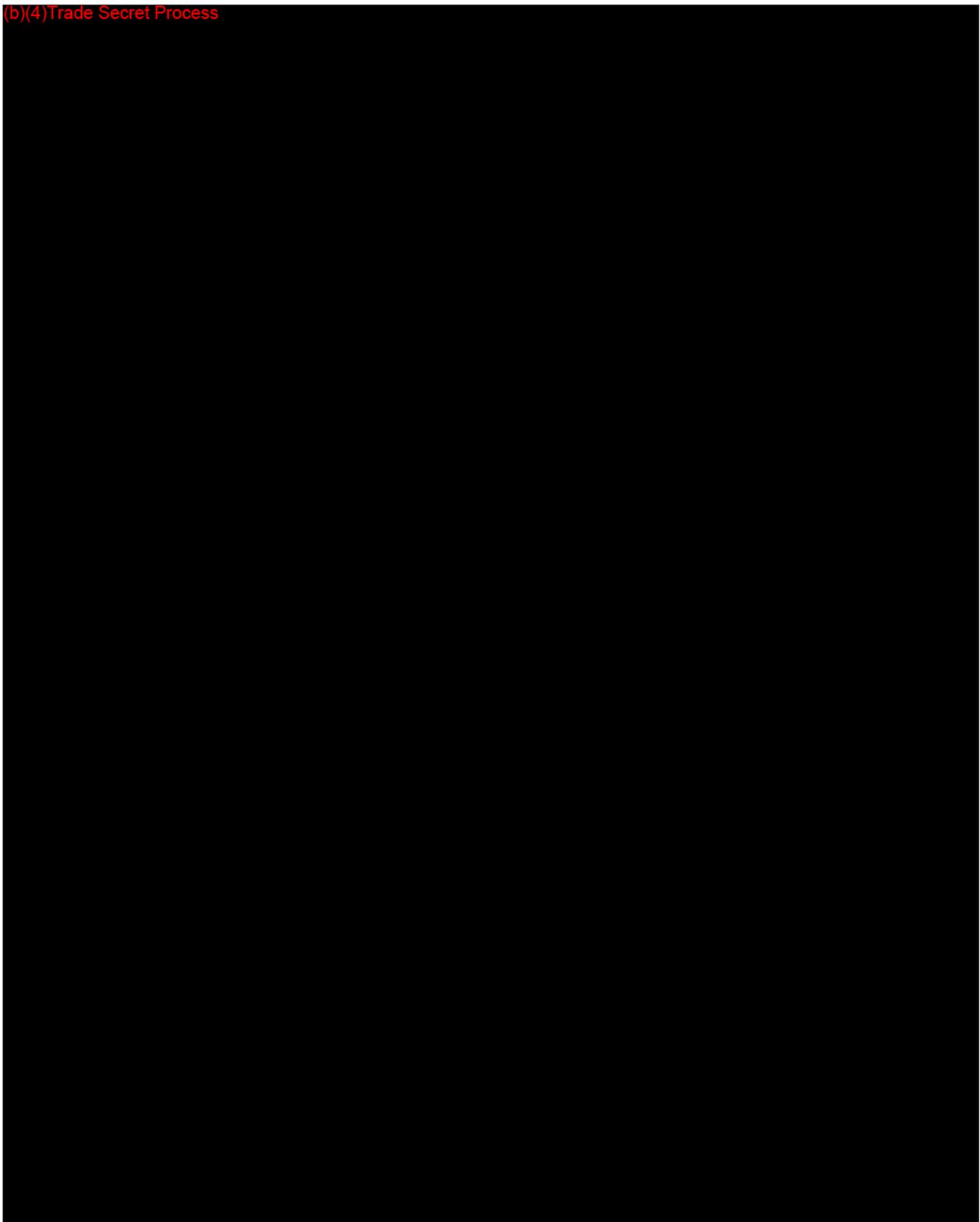
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



