

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 arthroscopy.

510(k) Summary  
BioloX<sup>®</sup> *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<sup>®</sup> *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



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<sup>®</sup> *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.

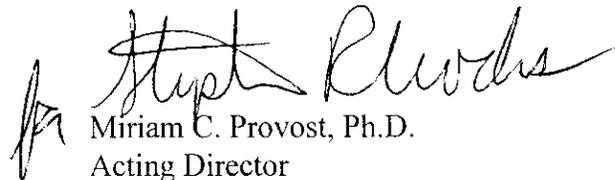
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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 with a large 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**

**510(k) Number** K042091



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<sup>®</sup> *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.

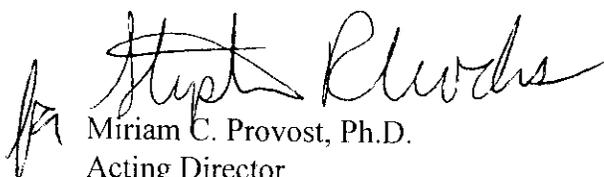
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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 with a large 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

November 26, 2004

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

BIOMET, INC.  
P.O. BOX 587  
WARSAW, IN 46581  
ATTN: PATRICIA SANDBORN BERES

510(k) Number: K042091  
Product: BIOLOX DELTA  
CERAMIC HEADS

Extended Until: 01-FEB-2005

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

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

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

Sincerely yours,

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



November 24, 2004

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Re: K042091  
BioloX® *delta* Ceramic Heads  
Reviewer: Peter Allen

507 Nov 24 4 19 52  
FOIA(b)(7)(C) - 10/20/04

Dear Mr. Allen:

Biomet requests a 60 day extension to complete the information requested in your November 1, 2004 deficiency letter for 510(k) K042091.

Sincerely,

  
Patricia Sandborn Beres  
Senior Regulatory Specialist

sk 30

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

SHIPPING ADDRESS  
56 E. Bell Drive  
Warsaw, IN 46582

OFFICE  
571.267.6639

FAX  
571.267.8137

E-MAIL  
biomet@biomet.com

132



NOV 1 - 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

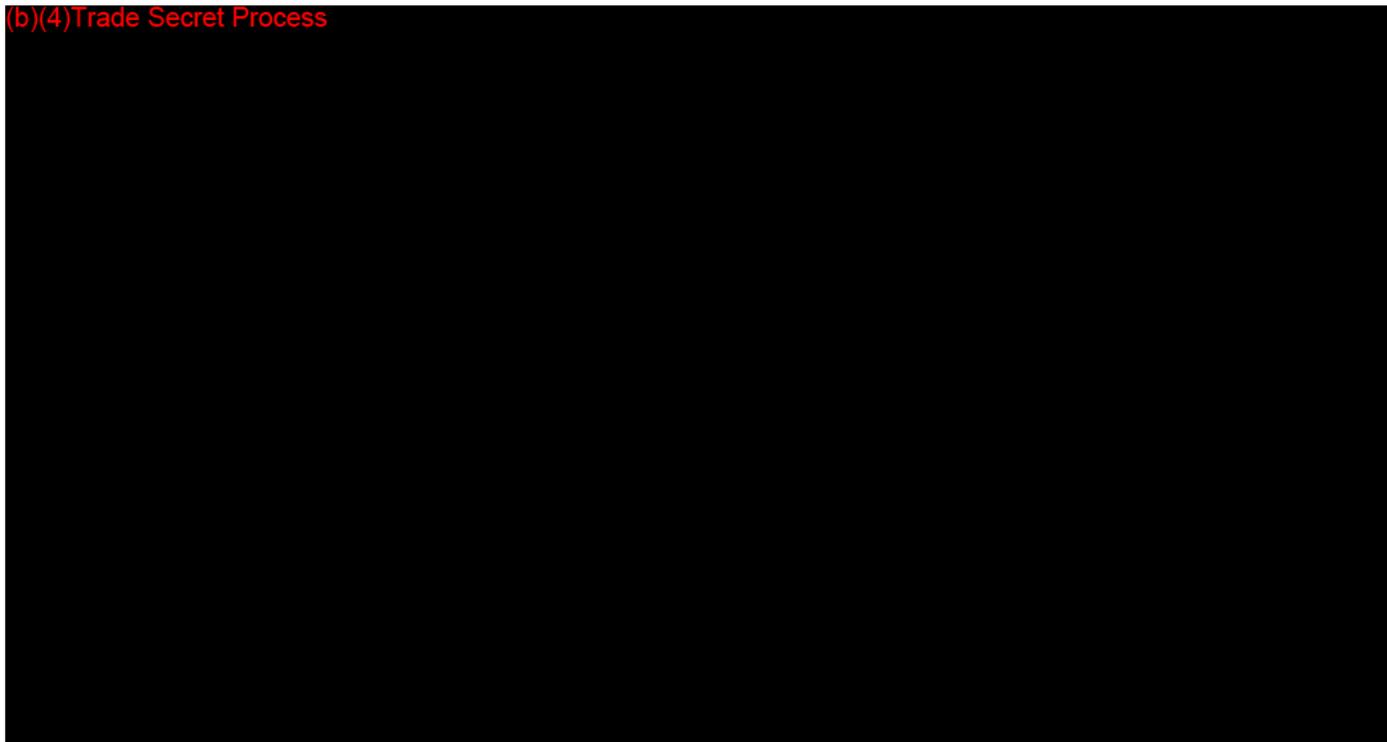
Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
Biomet Manufacturing Corporation  
56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K042091  
Trade Name: BioloX<sup>®</sup> *delta* Ceramic Heads  
Dated: August 2, 2004  
Received: August 3, 2004

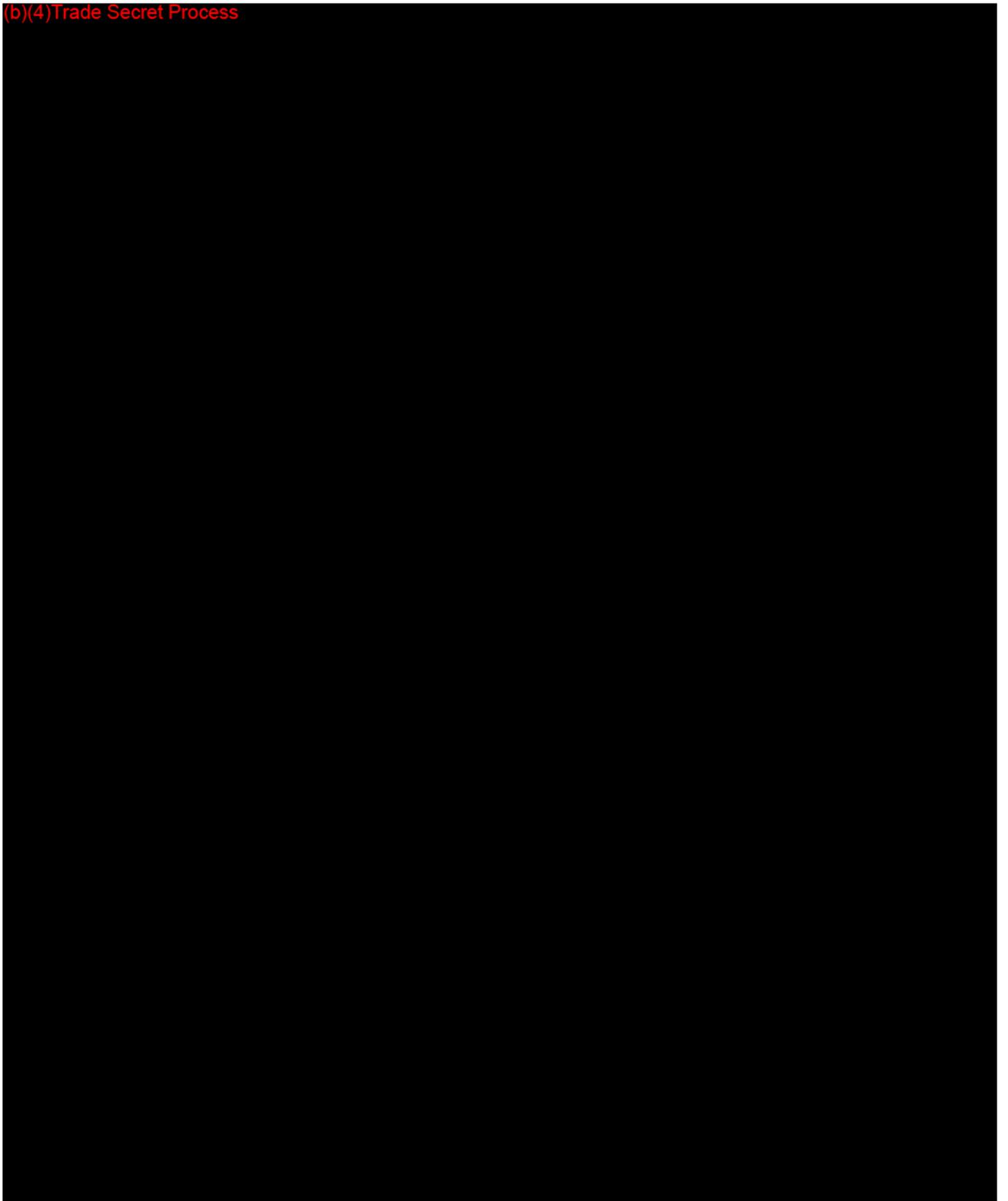
Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require additional information.

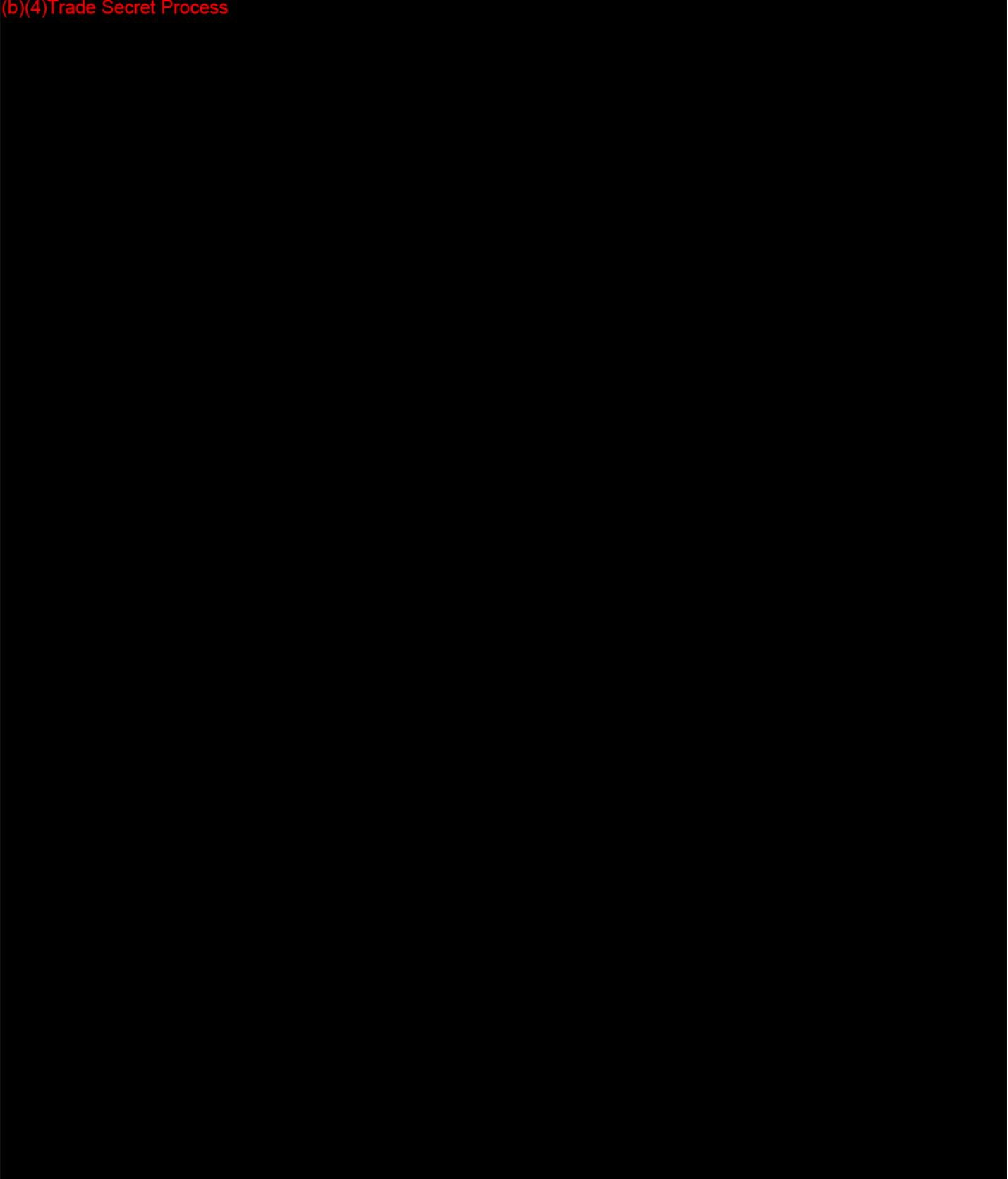
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

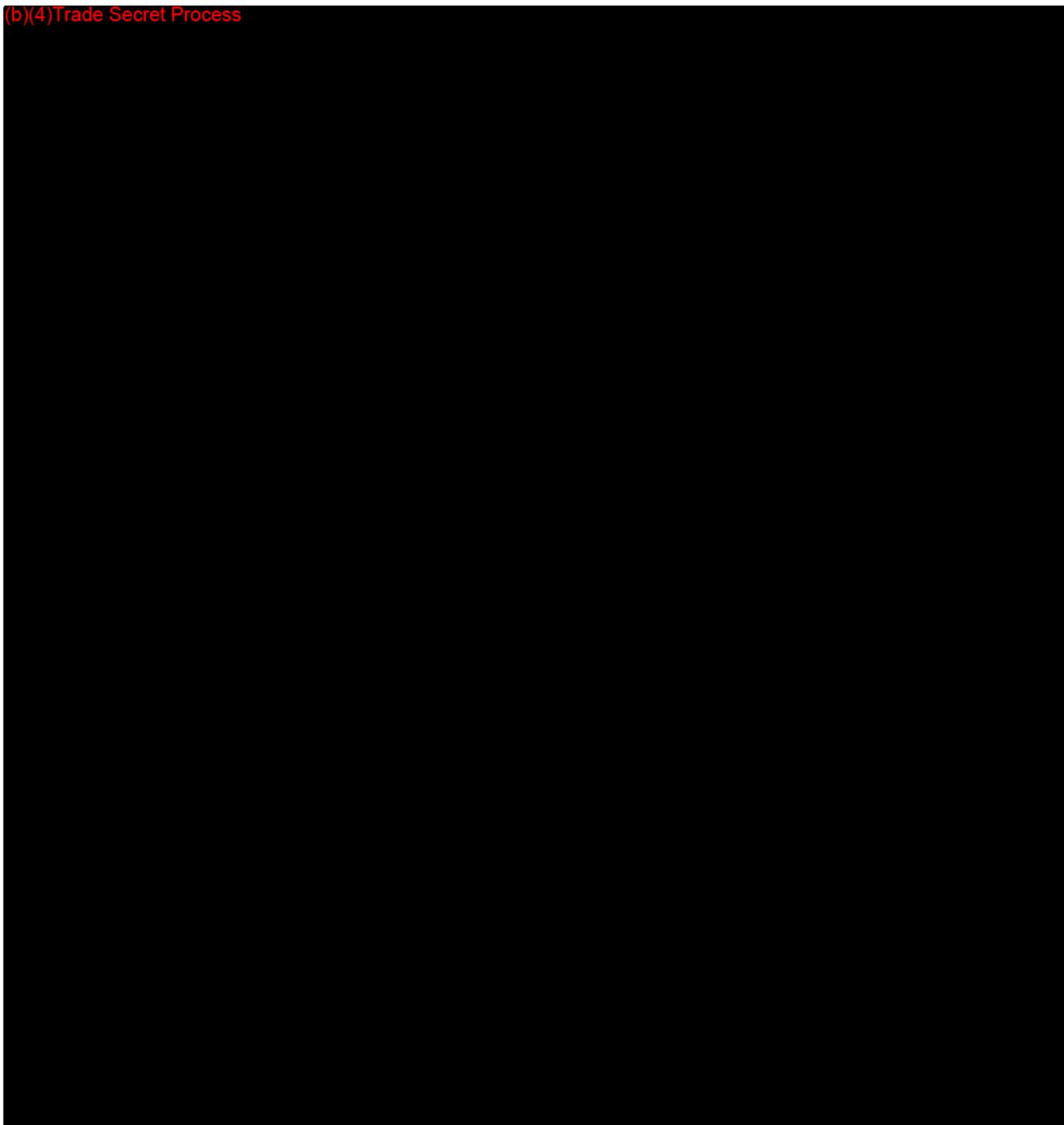


(b)(4)Trade Secret Process



15

(b)(4) Trade Secret Process



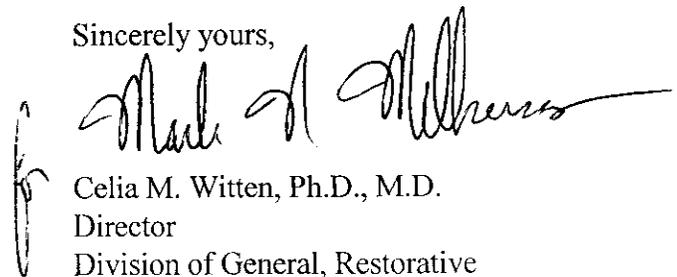
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, “Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment”. 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>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Mr. Peter Allen at (301) 594-2036. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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

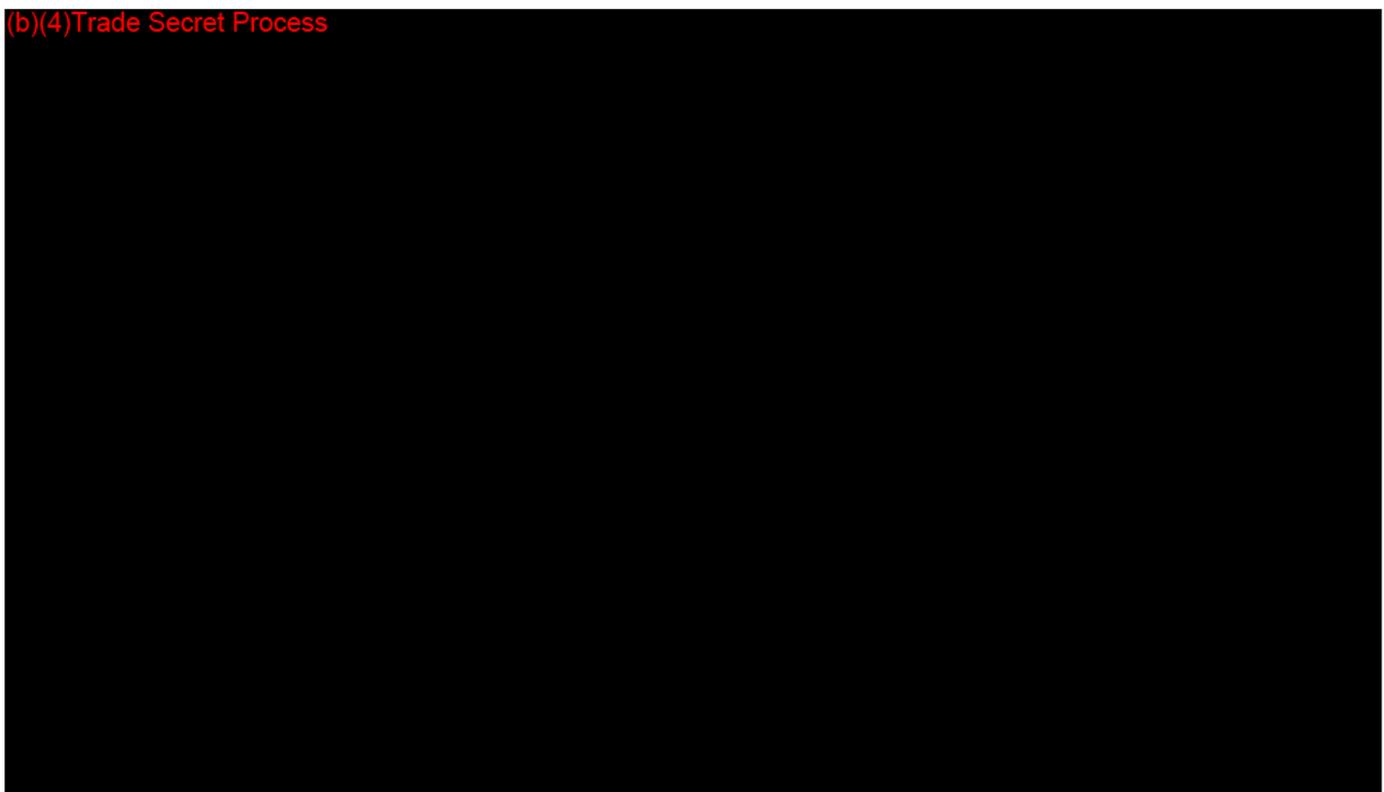
Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
Biomet Manufacturing Corporation  
56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K042091  
Trade Name: BioloX<sup>®</sup> *delta* Ceramic Heads  
Dated: August 2, 2004  
Received: August 3, 2004

