



MANUFACTURING CORP.

**510(k) Summary**

**Date:** December 8, 2008

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist

**Proprietary Name:** Biolox® *delta* Option Ceramic Heads

JAN 15 2009

**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:**  
Biolox® *delta* Ceramic Heads – K042091, K051411, K061312, K073102

**Device Description:** Biolox® *delta* Option Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. A highly polished spherical head in a variety of diameters articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem via a taper adapter. Adapters are available for either Biomet's Type I taper or Biomet's 12/14 taper in a variety of neck lengths.

**Indications For Use:** Biolox® *delta* Option 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:

**Mailing Address:**  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.8137  
www.biomet.com

**Shipping Address:**  
56 East Bell Drive  
Warsaw, IN 46582

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

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

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

**Summary of Technologies:** The Biolox® *delta* Option 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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet, Inc.  
% Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
56 East Bell Dr.  
P.O. Box 587  
Warsaw, Indiana 46581

JAN 15 2009

Re: K082996  
Trade/Device Name: BioloX *delta* Option Ceramic Heads  
Regulation Number: 21 CFR 888.3353  
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or  
nonporous uncemented prosthesis  
Regulatory Class: II  
Product Code: LZO  
Dated: December 15, 2008  
Received: December 17, 2008

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

Sincerely yours,



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

Enclosure

## Indications for Use

510(k) Number (if known): K082996 (pg 1/1)

Device Name: BioloX<sup>®</sup> delta Option Ceramic Heads

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

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

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

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

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

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

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

510(k) Number K082996

Page 1 of 1



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet, Inc.  
% Ms. Patricia Sandborn Beres  
Senior Regulatory Specialist  
56 East Bell Dr.  
P.O. Box 587  
Warsaw, Indiana 46581

JAN 15 2009

Re: K082996

Trade/Device Name: BioloX *delta* Option Ceramic Heads

Regulation Number: 21 CFR 888.3353

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

Regulatory Class: II

Product Code: LZO

Dated: December 15, 2008

Received: December 17, 2008

Dear Ms. Beres:

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Sincerely yours,



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

Enclosure

## Indications for Use

510(k) Number (if known): K082996 (pg 1/1)

Device Name: BioloX<sup>®</sup> delta Option Ceramic Heads

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

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Prescription Use X  
\_(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH/Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
**(Division Sign-Off)**

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

**510(k) Number** K082996

Page 1 of 1



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

December 17, 2008

BIOMET, INC.  
56 EAST BELL DR. P.O. BOX 587  
WARSAW, INDIANA 46581-0587  
UNITED STATES  
ATTN: PATRICIA SANDBORN BERES

510k Number: K082996

Product: BIOLOX DELTA OPTION CERAMIC HE

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). On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet Inc.  
% Ms. Patricia Beres  
56 East Bell Dr.  
P.O. Box 587  
Warsaw, IN 46581

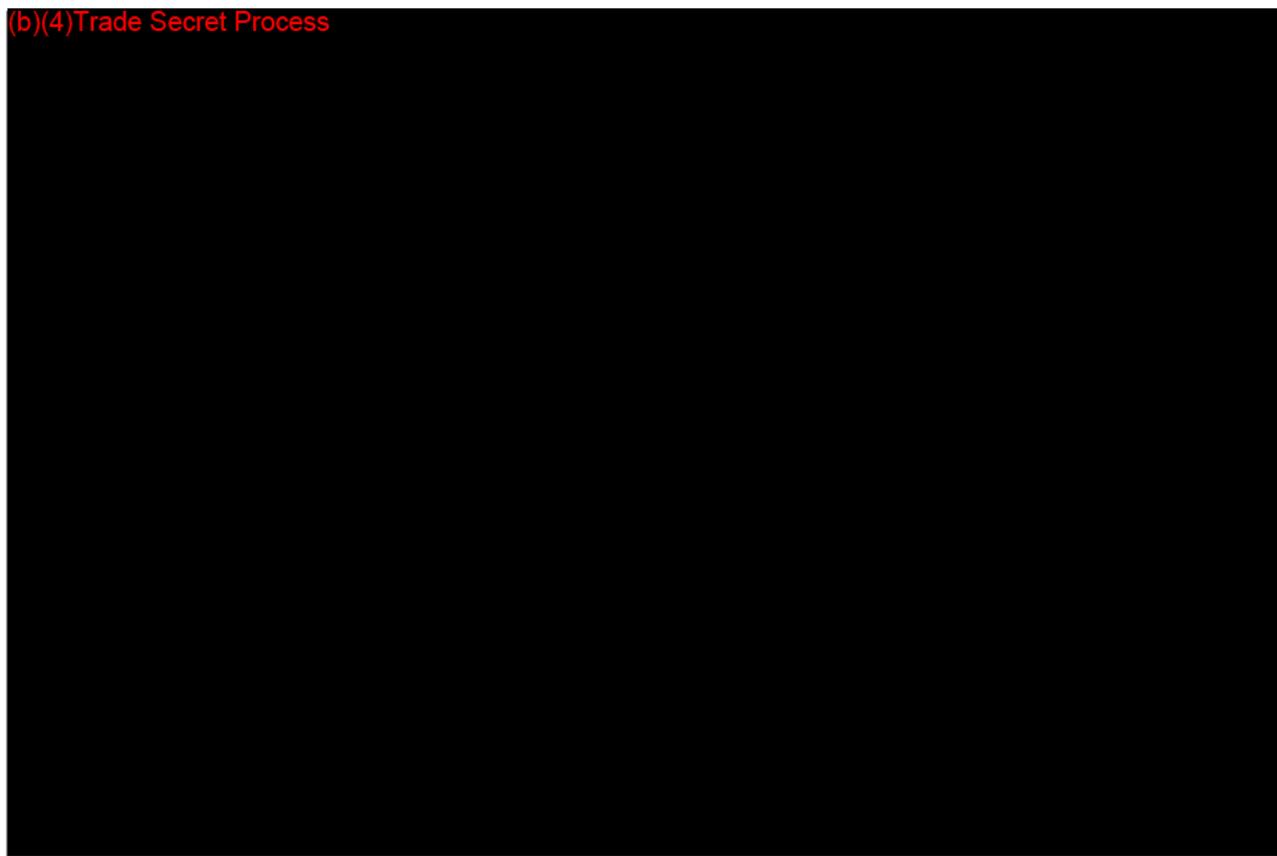
NOV 14 2008

Re: K082996  
Trade Name: BioloX *delta* Option Ceramic Heads  
Dated: October 6, 2008  
Received: October 20, 2008

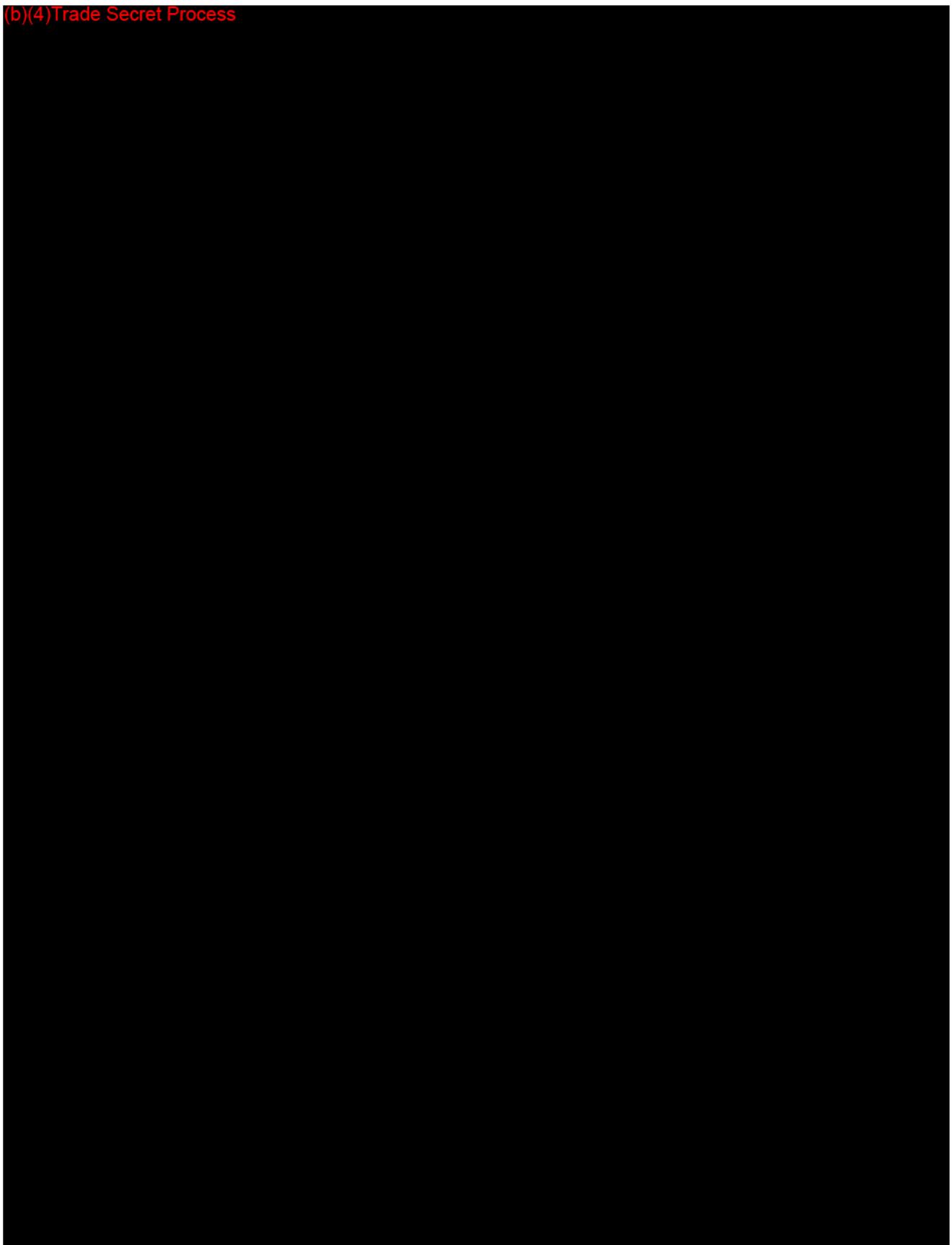
Dear Ms. Beres:

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 the following information:

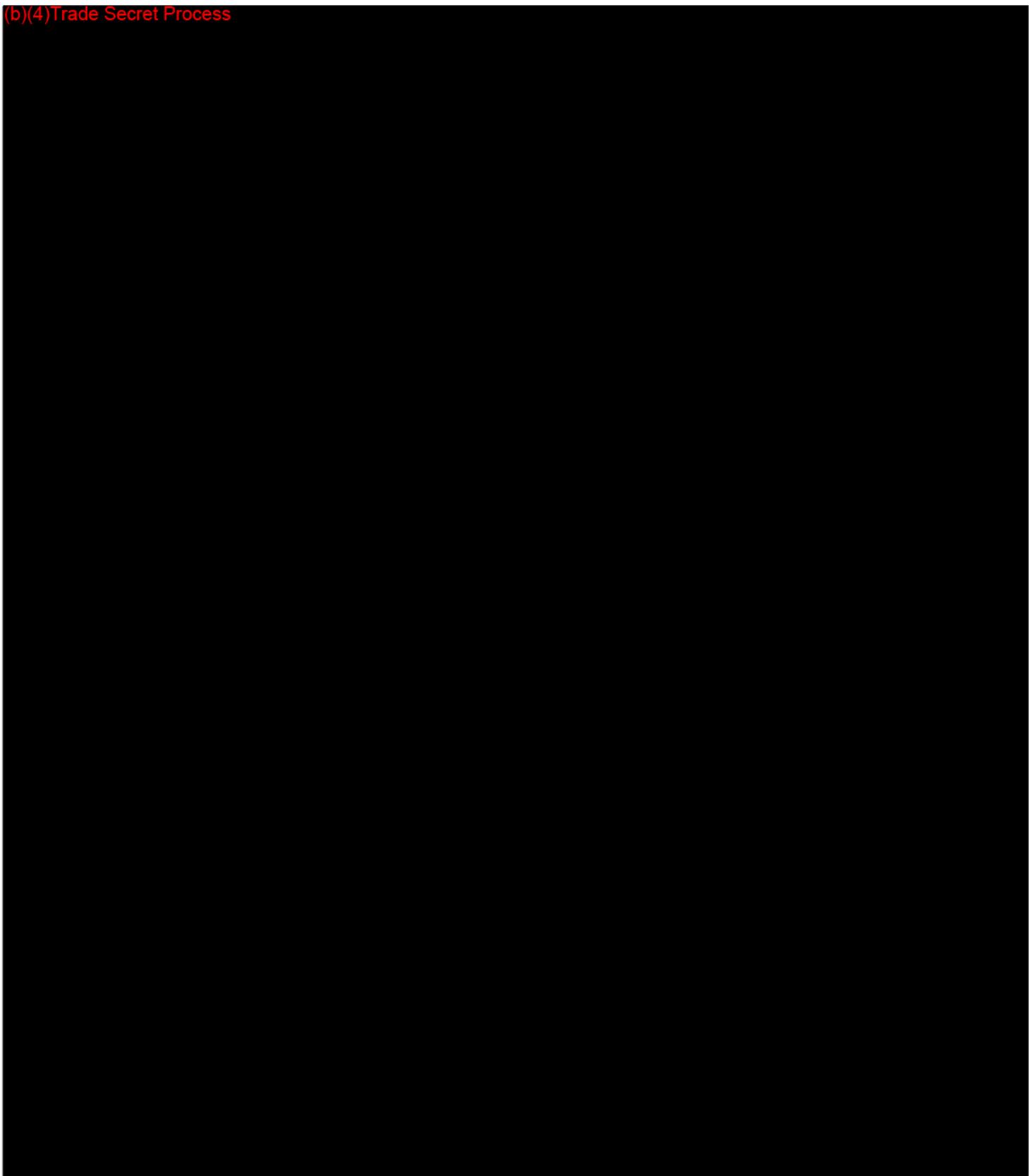
(b)(4)Trade Secret Process



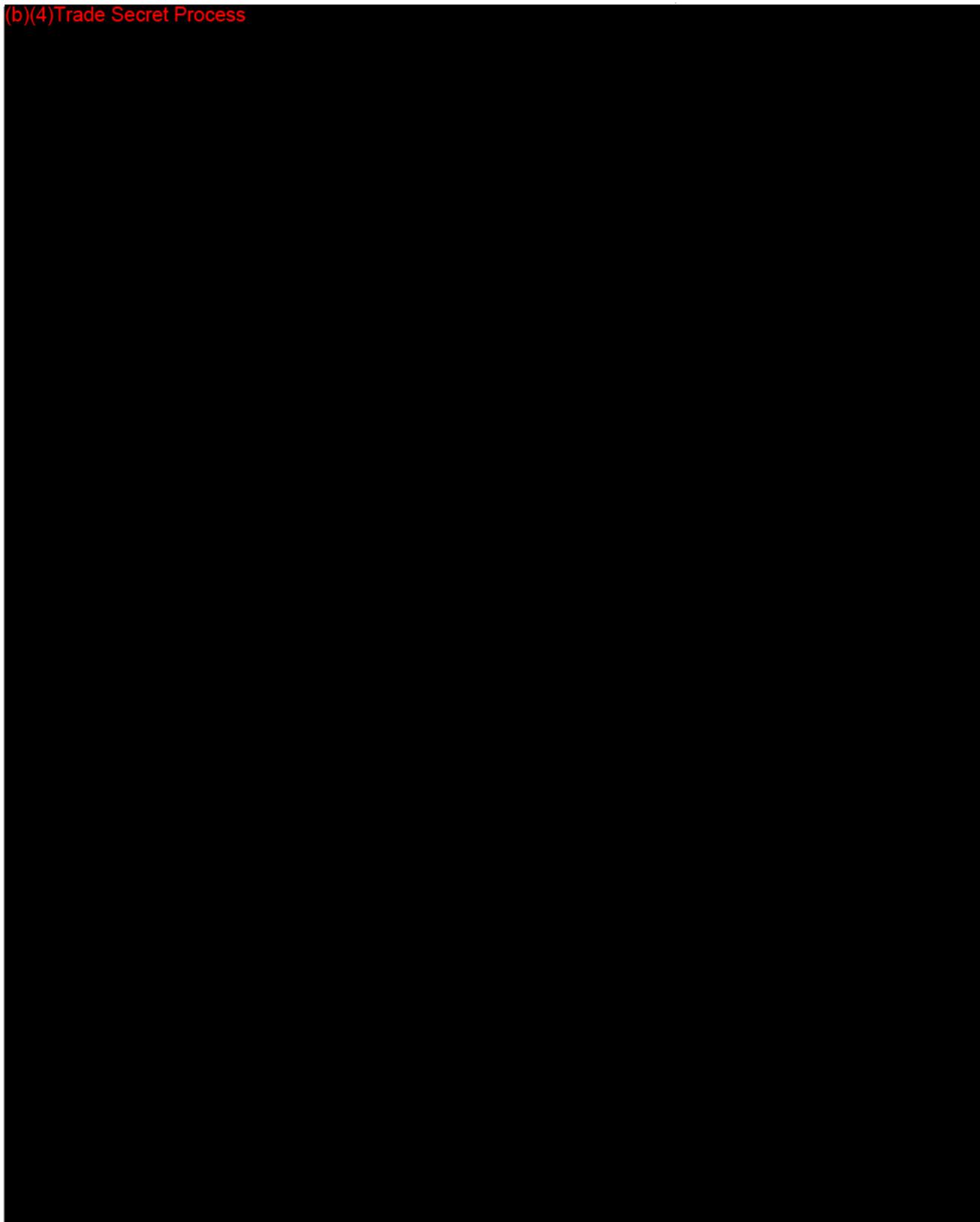
(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



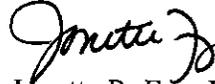
(b)(4)Trade Secret Process



Page 5 – Ms. Patricia Beres

If you have any questions concerning the contents of the letter, please contact Ms. Tara Shepherd at (240) 276-3683. 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 (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jonette R. Foy, Ph.D.  
Chief, Orthopaedic Joint Devices Branch  
Division of General, Restorative  
and Neurological Devices  
Center for Devices and  
Radiological Health



October 21, 2008

BIOMET, INC.  
56 EAST BELL DR. P.O. BOX 587  
WARSAW, INDIANA 46581-0587  
UNITED STATES  
ATTN: PATRICIA SANDBORN BERES

510k Number: K082996

Received: 10/20/2008

Product: BIOLOX DELTA OPTION CERAMIC HE

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

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

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

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007” ([http://www.fda.gov/oc/initiatives/fdaaa/guidance\\_certifications.html](http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html)). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

Sincerely yours,

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

October 08, 2008

BIOMET, INC.  
56 EAST BELL DR. P.O. BOX 587  
WARSAW, INDIANA 46581-0587  
UNITED STATES  
ATTN: PATRICIA SANDBORN BERES

510k Number: K082996  
Received: 10/8/2008  
User Fee ID Number: (b)  
Product: BIOLOX DELTA OPTION CERA

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 all future correspondence that relates to this submission. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. Please send a check to one of the addresses listed below:

<u>By Regular Mail</u>	<u>By Private Courier(e.g.,Fed Ex, UPS, etc.)</u>
Food and Drug Administration	U.S. Bank
P.O. Box 956733	956733
St. Louis, MO 63195-6733.	1005 Convention Plaza
	St. Louis, MO 63101
	(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at [www.fda.gov/oc/mdufma](http://www.fda.gov/oc/mdufma).

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

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address [www.fda.gov/cdrh/dsma/dsmastaf.html](http://www.fda.gov/cdrh/dsma/dsmastaf.html), or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at [Diane.Garcia@fda.hhs.gov](mailto:Diane.Garcia@fda.hhs.gov) or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia  
Public Affairs Specialist  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

K082996



ORTHOPEDICS, INC.

October 6, 2008

FDA CDRH DMC

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

OCT - 8 2008

Received

Reference: "Special" 510(k) – Biomet® Biolox® *delta* Option Ceramic Heads  
User Fee ID (b)(4)Trade Secret

Dear Sir or Madam:

Enclosed is a "**Special**" **510(k): Device Modifications** submission for Biolox® *delta* Option Ceramic Heads which is a modification of the Biolox® *delta* Ceramic Heads cleared in 510(k) K042091, K061312 and K073102. We believe this device is substantially equivalent\* to cleared devices and warrants a "Special" 510(k).

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. Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Sincerely,

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)]

Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.8137  
[www.biomet.com](http://www.biomet.com)

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

K082996



October 6, 2008

FDA CDRH DMC

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

OCT - 8 2008

Received

Reference: "Special" 510(k) – Biomet® Biolox® *delta* Option Ceramic Heads  
User Fee ID: (b)(4)Trade Secret

Dear Sir or Madam:

Enclosed is a "Special" 510(k): **Device Modifications** submission for Biolox® *delta* Option Ceramic Heads which is a modification of the Biolox® *delta* Ceramic Heads cleared in 510(k) K042091, K061312 and K073102. We believe this device is substantially equivalent\* to cleared devices and warrants a "Special" 510(k).

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. Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Sincerely,

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)]

K082996



October 6, 2008

FDA CDRH DMC

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

OCT - 8 2008

Received

Reference: "Special" 510(k) – Biomet® Biolox® *delta* Option Ceramic Heads  
User Fee ID: (b)(4)Trade Secret

Dear Sir or Madam:

Enclosed is a "Special" 510(k): Device Modifications submission for Biolox® *delta* Option Ceramic Heads which is a modification of the Biolox® *delta* Ceramic Heads cleared in 510(k) K042091, K061312 and K073102. We believe this device is substantially equivalent\* to cleared devices and warrants a "Special" 510(k).