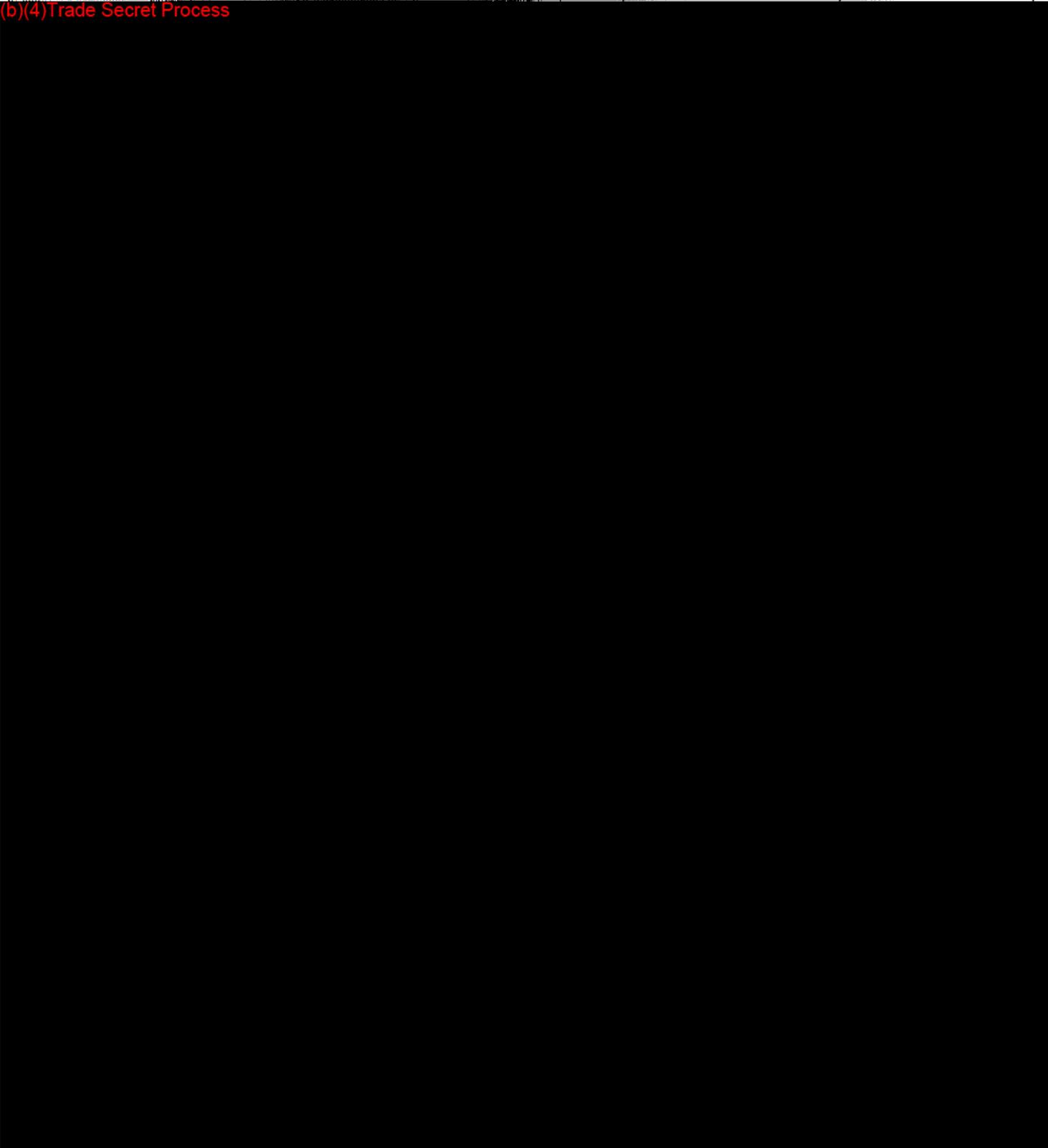
(b)(4) Trade Secret Process



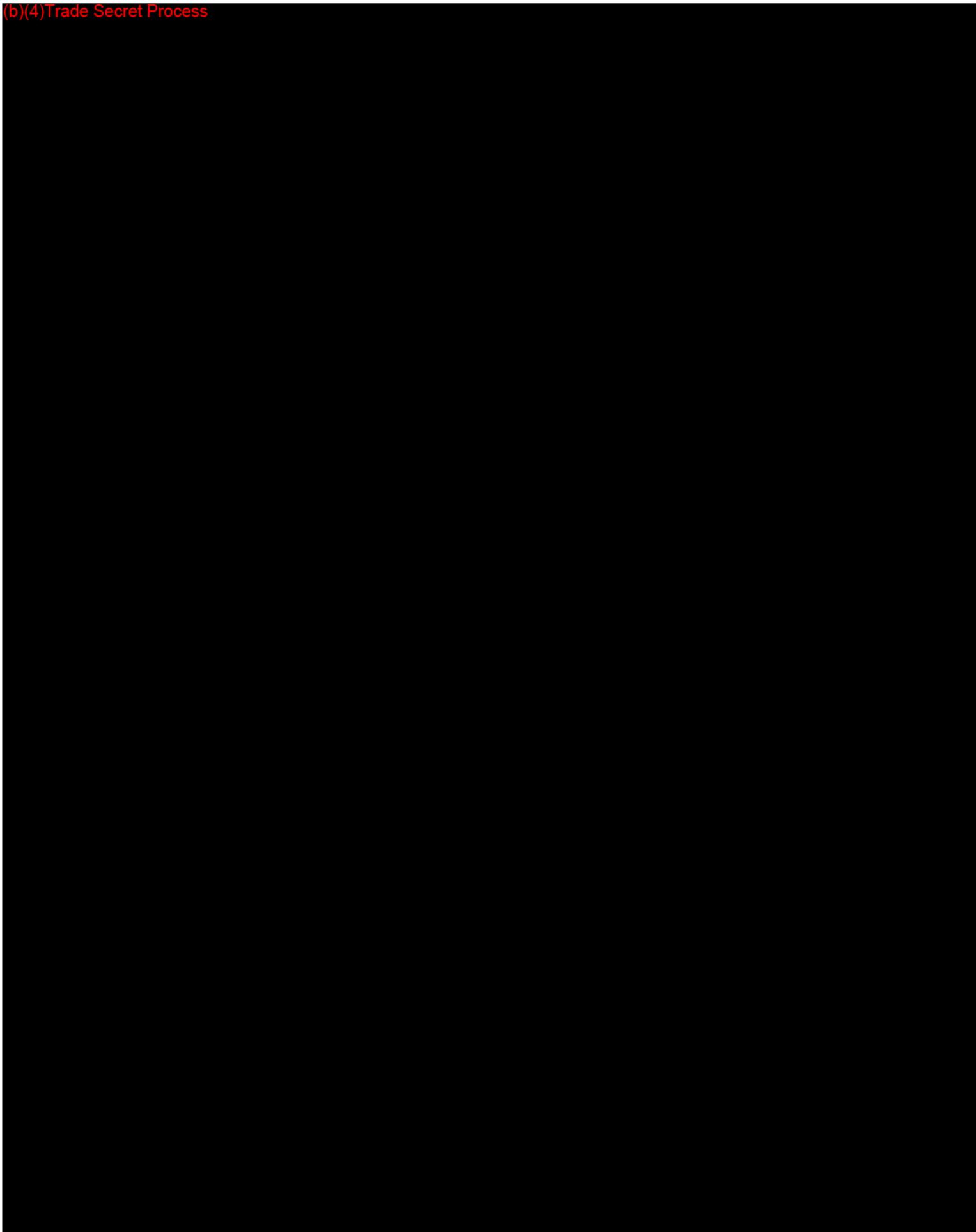
Sponsor's Response:

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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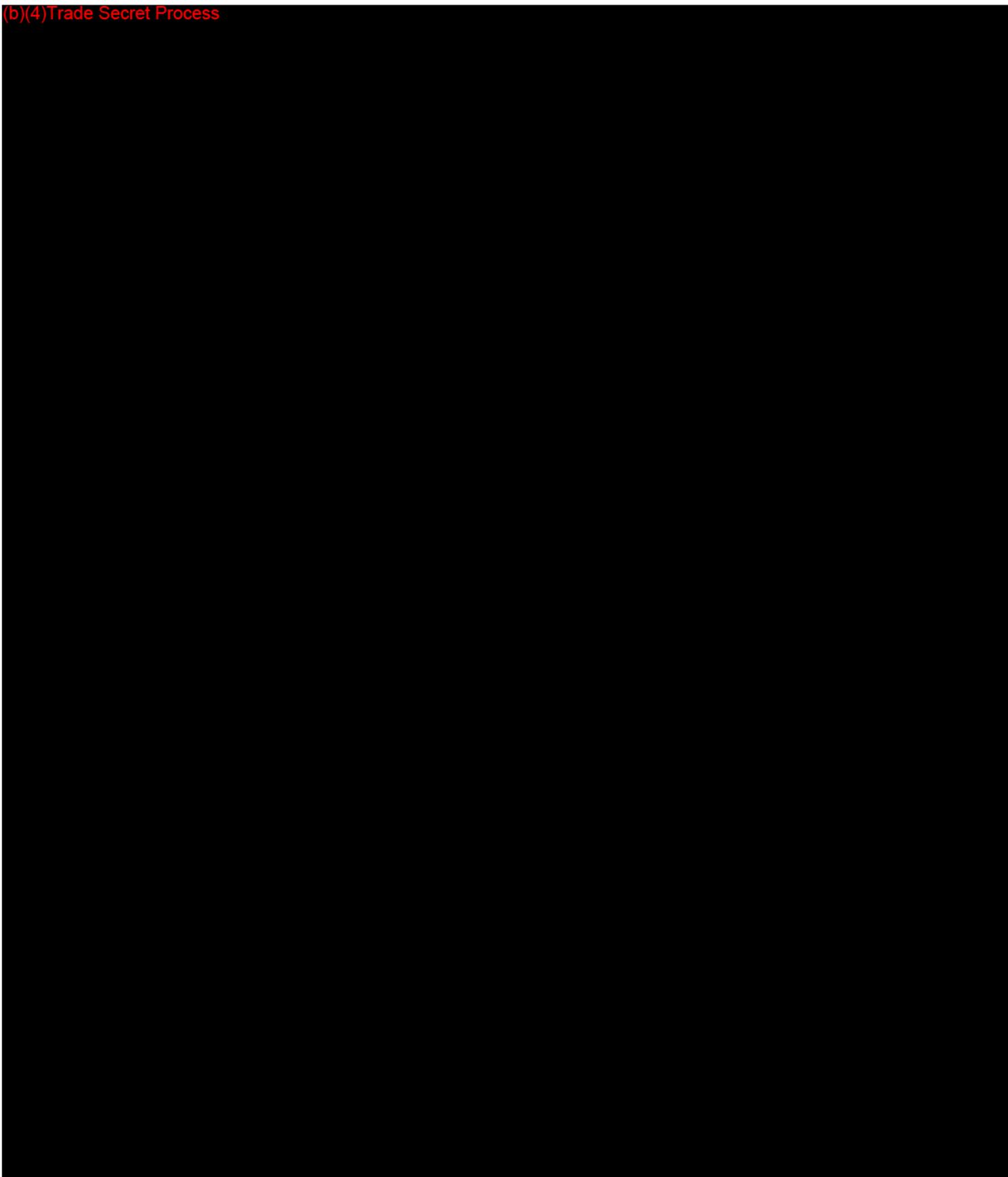
(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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?		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: AI