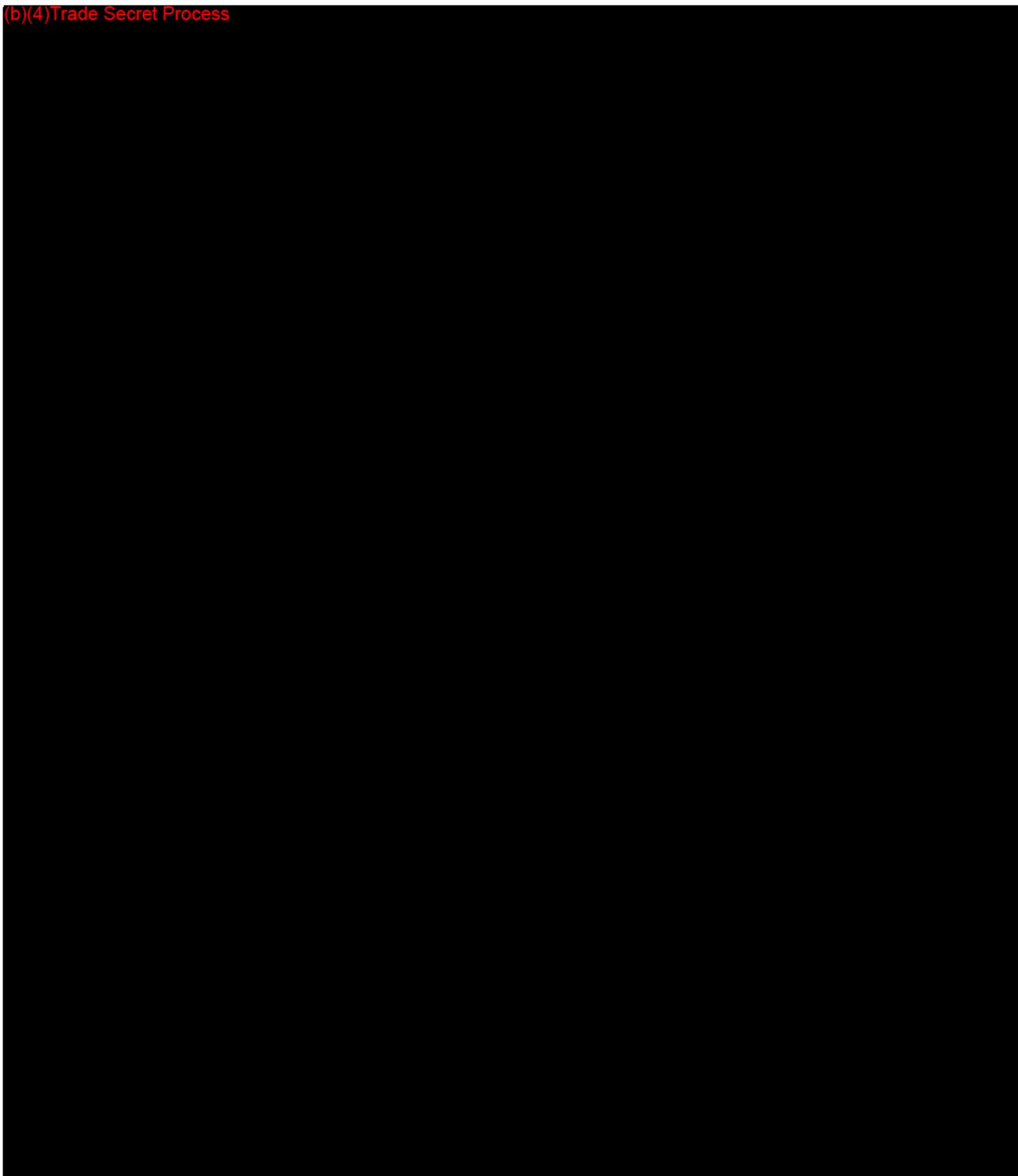
Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require additional information.

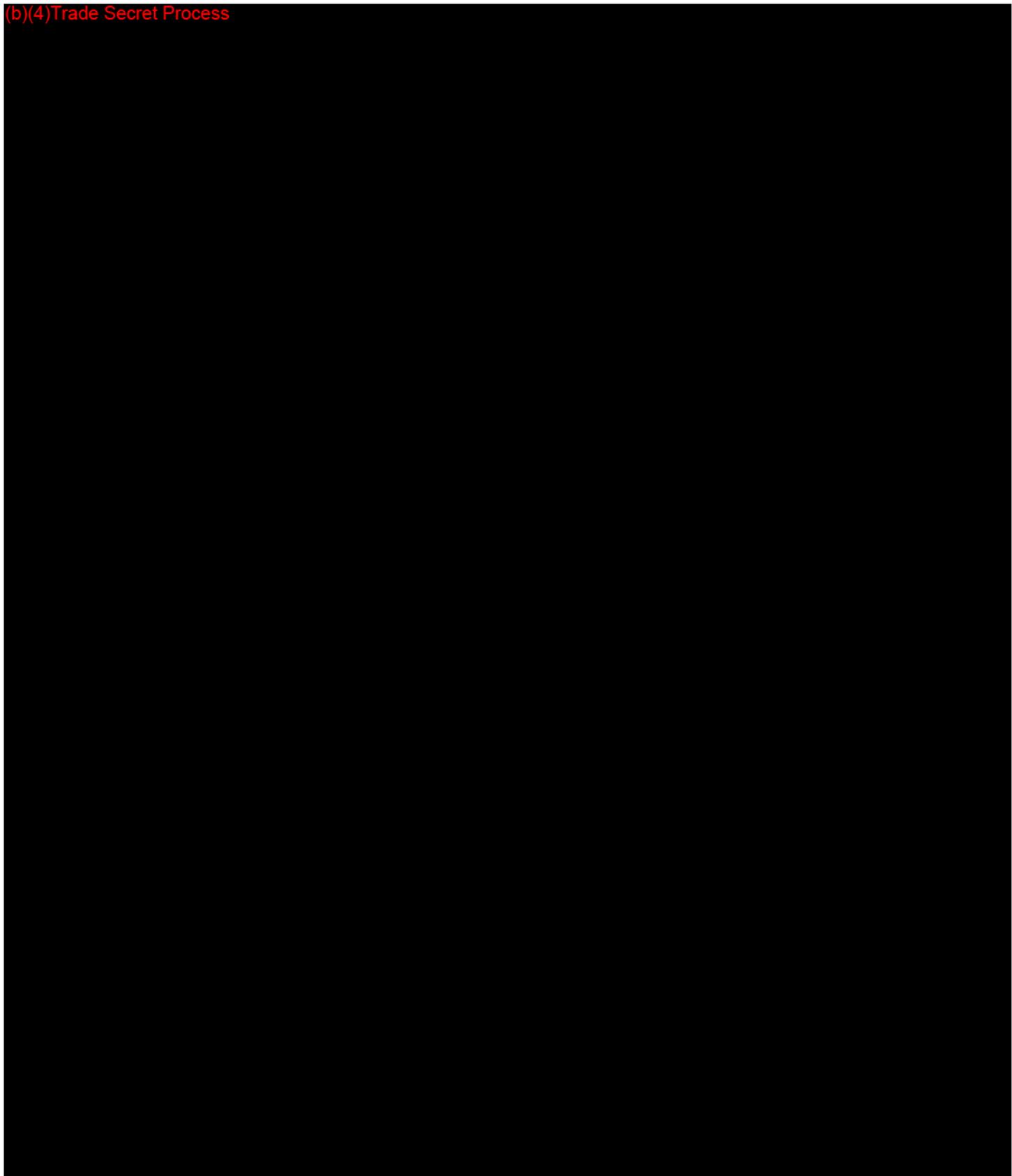
(b)(4)Trade Secret Process



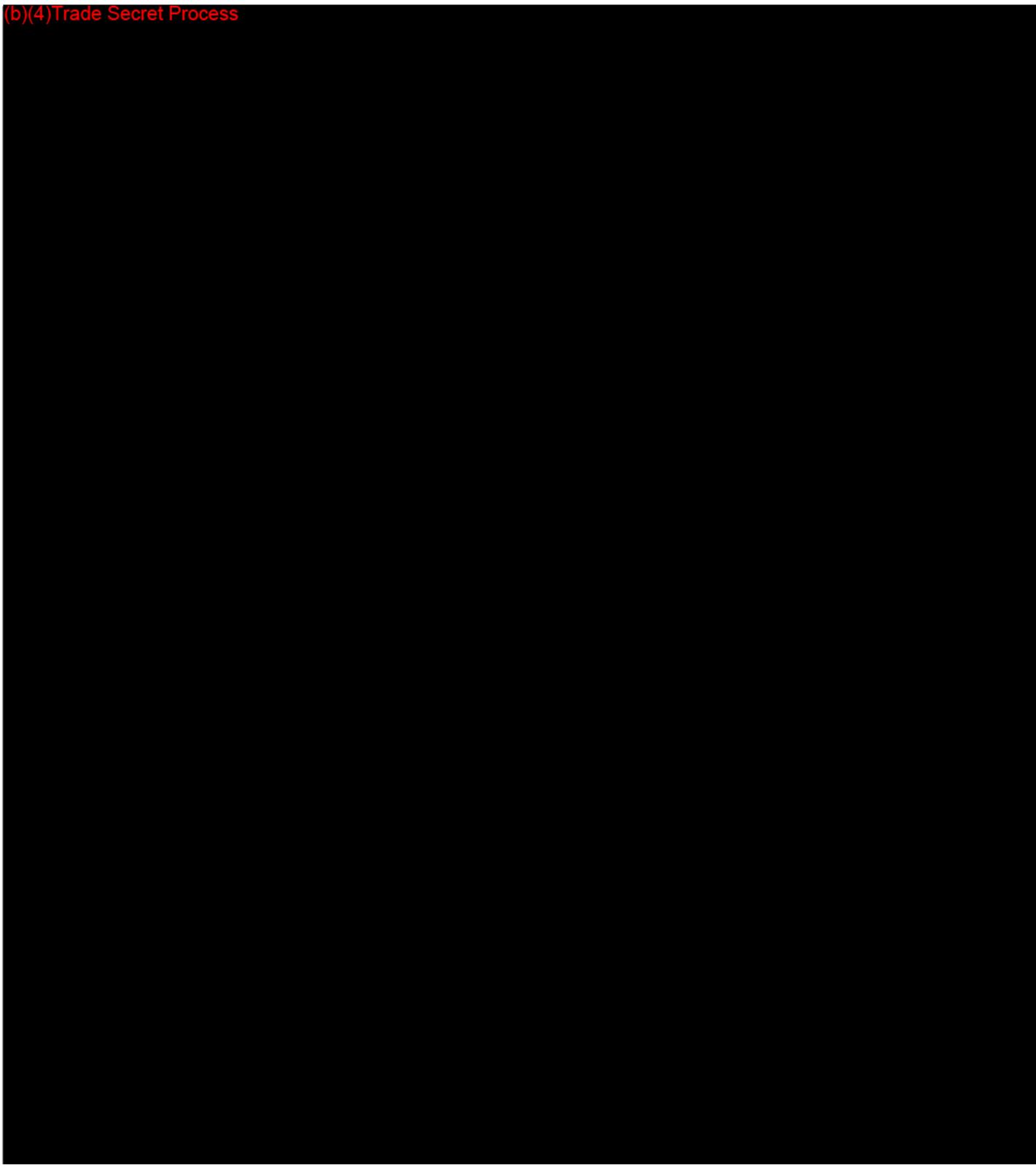
(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 5 – Ms. Patricia Sandborn Beres

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". 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/mdufima/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration  
 Center for Devices and  
 Radiological Health  
 Document Mail Center (HFZ-401)  
 9200 Corporate Boulevard  
 Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Mr. Peter Allen at (301) 594-2036. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

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

FILE  
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	P. Allen	10/29/04						
HFZ-410	Holden	11/1/04						
410	Witten	11/1/04						

142

Page 6 – Ms. Patricia Sandborn Beres

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ-410 Division  
D.O.  
f/t:PAllen:elh:10/29/04

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

August 03, 2004

BIOMET, INC.  
P.O. BOX 587  
WARSAW, IN 46581  
ATTN: PATRICIA SANDBORN BERES

510(k) Number: K042091  
Received: 03-AUG-2004  
Product: BIOLOX DELTA CERAMIC  
HEADS

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

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

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

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

Sincerely yours,

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

160209/



August 2, 2004

Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

For/For/For/For/For  
08/02/04 12:12:38

RE: BioloX® *delta* Ceramic Heads  
510(k) Premarket Notification  
Payment ID Number: 013131-956733

Dear Sir or Madam:

Enclosed is a 510(k) notification for BioloX® *delta* Ceramic Heads. We believe these devices to be substantially equivalent\* to other modular ceramic heads on the market.

The sponsor of this 510(k) considers the existence of this notification confidential until a determination of substantial equivalence is made. Permission to fax or e-mail information related to this submission is granted by the Sponsor.

Sincerely,

*Patricia Sandborn Beres*

Patricia Sandborn Beres  
Senior Regulatory Specialist  
Biomet Manufacturing Corp.

\*Any statement made in conjunction with this submission regarding and/or a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, 42 FR 42520 (Docket No. 76N-0355)]

OK  
II

5134

MAILING ADDRESS  
P.O. Box 5877  
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

162

## Table of Contents

User Fee Cover Sheet .....	1
Premarket Notification Truthful and Accurate Statements .....	2
Indications for Use Form.....	4
Masterfile Access Letter.....	5
<b>510(k) Notification</b>	
A. Administrative Information.....	6
B. Device Identification .....	6
C. Device Descriptive Information .....	7
D. 510(k) Summary.....	12
Exhibit 1 - Guidance Document.....	13
Exhibit 2 - Listing of Compatible Stems .....	21
Exhibit 3 - Cone Design .....	23
Exhibit 4 - Product Listing .....	32
Laser Etch Information.....	33
Exhibit 5 - Radiation.....	34
Exhibit 6 - Engineering Drawings.....	39
Exhibit 7 - Static Burst Testing.....	42
Exhibit 8 - Fatigue and Residual Strength Testing .....	79
Exhibit 9 - Pull-off Testing .....	95
Exhibit 10 - Wear Testing.....	101
Exhibit 11 - Sample Label.....	108
Package Insert.....	109
Exhibit 12 - Predicate device comparison and information .....	111
Exhibit 13 - 510(k) Summary .....	126

Form Approved OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: <b>(b)(4)Trade Secret Process</b> Write the Payment Identification Number on your check.		
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
<ol style="list-style-type: none"> <li>1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.</li> <li>2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.</li> <li>3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)</li> <li>4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)</li> <li>5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <a href="http://www.fda.gov/cdrh/mdufma/faqs.html#3a">http://www.fda.gov/cdrh/mdufma/faqs.html#3a</a>. You are responsible for paying all fees associated with wire transfers.</li> <li>6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.</li> </ol>			
1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)  BIOMET MANUFACTURING CORP 56 EAST BELL DRIVE P.O. BOX 587 WARSAW, IN 46581-0578  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 352074037	2. CONTACT NAME PATRICIA BERES  2.1 E-MAIL ADDRESS patty.beres@biometmail.com  2.2 TELEPHONE NUMBER (Include Area Code) 574-267-6639  2.3 FACSIMILE (FAX) NUMBER (include Area Code) 574-372-1683		
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> )  Select an application type: <table style="width:100%; border: none;"> <tr> <td style="width:50%; vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews  <input type="checkbox"/> Biologics License Application (BLA)  <input type="checkbox"/> Premarket Approval Application (PMA)  <input type="checkbox"/> Modular PMA  <input type="checkbox"/> Product Development Protocol (PDP)  <input type="checkbox"/> Premarket Report (PMR)                     </td> <td style="width:50%; vertical-align: top;">                     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 reviews <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	3.1 Select one of the types below: <input checked="" type="checkbox"/> Original Application  Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
<input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	3.1 Select one of the types below: <input checked="" type="checkbox"/> Original Application  Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)  <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business  4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table style="width:100%; border: none;"> <tr> <td style="width:50%; vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms   <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only                     </td> <td style="width:50%; vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population   <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially                     </td> </tr> </table>		<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms  <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population  <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms  <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population  <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)  <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)			

**(b)(4)Trade Secret**

(08/2003)

**PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT  
(As Required by 21 CFR 807.87(j))**

I certify, in my capacity as a Chief Scientist of Biomet Manufacturing Corp., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
\_\_\_\_\_  
Signature

David W. Schroeder  
Typed Name

July 29, 2004  
Date

Biolog® delta Ceramic Heads  
Device

165

**PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT**  
(As Required by 21 CFR 807.87(j))

I certify, in my capacity as Vice President of Regulatory Affairs and Quality Assurance, Biomet Manufacturing Corp., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
Signature

Robert E. Durgin  
Typed Name

2 AUGUST 04  
Date

Biolog® delta Ceramic Heads  
Device

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: BioloX® delta Ceramic Heads

Indications For Use:

BioloX® delta Ceramic Heads are indicated for use with cemented or non-cemented femoral 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.

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)



**510(k) Notification**

**A. ADMINISTRATIVE INFORMATION**

**Applicant or Sponsor:** Biomet Manufacturing Corp.  
56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581-0587

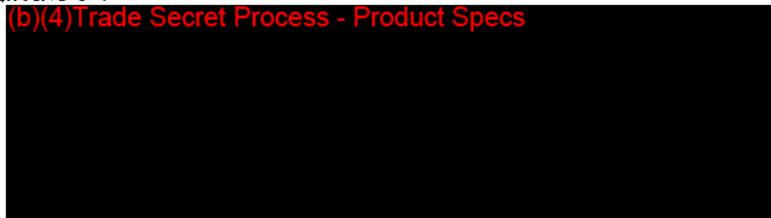
**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist  
Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, Indiana 46581-0587  
Phone: (574) 267-6639  
FAX: (574) 372-1683  
E-Mail: patty.beres@biometmail.com

**Manufacturing Site(s):**

Specification holder:  
Biomet Manufacturing Corp.  
56 East Bell Drive  
Warsaw, Indiana 46582  
Establishment Registration Number: 1825034

Contract Manufacturer:

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



Contract Sterilizer(s):

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



**B. DEVICE IDENTIFICATION**

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

**Common or Usual Name:** Ceramic Modular Head

**Classification Name:** Hip joint/ceramic/polymer, semi-constrained, cemented or non-cemented prosthesis

**Device Classification:** Class II

**Device Product Code:** LZO

**Performance Standards/Guidance Documents:** No performance standards have been developed for this type of device. The draft guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" was followed for the preparation of this 510(k). A copy of this document may be found in Exhibit 1.

**Previous FDA Status:** The ceramic heads in this submission are currently being used in Biomet's Ceramic on Ceramic IDE study G000075.

C. DEVICE DESCRIPTIVE INFORMATION

**Intended Use:** Biolox® *delta* Ceramic Heads are indicated for use with cemented or non-cemented femoral 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.

**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 modular heads 28mm in diameter with neck lengths of -3, 0, +3 and +5 and 32mm in diameter with neck lengths of -3, 0, +3 and +6.

The remainder of this Device Description section follows the format of the guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems".

Identification of the Stem

Exhibit 2 contains a listing of the femoral components compatible with Biolox® *delta* Ceramic Heads contained in this submission. For each stem design the following information is provided:

- 1) The name of each stem family is presented on the table in Exhibit 2.
- 2) The 510(k) numbers under which each stem was cleared are listed in the table in Exhibit 2.

170

- 3) In lieu of a drawing of each hip stem, a detailed drawing of the taper trunion is provided in Exhibit 3.
- 4) [REDACTED] (b)
- 5) The 510(k) numbers under which each stem was cleared are listed on the table presented in Exhibit 2.
- 6) All of the devices are metallic hip stems with or without porous coating. Each stem has a Biomet Type I trunion for attachment of the modular head.
- 7) The intended use of the stem (cemented or non-cemented) is listed on the table in Exhibit 2.
- 8) The BioloX® *delta* Ceramic Heads presented in this submission are compatible with all the stems listed in Exhibit 2.

Cone Design

Exhibit 3 contains a dimensioned engineering drawing of the taper cone including the following critical dimensions:

*Biomet Type I taper trunion*

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



A graphic depiction of the overlap may be found in Exhibit 3.

- A) Only one cone taper type is considered in this submission.
- B) The cone trunion described above was evaluated in all testing contained in this submission

Identification of the Ball

- 1) The name and manufacturer's model numbers for each modular head may be found in Exhibit 4.
- 2) None of the modular heads that are contained within this submission have previously been marketed in the United States.
- 3) The heads are manufactured from an alumina-based ceramic composite known as Transition-Toughened-Platelet Alumina (TTPA) under the trademark BioloX® *delta*. TTPA is a ceramic material that has optimized properties for hardness and strength. The TTPA material is made [REDACTED] (b) [REDACTED]. The complete composition of this material may be found in the following table and additional material information may found in [REDACTED] (b) [REDACTED]

(4) Trade Secret

Component	Content by Wt %
(b)(4)Trade Secret Process - Product Specs	

Regarding the engraving:

- 1) Magnified photos of the modular head engraving may be found in Exhibit 4. The engineering drawings contained within Exhibit 6 details the engraving marks.
- 2) [REDACTED] (b)(4)Trade Secret
- 3) A description of the engraving process and the point in the manufacturing process where engraving takes place is contained within the manufacturing information in [REDACTED] (b)

Regarding radioactive isotopes, an analysis of the natural radioactive impurities of the material is provided in Exhibit 5. The radioactivity level was below the proposed upper limit set by ISO 13356.