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Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
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Office: 574.267.6639  
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www.biomet.com

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

## Table of Contents

Cover Letter	
Medical Device User Fee Cover Sheet	
510(k) Body .....	1
Tab 1 Labeling .....	8
Tab 2 Indications for Use Form.....	11
Tab 3 Modified Component Listing and Prints .....	12
Predicate Component Listing and Prints.....	27
Tab 4 Compatible Components .....	45
Sample Drawing – Type I Taper .....	50
Sample Drawing – Type I Reduced Taper.....	51
Sample Drawing – 12/14 Taper .....	52
Tab 5 Risk Analysis Table and Discussion .....	53
Tab A CeramTach’s Testing Protocol .....	62
Tab B Mechanical Testing of 12/14 Taper Sleeves .....	66
Tab C Mechanical Testing of Type I Taper Sleeve .....	121
Tab D Corrosion .....	169
Tab E Wear Testing Justification .....	221
Tab 6 Declarations of Conformity.....	284
Tab 7 510(k) Summary .....	286
Tab 8 Truthful and Accurate Statements .....	288
Tab 9 Clinical Trails Certification.....	290
Tab 10 Standards Data Report For 510(k) .....	291



October 6, 2008

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

Reference: "Special" 510(k) – Biomet® BioloX® *delta* Option Ceramic Heads  
User Fee ID: (b)(4) Trade Secret  
Process

Dear Sir or Madam:

Enclosed is a "**Special**" **510(k): Device Modifications** submission for BioloX® *delta* Option Ceramic Heads which is a modification of the BioloX® *delta* Ceramic Heads cleared in 510(k) K042091, K061312 and K073102. We believe this device is substantially equivalent\* to cleared devices and warrants a "Special" 510(k).

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. Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

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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 Pre-market Notification Procedures, Final Regulation, Preamble, August 23, 1977, 42 FR 42520 (Docket No. 76N-0355)]

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Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.8137  
[www.biomet.com](http://www.biomet.com)

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  BIOMET INC P.O. Box 587 Warsaw IN 46581-0587 US		2. CONTACT NAME Patricia Beres 2.1 E-MAIL ADDRESS patty.beres@biometmail.com 2.2 TELEPHONE NUMBER (include Area code) 574-267-6639 1278 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 574-372-1683	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)Trade			
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/dc/mdufma">http://www.fda.gov/dc/mdufma</a> )			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	
<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 application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)			
<input type="checkbox"/> YES		<input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION			
(b)(4)Trade		29-Sep-2008	

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

**Device Name**

---

**Device Trade Name:** BioloX<sup>®</sup> *delta* Option Ceramic Heads  
**Common Name:** Ceramic Modular Heads

---

**Address and  
Registration #**

**Specification Holder:** Biomet Manufacturing Corp  
56 Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581-0587  
FDA Registration #: 1825034

**Contract Manufacturer:** (b)(4)Trade Secret Process



**Sterilization Site:**

**Contact  
Information**

---

**Name:** Patricia Sandborn Beres  
**Title:** Senior Regulatory Specialist  
**Address:** Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, IN 46581-0587  
**Telephone:** 574-267-6639  
**Fax:** 574-372-1683  
**E-mail:** [patty.beres@biometmail.com](mailto:patty.beres@biometmail.com)

**Alternate Contact:**

**Name:** Tracy B. Johnson  
**Title:** Director, Clinical and Regulatory Affairs  
**Address:** Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, IN 46581-0587  
**Telephone:** 574-267-6639  
**Fax:** 574-372-1683  
**E-mail:** [tracy.johnson@biometmail.com](mailto:tracy.johnson@biometmail.com)

**Device  
Classification**

---

**Class:** II  
**Product Code:** LZ0  
**Classification Names:** Hip joint metal/ceramic/polymer  
semi-constrained cemented or nonporous uncemented prosthesis

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Common Name.

The guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" was followed

for the preparation of the predicate BioloX<sup>®</sup> *delta* Ceramic Heads 510(k) K042091. Only those portions which are affected by the modifications required to create the new device will be addressed in this document.

**Predicate  
Device  
Information**

The predicate devices are the BioloX<sup>®</sup> *delta* Ceramic Heads cleared through 510(k)s K042091 (March 25, 2005), K051411, (June 29, 2005), 510(k) K061312 (June 6, 2006) and K073102 (November 27, 2007).

(b)(4)Trade Secret Process

**Labeling and  
Indications for  
Use**

Draft labels and Instructions for Use (package insert) can be found in Attachment 1. A new package insert which contains assembly instructions for the components has been developed. A specific surgical technique for the BioloX<sup>®</sup> *delta* Option Ceramic Heads has not been developed at this time. Placement of the head on the femoral stem trunion would be in keeping with the surgical procedure for the femoral stem or acetabular component being used in conjunction with the head.

Indications for Use

The BioloX<sup>®</sup> *delta* Option Ceramic Heads are intended for 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)

These are the same intended use as previously cleared for the predicate BioloX® *delta* Ceramic Heads. The Indications for Use Statement can be found in Attachment 2.

## Sterilization and Packaging

Devices are provided sterile by radiation methods as follows:

- Radiation Type: Gamma  
Radiation Source: (b)(4)Trade Secret  
Minimum Dosage: 25 kGy  
Maximum Dosage: 40 kGy
- Sterility Assurance Level: 10<sup>-6</sup>
- Sterility Validation Method: (b)(4)Trade Secret Process
- Pyrogen-Free: no claims will be made
- Packaging: Each component is placed within a plastic bag between two foam pads. They are then placed in an inner blister pack sealed with a Tyvek® lid which 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. All labeling will be on the outer Tyvek® lid as well as on the outer cardboard box.
- 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, 25 kGy
- Expiration Date: The BioloX® *delta* Option Ceramic Heads have a 10-year shelf-life. Supporting data is on file at Biomet and can be accessed at any future FDA inspection.

Note: The BioloX® *delta* Option Ceramic Head and Taper Adapter will be packaged separately.

## Device Description

The BioloX® *delta* Option Ceramic Heads consist of a series of BioloX® *delta* ceramic ball heads in combination with a titanium sleeve. The heads are available in a variety of diameters and taper adapters are available for Biomet's Type I and Biomet 12/14 tapers in a variety of neck lengths.

### Specific Characteristics – Heads

- Material - Transition-Toughened-Platelet Alumina (TTPA) (b)(4)Trade Secret Process (b)(4)Trade Secret Process



Head Size	28mm	32mm	36mm	38mm	40mm
(b)(4)Trade Secret Process					

**Specific Characteristics – Biomet Type I Adapter**

- Material -Titanium Alloy (Ti-6Al-4V, ISO 5832-3)
- (b)(4)Trade Secret Process
- Neck Lengths – x-small, small, medium, large, x-large (-6, -3, 0, +3, +6)

(b)(4)Trade Secret Process

Adapter Size	X-small -6	Small -3	Medium 0	Large +3	X-large +6
(b)(4)Trade Secret Process					

**Specific Characteristics – Biomet 12/14 Adapter**

- Material -Titanium Alloy (Ti-6Al-4V, ISO 5832-3)
- (b)(4)Trade Secret Process
- Neck Lengths – small, medium, large, x-large (-3, 0, +4, +7)

(b)(4)Trade Secret Process

Adapter Size	Small -3	Medium 0	Large +4	X-large +7
(b)(4)Trade Secret Process				

### Product Listing/Drawings

- The name and manufacturers model number for each BioloX<sup>®</sup> *delta* Option Ceramic Head may be found in Attachment 3.
- Dimensioned engineering drawings of the BioloX<sup>®</sup> *delta* Option Ceramic Heads and taper adapters may be found in Attachment 3.
- A product listing and engineering drawings of the predicate BioloX<sup>®</sup> *delta* Ceramic Heads may be found in Attachment 3.

### Compatible Products

- Attachment 4 contains a table of compatible hip stems for use with the BioloX<sup>®</sup> *delta* Option Ceramic Heads.
- All of the devices are metallic hip stems with or without porous coating.
- Each stem has a Biomet 12/14 or Biomet Type I trunion (standard or reduced) for attachment of the modular head. A sample engineering drawing of a femoral stem with each type of taper is included in Attachment 4.

(b)(4)Trade Secret Process

- Porous coating material conforms to ASTM F-1580.
- Attachment 4 also contains a list of the compatible acetabular components that may be used with this device.

(b)(4)Trade Secret Process

- Porous coating material conforms to ASTM F-1580.
- Polyethylene liners and all polyethylene cups are manufactured from material conforming to ASTM F-648.
- Screws for use in the acetabular shells are manufactured from titanium alloy conforming to ASTM F-136.

### Device Comparison

The following features have not changed as previously described in the predicate device 510(k) K042091.

- Material including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity.
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability

Modifications from the cleared product are as follows:

(b)(4)Trade Secret Process

- Additional head diameter of 40mm
- Use of a titanium taper adapter (sleeve)

**Substantial  
Equivalence**

---

The modified device have the following similarities to the Biolo<sup>®</sup>*x* *delta* Ceramic Heads which previously received 510(k) concurrence:

- They have identical indications statements
- They are compatible with Biomet femoral stems
- They are manufactured from the same materials
- They are packaged and sterilized using the same materials and processes
- They have the same shelf life
- Mechanical testing shows the modified devices meet the standards put forth in FDA's guidance document or are comparable to the predicate devices.

In summary, the Bolox<sup>®</sup> *delta* Option Ceramic Heads described in this submission are substantially equivalent to the predicate device.

**Summary of  
Design Control  
Activities**

---

The risk assessment has been conducted in accordance with ISO 14971 to determine the impact of the modifications. A discussion of the risks identified and supporting data is presented in Attachment 5.

A declaration of conformity with design control is included in Attachment 6.

Evidence of design transfer, as specified in QSR § 820.30(h), is found in Biomet SOP 4.1.7 under QM 4.1. "Final design transfer is conducted upon completion of the final design review pursuant to SOP 4.1.4 Design Review to ensure all transfer activities have been completed." The final design review and the design history file (DHF) have been completed for this project.

**Bench/Animal  
Testing**

---

Bench testing is summarized in detail in the risk section presented in Attachment 5. Properties measured include:

(b)(4)Trade Secret Process



Wear: Biolo<sup>®</sup>*x* *delta* Ceramic Heads have demonstrated superior wear properties as compared to cobalt alloy modular heads.

---

**510(k)  
Summary**

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A 510(k) Summary for the BioloX<sup>®</sup> *delta* Option Ceramic Heads is included in Attachment 7.

**Truthful and  
Accuracy  
Certification**

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A certification of the truthfulness and accuracy of the information presented in this submission is provided in Attachment 8.

**Additional  
Information**

---

Attachment 9 contains a Certificate of Compliance with ClinicalTrials.gov Data Bank.

Standards Data Reports for 510(k)s have been completed for the material and testing standards cited in this submission and are contained in Attachment 10.