5. Explain how descriptive characteristics are not precise enough:
Performance testing necessary
8. Explain what performance data is needed:
Testing of Biolox Option head with femoral taper in cases of revision
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Shepherd, Tara N

From: Shepherd, Tara N
Sent: Tuesday, October 21, 2008 12:25 PM
To: 'Hutto, Tefany'
Subject: K082844 - BioloX Delta Ceramic Femoral Head - Telephone Hold

Ms. Hutto,

(b)(4)Trade Secret Process



Tara N. Shepherd, M.S.
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Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

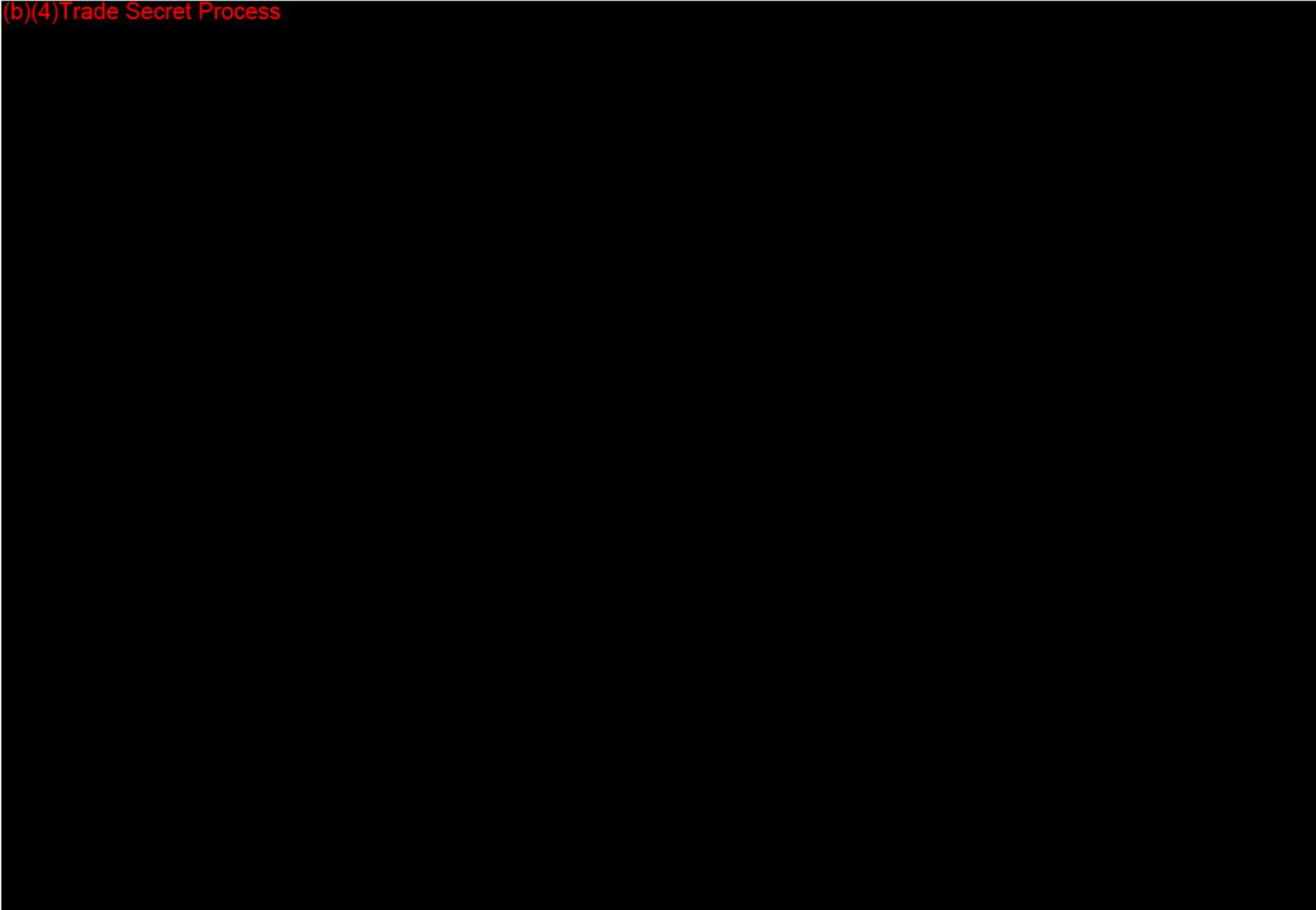
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Shepherd, Tara N

From: Shepherd, Tara N
Sent: Wednesday, October 15, 2008 1:30 PM
To: 'Hutto, Teffany'
Subject: K082844 - BioloX Delta Ceramic Femoral Head

Ms. Hutto,

(b)(4)Trade Secret Process



Tara N. Shepherd, M.S.
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tara.shepherd@fda.hhs.gov