Ball Design

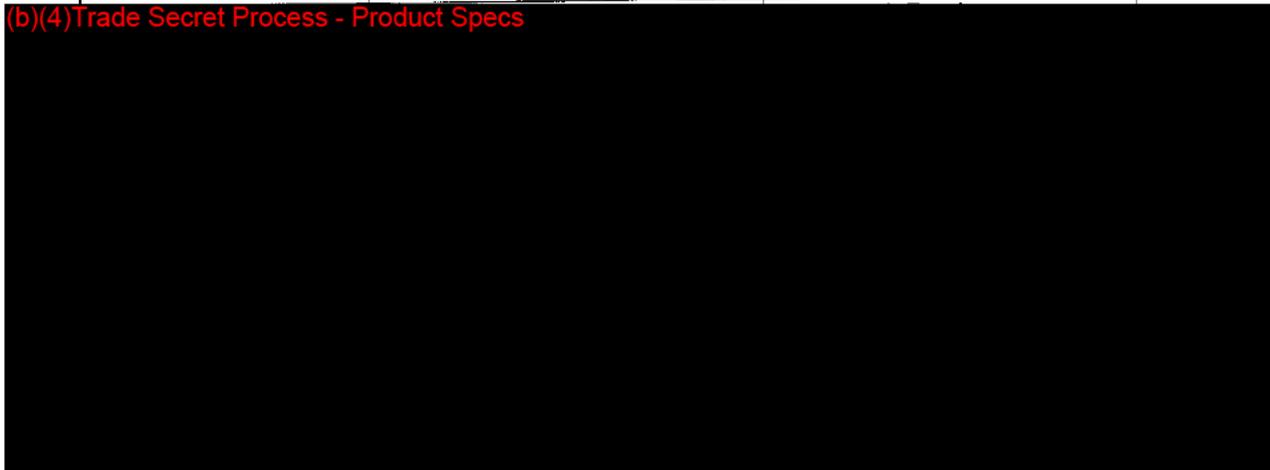
Dimensioned engineering drawings of the modular heads can be found in Exhibit 6. On these drawings may be found:

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

As the devices are an alumina-based ceramic composite, the following information from (b)(4)Trade Secret Process - Product Specs is provided:

	Guidance Document Limit	BioloX® <i>delta</i> Modular Heads
--	-------------------------	------------------------------------

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

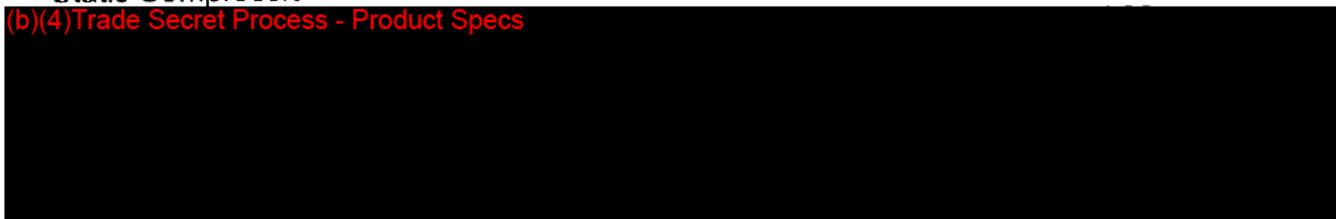


Mechanical Testing

The modular heads and taper trunions used for mechanical testing are representative of the design tolerances of the product to be shipped for clinical use and the ceramic test specimens have the same composition and structure as those to be marketed.

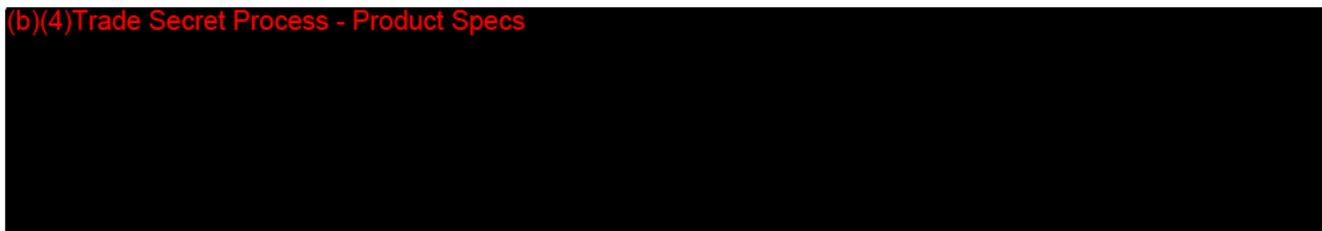
Static Compression

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



The +3mm, 28mm and 32mm, components have proven acceptable for the cobalt alloy tapers, as well as titanium alloy tapers. Reports may be found in Exhibit 7.

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

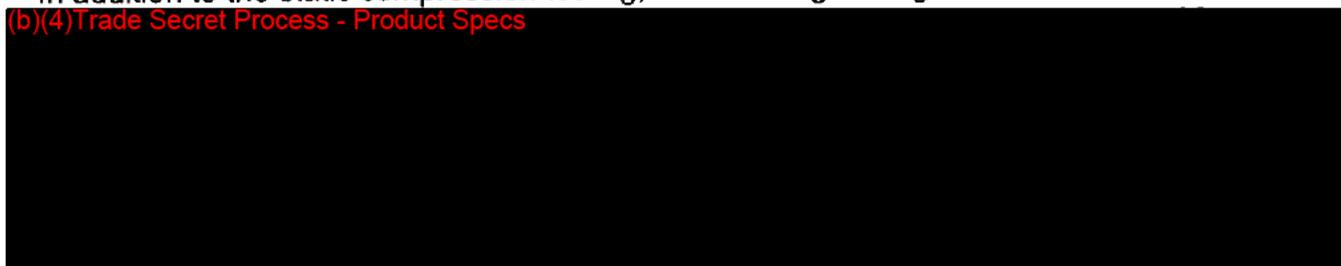


This testing may also be found in Exhibit 7.

New Ball Mechanical Testing

In addition to the static compression testing, the following testing has been conducted:

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



no. 4 doc 514, 32mm + 10mm heads



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

**Labeling:** Exhibit 11 contains the package insert for Biomet ceramic heads. This document has incorporated the following items from the guidance documents:

- 1) The package insert states that the devices should not be resterilized (under Sterility) thus eliminating the need for a statement that the ball must not be sterilized on the hip stem.
- 2) The package insert states that the devices should not be resterilized (under Sterility) thus eliminating the need for a statement that autoclaved balls should not be cooled rapidly.
- 3) The stem cone and ball bore should be dry and free of contamination. (Warning #8)
- 4) The ceramic ball should not be implanted if the ball or the cone of the stem are possibly damaged. (Warning #6)
- 5) The ball should be placed on the stem cone gently while keeping the ball and cone in alignment, then firmly attached by sharply hitting the ball with a soft plastic hammer. (Warning #7)

**Sterility Information:** Devices are provided sterile by radiation methods as follows:

- Radiation Type: Gamma
- Radiation Source: (b)
- Minimum Dosage: 2.5 Megarads
- Maximum Dosage: 4.0 Megarads
- Sterility Assurance Level: 10<sup>-6</sup>
- Sterility Validation Method: (b)
- Pyrogen-Free: no claims will be made
- Labeling: All packages will display a yellow to red chemical indication dot along with a statement that the device has been sterilized by gamma irradiation, 2.5 Mrads.
- Sterilization Sites:



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

A summary of Biomet's sterilization methods is presented in Biomet's Masterfile (b) (4) Trade Secret. Sample bioburden audits and pyrogen testing is also included. Both of these tests are done on a periodic basis for all Biomet devices.

**Packaging Description:** Each component is placed in a plastic bag and between two foam pads. They are then placed in an inner blister pack sealed with a Tyvek® lid that fits into an outer blister pack also sealed with a Tyvek® lid. The entire unit is placed in a cardboard box, shrink wrapped for protection.

**Substantial Equivalence:** In design, the BioloX® *delta* Ceramic Heads in this submission have a (b)(4) Trade Secret Biomet Zirconia Ceramic Modular Heads cleared through 510(k) K943586, K925345 and K905687.

#### Indications for Use

The predicate devices did not specify the indications for use but the devices were cleared for use with femoral hip stem components cleared for the indications identical to those for the BioloX® *delta* Ceramic Heads.

#### Technological Characteristics

Substantial equivalence between the Biomet device and those listed above can be based on the following factors:

- Head diameters are identical
- Neck lengths fall within the range of those previously cleared
- The angle of the taper bores are identical
- All devices meet the parameters outlined in the FDA's guidance document for Ceramic Ball Hip Systems

(b)(4) Trade Secret, the contract manufacturer, has informed Biomet that another 510(k) has cleared for BioloX-*delta* ceramic heads but would not specify the 510(k) number or Sponsor. We believe it is 510(k) K031803, DePuy Ceramic Femoral Heads. This predicate has similar indications for use and technological characteristics to the current device.

Exhibit 12 contains a comparison table and predicate device information.

#### D. 510(k) SUMMARY

A summary of information pertaining to the safety and effectiveness of this type of device is contained in Exhibit 13.

---

*All trademarks are owned by Biomet, Inc. except for the following:  
Tyvek is a trademark of trademark of E.I. duPont de Nemours and Company  
BioloX is a trademark of Feldmuhle Anlager und Produktions – GHBH Corporation*

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

**GUIDANCE DOCUMENT FOR THE PREPARATION OF PREMARKET  
NOTIFICATIONS FOR CERAMIC BALL HIP SYSTEMS**

**DRAFT**

**January 10, 1995**

**PLEASE FORWARD YOUR COMMENTS TO:**

Orthopedic Devices Branch  
Division of General and Restorative Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

9200 Corporate Boulevard  
Rockville, MD 20850  
301-594-2036

176

## CONTENTS

### PREFACE

The FDA has reclassified the hip joint metal/ceramic/polymer semi- constrained cemented or non-cemented prosthesis (referred to in this document as ceramic ball hip system) from class III (premarket approval) into class II (performance standards) (see Federal Register, vol. 53, No. 103). A premarket notification (510k) must be submitted by all distributors of ceramic balls and hip stems labeled for use with a ceramic ball.

The purpose of this document is to recommend to the device manufacturer or sponsor of premarket notifications (510(k)), Investigational Device Exemption (IDE), Premarket Approval (PMA), reclassification petition, or master file important information that should be submitted to FDA in order for FDA to determine the substantial equivalence and/or safety and effectiveness of hip systems which may include a ceramic ball. The development of this guidance document was based on data in a reclassification petition filed by PROTEK, Inc., Indianapolis, IN, and on the evaluation of the literature concerning ceramic ball hip systems by the Division of Surgical and Rehabilitation Devices (DSRD) . It suggests some important evaluation criteria, test procedures, and end points that FDA feels are necessary to provide reasonable assurance of substantial equivalence and/or safety and effectiveness of ceramic ball hip systems. Although this guidance document contains certain administrative requirements, it does not replace the requirements of the 21 CFR 801 or 807 or the statute.

FDA may require information in addition to what is contained in this document if circumstances require it. In other instances, the sponsor may be able to sufficiently justify the omission of some tests. Suggestions and recommendations presented in this document are not mandatory requirements, but reflect data and methodologies which ORDB has determined to be acceptable. Therefore, the words "should", "must" and "shall" are not used in a regulatory sense and should not be construed as such. They express FDA's current feeling as to what constitutes good scientific decision making.

The guidance document should be viewed as a living document. As scientific knowledge changes and scientific techniques are improved, FDA will revise the document. Nonetheless, the basic objectives will remain the same.

### IDENTIFICATION OF THE STEM

The following must be tabulated for each stem having the cone design and ceramic balls specified below:

- 1 the names,
- 2 510k or PMA numbers,
- 3 a drawing or photograph,
- 4 materials composition, standard number, trade name and original manufacturing source,
- 5 documentation of substantial equivalence or approval (e.g., a copy of the letter from FDA),
- 6 a brief description of the design and main processing methods (e.g., wrought, porous sintered coating, nitrided, radiation sterilized),

- 7 whether the stem was cleared for cemented use only, and
- 8 the model numbers of each ceramic ball to be used with each stem.

### CONE DESIGN

A table or dimensioned engineering design drawings must be provided which include tolerances for the following dimensions:

- 1 angle,
- 2 length,
- 3 diameter,
- 4 straightness,
- 5 surface texture (e.g., machined grooves),
- 6 surface roughness,
- 7 length of ball/cone overlap,

The table or dimensioned engineering design drawings must include all:

- A. cone tapers of all stems under consideration, and
- B. cone trunions evaluated in the tests listed below.

### IDENTIFICATION OF THE BALL

The following should be tabulated for the ceramic balls identified above:

- 1 the names and manufacturer model numbers,
- 2 known MAF, 510k and PMA numbers in which each ball was cleared for marketing and documentation of substantial equivalence or approval, and
- 3 material composition, standard number, trade name and names of establishments processing and providing the main ingredients.

The following must be provided regarding surface engravings:

- 1 magnified photos of any engravings on the ball,
- 2 an evaluation of any surface changes (e.g., phases) and defects (e.g., cracks, pits) in and around the engraving, and
- 3 a description of the engraving process and the point in the manufacturing of the ball where the engraving is made.

The following information on radioactive isotopes must be provided:

- 1 concentrations as determined from the spectra and intensity of the radiation;
- 2 half-lives;
- 3 sample size;
- 4 effect of the sample size on the measured radiation dose;
- 5 significance of the measured radiation level in the material, determined by demonstrating that the radiation level is equal to or less than the radiation level in a biocompatible, clinically accepted material, or causes no biocompatibility problems in humans for at least 15 years.

A letter of access from the ball manufacturer must be submitted to FDA for all ceramic balls which were not previously approved or found substantially equivalent. The letter of access must give FDA permission to examine data in the master file pertaining to the ceramic balls identified in the labeling of the stem.

#### BALL DESIGN

Dimensioned engineering drawings and tolerances for the following parameters must be provided for all ceramic balls which were not previously approved or found to be substantially equivalent. The values in parentheses are the boundaries of the reclassified ceramic ball hip system. A system does not have to be within these bounds to be determined substantially equivalent if the mechanical test results are adequate.

- 1 Bore angle (the bore angle is greater than the cone angle to assure that the cone-ball contact area is adequate).
- 2 Bore length (the stem/head length of overlap is greater than 50% of the axial length of the bore).
- 3 Bore diameter at the top and bottom of the taper.
- 4 Bore straightness (< 3 microns).
- 5 Bore surface roughness (no requirements).
- 6 Articulating surface roughness ( $R_a < 0.2$  microns).
- 7 Sphericity (< 5 microns).
- 8 Diameter (no requirements).
- 9 Defects (no defects on any part of the surface of any ball > 0.5 microns).

The following must be provided for alumina balls:

- 1 Grain size (< 5 microns).
- 2 Purity (> 99.7% aluminum oxide).

- 3 Composition (maximum percentage for each of the following trace elements is:  
MgO .2  
SiO<sub>2</sub> .01  
CaO .03  
Na<sub>2</sub>O .02  
Fe<sub>2</sub>O<sub>3</sub> .03  
TiO<sub>2</sub> .01)
- 4 Specific gravity (> 3.94 g/cm<sup>3</sup>).

The following must be provided for zirconia balls:

A description of the critical manufacturing methods, QC tests and pass/fail criteria must be provided.

### MECHANICAL TESTING

Each hip stem cone with a unique set of dimensions and tolerances, materials and design must be mechanically tested with either:

- 1 all ball models with which the stem will be labeled for use, or
- 2 the ball model having the highest critical stresses under all possible clinical loading conditions. However, it must be demonstrated that each of the other ball models under consideration will experience lower stresses under the same conditions.

Once a particular cone with a specified set of dimensions and tolerances has been cleared for use with a particular ball, other stems from the same manufacturer with the same set of cone dimensions and tolerances will not require mechanical testing.

A statement should be provided to the effect that the balls and cones which were mechanically tested, were representative of the design tolerances of the product shipped for clinical use and that ceramic test specimens had the same composition and structure (e.g., grain size, density) as the ball. All deviations from this statement must be listed and explained. The test result for each specimen must be provided and all specimens chosen for testing must be identified.

FDA may require additional mechanical tests for cone and ball designs whose mechanical performance can not be adequately predicted from the design specifications and mechanical tests listed in this document.

### STATIC COMPRESSION

A random sample of at least 5 balls of each combination shall be loaded axially in compression to failure following ISO 7206-5. The load may be applied to the ball through a copper ring or an equivalent method of loading (e.g., an appropriate copper ring to load a 32 mm ball would have a 1" O.D., 0.800" width and 0.055" thickness).

A detailed test report on static compression to failure must be provided. A copy of the entire report should be included in the 510k even if the same cone and ball designs were cleared in other documents. Each data point must identify the manufacturer and model numbers of each ceramic ball which was tested on the stem. The cone trunions mechanically tested must be identified as outlined above under CONE DESIGN.

The average fracture strength of the balls shall exceed 46 kN. No ball shall fail at less than 20 kN.

#### NEW BALL MECHANICAL TESTING

A ceramic ball made of a new material or manufacturing process or produced by a new manufacturer may require the following mechanical test data in addition to static compression to failure:

- 1 Balls shall be cycled axially between constant minimum and maximum compressive loads on a stem cone (trunnion) out to  $10^7$  cycles following ISO 7206-5. The load shall be applied to the ball through a copper ring or an equivalent method of loading (e.g., an appropriate copper ring to load a 32 mm ball would have a 1" O.D., 0.800" width and 0.055" thickness). The minimum load shall be  $\leq 10\%$  of the maximum load. At least 3 balls shall be cycled to a maximum load of at 14 kN. All balls which do not fail shall be inspected for cracks and then fractured in static compressive loading. There shall be no cracks or ball fracture after  $10^7$  cycles and no post-fatigue static compression failures below 20 kN. Unless data is available demonstrating no adverse effects of physiological solutions on the properties of the ball, each ball must be aged 4 weeks in a simulated physiological solution at 37° C prior to fatigue testing and kept moist during fatigue testing.
- 2 Axial pull-off loads shall be measured on at least 5 ceramic balls attached to the cones with a 2 kN preload.
- 3 The flexure strength of the ceramic shall be reported using ASTM C674 or an equivalent method.
- 4 Hardness shall be reported using ASTM E384, ISO 6507 or an equivalent method.
- 5 Wear rate of both the ceramic ball and PE cup.
- 6 Hardness of the ceramic material.
- 7 Elastic Modulus of the ceramic material.
- 8 Impact

#### LABELLING

The labeling for each stem must identify the manufacturer and model or catalogue numbers of each ceramic ball to be used with the stem. The labeling for the ball must state that the ball will be used only with stems labeled for use with the ball and that the stem labeling should be consulted to determine which stems are compatible with the ceramic ball. This allows the use of future hip stems with a ceramic ball without altering the ball labeling. It would also be appropriate to include the following in the ball labeling:

- 1 The ball must not be sterilized on the hip stem.
- 2 Autoclaved balls should not be cooled rapidly.
- 3 The stem cone and ball bore should be dry and free of contamination.
- 4 A ceramic ball should not be implanted if the ball or the cone of the stem are possibly damaged (e.g., if the ball is dropped on the floor or if the stem cone is scratched by an instrument or if the ball and stem cone are attached then detached).

- 5 The ball should be placed on the stem cone gently while keeping the ball and cone in alignment, then firmly attached by sharply hitting the ball with a soft plastic hammer.

Zirconia balls must contain the following labeling:

1. The contraindications of the labeling must include: "The Zirconia Ceramic Head is contraindicated for use with any other than an UHMWPE cup or a metal backed UHMWPE cup."
2. The Warnings and Precautions of the labeling must include: "The Zirconia Ceramic Head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular cups, the partially stabilized Zirconium ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the long term biological effects of these particulates are unknown."

#### OTHER INFORMATION

FDA may require additional testing for cone and ball designs whose performance can not be adequately predicted from the design specifications and tests listed in this document.

Clinical data may be accepted in support of but not in place of mechanical data since the mechanical properties of a stem-ball system may be inferior to that approved in the petition, yet still not demonstrate ball fracture or wear in clinical studies.

#### TEST REPORT CONTENT

Detailed reports should be organized and subdivided into separate sections (some sections may be combined to enhance clarification) having (if applicable) the following headings:

Can you provide the following?:

clinical fracture rate (number fractured/number implanted) of each type of ceramic ball (material, diameter, neck length)

evidence that a smaller ball is normally used in a lighter patient

copy of iso 6474

cracking or phase changes due to surface engraving

methods of evaluating radioactive isotopes

a list of material requirements for zirconia balls

Hip System Name	510(k) Number	(b)(4) Trade Secret Process - Product Specs	Indication
Answer Femoral Component	K931194 K991987		Cemented
Co-Cr Answer Femoral Components	K931194		Cemented
APF Femoral Component	K852584 K852585 K984154 K030055		Cemented and non-cemented
Bi-Metric® Femoral Components	K921224 K020580 K030055		Cemented and non-cemented
Bi-Metric® Head/Neck Replacement	K955350 K992058 K983710		Cemented
HA Bi-Metric® Femoral Component	K023409 K030055		Non-cemented
Bio-Groove Hip Component	K864085		Non-cemented
Bio-Groove HAP Hip Components	K912369 K912370		Non-cemented
Bohn Femoral Component	K000262		Non-cemented
Buchalter/Fausser Femoral Component	K952686		Cemented
Color Buffed Cemented stem	K992903 K012019		Cemented
Fenning (Osteocap RS®) Femoral Component	K960303		Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925		Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734		Cemented
Gross Femoral Component	K001580		Non-cemented
Impact Co-Cr Femoral Components	K942027		Cemented
Integral® Femoral Component	K921225 K984296 K984408 K030055 K030501		Cemented and non-cemented
Integral Co-Cr Femoral Component	K942479		Cemented
Interlocking Hip Stems	K990830		Non-cemented
Mallory/Head® Total Hip System	K853259 K921181 K994007 K000538 K003429 K030055		Cemented and non-cemented
HA Mallory/Head® Total Hip System	K021403 K030055		Non-cemented
Mallory/Head® Co-Cr Femoral Component	K911684		Cemented
Mallory/Head® Calcar Femoral Components (including HA)	K945115 K001660 K031693		Cemented and non-cemented
Modular Hip Stems	K912712 K921274 K030055		Cemented and non-cemented

184

OSS Les Proximal Femoral Component	K021380	(b)(4)Trade Secret Process - Product Specs	Cemented and non-cemented
PMI® Femoral Component	K911802 K923452 K030055		Cemented and non-cemented
HA PMI Femoral Stem	K030048		Non-cemented
Portrait Femoral Component	K010560		Non-cemented
Reach Femoral Component	K971824 K982367 K000760		Non-cemented
Modular Research	K994038		Non-cemented
HA Modular Reach®	K022463 K030055		Non-cemented
Rx-90 Femoral Stems	K942028 K023085		Cemented
SHP Hip System	K960984		Cemented
Taperloc® Femoral Component	K841437 K921301 K030055		Cemented and non-cemented
HA Taperloc® Femoral Component	K020963 K030055		Non-cemented

---

All trademarks are property of Biomet, Inc.



