---

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*All trademarks are property of Biomet, Inc. except for the following:  
BioloX is a trademark of CeramTec AG  
Tyvek is a trademark of E.I. duPont de Nemours and Company*

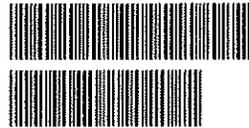


REF. 650-1054 LOT 123123

BIOLOX-DELTA® OPTION CERAMIC HEAD  
38MM HEAD DIAMETER  
TYPE 16/18 TAPER

ALUMINA / ZIRCONIA  
FOR USE W/BIOLOX OPTION -  
TAPER ADAPTER ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

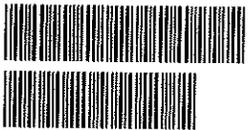
2008-07  
EXPIRY DATE: 2018-07

REF. 650-1068 LOT 123123

BIOLOX® OPTION TAPER ADAPTER  
PLUS 6 NECK  
TYPE I TAPER

TI-6AL-4V ALLOY  
FOR SINGLE USE WITH BIOMET -  
TYPE I TAPERS ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

2008-08  
EXPIRY DATE: 2018-08

BIOMET ORTHOPEDICS, INC.

BIOMET ORTHOPEDICS, INC.

REF. 650-1060 LOT 123123

BIOLOX® OPTION TAPER ADAPTER  
S / MINUS 3 NECK  
TYPE 12/14 TAPER

TI-6AL-4V ALLOY  
FOR SINGLE USE WITH BIOMET -  
12/14 TAPERS ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

2008-08  
EXPIRY DATE: 2018-08

BIOMET ORTHOPEDICS, INC.

BIOMET ORTHOPEDICS, INC.

## Biomet Orthopedics, Inc.

56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581 USA

01-50-0916

Date: 08/08

### Biomet® BioloX™ delta Option Modular Head Hip Joint Prostheses

#### ATTENTION OPERATING SURGEON

#### DESCRIPTION

The Biomet® BioloX™ delta Option Ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces in a variety of head sizes. The highly polished surface is designed to reduce friction and minimize wear. The titanium sleeves adapt the ceramic heads to either a Biomet® Type I or a Biomet® 12/14 taper.

#### MATERIALS

Head - TTPA Ceramic  
Sleeve - Titanium Alloy (Ti-6Al-4V)

#### 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 trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
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 Biomet® BioloX™ delta Option ceramic modular head with Biomet® metallic femoral components. Do not use Biomet® BioloX™ delta Option 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. Sleeves labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Sleeves labeled "12/14" are to be used with femoral stem components labeled "12/14" taper.
4. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal-backed UHMWPE acetabular components.
5. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
6. 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.
7. The femoral stem trunion, sleeves and the bore of the ceramic head should be dry and free of contamination prior to assembly.
8. During a revision surgery, extraction of the femoral head should be done with suitable extraction instruments to avoid unnecessary damage to the trunion.

9. Biomet® BioloX™ delta Option modular head components should not be used on trunions with damage greater than 0.25mm. The surgeon should inspect the taper for damage prior to placement of the sleeve. The following conditions are considered unsuitable for the use of the Biomet® BioloX™ delta Option Ceramic Head:



Slanted Taper



Taper with Scratches/Warping



Taper with Broad Truncation



Crushed Taper

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, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation 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.

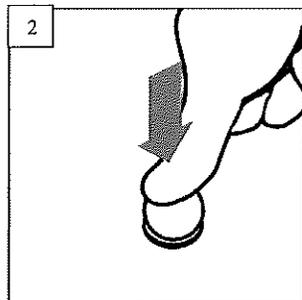
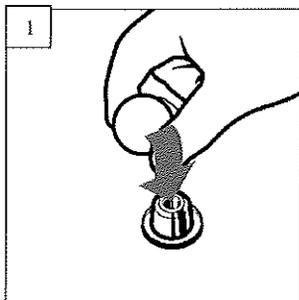
#### POSSIBLE ADVERSE EFFECTS

1. 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.

2. Early or late postoperative infection and allergic reaction.
3. 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.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption, and/or excessive, unusual and/or awkward movement and/or activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
12. 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.
13. 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.
14. Intraoperative and postoperative bone fracture and/or postoperative pain.
15. Ceramic head fractures have been reported.

#### ASSEMBLY INSTRUCTIONS



#### 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, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46582 USA, FAX: 574-372-3968.

Biomet® and all other trademarks herein are the property of Biomet, Inc. or its subsidiaries.



## Indications for Use

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

Device Name: Biolox<sup>®</sup> delta Option Ceramic Heads

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

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

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

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

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

Prescription Use  X   
\_(Part 21 CFR 801 Subpart D)

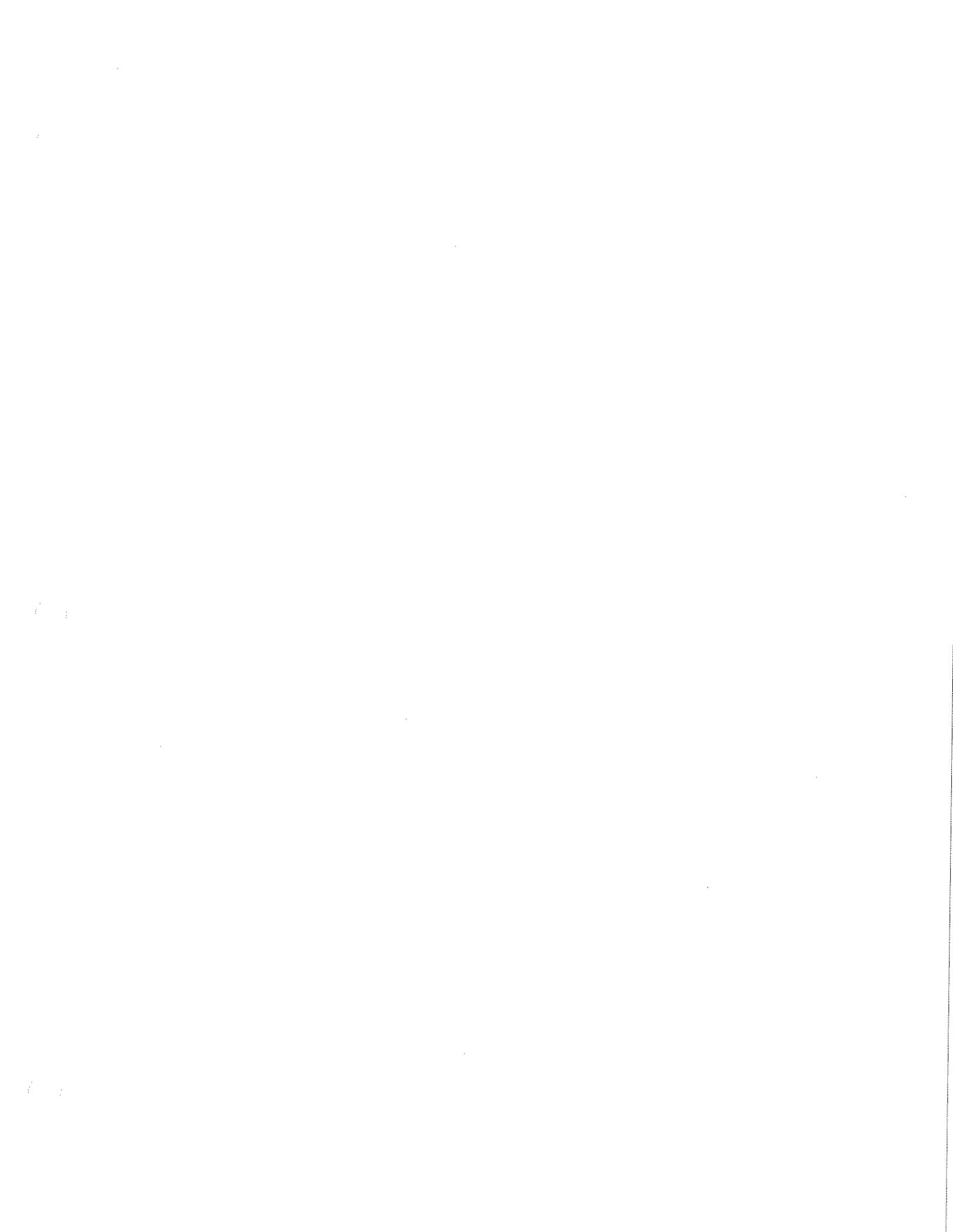
AND/OR

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

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



### Modified Component Listing

Biomet

<u>Part Number</u>	<u>Description</u>
650-1055	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 28mm
650-1056	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 32mm
650-1057	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 36mm
650-1054	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 38mm
650-1058	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 40mm
650-1060	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Small
650-1061	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Medium
650-1062	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Large
650-1063	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve X-Large
650-1064	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve X-Small
650-1065	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Small
650-1066	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Medium
650-1067	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Large
650-1068	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve X-Large

(b)(4)Trade Secret  
Process

Part Number

(b)(4)Trade Secret  
Process



























**Predicate Component Listing – K042091 and K051411**

Biomet

<u>Part Number</u>	<u>Description</u>
12-115109	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115110	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115111	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115112	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +5
12-115114	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115115	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115116	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115117	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade  
Secret Process  
Part Number

(b)(4)Trade Secret Process

**Predicate Component Listing – K061312**

Biomet

<u>Part Number</u>	<u>Description</u>
12-115120	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115121	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115122	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115123	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade Secret  
Process

Part Number

(b)(4)Trade Secret  
Process

**Predicate Component Listing – K073102**

Biomet

<u>Part Number</u>	<u>Description</u>
12-115130	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -6
12-115131	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115132	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, STD
12-115133	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115134	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade Secret  
Process

Part Number

(b)(4)Trade Secret  
Process



































### Compatible Component Listing

In order to complete a total hip replacement surgery, the BioloX<sup>®</sup> delta Option Ceramic Heads require the use of a femoral stem and an acetabular component. Listed below are those Biomet hip components that are compatible with the components that are the subject of this 510(k).