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10/15/2008

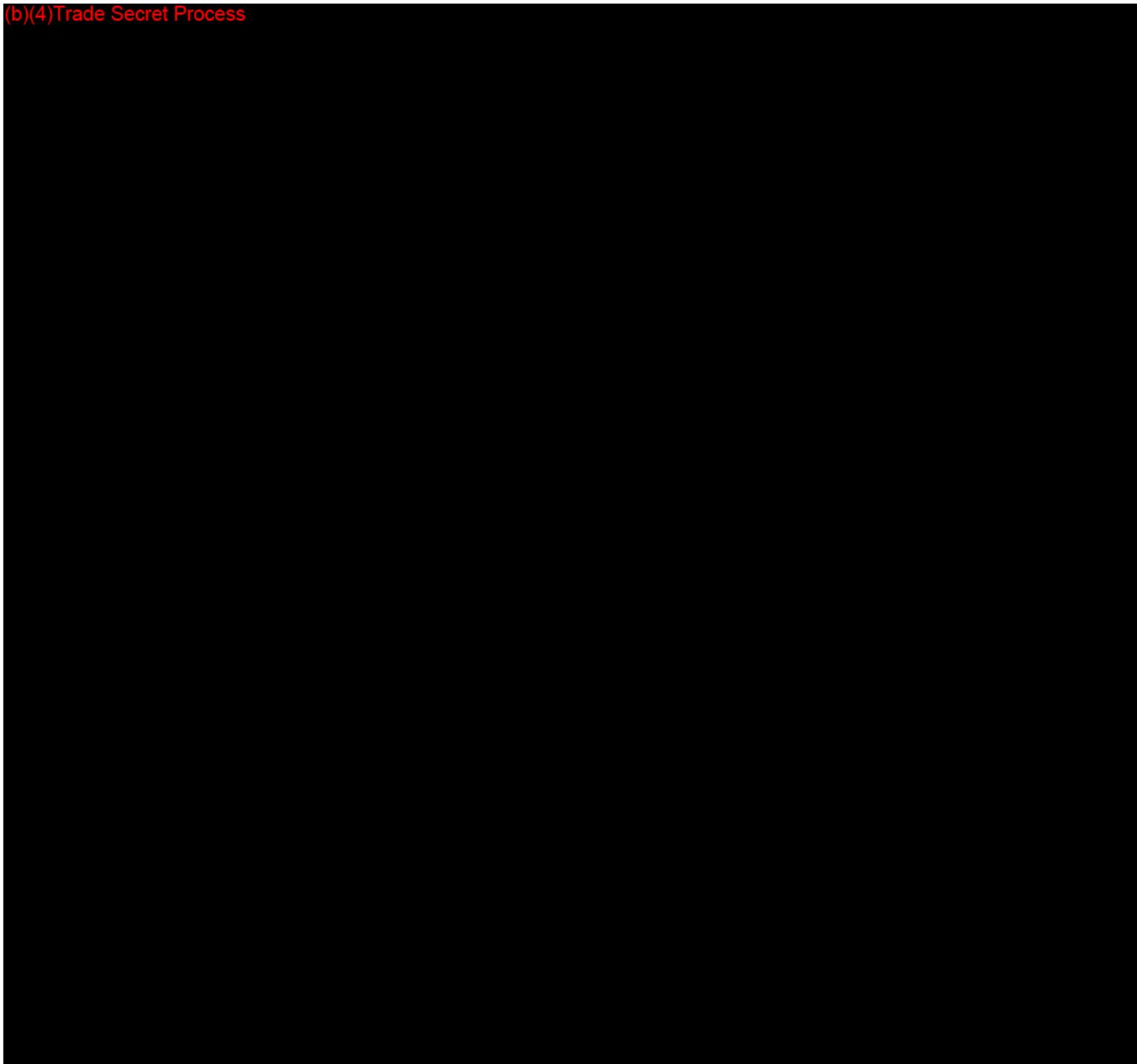
76

Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Monday, October 20, 2008 5:11 PM
To: Shepherd, Tara N
Subject: RE: K082844 - BioloX Delta Ceramic Femoral Head
Attachments: BioloX delta Option ST.pdf

Dear Ms. Shepherd,

(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



BIOLOX® * *delta* OPTION Ceramic Femoral Head

Data Sheet/
Surgical Technique

(* Trademark of CeramTec AG.)

DRAFT

What is delta?

The new alumina matrix composite *delta* meets the increased demands in hip replacement. This high-performance ceramic offers the same advantages as alumina ceramic, i.e. excellent biocompatibility, low wear, high hardness, outstanding chemical and hydrothermal stability, but with higher strength than alumina ceramic.

BIOLOX delta Head Family

The *BIOLOX delta* head family consists of two product lines:

- ***BIOLOX delta* Ceramic Femoral Heads**
a standard head, only for cases with new femoral stem components
- ***BIOLOX OPTION* Ceramic Femoral Head System**
a head and metal adapter, for primary and revision cases

The *BIOLOX delta* Ceramic Femoral Head Family is made from a new alumina matrix composite developed by CeramTec AG.

Benefits

- Improved mechanical properties compared to alumina heads
- Additional neck length for diameters larger than 32 mm
- Additional diameters providing more ROM and stability
- Same benefits as *BIOLOX forte* remain for *BIOLOX delta*, i.e. appropriate for patients who are sensitive to specific metal elements

Sizing

Diameter/Neck Length 28mm, 32mm, 36mm, 40mm, 44mm
S/ -3.5mm
M/ 0
L/ +3.5mm
XL/ +7.0mm

Science behind BIOLOX delta Material

BIOLOX delta is an aluminum oxide matrix composite ceramic consisting of approx. 75% alumina (Al_2O_3), 24% zirconia (ZrO_2) and other trace elements. The pink color is due to the chromium oxide (Cr_2O_3) that increases the hardness of the composite material.

Alumina provides the material's hardness and wear resistance, while zirconia, together with other additives, provides improved mechanical properties. The high density of the material and the very small grain size also contribute to the improved properties.

The result is a high-performance ceramic that offers the same advantages as *BIOLOX forte*: excellent biocompatibility, low wear, high hardness and good mechanical performance.

The Microstructure

The first toughening mechanism used in *BIOLOX delta* material results from the introduction of small, homogeneously distributed yttria-stabilized tetragonal zirconia particles (Y-TZP) in a stable alumina matrix. The spatial separation of these zirconia particles reduces the likelihood of structural transformation and prevents the initiation or propagation of cracks.

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

(images)

Improved Mechanical Properties

The excellent flexural strength and reduced grain size of *BIOLOX delta* material explain its value as an alternative bearing material, when articulating against highly-crosslinked polyethylene.

Mechanical Properties and Benefits of Third Generation Alumina and Alumina Matrix Composite Ceramic Property Provides Third-generation BIOLOX delta alumina

Bending strength (MPa)	Improved mechanical properties	> 550	> 950
Hardness (HV)	High hardness – low wear	2000	1925
Microstructure (µm)	Small grain size – increased strength	< 1.8	< 1.0
Density (g/cm ³)	High density – better surface finish	3.98	4.37
Young's modulus (GPa)	High Young's modulus – good stability (low deformation)	380	350
Laser marking	Improved product safety	yes	yes
Hipped	Reduced grain size, homogenous distribution	yes	yes
Proof tested (100%)	Quality control process	yes	yes
Bearing combination	Suitable for ceramic-on-polyethylene	yes	yes

Y
X

BIOLOX OPTION Head System

The *BIOLOX OPTION* head system addresses the needs of the orthopaedic surgical community for a system that can be used in cases of revision surgery in order to offer the patient a low-wear bearing option. Additional neck lengths and taper options are available for total hip replacement. This makes the *BIOLOX OPTION* head system a flexible system with a wide range of combination possibilities.

The *BIOLOX OPTION* head system consists of two components:

- An adapter sleeve and a
 - *BIOLOX delta* ceramic femoral head
- The adapter sleeve is made of titanium alloy TiAl6V4

(ISO 5832-3), with an 12/14 inner taper that interlocks with the femoral stem. The ceramic femoral head with a specially designed inner taper matches the outer taper of the adapter sleeve. The adapter can plastically deform to accommodate the small damaged areas (less than 0.25mm high) that could be present on the taper of a non-revised stem to maintain the optimal distribution of pressure on the ceramic head.

Brand-new
taper structure
Deformed taper
structure after
61 months *in vivo*

Benefits

- Possibility for low-wear ceramic solution in revision cases
- Femoral head can be combined with new stems, unused or slightly damaged stem tapers – i.e., those with scratches of less than 0.25mm
- Adapter does not reduce the range of motion
- Improved mechanical properties compared to alumina heads
- Easy assembly of head and adapter
- Same benefits for *BIOLOX forte* remain for *BIOLOX delta*

Sizing

- 4 head diameters: 28, 32, 36, 40 and 44mm
- 4 neck lengths: S/-3.0, M/+0, L/+3.5 and XL/+7.0mm
- 12/14 stem taper adapters

More Stability and Range of Motion

A large diameter articulation offers increased stability due to the increased displacement distance ($X < Y$) and a greater technical range of motion ($\alpha < \beta$) compared to a conventional 28 mm articulation. These obvious clinical benefits, in combination with low-wear alternative bearings (ceramic on highly cross-linked polyethylene), result in improved functionality and durability.

Clinical studies confirm that there is a statistically significant decrease in impingement, subluxation and dislocations with 36 mm ceramic-on-ceramic coupling (0.88%) when compared to 28 mm femoral heads (4.64%) in THR.

$\alpha < \beta$

$\alpha \beta$

Enhanced Variety with BIOLOX delta

The *BIOLOX delta* head and *BIOLOX OPTION* head system can be used in conjunction with compatible acetabular and femoral stem components for total hip arthroplasty. A variety of diameters and neck lengths are available for various patient anatomies, adjustment of the tension of the ligaments, and reconstruction of the center of the physiological head of the femur. The size of the femoral head selected must match the inner diameter of the articulating surface.