## Device Listing

Biomet

Part Number

Description

(b)(4)Trade; [REDACTED]

12-115109 (RD115109)	TTPA Head Taper Type I, -3mm x 28mm	<del>99.39</del> .1018.826.10
12-115110 (RD115110)	TTPA Head Taper Type I, std x 28mm	99.39.1018.826.20
12-115111 (RD115111)	TTPA Head Taper Type I, +3mm x 28mm	99.39.1018.826.30
12-115112 (RD115112)	TTPA Head Taper Type I, +5mm x 28mm	99.39.1018.826.40
12-115114 (RD115114)	TTPA Head Taper Type I, -3mm x 32mm	99.39.0058.412.00
12-115115 (RD115115)	TTPA Head Taper Type I, std x 32mm	99.39.0058.412.10
12-115116 (RD115116)	TTPA Head Taper Type I, +3mm x 32mm	99.39.0058.412.20
12-115117 (RD115117)	TTPA Head Taper Type I, +6mm x 32mm	99.39.0058.412.30

195



























































































































































REF. RD115109 LOT 123123

MODULAR TTPA CERAMIC HEAD  
28 MM HEAD DIAMETER  
MINUS 3 MM NECK TYPE I TAPER

ALUMINA/ZIRCONIA CERAMIC LINERS ONLY  
USE WITH RD134109/04-10/19  
~~CAUTION - INVESTIGATIONAL DEVICE - LIMITED BY FEDERAL LAW (USA) TO INVESTIGATIONAL USE. SEE INVESTIGATIONAL PROTOCOL FOR COMPLETE INFORMATION.~~

LOT 123123 QTY. 1

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587  
WARSAW, IN 46581 USA



STERILE R

2004-05

CE 0086

EXPIRY DATE: 2014-05



REF. RD115117 LOT 123123

MODULAR TTPA CERAMIC HEAD  
32 MM HEAD DIAMETER  
PLUS 6 MM NECK TYPE I TAPER

ALUMINA/ZIRCONIA  
USE WITH RD134105/09 CERAMIC LINERS ONLY  
USE WITH TI 6AL 4V TYPE 1 TAPER ONLY  
~~CAUTION - INVESTIGATIONAL DEVICE - LIMITED BY FEDERAL LAW (USA) TO INVESTIGATIONAL USE.~~

LOT 123123 QTY. 1

BIOMET ORTHOPEDICS, INC.

56 EAST BELL DRIVE  
P.O. BOX 587  
WARSAW, IN 46581 USA



STERILE R

2004-05

CE 0086

EXPIRY DATE: 2014-05



273

## Biomet TTPA Ceramic Modular Head Hip Joint Prostheses

### Attention Operating Surgeon

#### DESCRIPTION

Biomet ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces. Ceramic heads are available in a variety of head sizes and neck length variations. The highly polished surface is designed to reduce friction and minimizes wear.

#### MATERIALS

TTPA Ceramic

#### INDICATIONS

- 1) Noninflammatory 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 throchanteric fractures of the proximal femur with head involvement, unmanageable using techniques other than joint replacement.
- 5) Revision procedures where other devices or treatments have failed.

#### CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

#### WARNINGS

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue, have lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Use TTPA ceramic modular head with Biomet metallic femoral components. Do not use Biomet TTPA ceramic modular heads with femoral stems or acetabular components offered by other manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture of ceramic heads.
2. Ceramic heads labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal backed UHMWPE acetabular components.
4. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
5. Do not use a metallic hammer when seating the ceramic head. Use a nylon or polyethylene seating instrument. Do not use excessive force. The TTPA ceramic head can fracture with excessive force.
6. The femoral stem trunion and the bore of the ceramic head should be dry and free of contamination prior to assembly.

Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient

is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

#### **PRECAUTIONS**

Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, and/or excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

#### **POSSIBLE ADVERSE EFFECTS**

Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of 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. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.

1. Early or late postoperative, infection, and allergic reaction.
2. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
3. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, non-union, bone resorption, and excessive activity.
4. Periarticular calcification or ossification, with or without impediment of joint mobility.
5. Inadequate range of motion due to improper selection or positioning of components.
6. Undesirable shortening of limb.
7. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
8. Fretting and crevice corrosion can occur at interfaces between components.
9. Wear and/or deformation of articulating surfaces.
10. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
11. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
12. The TTPA ceramic modular head is composed of ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular components, ceramic balls produce a relatively low amount of particles, the total amount of particulate produced remains undetermined. Because of the limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown.
13. Intraoperative and postoperative bone fracture and/or postoperative pain.
14. Ceramic head fractures have been reported.

#### **STERILITY**

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, P.O. Box 587, Warsaw, IN 46582 USA, FAX: 574-372-1683.

## Predicate Device Comparison Table

	Biolog® della	Predicate	Predicate	Predicate	Predicate
510(k) Sponsor	Biomet	Biomet	Biomet	Biomet	DePuy
510(k) Number	New	K943586	K925345	K905687	K031803
Indications for Use	<p>1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis</p> <p>2) Rheumatoid arthritis</p> <p>3) Correction of functional deformity</p> <p>4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.</p> <p>5) Revision procedures where other treatment or devices have failed.</p>	Not specified	Not specified	Not specified	<p>1) A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia</p> <p>2) Avascular necrosis</p> <p>3) Acute traumatic fracture of the femoral head or neck</p> <p>4) Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.</p> <p>5) Certain cases of ankylosis</p>
Intended Use	Total hip replacement with cemented or non-cemented femoral components	Articular surface of an artificial hip joint	Articular surface of an artificial hip joint	Articular surface of an artificial hip joint	Femoral head component in total hip arthroplasty procedures Cemented or uncemented

(b) (4) Trade Secret Process

	BioloX® delta	Predicate	Predicate	Predicate
510(k) Sponsor	Biomet	Biomet	Biomet	DePuy
510(k) Number	New	K943586	K925345	K031803
Ceramic Manufacturer	(b)(4) Trade Secret Process			
Material				
	75% Alumina, 24% Zirconia and 1% Platelet	95% Zirconia, 5% Yttria	55% Zirconia, 37% Yttria	Zirconia and 1% Platelet
Technological Characteristics	Heads have been shown to meet the parameters outlined in the FDA guidance document for Ceramic Ball Hip Systems	Heads have been shown to meet the parameters outlined in the FDA guidance document for Ceramic Ball Hip Systems	Heads have been shown to meet the parameters outlined in the FDA guidance document for Ceramic Ball Hip Systems	Unknown
Design: Diameter(s): Neck Lengths	28mm: -3, std, +3, +5mm 32mm: -3, std, +3, +6mm	28mm: -5, -3, std, +3mm	28mm: +6mm	28mm: "various" 32mm: "various"
Taper Design:	(b)(4) Trade Secret Process			
- Taper Angle				
- Taper Length				
- Taper				
Diameter*				

\* Each series of prints references the taper diameters in a slightly different manner leading to different values



OCT 17 1994

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

Ms. Patricia Sandborn Beres  
Director, Regulatory Affairs  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K943586  
Zirconia Ceramic Modular Heads (Astro Met)  
Regulatory Class: II  
Product Code: LZ0  
Dated: July 19, 1994  
Received: July 22, 1994

Dear Ms. Beres:

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

1. Biomet's hip stems as listed in this 510(k) should be labeled for use with the following zirconia heads:

<u>Part No.</u>	<u>Diameter, Neck Length</u>
163130	28mm, -5
163131	28mm, -3
163132	28mm, standard
163133	28mm, +3

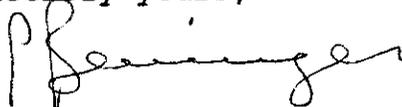
2. The contraindications of the labeling must include: "The Zirconia Ceramic Head is contraindicated for use with any other than an UHMWPE cup or a metal backed UHMWPE cup."
3. The Warnings and Precautions of the labeling must include: "The Zirconia Ceramic Head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular cups, the partially stabilized Zirconium ball produces a

278

Page 3 - Ms. Patricia Sandborn Beres

your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "P. Beninger".

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

27A

relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the long term biological effects of these particulates are unknown."

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

If your device is classified (see above) into either class II (Performance Standards) 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. 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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on



MAR 10 1994

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

• Ms. Patricia Sandborn Beres  
Research Manager  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K925345  
Zirconia Ceramic Modular Heads  
(Type I Taper, 28mm and 32mm, +6)  
Regulatory Class: II  
Dated: March 15, 1993  
Received: March 19, 1993

Dear Ms. Beres:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. This decision is based upon the use of the Morgan Matroc Zirconia Hip Joint Balls with the stems listed below:

<u>Femoral Components</u>	<u>Document Number</u>
Bimetric Collarless	K852584
* Bimetric Collared/Integral	K852585
* Taperloc	K830313
Rothman Institute	K841437
Bio-Moore	K845025
* Mallory-Head (Ti)	K853259
* Mallory-Head (Co)	K911684
Wisconsin	K830314
Bio-Groove	K864085
** HAP Bio-Groove (Bio-Coat)	K912369
** HAP Bio-Groove (Bio-Interfaces)	K912370
Modular Total Hips	K912712
* PMI	K911802

You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The contraindications of the labeling must include: "The Zirconia Ceramic Head is contraindicated for use with any other than an UHMWPE cup or a metal backed UHMWPE cup."

281

2. The Warnings and Precautions of the labeling must include: "The Zirconia Ceramic Head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that, (b)(4)Trade Secret

Process



3. The stems identified above are labeled for use with the following Zirconia Ceramic Heads:

<u>Cat. No.</u>	<u>Diameter</u>	<u>Neck Length</u>
AEG 171/2y/B	28mm	+6mm
AEG 170/2y/B	32mm	+6mm

4. The systems marked by \* may not be labeled or promoted for noncemented use.
5. All labeling for the systems marked by \*, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.
6. Any non-cemented fixation of the systems marked by \* is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.
7. You may not label or in any way promote the systems marked by \*\* for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

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

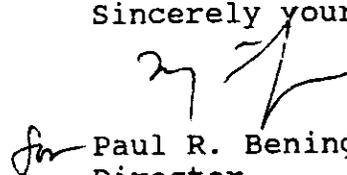
If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major

282

regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

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

Sincerely yours,

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



APR 15 1991



Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850

Ms. Patricia M. Sandborn  
Research Manager  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46580-0587

Re: K905687  
Zirconia Ceramic Modular Head  
Regulatory Class: II  
Dated: February 7, 1991  
Received: February 13, 1991

Dear Ms. Sandborn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based on data provided for the reclassified Biolox Ball manufactured by Feldmuhle Aktiengesellschaft and the Biomet Ti-6Al-4V stems with the same trunion as that described in this 510(k).

You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the limitation that the stems are labeled for use with the following Metoxit/Precomp Zirconia Hip Joint Balls:

- 28 mm, -3 neck
- 28 mm, Std neck
- 28 mm, +3 neck
- 32 mm, -3 neck
- 32 mm, Std neck
- 32 mm, +3 neck
- 32 mm, +6 neck

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

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

284

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

*Carl A. Larson*

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 1 2003**

Ms. Karla A. Ham  
Senior Regulatory Associate  
DePuy Orthopaedics, Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Re: K031803

Trade/Device Name: DePuy Ceramic Femoral Heads

Regulation Number: 21 CFR 888.3353

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

Regulatory Class: II

Product Code: LZO

Dated: June 10, 2003

Received: June 11, 2003

Dear Ms. Ham:

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.

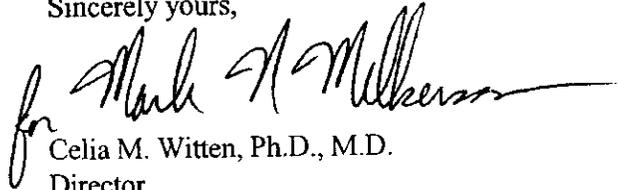
286

Page 2 - Ms. Karla A. Ham

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned above the typed name and title.

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

JUL 1 2003

K031803  
10F2

**510(k) Summary**

---

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

**510(k) CONTACT:** Karla Ham  
Sr. Regulatory Affairs Associate

**TRADE NAME:** DePuy Ceramic Femoral Heads

**COMMON NAME:** Ceramic Femoral Ball Prosthesis

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

**DEVICE PRODUCT CODE:** 87 LZO

**SUBSTANTIALLY EQUIVALENT  
DEVICE:** DePuy Femoral Heads, K011533

**DEVICE DESCRIPTION AND INTENDED USE:**

The DePuy Ceramic Femoral Heads are composed of an alumina composite material and are available in head diameters of 32mm and 36mm sizes with various offset options. The internal bore of the ceramic femoral head, which is designed to interlock with the external taper on the femoral hip stem, is available in two variations (11/13 SROM and 12/14 Articul/eze taper options).

The ceramic heads are designed to mate with a corresponding DePuy femoral hip stem and provide the femoral articular surface of a total hip replacement.

**INDICATIONS FOR USE:**

The DePuy Ceramic Femoral Heads are 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.

000005

288

K031803  
20F2

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

DePuy considers the Ceramic Femoral Heads to be substantially equivalent to the DePuy Femoral Heads submitted in K011533 based on similarities in design, same material composition, same sterilization and packaging methods, same intended use/indications for use, and similar labels.

**0000006**

289

510(k) Number (if known): K031803

Device Name: DePuy Ceramic Femoral Heads

**Indications for Use:**

The DePuy Ceramic Femoral Heads are 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.

---

Concurrence of CDRH, Office of Device Evaluation

*for Mark A. Milbrink*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K031803

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use  
(Per 21 CFR 801.109)

**0000003**

290



**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/ceramic/polymer semiconstrained cemented or non-cemented 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.

**Intended Use:** Biolox® *delta* Ceramic Heads are indicated for use with cemented or non-cemented femoral 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.

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

MAILING ADDRESS  
P.O. Box 587  
Warsaw, IN 46584-0587

SHIPPING ADDRESS  
36 E. Bell Drive  
Warsaw, IN 46584

OFFICE  
574.267.6639

FAX  
574.267.8113

E-MAIL  
biomet@biomet.com

291

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

**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

---

*BioloX is a trademark of Feldmühle Anlager und Produktions – GHBH Corporation.*

292

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Peter Allen  
Subject: 510(k) Number K042091/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

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

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

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

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

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

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90

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

LZO, II

Review: \_\_\_\_\_ (Branch Chief) \_\_\_\_\_ (Branch Code) \_\_\_\_\_ (Date)

Final Review: Steph Rhoda \_\_\_\_\_ (Date) 3/24/05

(Division Director)

---

510 (k) MEMORANDUM

---

**TO:** K042091/S1  
**FROM:** Peter G. Allen, Biomedical Engineer  
ODE/DGRND/Orthopedic Devices Branch  
**DATE:** March 21, 2005  
**SUBJ:** **BioloX *delta* Ceramic Heads** – alumina/zirconia composite heads  
Product Code: 87 LZO; 21 CFR 888.3353; Class II  
**Firm:** **Biomet, Inc.**  
**Contact:** Patricia Sandborn Beres, Senior Regulatory Specialist  
Phone: (574) 267-6639 Email: patty.beres@biometmail.com

*Peter G Allen*

Fax: (574) 372-1683

---

**Recommendation:** Based on similarities in design, materials, mechanical properties, size, method of fixation, and intended use, I recommend the subject devices be found Substantially Equivalent (SE) to legally marketed predicate devices.

**Review:**

1. **Administrative Requirements:**

Notification contains a 510(k) Summary, Truthful and Accuracy Statement, and Indications for Use page. A revised Indications for Use page was provided in Exhibit 10 of Supplement 1, and an updated 510(k) Summary with the revised indications was provided via email on 3/21/05.

**EXPLANATIONS TO "YES" RESPONSES TO QUESTIONS 4, 6, 8, and 11 AND EVERY "NO" RESPONSE ON THE "SE" DECISION MAKING CHECKLIST AS NEEDED:**

Question 4, 6, and 8 are not applicable. See SE Decision Making Checklist.

- 7. *Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?* No. Extensive performance testing is required to evaluate the ball heads and mating trunnion tapers.
- 10. *Are Performance Data Available to Assess Equivalence?* Yes. Some testing was provided in the original submission, and additional testing and characterization information was provided in Supplement 1.
- 11. *Does Performance Data Demonstrate Equivalence?* Yes.

2. **Device Description:**

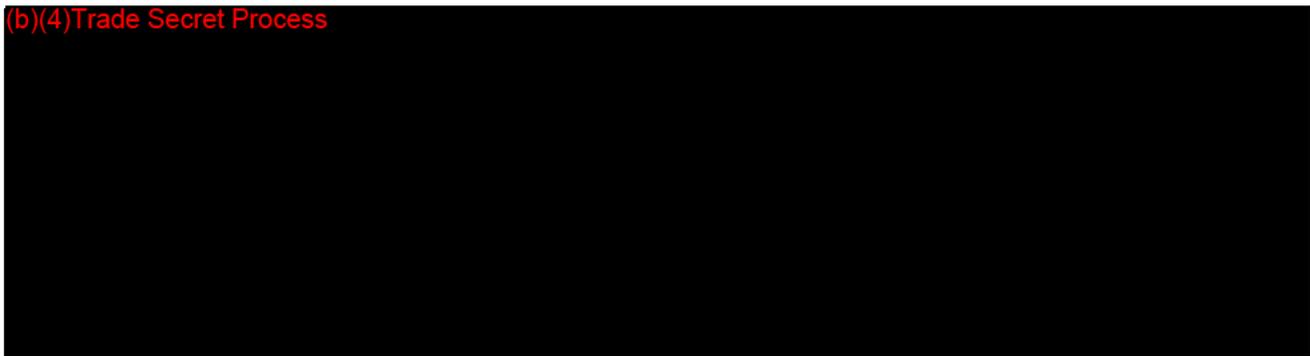
The subject BioloX *delta* Ceramic Heads consist of an "alumina composite matrix" that is known as Transition-Toughened-Platelet Alumina (TTPA) that has been processed using a toughening

(b)(4) Trade Secret Process



*J. P. Miller* 4/21/05  
6

(b)(4)Trade Secret Process



(b) [redacted], the manufacturer of the Biolox *delta* Ceramic Heads, has allowed permission to examine their Master File (b) [redacted] that contains data on the subject alumina composite material. (b) [redacted] has given this new material the trade name Biolox Delta.

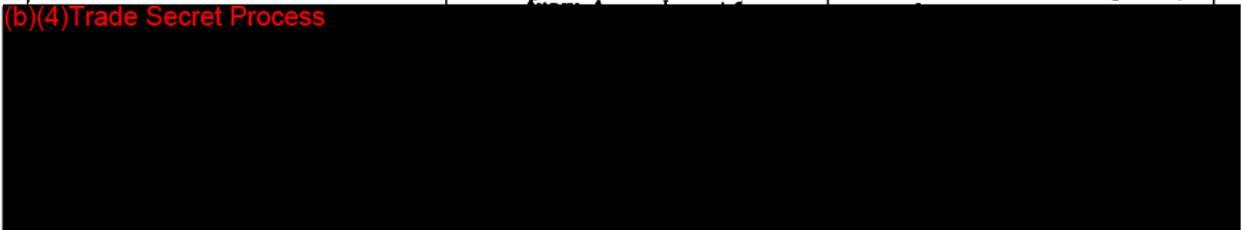
The Biolox *delta* Ceramic Heads are ceramic femoral ball prostheses that are intended to be used with Biomet femoral stems with a matching taper design. The femoral heads are 28mm and 32mm in diameter and are offered only with Biomet's Type 1 Taper trunnion. The offset options (neck lengths) are -3mm, 0, +3mm, and +5mm for the 28mm head, and -3mm, 0, +3mm, and +6mm for the 32mm head. The 28mm +5 and 32mm +6 heads are indicated for use with titanium alloy stems, only. All others may be used with either a CoCrMo or Ti alloy stem. The heads mechanically lock with the femoral stem via a Morse-type taper and articulate with a polyethylene acetabular component.

The subject heads are identical to the zirconia heads cleared in K943586, K925345, and K905687 in terms of taper locking design and taper angles. The material is similar to (b)(4)Trade Secret Process alumina material, but has been modified in order to provide improved material characteristics.