Table 1a - Compatible Femoral Stems - Type I Tapers			
	510(k) Number	Product Code	Indication
Answer <sup>®</sup> Femoral Component	K991987	JDI	Cemented
Co-Cr Answer <sup>®</sup> Femoral Components	K931194	JDG <sup>1</sup>	Cemented
Altra Press-Fit Hip Stem (Echo <sup>™</sup> )	K063002	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY	Uncemented
Altra FX Hip System (Echo <sup>™</sup> )	K063614	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY	Cemented and non-cemented
APF Femoral Component	K852585 K984154 K030055	JDI JDI LPH	Cemented and non-cemented
Balance <sup>®</sup> Hip System Microplasty <sup>®</sup> Stems	K050251	KWZ, JDL, KWA, JDI, LZO, MEH, LPH, LZY, KWY	Non-cemented
Bi-Metric <sup>®</sup> Femoral Components	K921224 K020580 K030055	LZO LPH LPH	Cemented and non-cemented
Bi-Metric <sup>®</sup> Head/Neck Replacement	K955350 K992058 K983710	LZO JDI JDI	Cemented
HA Bi-Metric <sup>®</sup> Femoral Component	K023409 K030055	LPH LPH	Non-cemented
Bio-Groove <sup>®</sup> HAP Hip Components	K912369 K912370	MEH MEH	Non-cemented
Bohn Femoral Component	K000262	LZO, MEH	Non-cemented
Buchalter/Fausser Femoral Component	K952686	LZO	Cemented
Color Buffered Cemented Stem	K992903 K012019	JDI JDI	Cemented
Echo B-Metric <sup>®</sup> Press Fit Stem	K070274	KWA	Non-cemented
Fenning (Osteocap RS <sup>®</sup> ) Femoral Component	K960303	LPH	Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO	Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734 K052639	JDI JDI, LZO, KWZ, MEH, LPH, LZY, KWY, JDG	Cemented

(b)(4) Trade Secret Process

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

	510(k) Number	Product Code	Indication
Gross Femoral Component	K001580	MEH	Non-cemented
Impact <sup>®</sup> Co-Cr Femoral Components	K942027	JDG <sup>2</sup>	Cemented
Integral <sup>®</sup> Femoral Component	K921225	LZO	Cemented and non-cemented
	K984296	LPH	
	K984408	LPH	
	K030055	LPH	
	K030501	LPH	
	K042029	LPH	
	K942479	LZO	
Integral <sup>®</sup> Co-Cr Femoral Component			Cemented
Interlocking Hip Stems	K990830	LPH	Non-cemented
	K042774	LPH <sup>3</sup>	
Mallory/Head <sup>®</sup> Total Hip System	K921181	LZO	Cemented and non-cemented
	K994007	JDI	
	K000538	LPH	
	K003429	LPH	
	K030055	LPH	
	K021403	LPH, MEH	
HA Mallory/Head <sup>®</sup> Total Hip System	K030055	LPH, MEH	Non-cemented
Mallory/Head <sup>®</sup> Co-Cr Femoral Component	K911684	JDI	Cemented
Mallory/Head <sup>®</sup> Calcar Femoral Components (including HA)	K945115	LPH, LZO	Cemented and non-cemented
	K001660	LPH	
	K031693	LPH	
Medallion Hip	K041850	LPH	Uncemented
Modular Hip Stems	K912712	JDI	Cemented and non-cemented
	K921274	LPH	
	K030055	LPH	
Oncology Salvage System	K002757	JDI	Cemented
OSS <sup>™</sup> Les Proximal Femoral Component	K021380	JDI, LPH	Cemented and non-cemented
PMI <sup>®</sup> Femoral Component	K911802	JDI	Cemented and non-cemented
	K923452	LPH	
	K030055	LPH	
	K030048	LPH	
HA PMI <sup>®</sup> Femoral Stem	K010560	LZO	Non-cemented
Portrait <sup>™</sup> Femoral Component			Non-cemented

(b)(4) Trade Secret Process

<sup>2</sup> Submitted under classification 888.3350 JDI

<sup>3</sup> Cleared under product codes JDL, KWA, LPH, LZO, KWZ, JDI and KWY based on available modular head and acetabular components for use with this stem

	510(k) Number	Product Code	Indication
Reach® Femoral Component	K971824	LPH	Non-cemented
	K982367	LPH	
	K000760	LPH	
Modular Reach®	K994038	LPH	Non-cemented
	K022463	LPH	
HA Modular Reach®	K030055	LPH	Non-cemented
	K942028	JDG <sup>4</sup>	
Rx-90® Femoral Stems	K023085	JDI	Cemented
	K960984	JDI	
SHP™ Hip System	K050441	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH,	Non-cemented
	K062994	KWB, LZY, KWY	
	K830313	JDI	
Taper2™ Porous Femoral Stem (Taperloc® Microplasty)	K921301	LPH	Cemented and non-cemented
	K030055	LPH	
	K020963	MEH	
HA Taperloc® Femoral Component	K030055	LPH	Non-cemented
	K033871	JDI	
Total IM Femur	K974558	JDI	Cemented
Total Femur	K052089	LPH, JDI, LZO, KWY, KWZ	Cemented and non-cemented
<b>Table 1b - Compatible Femoral Stems - 12/14 Tapers</b>			
Taperloc® Femoral Component	510(k) Number	Product Code	Indication
	K043537	LPH	

(b)(4) Trade Secret Process

<sup>4</sup> Submitted under classification 888 3350 JDI

The modular heads in this submission are compatible with the corresponding size of liners, which are compatible with any corresponding size of acetabular system shells listed in the following tables:

Table 2a - All Polyethylene Acetabular Systems			
	510(k) Number	Product Code	Indications
Bio-Clad™ Reinforced All-Poly Acetabular Components	K810120	JDI	Cemented
	K926107	LPH	
All-Poly (Ranawat/Burstein) Acetabular Components	Pre-amendment	N/A	Cemented

Table 2b - Compatible Low Profile Liners and Shells						
	510(k) Number	Product Code	Acetabular System Compatible w/ Liner	510(k) Number	Product Code	Indications
ARCOM® XL RX-90 Low Profile Liners	K052255	LPH	RX-90 Low Profile Acetabular Components	K920639	JDL	Cemented and non-cemented
				K042989	LPH	

Table 2c - Compatible Full Hemispherical Liners and Shells							
	510(k) Number	Product Code	Acetabular System Compatible w/ Liner	510(k) Number	Product Code	Indications	
ARCOM® RingLoc® Liners	K926107	LPH	A-B (Precept®) Acetabular System	K954417	LPH	Cemented and non-cemented	
	K950761	JDI		K030055	LPH, MEH		
	K970501	LPH		Flanged Acetabular Component	K983035	LPH	Cemented and non-cemented
	K023357	LPH			K030055	LPH, MEH	
	K030055	LPH, MEH			K920640	JDL <sup>2</sup>	
ARCOM® RingLoc® Constrained Liner	K021728	KWZ	Full Hemisphere Acetabular Components				
ARCOM® XL RingLoc® Liners	K042051	JDI, LPH	Healy™ Flanged Revision	K921139	JDL <sup>2</sup>	Cemented	
	K051411	LZO					
ARCOM® 36mm RingLoc® Liners	K032396	JDI, LPH	Index® Acetabular Components	K950761	JDI	Cemented and non-cemented	
				K030055	LPH, MEH		
E-Poly Acetabular Liners	K050327	LPH, JDI, LWJ, MAY	Mallory/Head® Acetabular Components	K861114	JDL <sup>3</sup>	Cemented and non-cemented	
	K070364	LPH, JDI, LWJ, MAY		K921181	LZO		
	K070399	LPH, JDI, LWJ, MAY		K030055	LPH, MEH		
	K073102	LZO, LPH, JDI, LWJ, MAY					

510(k) Number	Product Code	Acetabular System Compatible w/ Liner <sup>5</sup>	510(k) Number	Product Code	Indications
		Mars <sup>®</sup> Modular Acetabular Reconstructive System	K911718	JDI	Cemented
		Par 5 <sup>™</sup> Acetabular Components	K022094	JDI	Cemented and non-cemented
		Quadrant Sparing Acetabular Components	K920640 K050124	JDL <sup>5</sup> KWA	Cemented non-cemented
		Ranawat/Burstein <sup>®</sup> Acetabular Component s	K911685 K921277 K050124	JDI LPH KWA	Cemented and non-cemented (NIDJD only)
		Regenerex <sup>™</sup> Porous Titanium Acetabular Components	K052996	LPH	Cemented and non-cemented
		TRI-SPIKE <sup>™</sup> Pegged Acetabular Components	K970501 K030055	LPH LPH, MEH	Cemented and non-cemented
		Tri-Polar Acetabular System including liners	K991990	KWY	Cemented and non-cemented
		Universal <sup>®</sup> Acetabular Components	K861433 K921301 K030055	JDL <sup>5</sup> LPH LPH, MEH	Cemented and non-cemented
		Vision Acetabular Components	K954417 K030055	LPH/JDI LPH, MEH	Cemented and non-cemented

All acetabular shells with screw holes may be used with Biomet titanium screws cleared under the following 510(k)s as well as any screws contained within the 510(k)s for the acetabular cups:

Table 2d - Biomet Titanium Acetabular Screws		
510(k) number	Product Code	Indications
Titanium Screw LP 5mm	LPH	Cemented and non-cemented
Titanium Screw LP 6.5mm	LPH	Cemented and non-cemented

<sup>5</sup> 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 submissions were for metal on polyethylene systems (JDI).





























































































































































































































































































































































































































































# Appendix 1

**Drawings**























# Appendix 2

(b)(4) Trade Secret Process - Testing Report



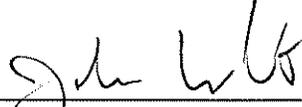
(b)(4)Trade Secret Process - Testing Report



### Declarations Of Conformity With Design Controls

#### Verification Activities

To the best of my knowledge, all verification and validation activities were performed by the designated individual(s) and the result of the activities demonstrated that the predetermined acceptance criteria were met.



\_\_\_\_\_  
John White  
Director of Hip Engineering  
Biomet Manufacturing Corp.

9/15/08

\_\_\_\_\_  
Date

## Declarations Of Conformity With Design Controls

### Manufacturing Facility

The manufacturing facility, Biomet, Inc., is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.



\_\_\_\_\_  
Rex A. White

Vice President, Regulatory Compliance and Quality Assurance  
Biomet Manufacturing Corp.

22 Sept 08

\_\_\_\_\_  
Date



### 510(k) Summary

**Date:** September 10, 2008

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist

**Proprietary Name:** BioloX<sup>®</sup> *delta* Option Ceramic Heads

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

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

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**  
BioloX<sup>®</sup> *delta* Ceramic Heads – K042091, K051411, K061312, K073102

**Device Description:** BioloX<sup>®</sup> *delta* Option Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. A highly polished spherical head in a variety of diameters articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem via a taper adapter. Adapters are available for either Biomet's Type I taper or Biomet's 12/14 taper in a variety of neck lengths.