The *BIOLOX delta* head and *BIOLOX OPTION* head system may only be used in combination with highly cross-linked or conventional polyethylene (PE). To determine whether these devices have been authorized for use in a desired combination, please contact your DJO Surgical sales representative or visit the DJO Surgical Web site: www.djo.com.

Surgical Technique Considerations BIOLOX OPTION Head System

The *BIOLOX OPTION* head system is only cleared with DJO Surgical stems, and in combination with highly cross-linked or conventional polyethylene.

Preoperative Planning

Planning of the operation is based on the information available. Identification of the stem, which remains *in situ*, and the condition of the stem taper, is of prime importance during the preoperative planning. The inner taper of the adapter sleeve must fit the stem taper.

The *BIOLOX OPTION* head system can be used on a:

- new stem taper for primary and revision cases, or on a
- implanted or slightly damaged stem taper in revision cases

Definition regarding stem taper condition:

- **Implanted stem taper:** condition of the stem taper after removal of the intact head
- **Slightly damaged stem taper:** condition of the stem taper after revision of the femoral head

Head Removal and Inspection of the Stem Taper

- In case of revision surgery, extract the remaining femoral head (and adapter, if applicable) with a suitable extraction instrument to avoid unnecessary damage to the stem taper.
- Inspection of the stem taper and decision:
 - Pristine taper (see fig. 1)
 - Tolerable condition with scratches of less than 0.25mm (see fig. 2)
 - Intolerable condition (see figs. 3 through 5)

Do not use the *BIOLOX OPTION* head system with tapers in these circumstances!

Use trial heads

- Determine the neck length
- Check tissue balance
- Check range of motion

Assembly of Femoral Head and Adapter

- Ensure selection of the correct *BIOLOX OPTION* head system (i.e., diameter, taper size, neck length, material, manufacturer, etc.)
- The *BIOLOX OPTION* femoral head and adapter must be implanted together. Before the final positioning of the *BIOLOX OPTION* ceramic femoral head, the operating surgeon must assemble the *BIOLOX OPTION* head system in the packaging shell according to the diagrams (see figures below).
- Please note, the *BIOLOX OPTION* head and adapter are packaged together.

Assembling of the *BIOLOX OPTION* Head System

- The ceramic femoral head is placed on the adapter sleeve, which remains in its position, and pressure is applied until resistance is felt. The ceramic femoral head must be placed straight down on the sleeve.
- The system components are ready for assembly on the femoral stem; no washing or cleaning is necessary.

Final Setting onto the Stem

- The stem taper must be dry and free of any blood or debris (i.e., tissue, bone or cement particles).
- Place the *BIOLOX OPTION* head assembly on the stem taper with a twisting motion, while applying manual pressure until it locks.
- As a rule, it should be easy to place the head with the assembled adapter onto the stem taper. Do not use the *BIOLOX OPTION* head system if pressure is necessary to seat the device.
- Seat the assembly using the plastic impactor on the pole of the femoral head and a light hammer.
- Test the assembly of the head fixation by trying to remove the head by hand.

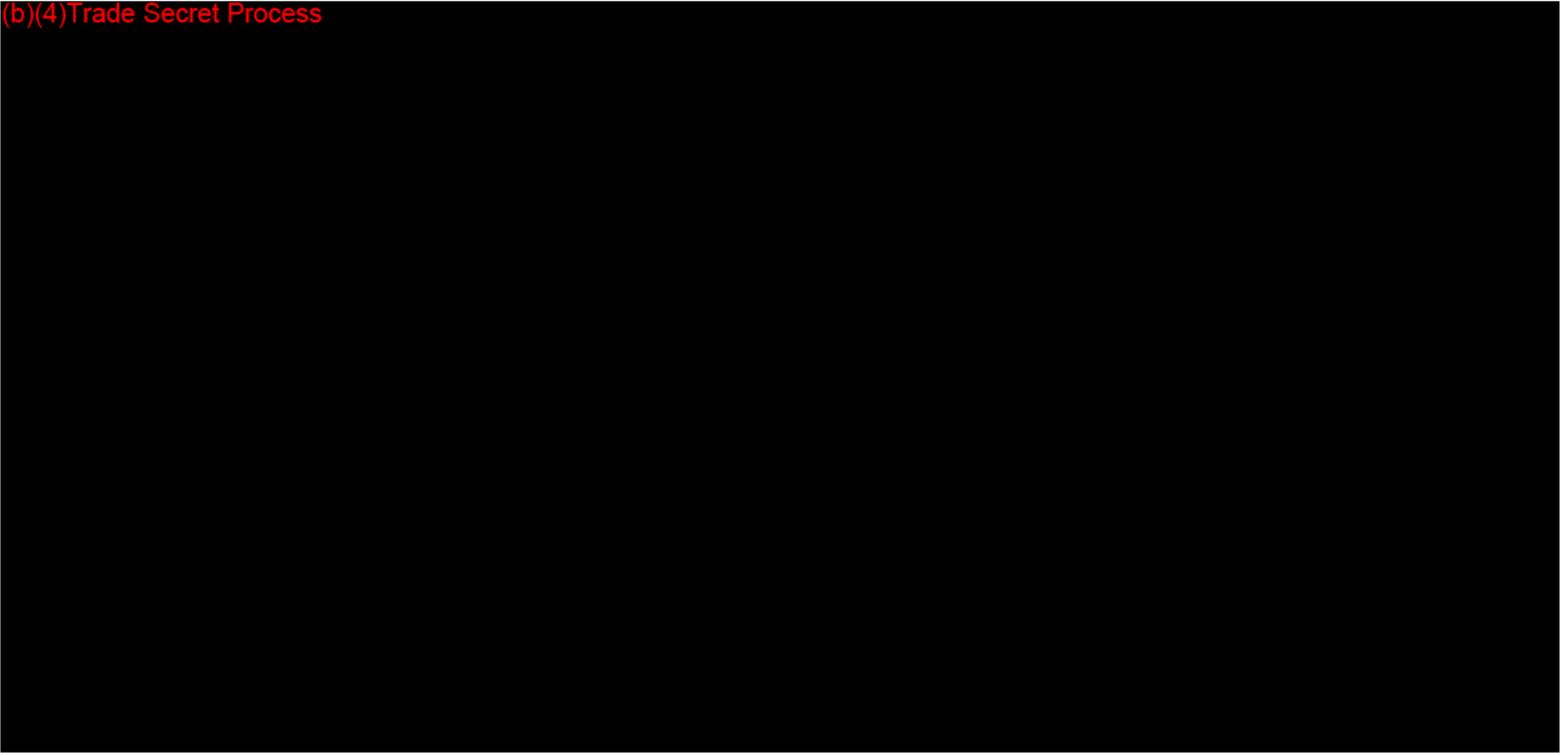
Shepherd, Tara N

From: Shepherd, Tara N
Sent: Monday, October 06, 2008 10:55 AM
To: 'teffany.hutto@djosurgical.com'
Subject: K082844 - Biolox Delta Ceramic Femoral Head

Attachments: Sample Design Control Activities Summary Table.doc

Ms. Hutto,

(b)(4)Trade Secret Process



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Biomedical Engineer
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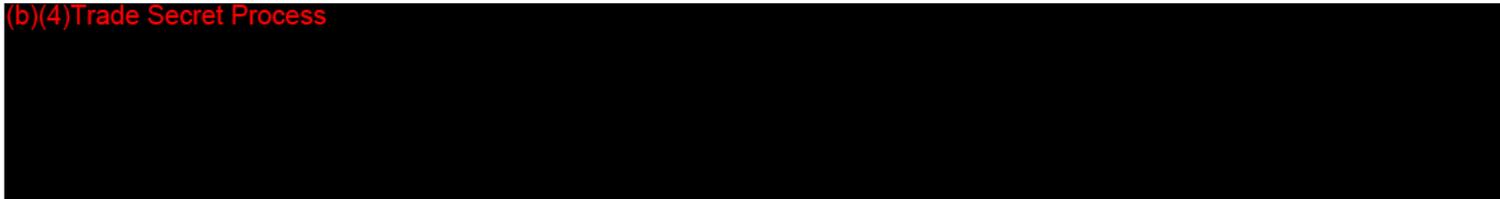
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Shepherd, Tara N