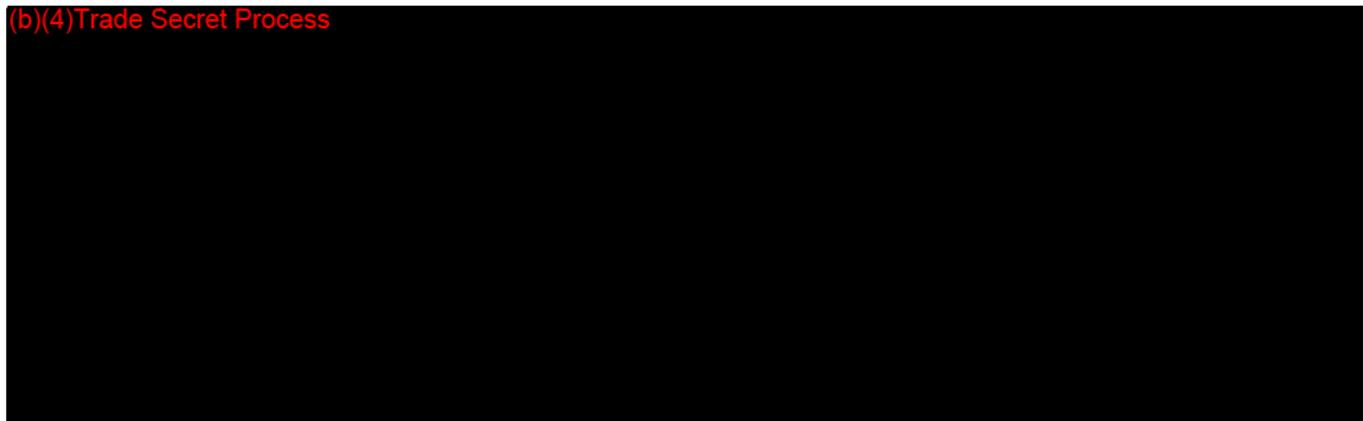
The TTPA material is made of 75% alumina, 24% zirconia, and 1% platelet. The complete chemical composition of the TTPA, as listed in Master File (b) [redacted], and provided on page 9 of the submission is: (4)T

Component	Content in wt %
(b)(4)Trade Secret Process	

Physical Properties	Biolox Forte (Alumina)	Biolox Delta (Alumina Matrix Composite)
---------------------	------------------------	---



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

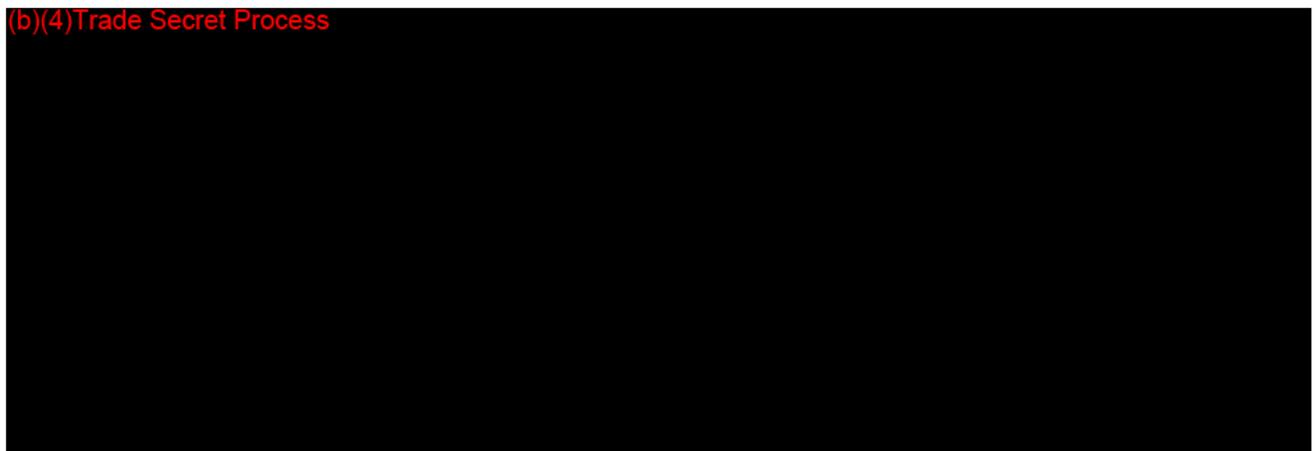
  
  


These values are similar to those cited in K011533, the first Biolox delta heads cleared (for DePuy) (again, values are slightly different due to changes in measurement techniques but MAF provided correlation information).

Cone

Exhibit 3 contains dimensioned engineering drawings of the Biomet Type 1 trunnion taper including the following dimensions. This is the only cone taper that is compatible with the subject femoral heads.

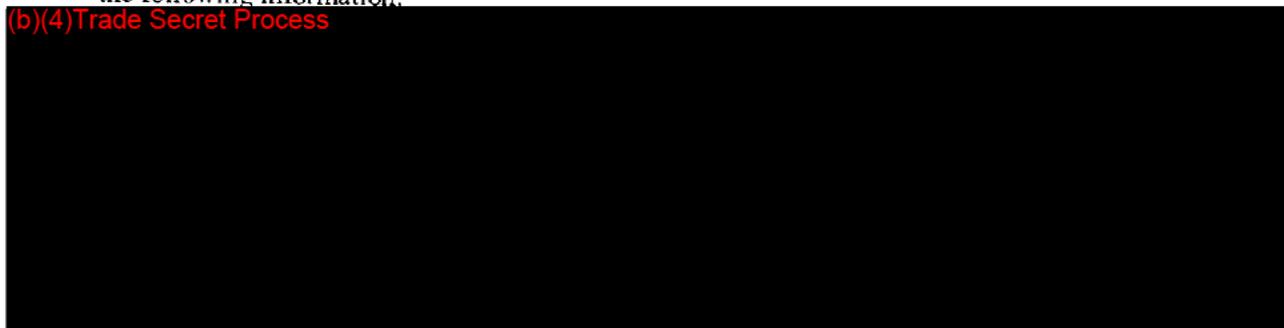
(b)(4)Trade Secret Process



Ball

Dimensioned engineering drawings of the modular heads may be found in Exhibit 6. They contain the following information:

(b)(4)Trade Secret Process



Magnified photos of the modular head engraving may be found in Exhibit 4. A description of this laser etching process is included in (b)(4)Trade Secret (redacted). An analysis of the natural

radioactive impurities of the material is provided in Exhibit 5. The radioactivity level is below the proposed upper limit set by ISO 13356.

Exhibit 12 contains a comparison table and predicate device information.

#### Stems

Exhibit 2 contains a list of the femoral components (and their 510k numbers) compatible with the subject femoral heads. The list is quite extensive. All stems utilize the Biomet Type 1 taper, a detailed drawing of which is provided in Exhibit 3. (b)(4)Trade Secret. Stems are available with or without a porous coating and intended for cemented or cementless use. An updated listing was provided in Exhibit 9 of Supplement 1.

#### Acetabular Inserts/Shells

In the original submission no information was provided on compatible acetabular components. The sponsor was asked to provide this in the deficiency letter of November 1, 2004. The sponsor provided a complete list of all compatible acetabular components (and their 510k numbers) in Exhibit 9 of Supplement 1. All acetabular components are of a metal on polyethylene design and indicated for cemented and/or cementless use.

### 3. **Intended Use:**

In deficiency number 5 of the November 1, 2004, deficiency letter, the sponsor was asked to include a reference to total hip replacement (i.e., for use with femoral and acetabular components, not hemiarthroplasty). In Exhibit 10 of Supplement 1 the sponsor provided a revised Indications for Use form, as requested. In addition, based on correspondence with FDA regarding other 510(k)s, this document was further revised to incorporate indications that are specific for certain other compatible components of this system. The Indications for Use now reads:

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

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

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

Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma, and revision of unsuccessful osteotomy or arthroplasty. (K974558, K002757, K021389, 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)

7

4. **Sterilization:**

Device is provided Sterile.

Method: (b)(4)Trade Secret Process

SAL: 10<sup>6</sup>

Validation Method: (b)(4)Trade Secret Process

Pyrogenicity: no claims will be made

Description of packaging: each component is placed in a plastic bag and between two foam pads, and then placed in an inner blister pack sealed with a Tyvek lid that fits into an outer blister pack also sealed with a Tyvek lid. The entire unit is placed in a cardboard box and shrink-wrapped.

Recommended re-sterilization method: specifically not recommended (this information was taken from the package insert and the labeling section, not the sterilization section of the submission)

5. **Labeling:**

Labeling in the form of draft package labels, and a package insert were provided. They are adequate. The material designation on the label reads "TTPA Ceramic Head" and "Alumina/Zirconia". This is acceptable. The package label for the 32mm +6 head notes that the head is for, "Use with Ti-6Al-4V Type 1 Taper Only". However, no such label was provided for the 28mm +5 head which is also limited to use with titanium stems. (b)(4)Trade Secret Process (4)Trade Secret Process

(b)(4)Trade Secret Process

6. **Testing:**

(b)(4)Trade Secret Process

In Supplement 1 the sponsor provided additional testing as requested in the deficiency letter of November 1, 2004. Please see Section 10 Contact History/Request for More Information, below, for the deficiencies and a summary of the results of the additional testing that was performed.

**Burst Strength**

(b)(4)Trade Secret Process





7. **Sponsor's information in support of SE:**

K031803, DePuy Ceramic Femoral Heads, DePuy Orthopaedics (J&J)  
K943586, Zirconia Ceramic Modular Heads (Astro Met), Biomet Inc.  
K925345, Zirconia Ceramic Modular Heads, Biomet Inc.  
K905687, Zirconia Ceramic Modular Head, Biomet Inc.

8. **Review of other 510(k)s for SE:**

K011533, DePuy Femoral Heads (alumina/zirconia composite), DePuy Orthopaedics (J&J)  
K040644, DePuy Femoral Heads (alumina/zirconia composite), DePuy Orthopaedics (J&J)

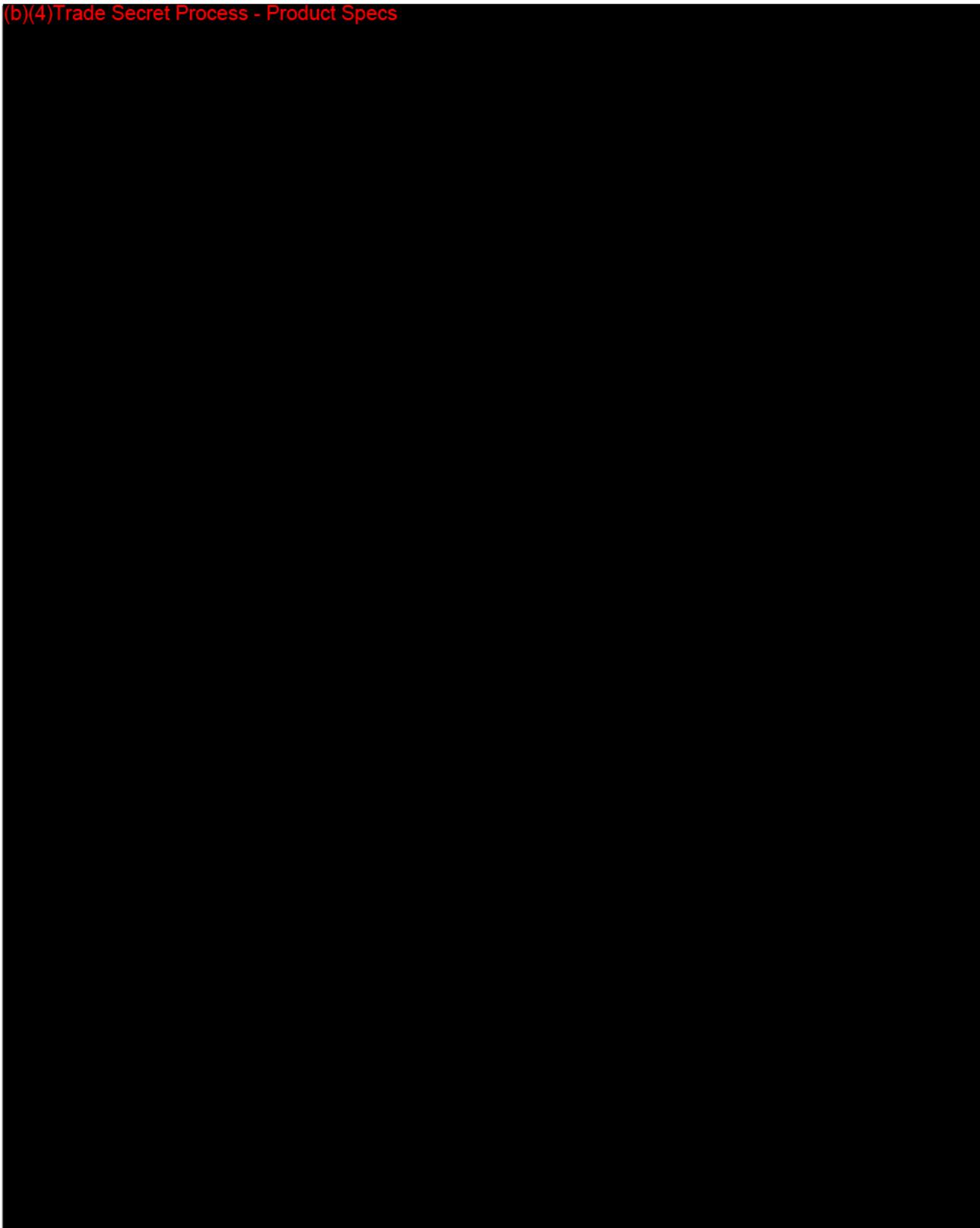
9. **Summary:**

The Biolox *delta* Ceramic Heads of this submission have essentially the same technological characteristics as the predicate devices reviewed above. The pre-clinical test results are similar to the predicates and they have the same intended use, method of fixation, sizes and design as the predicates. The requested fatigue testing and hydrothermal stability (phase transformation) evaluations demonstrate that they should perform as well as, or better than, the predicate devices. Therefore, I recommend that they be found SE to the marketed predicate devices.

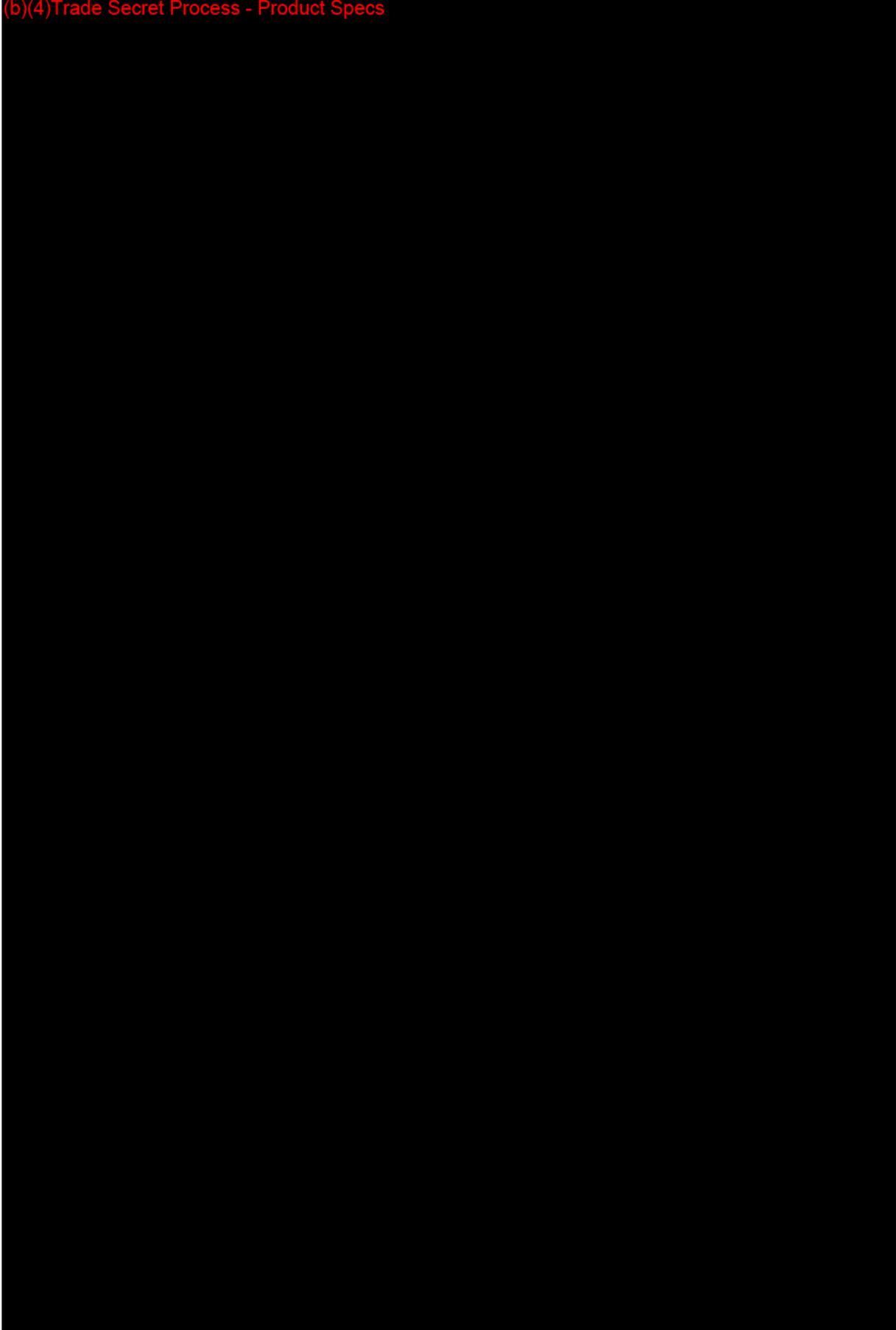
10. **Contact History/Requests for More Information:**

An AI letter was sent to the sponsor on November 1, 2004, requesting the following additional information. A summary of the sponsor's response is provided in **boldface** after each question, and my comments follow in *italics*.

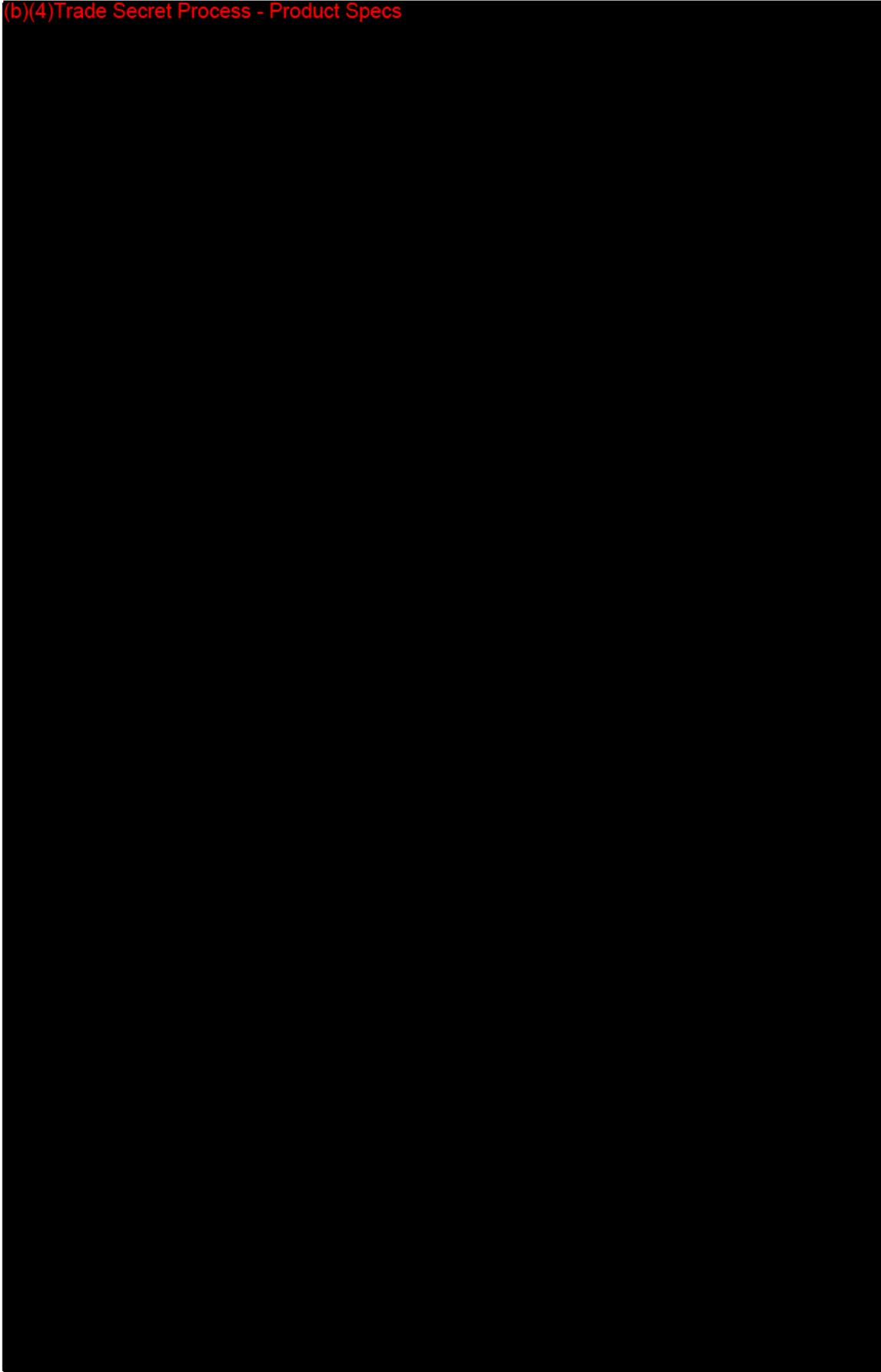
(b)(4)Trade Secret Process - Product Specs