**Indications For Use:** BioloX<sup>®</sup> *delta* Option 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:

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

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

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

**Summary of Technologies:** The Biolox® *delta* Option 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

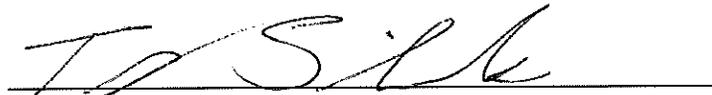
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*Biolox is a trademark of CeramTec AG*



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

I certify, in my capacity as a Development Engineer 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

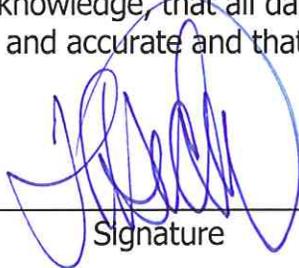
Anthony Siebeneck  
Typed Name

09/10/08  
Date

Biolog<sup>®</sup> delta Option Ceramic Heads  
Device

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

I certify, in my capacity as Director of Clinical and Regulatory Affairs, 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

Tracy B. Johnson  
Typed Name

14 September 2008  
Date

BioloX<sup>®</sup> delta Option Ceramic Heads  
Device





**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Food and Drug Administration

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

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

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Biomet Manufacturing Corp.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Oct 6, 2008
3. ADDRESS (Number, Street, State, and ZIP Code) 56 Bell Drive Warsaw, IN 46582	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 574-267-6639 (Fax) 574-372-1683

**PRODUCT INFORMATION**

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

Device Trade Name: BioloX® delta Option Ceramic Heads

Common Name: Ceramic Modular Heads

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

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

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

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

**CERTIFICATION STATEMENT / INFORMATION**

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

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

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

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

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

NCT Number(s):

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) Patricia S. Beres (Title) Senior Regulatory Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) P.O. Box 587 Warsaw, IN 46581	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 574-267-6639 x1278 (Fax) 574-372-1683
	15. DATE OF CERTIFICATION 08/11/2008



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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 5832-3, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy. 1996

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... NA # (List 017, Item 58)

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 5832-3, IMPLANTS FOR SURGERY -- METALLIC MATERIALS -- PART 3: WROUGHT TITANIUM 6-ALUMINIUM 4-VANADIUM ALLOY, 1996

**CONFORMANCE WITH STANDARD SECTIONS\***

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

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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

**Paperwork Reduction Act Statement**

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

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1350 Piccard Drive  
Rockville, MD 20850

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F75-07, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075). 2007

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 018, Item 8-137

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F75-07, STANDARD SPECIFICATION FOR COBALT-28 CHROMIUM-6 MOLYBDENUM ALLOY CASTINGS AND CASTING ALLOY  
JR SURGICAL IMPLANTS (UNS R30075).

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*  
None

DESCRIPTION  
Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

JUSTIFICATION

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

DESCRIPTION

JUSTIFICATION

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

DESCRIPTION

JUSTIFICATION

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

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

**Paperwork Reduction Act Statement**

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Rockville, MD 20850

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

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F136-02a, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications 2002

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA<sup>2</sup>? .....                      

FDA Recognition number<sup>3</sup> ..... # List 017, Item 44

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ASTM F136-02A, STANDARD SPECIFICATION FOR WROUGHT TITANIUM-6 ALUMINUM-4 VANADIUM ELI (EXTRA LOW INTERSTITIAL) ALLOY FOR SURGICAL IMPLANT APPLICATIONS 2002

**CONFORMANCE WITH STANDARD SECTIONS\***

**SECTION NUMBER**

**SECTION TITLE**

**CONFORMANCE?**

Yes  No  N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

**SECTION NUMBER**

**SECTION TITLE**

**CONFORMANCE?**

Yes  No  N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

**SECTION NUMBER**

**SECTION TITLE**

**CONFORMANCE?**

Yes  No  N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

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

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

**Paperwork Reduction Act Statement**

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Department of Health and Human Services  
Food and Drug Administration

**STANDARDS DATA REPORT FOR 510(K)S**

*(To be filled in by applicant)*

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F648-07, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants. 2007

*Please answer the following questions*

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 018, Item 143

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

3TM F648-07, STANDARD SPECIFICATION FOR ULTRA-HIGH-MOLECULAR-WEIGHT POLYETHYLENE POWDER AND FABRICATED FORM FOR SURGICAL IMPLANTS.

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*  
None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F799-06, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539), 2006

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 17  
# Item 8-131

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F799-06, STANDARD SPECIFICATION FOR COBALT-28 CHROMIUM-6 MOLYBDENUM ALLOY FORGINGS FOR SURGICAL IMPLANTS (UNS R31537, R31538, R31539)

**CONFORMANCE WITH STANDARD SECTIONS\***

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

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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

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Department of Health and Human Services  
Food and Drug Administration

**STANDARDS DATA REPORT FOR 510(K)S**

*(To be filled in by applicant)*

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F1580-01, Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants. 2001

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # List 017, Item 54

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F1580-01, STANDARD SPECIFICATION FOR TITANIUM AND TITANIUM-6 ALUMINUM-4 VANADIUM ALLOY POWDERS FOR COATINGS OF SURGICAL IMPLANTS. 2001

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	--

**TYPE OF DEVIATION OR OPTION SELECTED\***

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

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

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 7206-10:2003, Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....  Yes       No

FDA Recognition number<sup>3</sup> ..... # \_\_\_\_\_

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

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes       No

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 7206-10:2003, IMPLANTS FOR SURGERY -- PARTIAL AND TOTAL HIP-JOINT PROSTHESES -- PART 10: DETERMINATION OF RESISTANCE TO STATIC LOAD OF MODULAR FEMORAL HEADS

**CONFORMANCE WITH STANDARD SECTIONS\***

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

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

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*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F1875-98(2004), Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA<sup>2</sup>? .....                      

FDA Recognition number<sup>3</sup> ..... List 017,  
# Item 11-183

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

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

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

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

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

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

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

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

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

Title of guidance: Guidance Document for Femoral Stem Prostheses

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

TM F1875-98(2004), STANDARD PRACTICE FOR FRETTING CORROSION TESTING OF MODULAR IMPLANT INTERFACES: HIP  
MEMORAL HEAD-BORE AND CONE TAPER INTERFACE

**CONFORMANCE WITH STANDARD SECTIONS\***

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

DESCRIPTION

JUSTIFICATION

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 7206-10:2003, Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

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

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 If yes, report these exclusions in the summary report table.

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

Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

7206-10:2003, IMPLANTS FOR SURGERY -- PARTIAL AND TOTAL HIP-JOINT PROSTHESES -- PART 10: DETERMINATION OF RESISTANCE TO STATIC LOAD OF MODULAR FEMORAL HEADS

**CONFORMANCE WITH STANDARD SECTIONS\***

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

**DESCRIPTION**

**JUSTIFICATION**

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

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## Table of Contents

Cover Letter	
Medical Device User Fee Cover Sheet	
510(k) Body .....	1
Tab 1 Labeling .....	8
Tab 2 Indications for Use Form.....	11
Tab 3 Modified Component Listing and Prints .....	12
Predicate Component Listing and Prints.....	27
Tab 4 Compatible Components .....	45
Sample Drawing – Type I Taper .....	50
Sample Drawing – Type I Reduced Taper.....	51
Sample Drawing – 12/14 Taper .....	52
Tab 5 Risk Analysis Table and Discussion .....	53
Tab A CeramTach’s Testing Protocol .....	62
Tab B Mechanical Testing of 12/14 Taper Sleeves .....	66
Tab C Mechanical Testing of Type I Taper Sleeve .....	121
Tab D Corrosion .....	169
Tab E Wear Testing Justification .....	221
Tab 6 Declarations of Conformity.....	284
Tab 7 510(k) Summary .....	286
Tab 8 Truthful and Accurate Statements .....	288
Tab 9 Clinical Trails Certification.....	290
Tab 10 Standards Data Report For 510(k) .....	291



October 6, 2008

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

Reference: "Special" 510(k) – Biomet® BioloX® *delta* Option Ceramic Heads  
User Fee ID: (b)(4)Trade Secret Process

Dear Sir or Madam:

Enclosed is a "**Special**" 510(k): **Device Modifications** submission for BioloX® *delta* Option Ceramic Heads which is a modification of the BioloX® *delta* Ceramic Heads cleared in 510(k) K042091, K061312 and K073102. We believe this device is substantially equivalent\* to cleared devices and warrants a "Special" 510(k).

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. Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Sincerely,

A handwritten signature in dark ink, appearing to read "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)]

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Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  BIOMET INC P.O. Box 587 Warsaw IN 46581-0587 US		2. CONTACT NAME Patricia Beres 2.1 E-MAIL ADDRESS patty.beres@biometmail.com 2.2 TELEPHONE NUMBER (include Area code) 574-267-6639 1278 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 574-372-1683	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)Trade Secret			
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/dc/mdufma">http://www.fda.gov/dc/mdufma</a> )			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <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 application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)Trade Secret		29-Sep-2008	

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

**Device Name**

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**Device Trade Name:** BioloX<sup>®</sup> *delta* Option Ceramic Heads  
**Common Name:** Ceramic Modular Heads

---

**Address and  
Registration #**

**Specification Holder:** Biomet Manufacturing Corp  
56 Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581-0587  
FDA Registration #: 1825034

**Contract Manufacturer:** (b)(4)Trade Secret Process



**Sterilization Site:**

**Contact  
Information**

---

**Name:** Patricia Sandborn Beres  
**Title:** Senior Regulatory Specialist  
**Address:** Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, IN 46581-0587  
**Telephone:** 574-267-6639  
**Fax:** 574-372-1683  
**E-mail:** [patty.beres@biometmail.com](mailto:patty.beres@biometmail.com)

**Alternate Contact:**

**Name:** Tracy B. Johnson  
**Title:** Director, Clinical and Regulatory Affairs  
**Address:** Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, IN 46581-0587  
**Telephone:** 574-267-6639  
**Fax:** 574-372-1683  
**E-mail:** [tracy.johnson@biometmail.com](mailto:tracy.johnson@biometmail.com)

**Device  
Classification**

---

**Class:** II  
**Product Code:** LZ0  
**Classification Names:** Hip joint metal/ceramic/polymer  
semi-constrained cemented or nonporous uncemented prosthesis

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Common Name.

The guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" was followed

for the preparation of the predicate BioloX<sup>®</sup> *delta* Ceramic Heads 510(k) K042091. Only those portions which are affected by the modifications required to create the new device will be addressed in this document.

**Predicate  
Device  
Information**

The predicate devices are the BioloX<sup>®</sup> *delta* Ceramic Heads cleared through 510(k)s K042091 (March 25, 2005), K051411, (June 29, 2005), 510(k) K061312 (June 6, 2006) and K073102 (November 27, 2007).

(b)(4)Trade Secret Process

**Labeling and  
Indications for  
Use**

Draft labels and Instructions for Use (package insert) can be found in Attachment 1. A new package insert which contains assembly instructions for the components has been developed. A specific surgical technique for the BioloX<sup>®</sup> *delta* Option Ceramic Heads has not been developed at this time. Placement of the head on the femoral stem trunion would be in keeping with the surgical procedure for the femoral stem or acetabular component being used in conjunction with the head.

Indications for Use

The BioloX<sup>®</sup> *delta* Option Ceramic Heads are intended for 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)

These are the same intended use as previously cleared for the predicate BioloX<sup>®</sup> *delta* Ceramic Heads. The Indications for Use Statement can be found in Attachment 2.

**Sterilization and Packaging**

Devices are provided sterile by radiation methods as follows:

1. Radiation Type: Gamma  
Radiation Source: (b)(4)Trade Secret  
Minimum Dosage: 25 kGy  
Maximum Dosage: 40 kGy
2. Sterility Assurance Level: 10<sup>-6</sup>
3. Sterility Validation Method: (b)(4)Trade Secret Process
4. Pyrogen-Free: no claims will be made
5. Packaging: Each component is placed within a plastic bag between two foam pads. They are then placed in an inner blister pack sealed with a Tyvek<sup>®</sup> lid which fits into an outer blister pack also sealed with a Tyvek<sup>®</sup> lid. The entire unit is placed in a cardboard box, shrink wrapped for protection. All labeling will be on the outer Tyvek<sup>®</sup> lid as well as on the outer cardboard box.
6. 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, 25 kGy
7. Expiration Date: The BioloX<sup>®</sup> *delta* Option Ceramic Heads have a 10-year shelf-life. Supporting data is on file at Biomet and can be accessed at any future FDA inspection.