From: Hutto, Teffany [Teffany.Hutto@djosurgical.com]
Sent: Monday, October 06, 2008 4:28 PM
To: Shepherd, Tara N
Subject: RE: K082844 - BioloX Delta Ceramic Femoral Head
Attachments: Design Control Activities Summary.doc; FDA-3654_F1875-98.doc; FDA-3654_ISO 7206-10.doc

Dear Ms. Shepherd,

(b)(4)Trade Secret Process

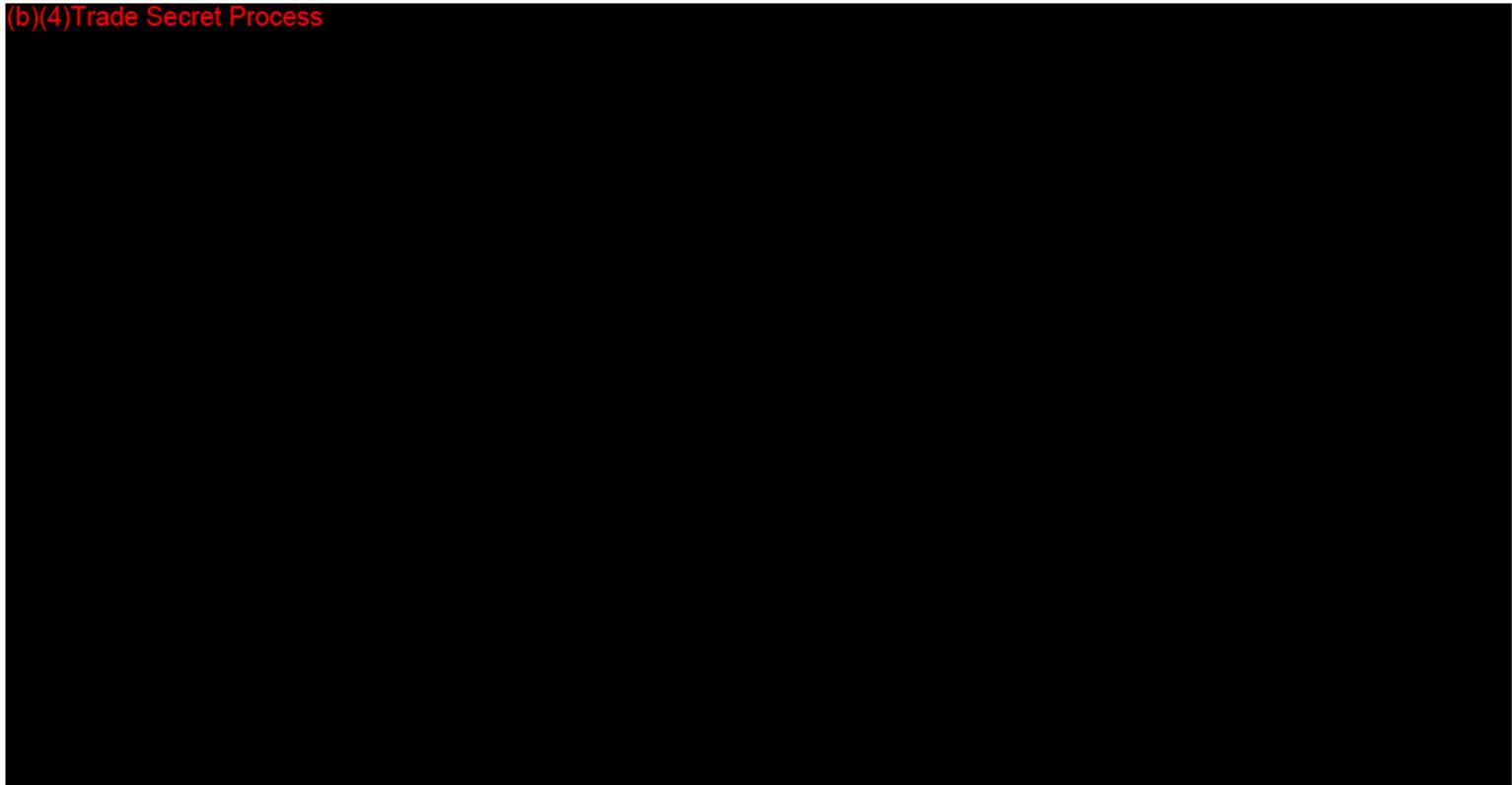


Best regards,
Teffany

From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Monday, October 06, 2008 9:55 AM
To: Hutto, Teffany
Subject: K082844 - BioloX Delta Ceramic Femoral Head

Ms. Hutto,

(b)(4)Trade Secret Process



(b)(4)Trade
Secret

Tara N. Shepherd, M.S.
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tara.shepherd@fda.hhs.gov

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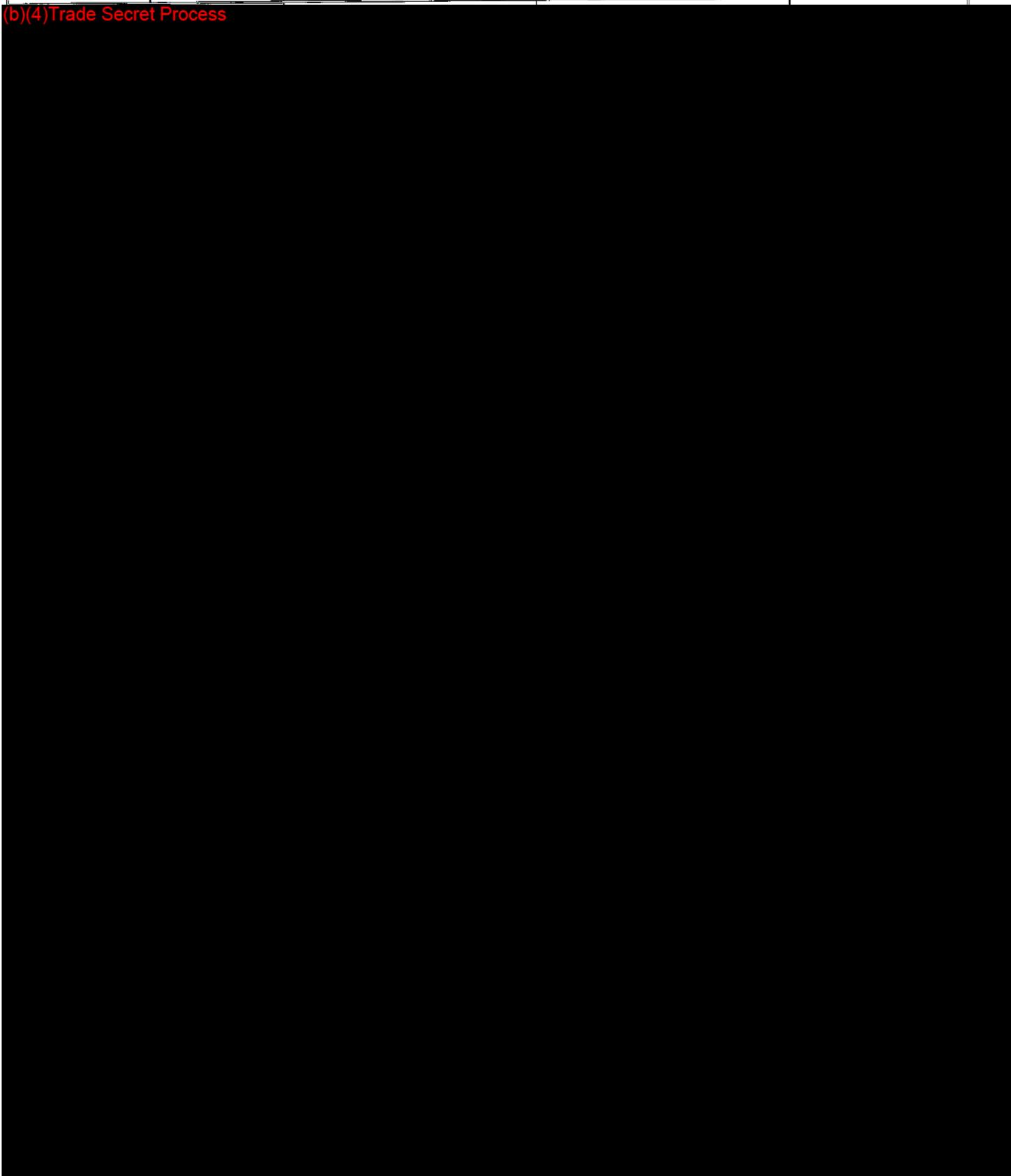
10/6/2008