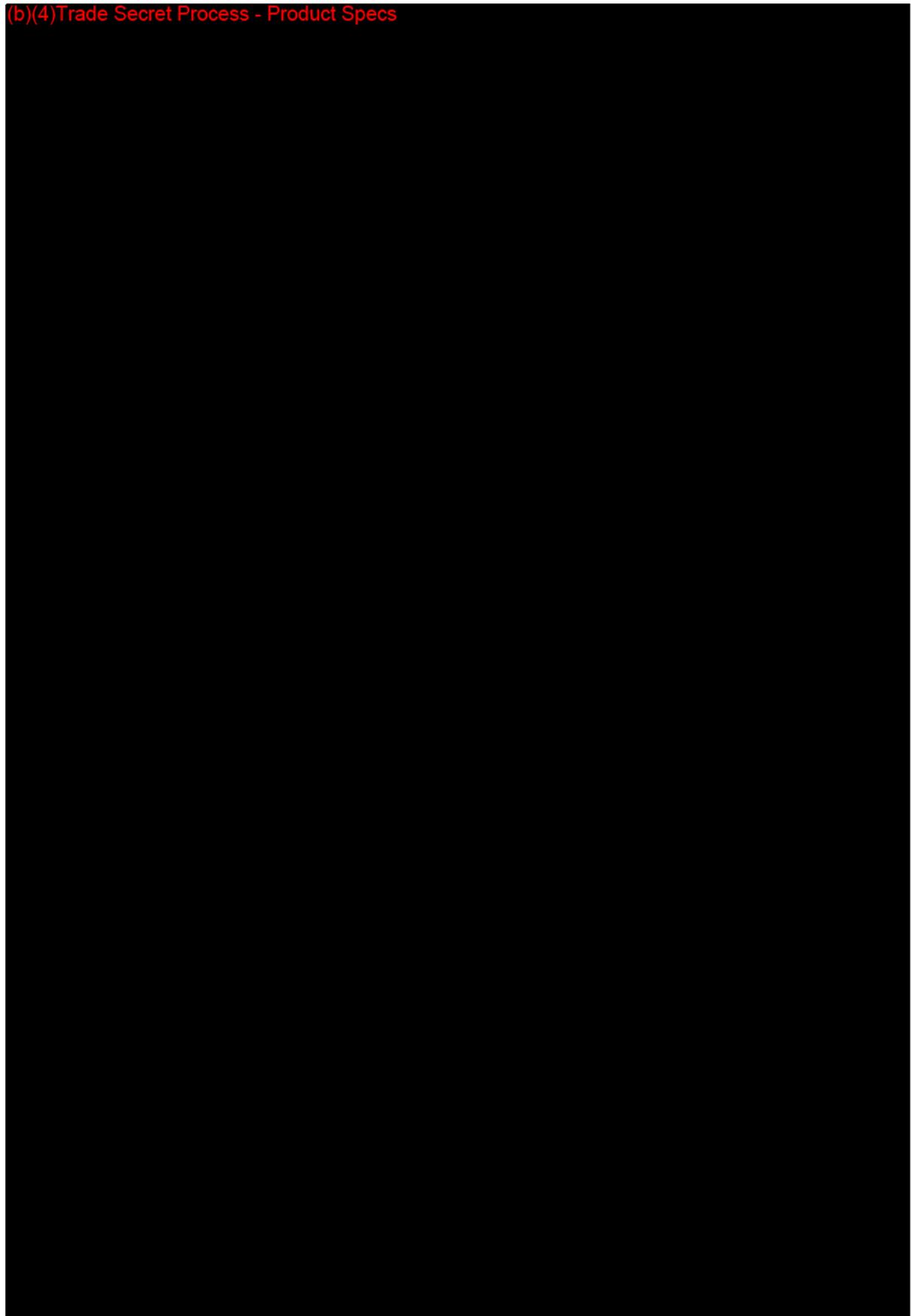
(b)(4)Trade Secret Process - Product Specs



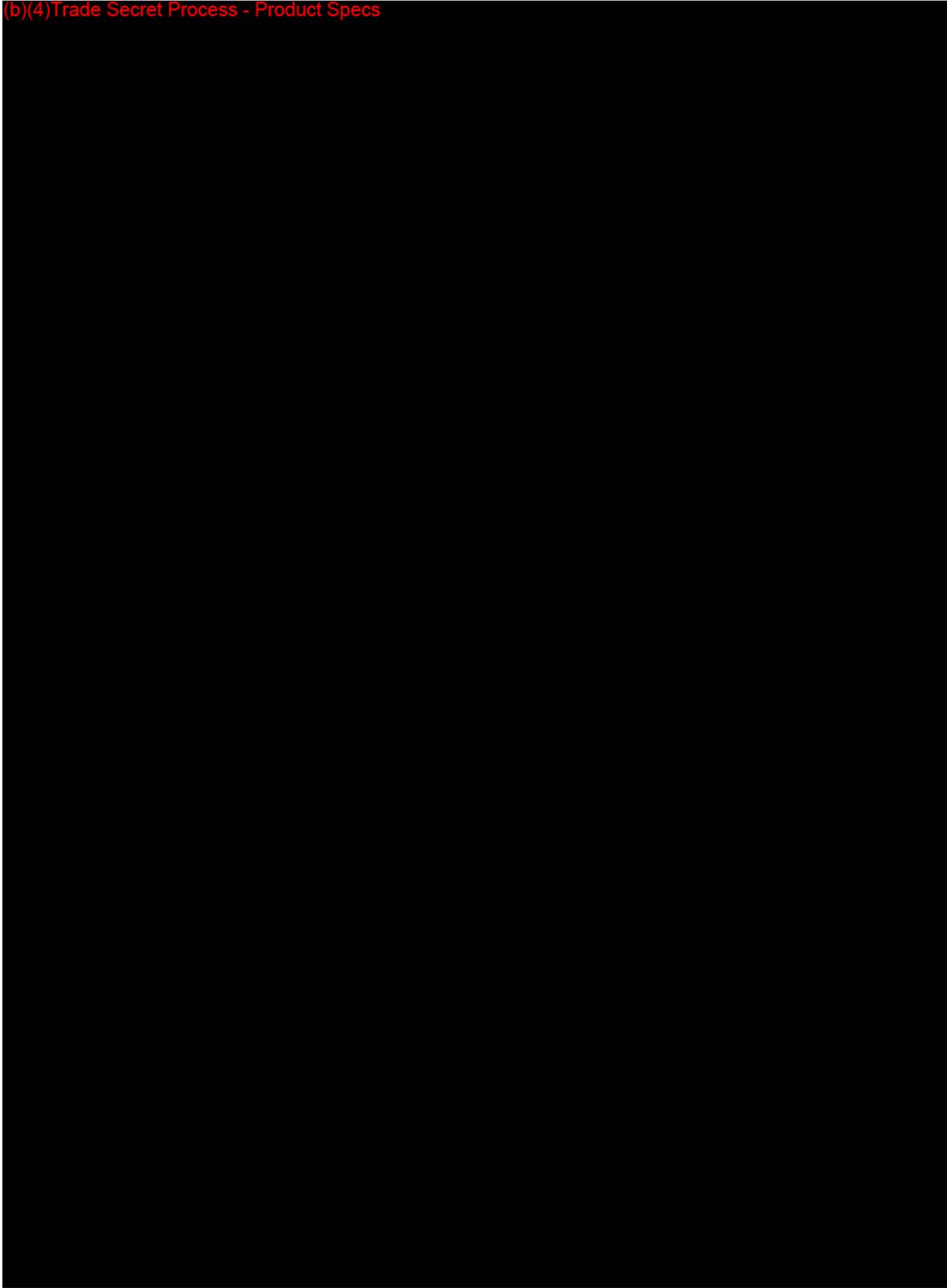
(b)(4)Trade Secret Process - Product Specs



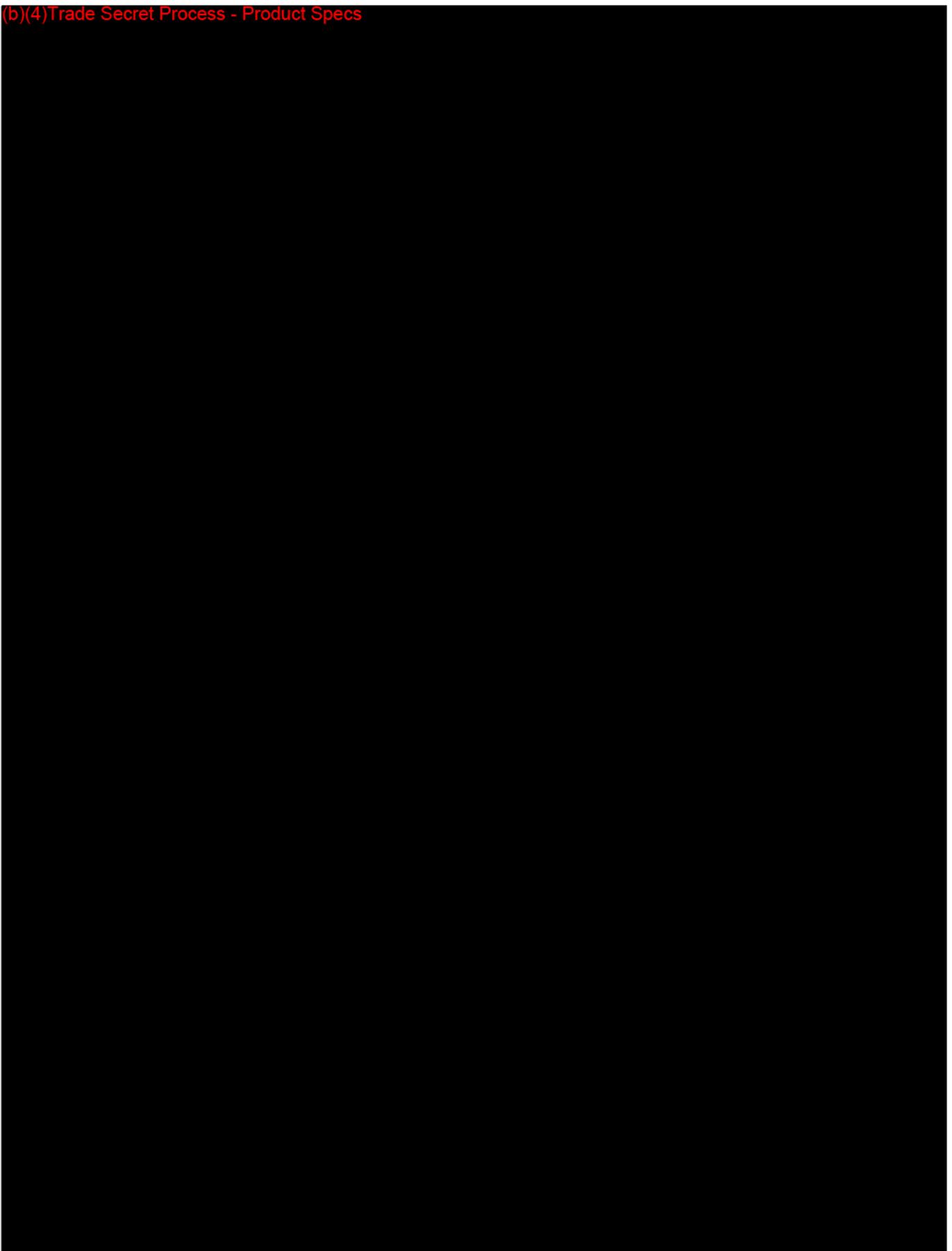
(b)(4)Trade Secret Process - Product Specs



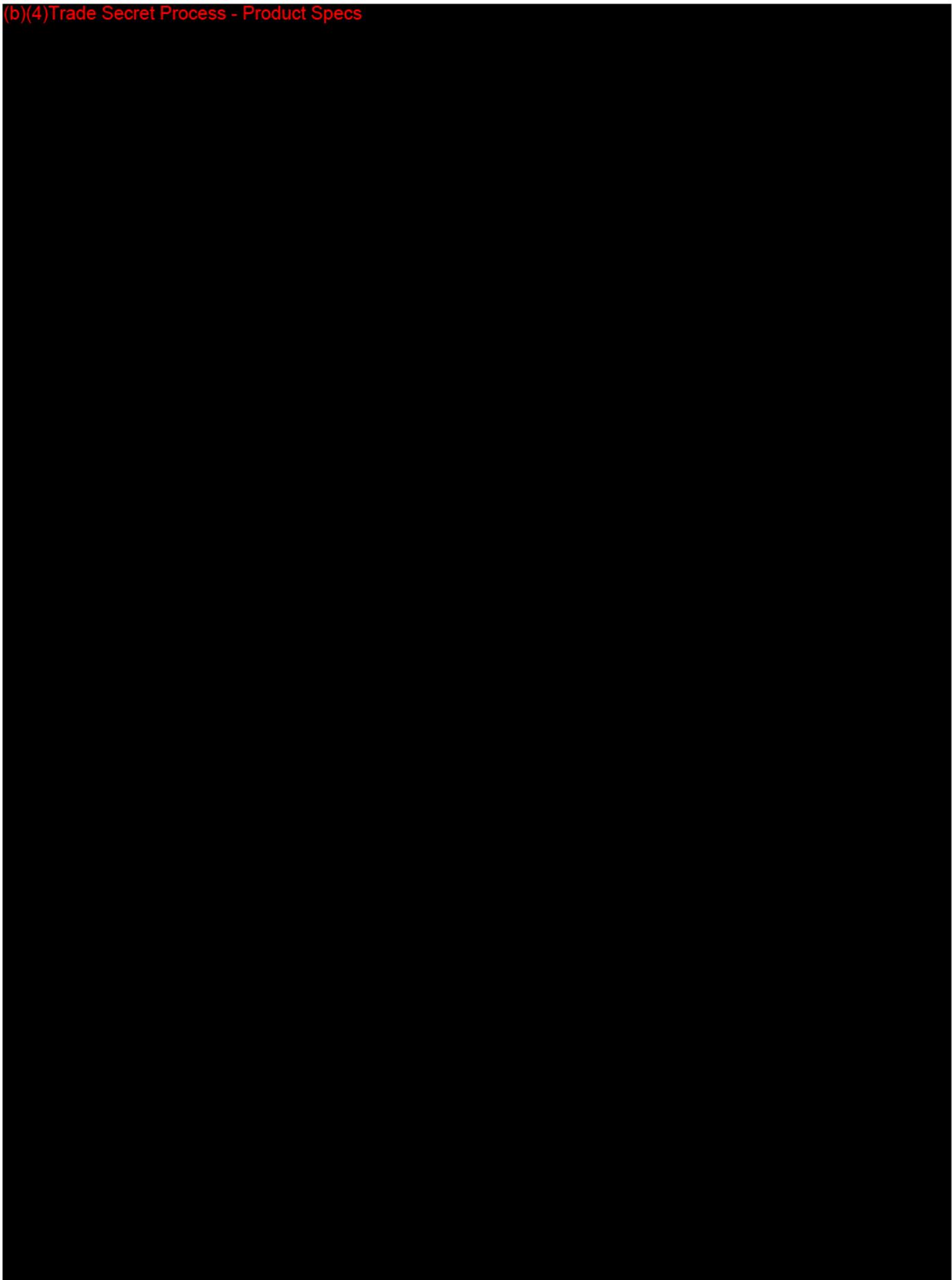
(b)(4)Trade Secret Process - Product Specs



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



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



**Allen, Peter**

---

**From:** Patty.Beres@Biometmail.com  
**Sent:** Monday, March 21, 2005 8:20 AM  
**To:** Allen, Peter  
**Subject:** Re: FW: K042091/S1 - Biolox Delta Ceramic Heads

Peter,

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



Attached is the updated 510(k) Summary.

I am in the office today if there are any more questions.

Patty

3/21/2005

21

## 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 arthroscopy.

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<sup>®</sup> *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

# Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	✓
4. If, not, has POS been notified?	✓	✓
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		✓
8. Are you aware that this device has been the subject of a previous NSE decision?	N/A	✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	✓
10. Are you aware of the submitter being the subject of an integrity investigation?	N/A	✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.	N/A	✓

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: Peter Allen <sup>K 042091</sup>

Division/Branch: DGRND/ORDB

Device Name: BioloX delta Ceramic Heads

Product To Which Compared (510(K) Number If Known): K031803, K94386, K925345  
K040644

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

*See Memo*

see Memo

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

From: Reviewer(s) - Name(s) Peter Allen  
Subject: 510(k) Number K 042091

To: The Record - It is my recommendation that the subject 510(k) Notification:

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

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

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

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):  
 No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

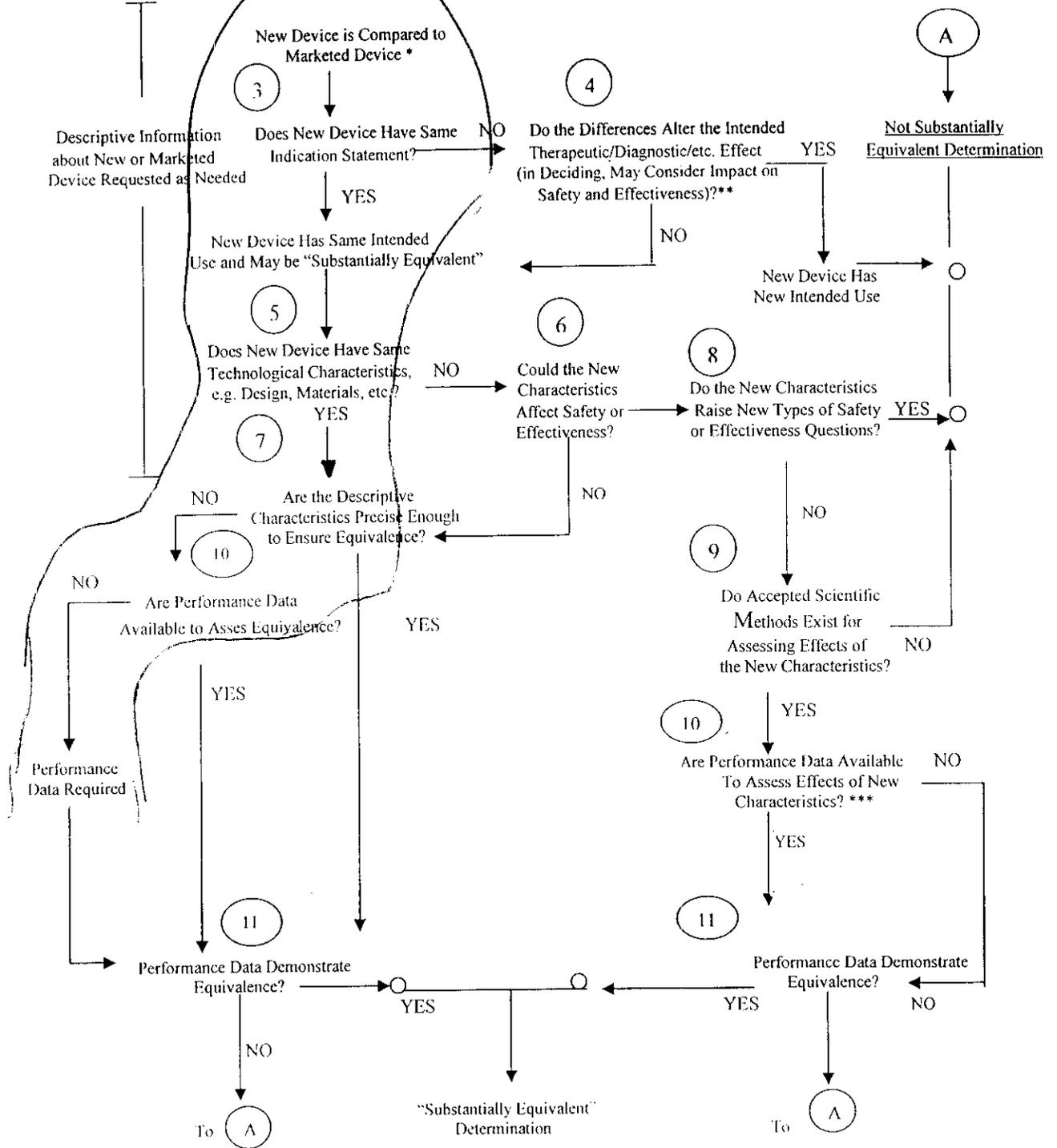
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

LZO, II

Review: John Hold ORDB 11/1/04  
(Branch Chief) (Branch Code) (Date)

Final Review: Mark A. Melhars 11/1/04 144  
(Division Director) (Date)

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



- \* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- \*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- \*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

---

**510(k) MEMORANDUM**

---

**TO:** K042091  
**FROM:** Peter G. Allen, Biomedical Engineer  
ODE/DGRND/Orthopedic Devices Branch  
**DATE:** October 29, 2004  
**SUBJ:** **BioloX delta Ceramic Heads** -- alumina/zirconia composite heads  
Product Code: 87 LZ0; 21 CFR 888.3353; Class II  
**Firm:** **Biomet, Inc.**  
**Contact:** Patricia Sandborn Beres, Senior Regulatory Specialist  
Phone: (574) 267-6639 Email: patty.beres@biometmail.com Fax: (574) 372-1683

---

**Recommendation:** Before an SE determination can be made, clarification needs to be made on a number of points, and additional fatigue and hydrothermal stability testing is requested, as well as some other additional information. Therefore, I recommend that this submission be placed on hold and an AI letter sent to the sponsor.