Note: The BioloX<sup>®</sup> *delta* Option Ceramic Head and Taper Adapter will be packaged separately.

**Device Description**

The BioloX<sup>®</sup> *delta* Option Ceramic Heads consist of a series of BioloX<sup>®</sup> *delta* ceramic ball heads in combination with a titanium sleeve. The heads are available in a variety of diameters and taper adapters are available for Biomet's Type I and Biomet 12/14 tapers in a variety of neck lengths.

**Specific Characteristics – Heads**

- Material - Transition-Toughened-Platelet Alumina (TTPA) (b)(4)Trade Secret Process



Head Size	28mm	32mm	36mm	38mm	40mm
(b)(4)Trade Secret Process					

**Specific Characteristics – Biomet Type I Adapter**

- Material -Titanium Alloy (Ti-6Al-4V, ISO 5832-3)
- (b)(4)Trade Secret Process
- Neck Lengths – x-small, small, medium, large, x-large (-6, -3, 0, +3, +6)

(b)(4)Trade Secret Process

Adapter Size	X-small -6	Small -3	Medium 0	Large +3	X-large +6
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(b)(4)Trade Secret Process

**Specific Characteristics – Biomet 12/14 Adapter**

- Material -Titanium Alloy (Ti-6Al-4V, ISO 5832-3)
- (b)(4)Trade Secret Process
- Neck Lengths – small, medium, large, x-large (-3, 0, +4, +7)

(b)(4)Trade Secret Process

Adapter Size	Small -3	Medium 0	Large +4	X-large +7
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(b)(4)Trade Secret Process

### Product Listing/Drawings

- The name and manufacturers model number for each BioloX<sup>®</sup> *delta* Option Ceramic Head may be found in Attachment 3.
- Dimensioned engineering drawings of the BioloX<sup>®</sup> *delta* Option Ceramic Heads and taper adapters may be found in Attachment 3.
- A product listing and engineering drawings of the predicate BioloX<sup>®</sup> *delta* Ceramic Heads may be found in Attachment 3.

### Compatible Products

- Attachment 4 contains a table of compatible hip stems for use with the BioloX<sup>®</sup> *delta* Option Ceramic Heads.
- All of the devices are metallic hip stems with or without porous coating.
- Each stem has a Biomet 12/14 or Biomet Type I trunion (standard or reduced) for attachment of the modular head. A sample engineering drawing of a femoral stem with each type of taper is included in Attachment 4.

(b)(4)Trade Secret Process

- Porous coating material conforms to ASTM F-1580.
- Attachment 4 also contains a list of the compatible acetabular components that may be used with this device.

(b)(4)Trade Secret Process

- Porous coating material conforms to ASTM F-1580.
- Polyethylene liners and all polyethylene cups are manufactured from material conforming to ASTM F-648.
- Screws for use in the acetabular shells are manufactured from titanium alloy conforming to ASTM F-136.

### Device Comparison

The following features have not changed as previously described in the predicate device 510(k) K042091.

- Material including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity.
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability

Modifications from the cleared product are as follows:

(b)(4)Trade Secret Process

- Additional head diameter of 40mm
- Use of a titanium taper adapter (sleeve)

**Substantial  
Equivalence**

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The modified device have the following similarities to the Biolo<sup>®</sup>*x* *delta* Ceramic Heads which previously received 510(k) concurrence:

- They have identical indications statements
- They are compatible with Biomet femoral stems
- They are manufactured from the same materials
- They are packaged and sterilized using the same materials and processes
- They have the same shelf life
- Mechanical testing shows the modified devices meet the standards put forth in FDA's guidance document or are comparable to the predicate devices.

In summary, the Bolox<sup>®</sup> *delta* Option Ceramic Heads described in this submission are substantially equivalent to the predicate device.

**Summary of  
Design Control  
Activities**

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The risk assessment has been conducted in accordance with ISO 14971 to determine the impact of the modifications. A discussion of the risks identified and supporting data is presented in Attachment 5.

A declaration of conformity with design control is included in Attachment 6.

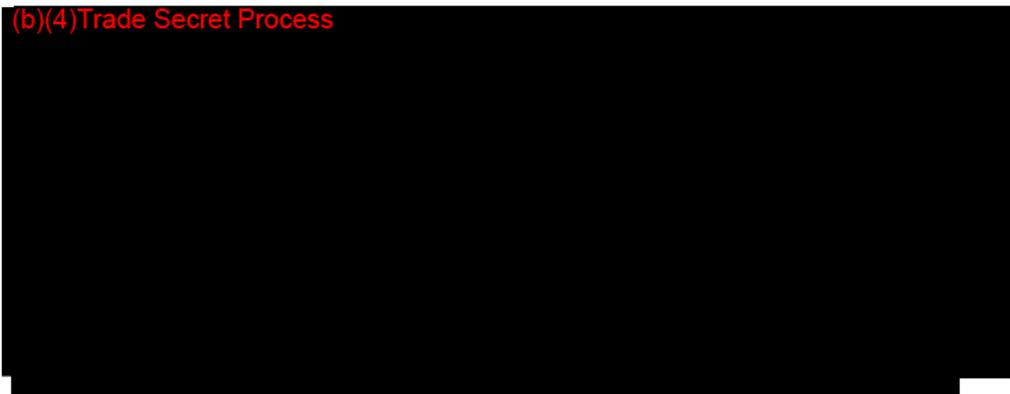
Evidence of design transfer, as specified in QSR § 820.30(h), is found in Biomet SOP 4.1.7 under QM 4.1. "Final design transfer is conducted upon completion of the final design review pursuant to SOP 4.1.4 Design Review to ensure all transfer activities have been completed." The final design review and the design history file (DHF) have been completed for this project.

**Bench/Animal  
Testing**

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Bench testing is summarized in detail in the risk section presented in Attachment 5. Properties measured include:

(b)(4)Trade Secret Process



Wear: Biolo<sup>®</sup>*x* *delta* Ceramic Heads have demonstrated superior wear properties as compared to cobalt alloy modular heads.

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**510(k)  
Summary**

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A 510(k) Summary for the Biolox<sup>®</sup> *delta* Option Ceramic Heads is included in Attachment 7.

**Truthful and  
Accuracy  
Certification**

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A certification of the truthfulness and accuracy of the information presented in this submission is provided in Attachment 8.

**Additional  
Information**

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Attachment 9 contains a Certificate of Compliance with ClinicalTrials.gov Data Bank.

Standards Data Reports for 510(k)s have been completed for the material and testing standards cited in this submission and are contained in Attachment 10.

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*All trademarks are property of Biomet, Inc. except for the following:  
Biolox is a trademark of CeramTec AG  
Tyvek is a trademark of E.I. duPont de Nemours and Company*

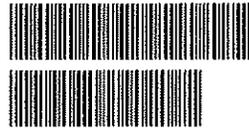


REF. 650-1054 LOT 123123

BIOLOX-DELTA® OPTION CERAMIC HEAD  
38MM HEAD DIAMETER  
TYPE 16/18 TAPER

ALUMINA / ZIRCONIA  
FOR USE W/BIOLOX OPTION -  
TAPER ADAPTER ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

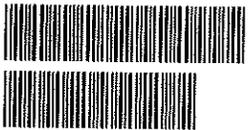
2008-07  
EXPIRY DATE: 2018-07

REF. 650-1068 LOT 123123

BIOLOX® OPTION TAPER ADAPTER  
PLUS 6 NECK  
TYPE I TAPER

TI-6AL-4V ALLOY  
FOR SINGLE USE WITH BIOMET -  
TYPE I TAPERS ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

2008-08  
EXPIRY DATE: 2018-08

BIOMET ORTHOPEDICS, INC.

BIOMET ORTHOPEDICS, INC.

REF. 650-1060 LOT 123123

BIOLOX® OPTION TAPER ADAPTER  
S / MINUS 3 NECK  
TYPE 12/14 TAPER

TI-6AL-4V ALLOY  
FOR SINGLE USE WITH BIOMET -  
12/14 TAPERS ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

2008-08  
EXPIRY DATE: 2018-08

BIOMET ORTHOPEDICS, INC.

BIOMET ORTHOPEDICS, INC.

## Biomet Orthopedics, Inc.

56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581 USA

01-50-0916

Date: 08/08

### Biomet® BioloX™ delta Option Modular Head Hip Joint Prostheses

#### ATTENTION OPERATING SURGEON

#### DESCRIPTION

The Biomet® BioloX™ delta Option Ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces in a variety of head sizes. The highly polished surface is designed to reduce friction and minimize wear. The titanium sleeves adapt the ceramic heads to either a Biomet® Type I or a Biomet® 12/14 taper.

#### MATERIALS

Head - TTPA Ceramic  
Sleeve - Titanium Alloy (Ti-6Al-4V)

#### 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 trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
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 Biomet® BioloX™ delta Option ceramic modular head with Biomet® metallic femoral components. Do not use Biomet® BioloX™ delta Option 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. Sleeves labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Sleeves labeled "12/14" are to be used with femoral stem components labeled "12/14" taper.
4. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal-backed UHMWPE acetabular components.
5. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
6. 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.
7. The femoral stem trunion, sleeves and the bore of the ceramic head should be dry and free of contamination prior to assembly.
8. During a revision surgery, extraction of the femoral head should be done with suitable extraction instruments to avoid unnecessary damage to the trunion.

9. Biomet® BioloX™ delta Option modular head components should not be used on trunions with damage greater than 0.25mm. The surgeon should inspect the taper for damage prior to placement of the sleeve. The following conditions are considered unsuitable for the use of the Biomet® BioloX™ delta Option Ceramic Head:



Slanted Taper



Taper with Scratches/Warping



Taper with Broad Truncation



Crushed Taper

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, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation 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.

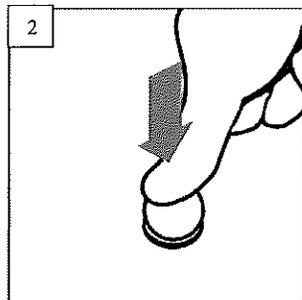
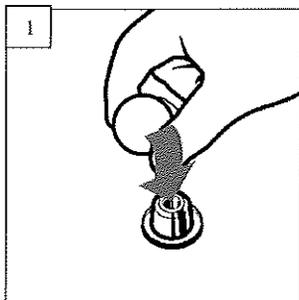
#### POSSIBLE ADVERSE EFFECTS

1. 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.