86

Encore Medical BioloX *delta* Ceramic and *delta* Option Femoral Heads
"Design Control Activities Summary"

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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(b)(4) Trade Secret Process



Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F-1875-98- Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface.

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 020

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

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

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

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

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

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

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

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

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

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

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

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

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

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search of 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
----------------	---------------	---

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
----------------	---------------	---

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
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

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

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 7206-10 - Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
 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? Yes No

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

Does this standard include more than one option or selection of the standard? Yes No
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? Yes No
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS? Yes No
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? Yes No
 If yes, was the guidance document followed in preparation of this 510k? Yes No

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

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**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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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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TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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



November 10, 2008

ENCORE MEDICAL, L.P.
9800 METRIC BLVD.
AUSTIN, TEXAS 78758
UNITED STATES
ATTN: TEFFANY HUTTO

510k Number: K082844

Product: BIOLOX DELTA CERAMIC 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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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



~~K955563/A5~~

DJO Surgical
9800 Metric Boulevard
Austin, TX 78758-5445
T 800.456.9696
djosurgical.com

October 30, 2008

K082844/S1

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

FDA CDRH DMC
OCT 31 2008
Received

RE: Tara Shepherd

Re: Special 510(k) Notification - ~~K955563~~ - Foundation® Stems with BioloX® Heads

Dear Ms. Shepherd:

(b)(4)Trade Secret Process



Sincerely,

Tiffany Hutto
Tiffany Hutto
Manager, Regulatory Affairs

enclosure (as stated)

K34

S7

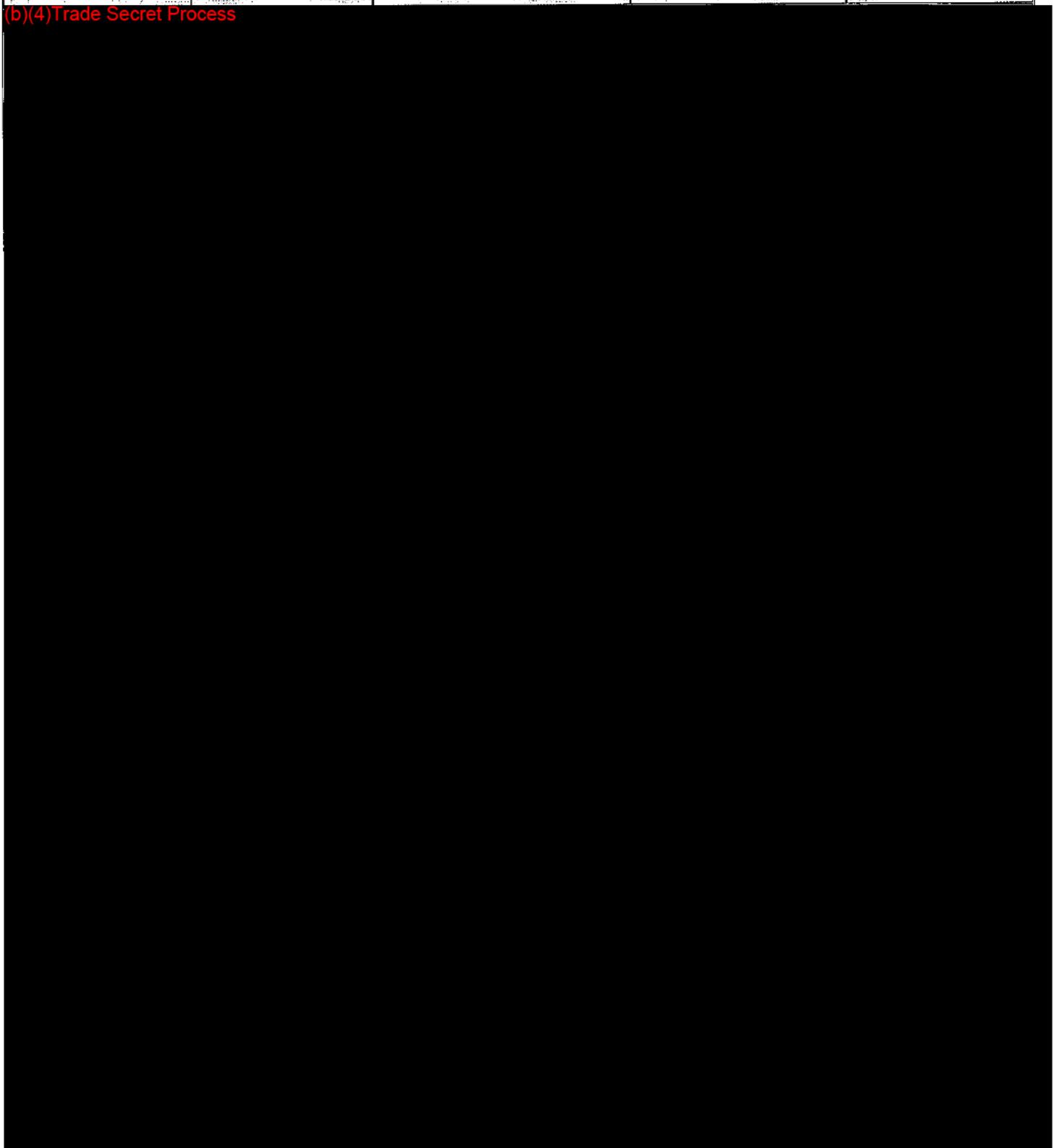


DJOglobal.com

Encore Medical BioloX *delta* Ceramic and *delta* Option Femoral Heads
"Design Control Activities Summary"
October 30, 2008