**Review:**

**1. Administrative Requirements:**

Notification contains a 510(k) Summary, Truthful and Accuracy Statement, and Indications for Use page.

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



**2. Device Description:**

The subject BioloX delta Ceramic Heads consist of an "alumina composite matrix" that is known as Transition-Toughened-Platelet Alumina (TPA) that has been processed using a toughening

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



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

(the manufacturer of the Biolox *delta* Ceramic Heads, has allowed permission to examine their Master File (b)(4)Trade Secret Process - contains data on the subject alumina composite material. (b) has given this new material the trade name Biolox Delta.

The Biolox *delta* Ceramic Heads are ceramic femoral ball prostheses that are intended to be used with Biomet femoral stems with a matching taper design. The femoral heads are 28mm and 32mm in diameter and are offered only with Biomet's Type 1 Taper trunnion. The offset options (neck lengths) are -3mm, 0, +3mm, and +5mm for the 28mm head, and -3mm, 0, +3mm, and +6mm for the 32mm head. The heads mechanically lock with the femoral stem via a Morse-type taper and articulate with a polyethylene acetabular component.

The subject heads are identical to the zirconia heads cleared in K943586, K925345, and K905687 in terms of taper locking design and taper angles. The material is similar to (b)(4)Trade's Biolox *forte*, alumina material, but has been modified in order to provide improved material characteristics.

The TTPA material is made of (b)(4)Trade Secret Process - Product Specs. The complete chemical composition of the TTPA, as listed in (b)(4)Trade Secret Process - from (b) and provided on page 9 of the submission is: P d t S b

Component	Content in wt %
(b)(4)Trade Secret Process - Product Specs	

Physical Properties	Biolox Forte (Alumina) from Amendment 1	Biolox Delta (Alumina Matrix Composite) from Amendment 5
(b)(4)Trade Secret Process - Product Specs		

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



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



These values are similar to those cited in K011533, the first Biolog delta heads cleared for DePuy (again, values are slightly different due to changes in measurement techniques but MAF provided correlation information).

Cone

Exhibit 3 contains dimensioned engineering drawings of the Biomet Type 1 trunnion taper including the following dimensions. This is the only cone taper that is compatible with the subject femoral heads.

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



Ball

Dimensioned engineering drawings of the modular heads may be found in Exhibit 6. They contain the following information:

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



Magnified photos of the modular head engraving may be found in Exhibit 4. A description of this laser etching process is included in (b)(4)Trade Secret Process - . An analysis of the natural radioactive impurities of the material is provided in Exhibit 5. The radioactivity level is below the proposed upper limit set by ISO 13356.

Exhibit 12 contains a comparison table and predicate device information.

#### Stems

Exhibit 2 contains a list of the femoral components (and their 510k numbers) compatible with the subject femoral heads. The list is quite extensive. All stems utilize the Biomet Type 1 taper, a detailed drawing of which is provided in Exhibit 3. (b)(4)Trade Secret Process - Product Specs

Stems are available with or without a porous coating and intended for cemented or cementless use.

#### Acetabular Inserts/Shells

No information was provided on compatible acetabular components. The sponsor will be asked for these in the deficiency letter.

### 3. **Intended Use:**

BioloX *delta* Ceramic Heads are indicated for use with cemented or non-cemented femoral 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.

I believe the sponsor should include a reference to total hip replacement (i.e., for use with femoral and acetabular components, not hemi-arthroplasty).

### 4. **Sterilization:**

Device is provided Sterile.

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

SAL:  $10^{-6}$

Validation Method: (b)(4)Trade Secret Process -

Pyrogenicity: no claims will be made

Description of packaging: each component is placed in a plastic bag and between two foam pads, and then placed in an inner blister pack sealed with a Tyvek lid that fits into an outer blister pack also sealed with a Tyvek lid. The entire unit is placed in a cardboard box and shrink-wrapped.

Recommended re-sterilization method: specifically not recommended (this information was taken from the package insert and the labeling section, not the sterilization section of the submission)

### 5. **Labeling:**

Labeling in the form of draft package labels, and a package insert were provided. They are adequate. The material designation on the label reads "TTPA Ceramic Head" and "Alumina/Zirconia". This is acceptable. (b)(4)Trade Secret Process - Product Specs

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





7. **Sponsor's information in support of SE:**

K031803, DePuy Ceramic Femoral Heads, DePuy Orthopaedics (J&J)  
K943586, Zirconia Ceramic Modular Heads (Astro Met), Biomet Inc.  
K925345, Zirconia Ceramic Modular Heads, Biomet Inc.  
K905687, Zirconia Ceramic Modular Head, Biomet Inc.

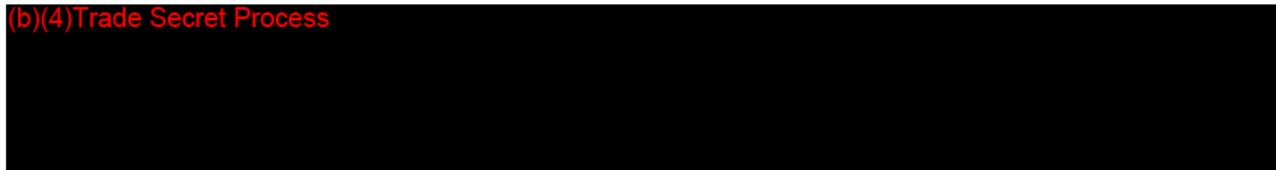
8. **Review of other 510(k)s for SE:**

K011533, DePuy Femoral Heads (alumina/zirconia composite), DePuy Orthopaedics (J&J)  
K040644, DePuy Femoral Heads (alumina/zirconia composite), DePuy Orthopaedics (J&J)

9. **Summary:**

The Biolox *delta* Ceramic Heads of this submission have essentially the same technological characteristics as the predicate devices reviewed above. The pre-clinical test results are similar to the predicates; however, the composition of the ceramic differs from standard alumina and zirconia predicates, in that it is a composite of these device materials. Otherwise, the subject devices have the same intended use, method of fixation, sizes and design as the predicates. Before an SE

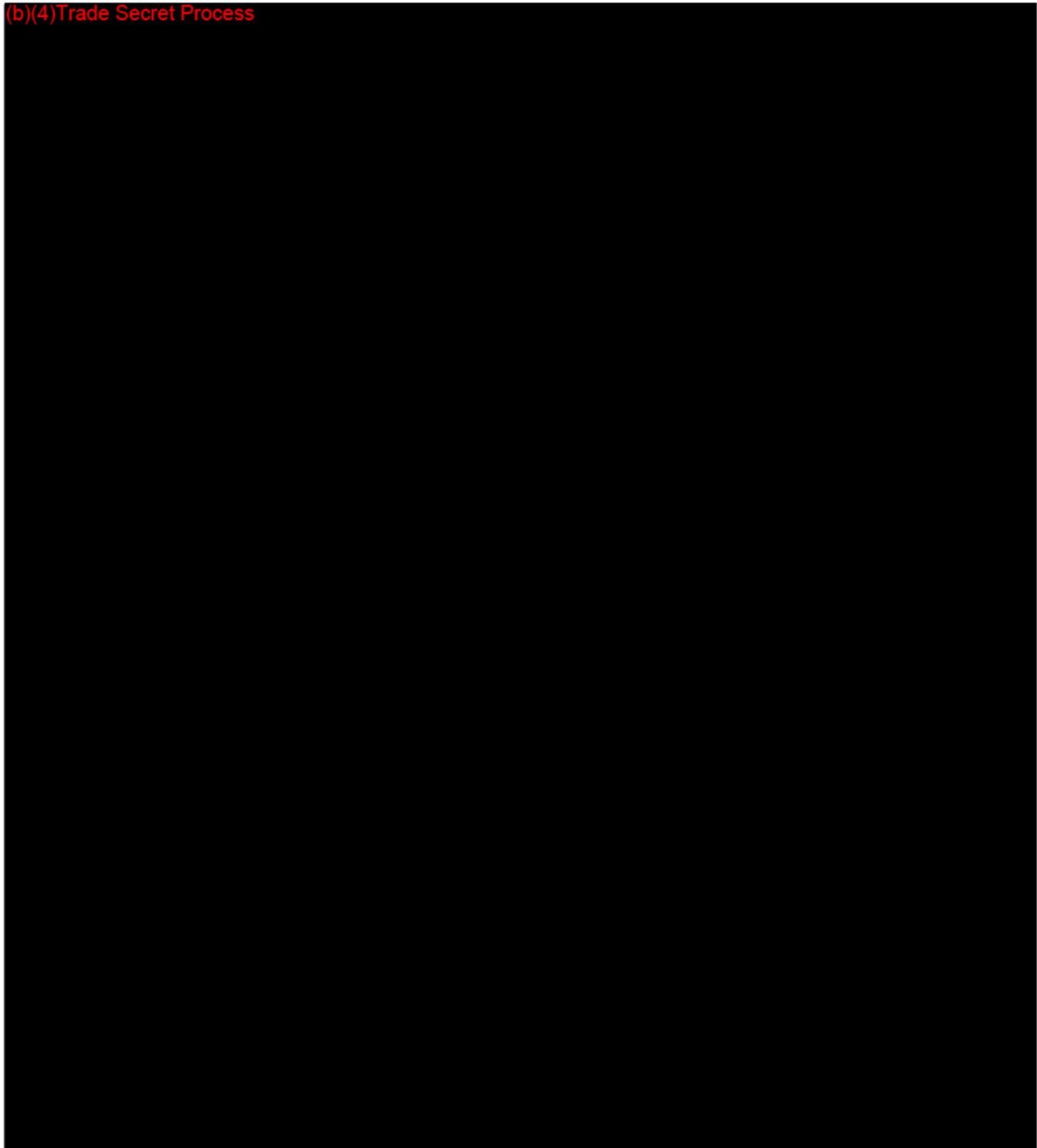
(b)(4)Trade Secret Process



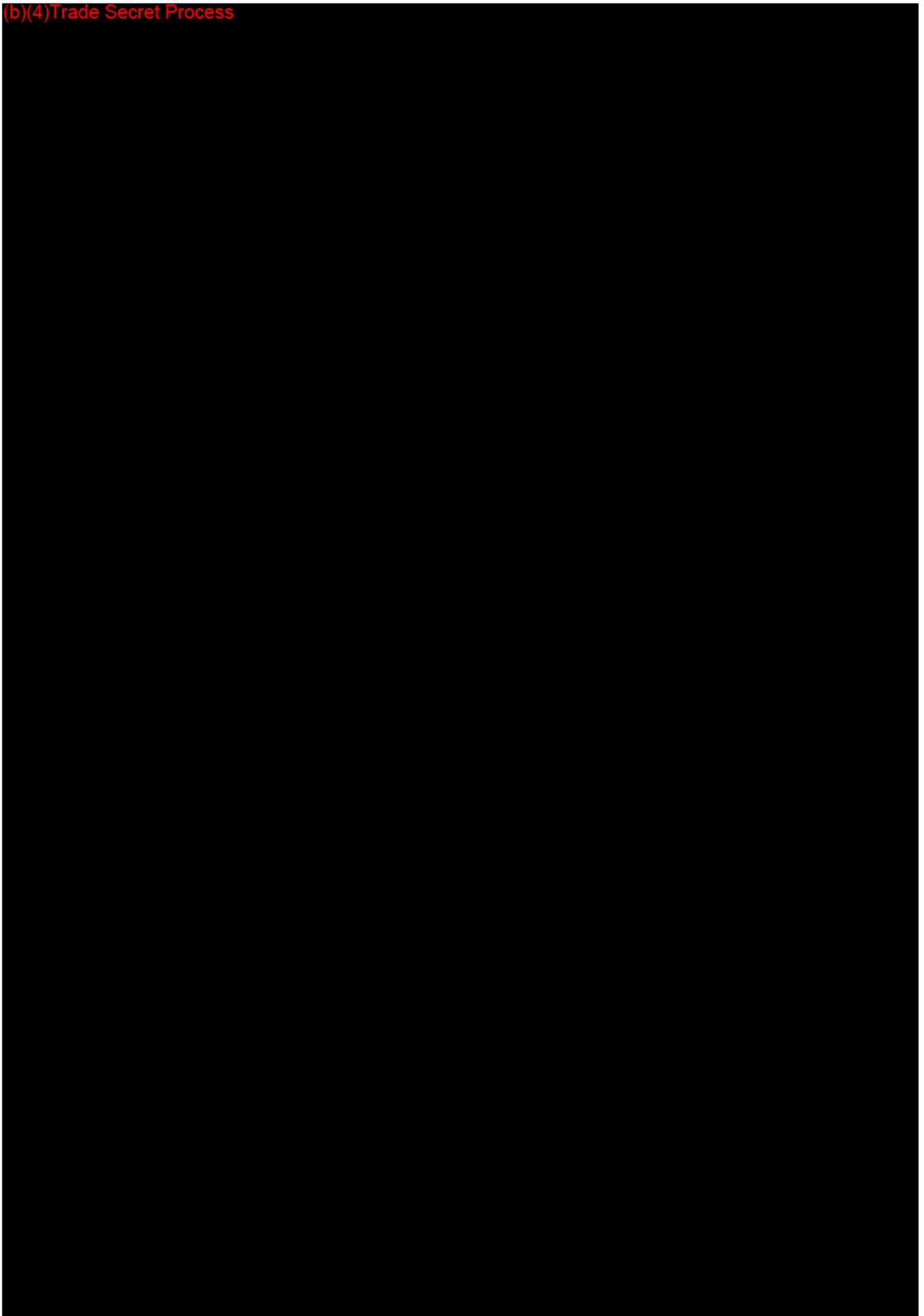
**10. Contact History/Requests for More Information:**

An AI letter will be sent to the sponsor requesting the following additional information:

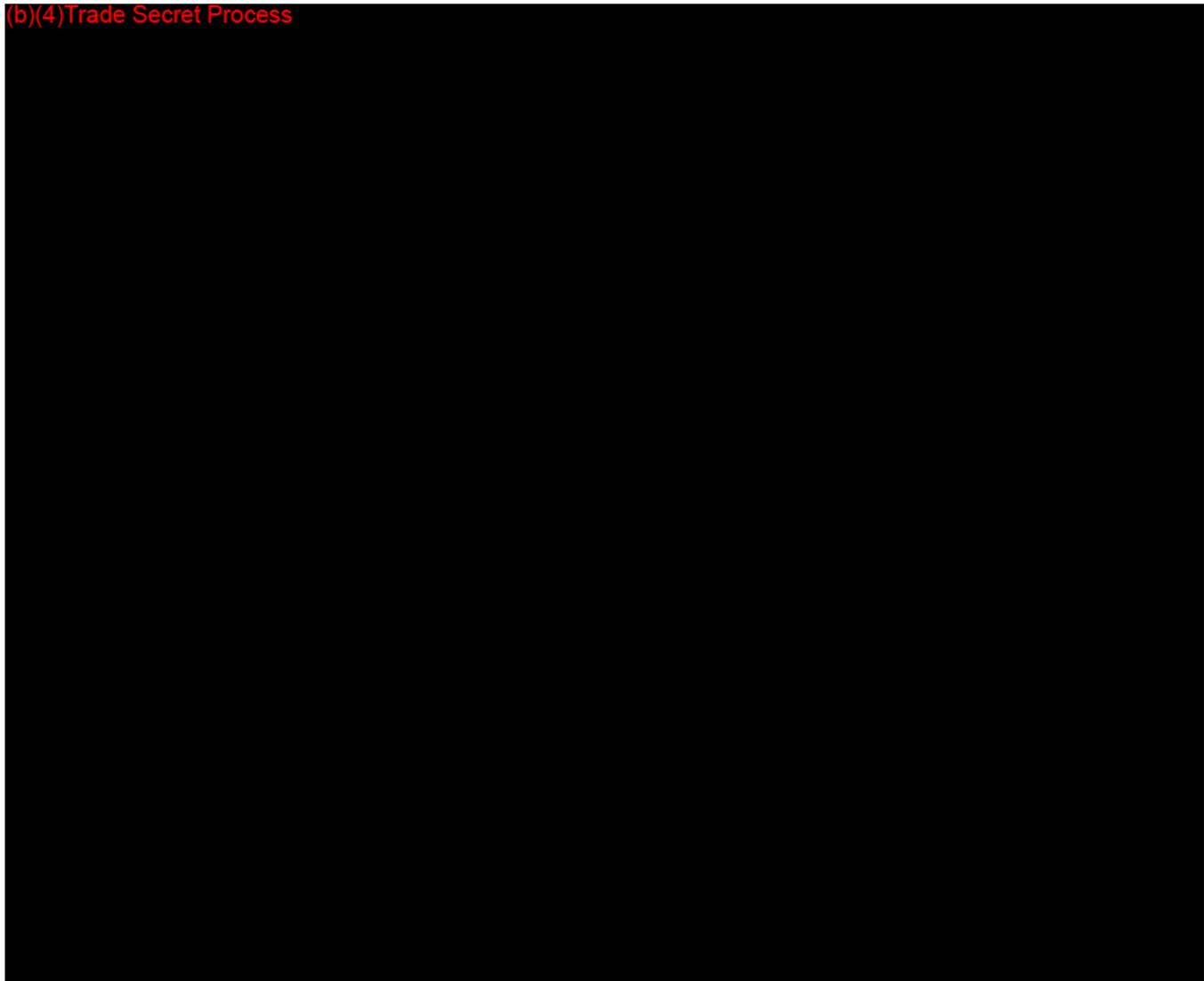
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



Peter G. Allen, MS; Biomedical Engineer  
ODE/DGRND/ORDB  
October 29, 2004

Peter G Allen

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	<del>XXXXXXXXXX</del>	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

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

510(k) Number: K042091

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

**Section 1: Required Elements for All Types of 510(k) submissions:**

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	↓	
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [Sec 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

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

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

\*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

**Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:**

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- \* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):**

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	↓	
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

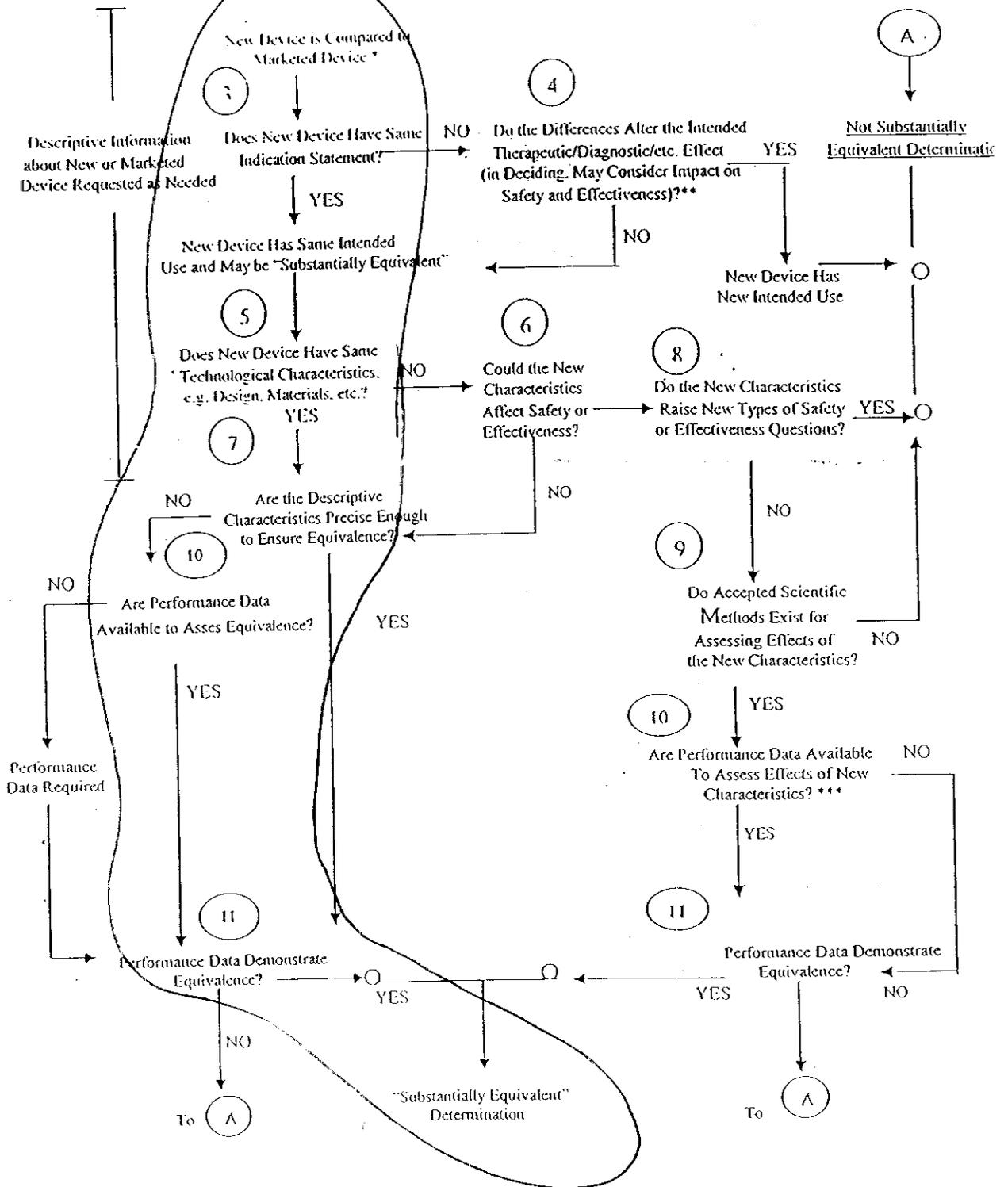
*Items with checks in the "Present or Adequate" column do not require additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

Passed Screening  Yes  No  
 Reviewer: Peter Allen  
 Concurrence by Review Branch: \_\_\_\_\_

Date: \_\_\_\_\_

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

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



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

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

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

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

January 28, 2005

BIOMET, INC.  
P.O. BOX 587  
WARSAW, IN 46581  
ATTN: PATRICIA SANDBORN BERES

510(k) Number: K042091  
Product: BIOLOX DELTA  
CERAMIC HEADS

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](http://www.fda.gov/cdrh/ode/a02-01.html).