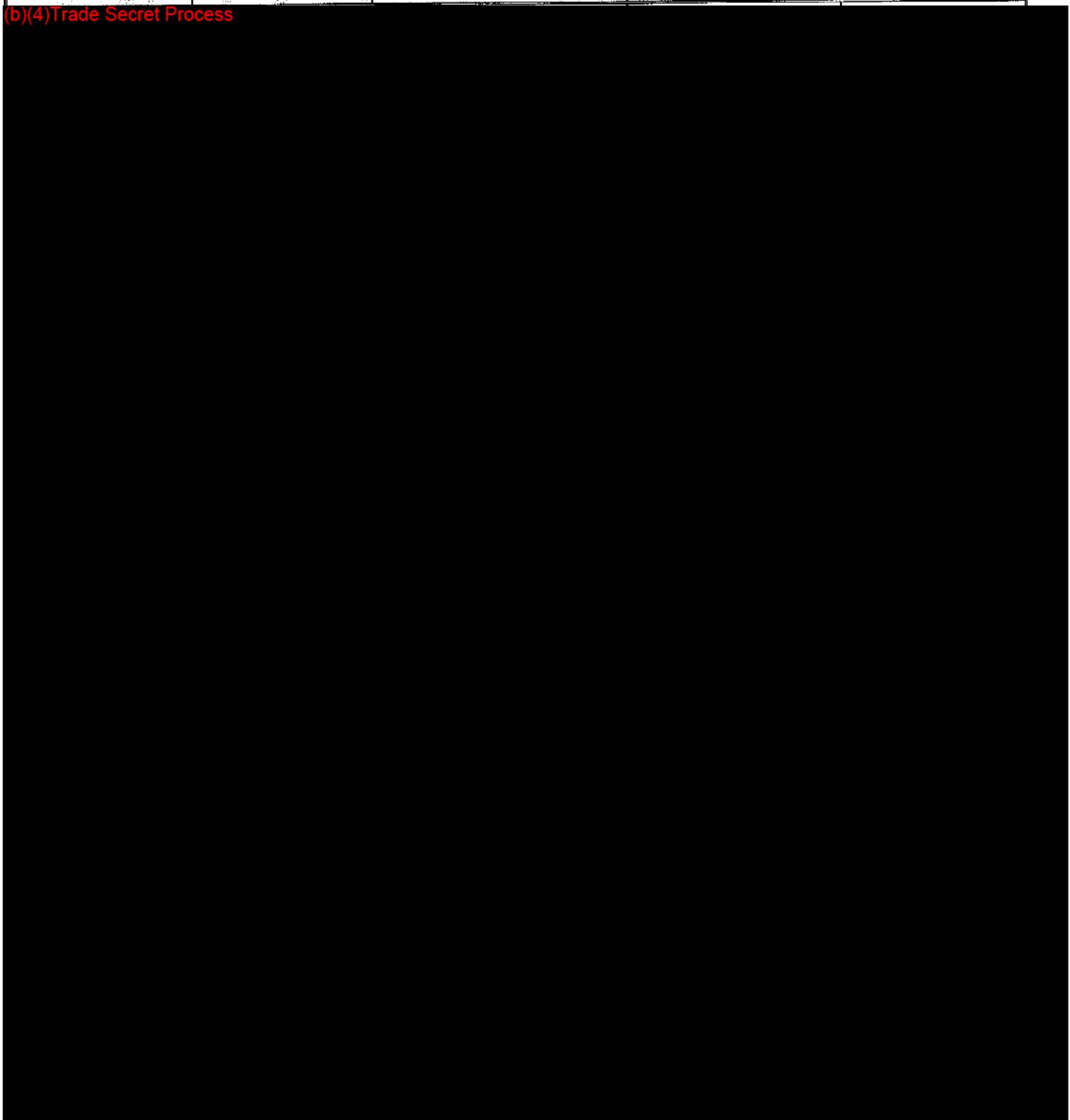
Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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(b)(4) Trade Secret Process



Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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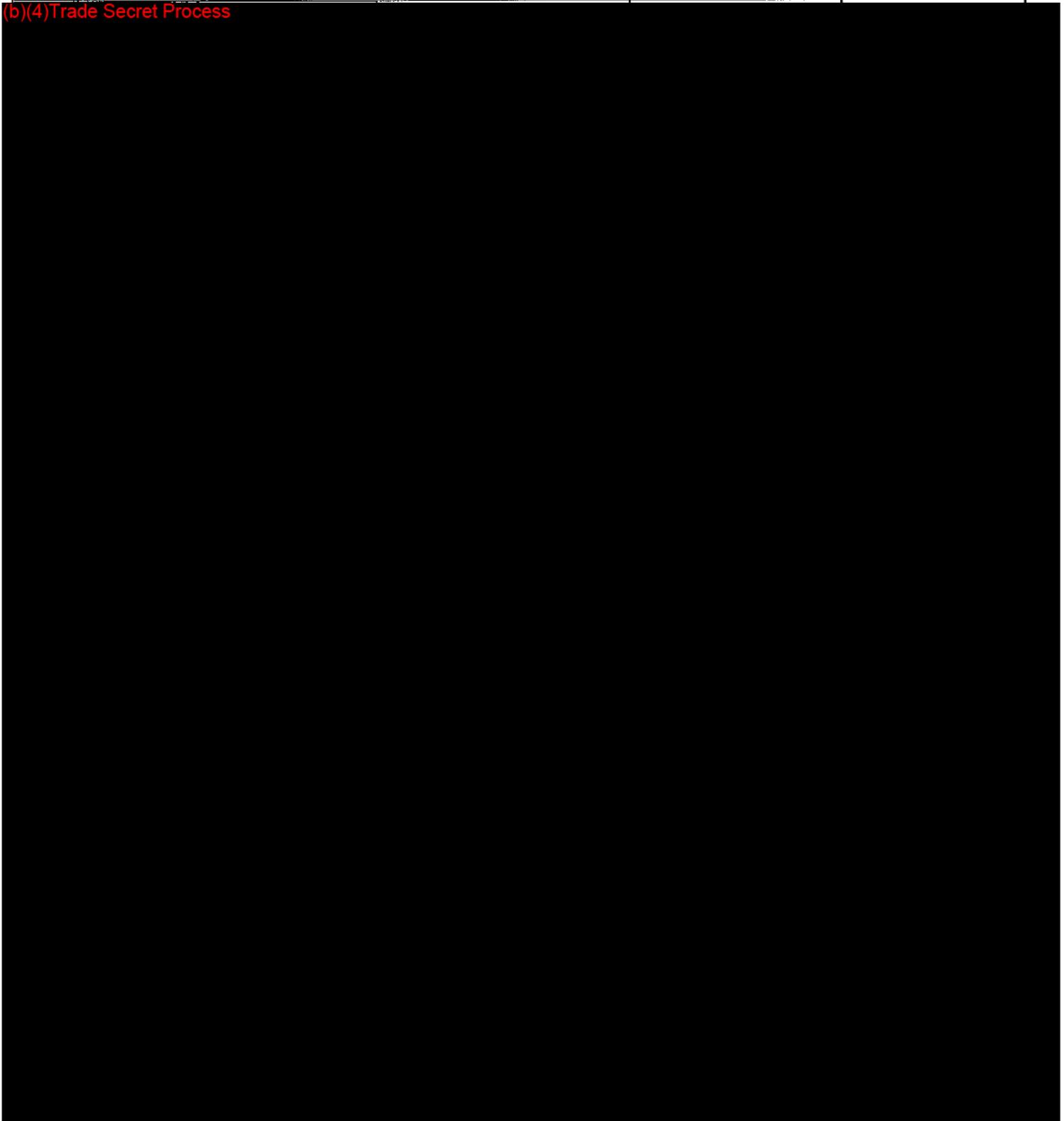
(b)(4) Trade Secret Process



Encore Medical BioloX *delta* Ceramic and *delta* Option Femoral Heads
"Design Control Activities Summary"
October 30, 2008

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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(b)(4) Trade Secret Process



Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
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(b)(4) Trade Secret Process