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. In the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

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

Sincerely yours,

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

K042091/S1



January 27, 2005

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

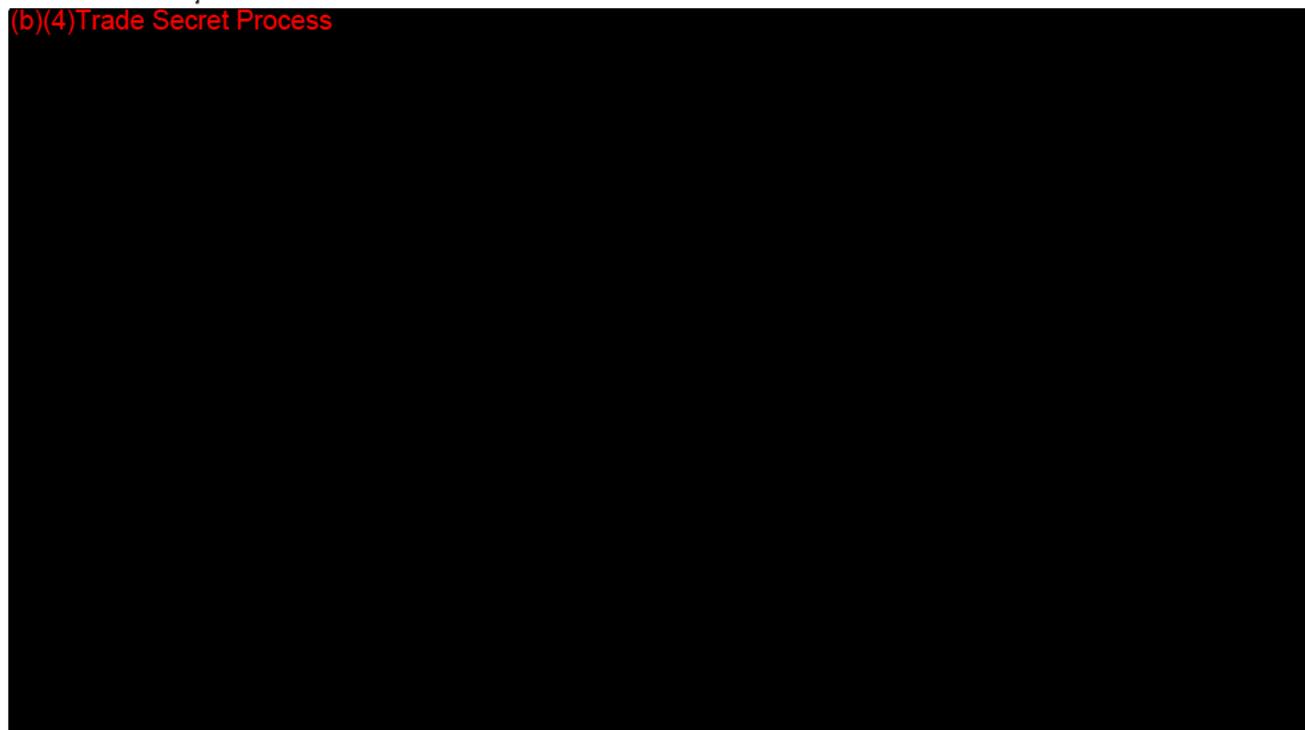
01/27/05  
10:00 AM  
K042091/S1

Re: K042091  
Device: BioloX® *delta* Ceramic Heads  
Reviewer: Peter Allen

Dear Mr. Allen:

The following additional information is being supplied in response to your November 1, 2004 request for additional information.

(b)(4)Trade Secret Process



MAILING ADDRESS  
P.O. Box 5887  
Warsaw, IN 46581-0587

SHIPPING ADDRESS  
56 E. Bell Drive  
Warsaw, IN 46582

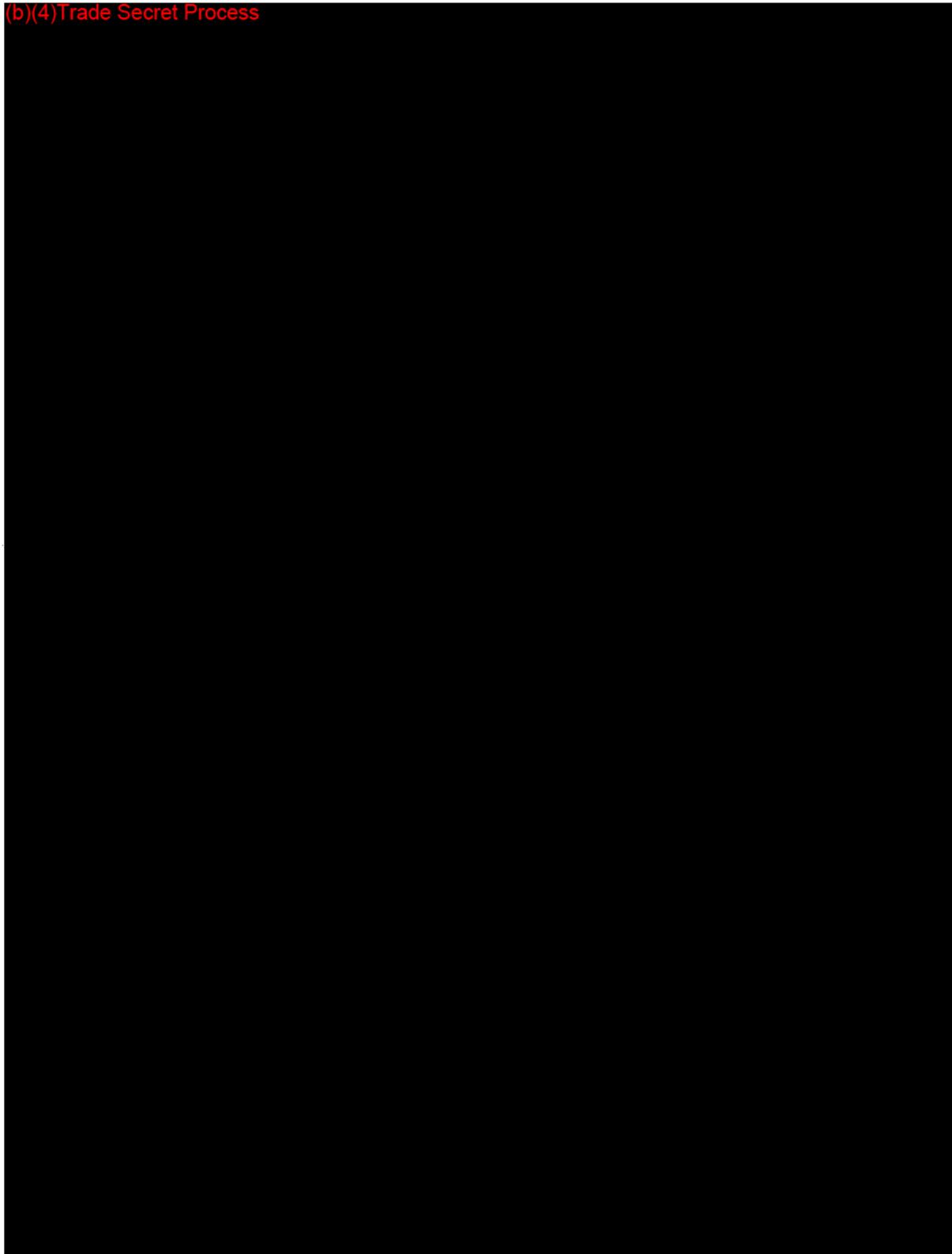
OFFICE  
571-267-6639

FAX  
571-267-8137

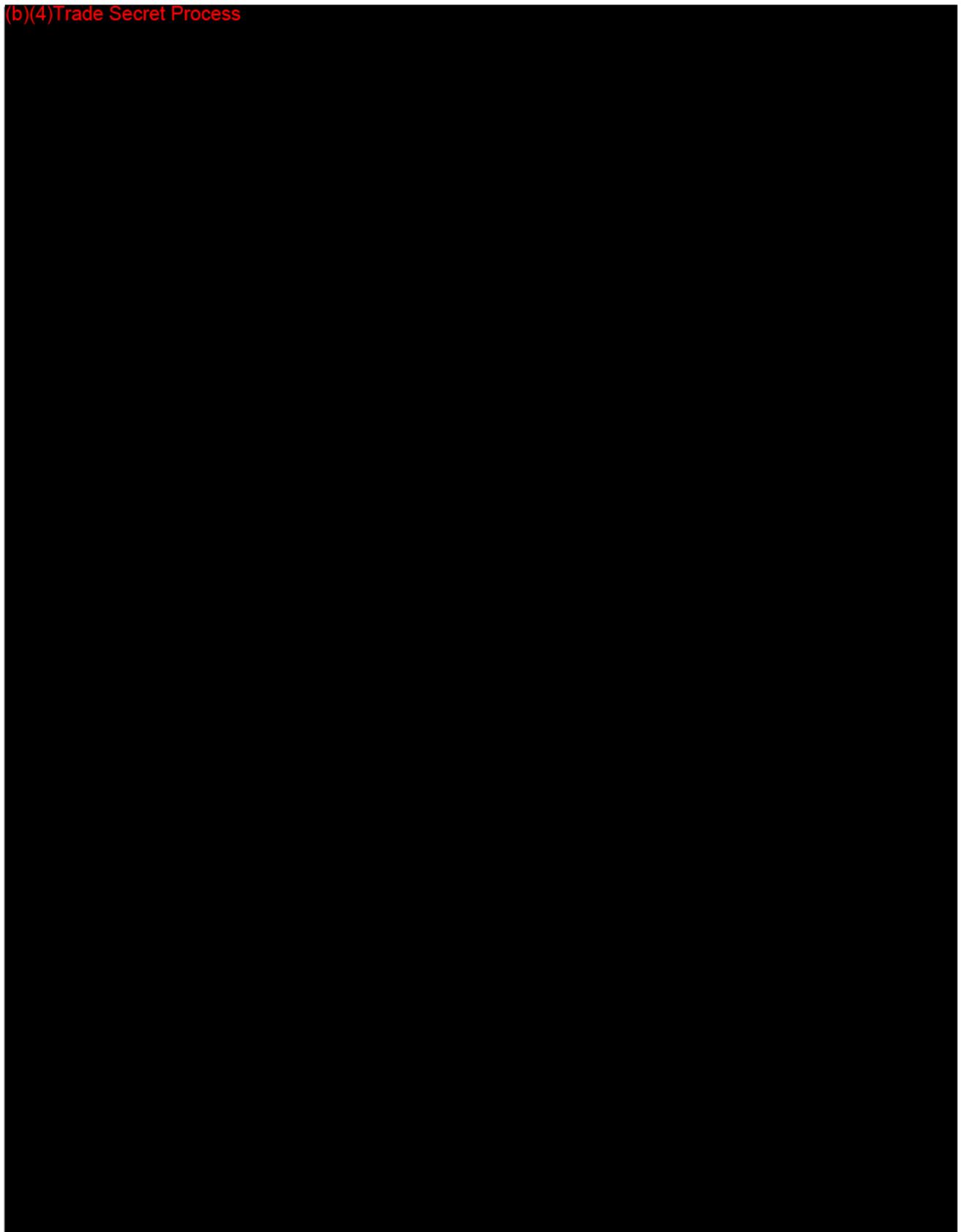
E-MAIL  
biomet@biomet.com

28  
JK-27

(b)(4)Trade Secret Process

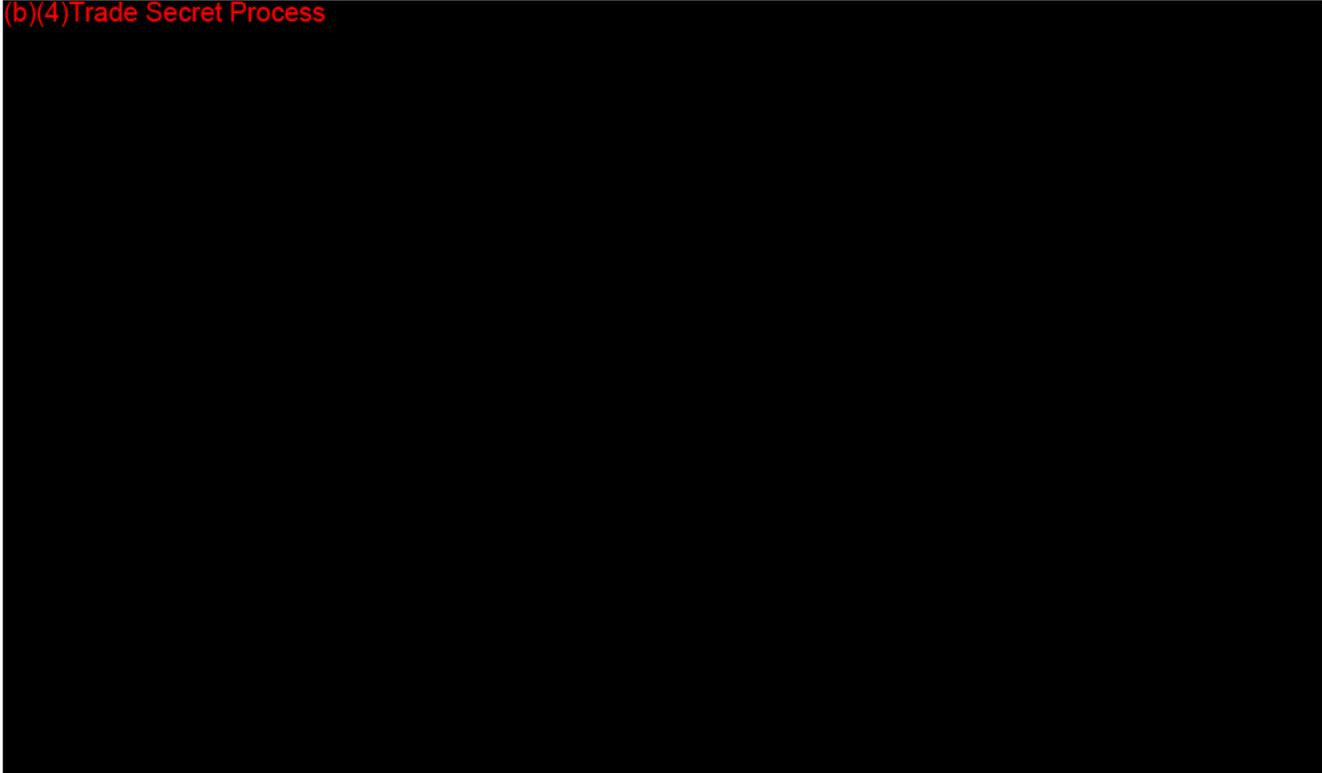


(b)(4)Trade Secret Process



Food and Drug Administration  
510(k) K042091  
January 27, 2005  
Page 4

(b)(4)Trade Secret Process



Sincerely,

*Patricia S Beres*

Patricia Sandborn Beres  
Senior Regulatory Specialist



































# Appendix C

Drawings





























































# Appendix C

**Biomet Test Request Form**































# Appendix A

Biomet Mechanical Test Request Form





# Appendix B

**Metcut Research Inc. Test Report**







# Appendix C

Drawing















































The Modular Head Components contained in this submission may be used with Biomet acetabular components cleared under the following 510(k)s:

Acetabular System Name	510(k) number	Product Code	Indications
A-B Acetabular System	K954417 K030055	LPH LPH	Cemented and non-cemented
All-Poly Acetabular Components	Preamendment		Cemented
ARCOM® Ringloc® Liners	K926107 K950761 K970501 K023357 K030055	LPH JDI LPH LPH LPH	Indication based on mating shell
ARCOM® Ringloc® Low Profile Liners	K926107 K970501 K023357	LPH LPH LPH	Indication based on mating shell
Bio-Clad™ All-Poly	K926107	LPH	Cemented
Flanged Acetabular Component	K983035 K030055	LPH LPH	Cemented and non-cemented
Full Hemisphere Acetabular Components	K920640	JDL*	Cemented
Healy™ Flanged Revision	K921139	JDL*	Cemented
Index® Acetabular Components	K950761 K030055	JDI LPH	Cemented and non-cemented
Mallory/Head® Acetabular Components	K861114 K921181 K030055	JDL* LZO LPH	Cemented and non-cemented
Mars® Modular Acetabular Reconstructive System	K911718	JDI	Cemented
Par 5™ Acetabular Components	K022094	JDI	Cemented and non-cemented
Pegged (TRI-SPIKE™) Acetabular Components	K970501 K030055	LPH LPH	Cemented and non-cemented
Protrusio Cages	K971890 K020076	JDI JDI	Cemented
Ranawat/Burstein® Acetabular Components	K911685 K921277	JDI LPH	Cemented and non-cemented (NIDJD only)
RX 90® Low Profile Acetabular Components	K920639	JDL*	Cemented
Universal® Acetabular Components	K861433 K921301 K030055	JDL* LPH LPH	Cemented and non-cemented

\*The JDL product code for metal on metal, cemented components (21 CFR 888.3320) is listed in the FDA's web database for these submissions. All of these submission were for metal on polyethylene systems (JDI).

The Modular Head Components contained in this submission may be used with Biomet femoral components cleared under the following 510(k)s:

Femoral Component Name	510(k) Number	Product Code	(b)(4)Trade Secret Process	Indication
Answer® Femoral Component	K991987	JDI		Cemented
Co-Cr Answer® Femoral Components	K931194	JDG <sup>1</sup>		Cemented
APF Femoral Component	K852585	JDI		Cemented and non-cemented
	K984154	JDI		
	K030055	LPH		
Bi-Metric® Femoral Components	K921224	LZO		Cemented and non-cemented
	K020580	LPH		
	K030055	LPH		
Bi-Metric® Head/Neck Replacement	K955350	LZO		Cemented
	K992058	JDI		
	K983710	JDI		
HA Bi-Metric® Femoral Component	K023409	LPH		Non-cemented
	K030055	LPH		
Bio-Groove® Hip Component	K864085	KWL <sup>2</sup>		Non-cemented
Bio-Groove® HAP Hip Components	K912369	MEH		Non-cemented
	K912370	MEH		
Bohn Femoral Component	K000262	LZO, MEH		Non-cemented
Buchalter/Fauser Femoral Component	K952686	LZO		Cemented
Color Buffed Cemented stem	K992903	JDI		Cemented
	K012019	JDI		
Fenning (Osteocap RS®) Femoral Component	K960303	LPH		Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO		Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734	JDI		Cemented
Gross Femoral Component	K001580	MEH		Non-cemented
Impact® Co-Cr Femoral Components	K942027	JDG <sup>3</sup>		Cemented
Integral® Femoral Component	K921225	LZO		Cemented and non-cemented
	K984296	LPH		
	K984408	LPH		
	K030055	LPH		
	K030501	LPH		
Integral® Co-Cr Femoral Component	K042029	LPH		Cemented
	K942479	LZO		
Interlocking Hip Stems	K990830	LPH		Non-cemented
	K042774	LPH <sup>4</sup>		
Mallory/Head® Total Hip System	K921181	LZO		Cemented and non-cemented
	K994007	JDI		
	K000538	LPH		
	K003429	LPH		
	K030055	LPH		
HA Mallory/Head® Total Hip System	K021403	LPH, MEH		Non-cemented

<sup>1</sup> Submitted under classification 888.3350 JDI

<sup>2</sup> Not stated in submission

<sup>3</sup> Submitted under classification 888.3350 JDI

<sup>4</sup> Cleared under product codes JDL, KWA, LPH, LZO, KWZ, JDI and KQY based on available modular head and acetabular components for use with this stem

	K030055	LPH, MEH	(b)(4) Trade Secret Process	
Mallory/Head® Co-Cr Femoral Component	K911684	JDI		Cemented
Mallory/Head® Calcar Femoral Components (including HA)	K945115 K001660 K031693	LPH LPH LPH		Cemented and non-cemented
Modular Hip Stems	K912712 K921274 K030055	JDI LPH LPH		Cemented and non-cemented
Oncology Salvage System	K002757	JDI		Cemented
OSS™ Les Proximal Femoral Component	K021380	JDI		Cemented and non-cemented
PMI® Femoral Component	K911802 K923452 K030055	JDI LPH LPH		Cemented and non-cemented
HA PMI® Femoral Stem	K030048	LPH		Non-cemented
Portrait™ Femoral Component	K010560	LZO		Non-cemented
Reach® Femoral Component	K971824 K982367 K000760	LPH LPH LPH		Non-cemented
Modular Reach®	K994038	LPH		Non-cemented
HA Modular Reach®	K022463 K030055	LPH LPH		Non-cemented
Rx-90® Femoral Stems	K942028 K023085	JDG <sup>5</sup> JDI		Cemented
Taperloc® Femoral Component	K921301 K030055	LPH LPH		Cemented and non-cemented
HA Taperloc® Femoral Component	K020963 K030055	MEH LPH		Non-cemented
Total IM Femur	K033871	JDI		Cemented
Total Femur	K974558	JDI		Cemented

<sup>5</sup> Submitted under classification 888.3350 JDI

## 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)