2. Early or late postoperative infection and allergic reaction.
3. 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.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption, and/or excessive, unusual and/or awkward movement and/or activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
12. 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.
13. 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.
14. Intraoperative and postoperative bone fracture and/or postoperative pain.
15. Ceramic head fractures have been reported.

#### ASSEMBLY INSTRUCTIONS



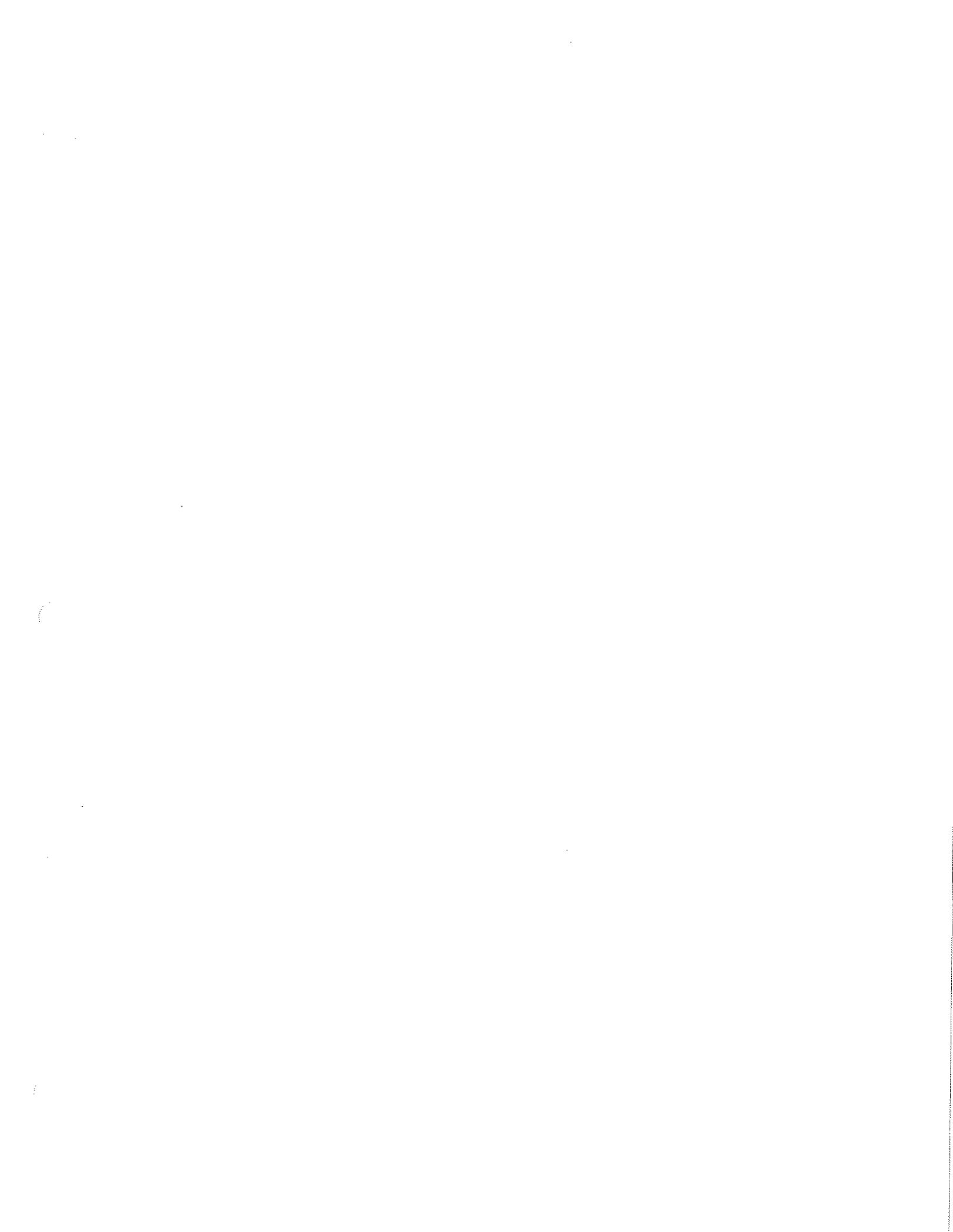
#### STERILITY

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, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46582 USA, FAX: 574-372-3968.

Biomet® and all other trademarks herein are the property of Biomet, Inc. or its subsidiaries.



## Indications for Use

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

Device Name: Biolox<sup>®</sup> delta Option Ceramic Heads

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

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

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

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

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

Prescription Use  X   
\_(Part 21 CFR 801 Subpart D)

AND/OR

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

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



## Modified Component Listing

Biomet

<u>Part Number</u>	<u>Description</u>
650-1055	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 28mm
650-1056	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 32mm
650-1057	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 36mm
650-1054	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 38mm
650-1058	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 40mm
650-1060	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Small
650-1061	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Medium
650-1062	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Large
650-1063	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve X-Large
650-1064	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve X-Small
650-1065	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Small
650-1066	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Medium
650-1067	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Large
650-1068	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve X-Large

(b)(4)Trade Secret  
Process

Part Number

(b)(4)Trade Secret  
Process



























**Predicate Component Listing – K042091 and K051411**

Biomet

<u>Part Number</u>	<u>Description</u>
12-115109	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115110	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115111	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115112	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +5
12-115114	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115115	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115116	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115117	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade  
S Part Number  
(b)(4)Trade Secret  
Process

**Predicate Component Listing – K061312**

Biomet

<u>Part Number</u>	<u>Description</u>
12-115120	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115121	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115122	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115123	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade  
S Part Number  
(b)(4)Trade Secret  
Process

**Predicate Component Listing – K073102**

Biomet

<u>Part Number</u>	<u>Description</u>
12-115130	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -6
12-115131	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115132	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, STD
12-115133	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115134	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade  
Secret  
Part Number  
(b)(4)Trade Secret  
Process



































## Compatible Component Listing

In order to complete a total hip replacement surgery, the BioloX<sup>®</sup> delta Option Ceramic Heads require the use of a femoral stem and an acetabular component. Listed below are those Biomet hip components that are compatible with the components that are the subject of this 510(k).

Table 1a - Compatible Femoral Stems - Type I Tapers			
	510(k) Number	Product Code	Indication
Answer <sup>®</sup> Femoral Component	K991987	JDI	Cemented
Co-Cr Answer <sup>®</sup> Femoral Components	K931194	JDG <sup>1</sup>	Cemented
Altra Press-Fit Hip Stem (Echo <sup>™</sup> )	K063002	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY	Uncemented
Altra FX Hip System (Echo <sup>™</sup> )	K063614	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY	Cemented and non-cemented
APF Femoral Component	K852585 K984154 K030055	JDI JDI LPH	Cemented and non-cemented
Balance <sup>®</sup> Hip System Microplasty <sup>®</sup> Stems	K050251	KWZ, JDL, KWA, JDI, LZO, MEH, LPH, LZY, KWY	Non-cemented
Bi-Metric <sup>®</sup> Femoral Components	K921224 K020580 K030055	LZO LPH LPH	Cemented and non-cemented
Bi-Metric <sup>®</sup> Head/Neck Replacement	K955350 K992058 K983710	LZO JDI JDI	Cemented
HA Bi-Metric <sup>®</sup> Femoral Component	K023409 K030055	LPH LPH	Non-cemented
Bio-Groove <sup>®</sup> HAP Hip Components	K912369 K912370	MEH MEH	Non-cemented
Bohn Femoral Component	K000262	LZO, MEH	Non-cemented
Buchalter/Fausser Femoral Component	K952686	LZO	Cemented
Color Buffered Cemented Stem	K992903 K012019	JDI JDI	Cemented
Echo B-Metric <sup>®</sup> Press Fit Stem	K070274	KWA	Non-cemented
Fenning (Osteocap RS <sup>®</sup> ) Femoral Component	K960303	LPH	Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO	Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734 K052639	JDI JDI, LZO, KWZ, MEH, LPH, LZY, KWY, JDG	Cemented

(b)(4) Trade Secret Process

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

	510(k) Number	Product Code	Indication
Gross Femoral Component	K001580	MEH	Non-cemented
Impact <sup>®</sup> Co-Cr Femoral Components	K942027	JDG <sup>2</sup>	Cemented
Integral <sup>®</sup> Femoral Component	K921225	LZO	Cemented and non-cemented
	K984296	LPH	
	K984408	LPH	
	K030055	LPH	
	K030501	LPH	
	K042029	LPH	
	K942479	LZO	
Integral <sup>®</sup> Co-Cr Femoral Component	K990830	LPH	Cemented
Interlocking Hip Stems	K042774	LPH <sup>3</sup>	Non-cemented
Mallory/Head <sup>®</sup> Total Hip System	K921181	LZO	Cemented and non-cemented
	K994007	JDI	
	K000538	LPH	
	K003429	LPH	
	K030055	LPH	
	K021403	LPH, MEH	
HA Mallory/Head <sup>®</sup> Total Hip System	K030055	LPH, MEH	Non-cemented
Mallory/Head <sup>®</sup> Co-Cr Femoral Component	K911684	JDI	Cemented
Mallory/Head <sup>®</sup> Calcar Femoral Components (including HA)	K945115	LPH, LZO	Cemented and non-cemented
	K001660	LPH	
	K031693	LPH	
	K041850	LPH	
Medallion Hip	K912712	JDI	Uncemented
Modular Hip Stems	K921274	LPH	Cemented and non-cemented
	K030055	LPH	
	K002757	JDI	
Oncology Salvage System	K021380	JDI, LPH	Cemented
OSS <sup>™</sup> Les Proximal Femoral Component			Cemented and non-cemented
PMI <sup>®</sup> Femoral Component	K911802	JDI	Cemented and non-cemented
	K923452	LPH	
	K030055	LPH	
	K030048	LPH	
HA PMI <sup>®</sup> Femoral Stem	K010560	LZO	Non-cemented
Portrait <sup>™</sup> Femoral Component			Non-cemented

(b)(4)Trade Secret Process

<sup>2</sup> Submitted under classification 888.3350 JDI

<sup>3</sup> Cleared under product codes JDL, KWA, LPH, LZO, KWZ, JDI and KWY based on available modular head and acetabular components for use with this stem

	510(k) Number	Product Code	Indication
Reach® Femoral Component	K971824	LPH	Non-cemented
	K982367	LPH	
	K000760	LPH	
Modular Reach®	K994038	LPH	Non-cemented
	K022463	LPH	
HA Modular Reach®	K030055	LPH	Non-cemented
	K942028	JDG <sup>4</sup>	
Rx-90® Femoral Stems	K023085	JDI	Cemented
	K960984	JDI	
SHP™ Hip System	K050441	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH,	Cemented
	K062994	KWB, LZY, KWY	
	K830313	JDI	
Taper2™ Porous Femoral Stem (Taperloc® Microplasty)	K921301	LPH	Cemented and non-cemented
	K030055	LPH	
	K020963	MEH	
HA Taperloc® Femoral Component	K030055	LPH	Non-cemented
	K033871	JDI	
Total IM Femur	K974558	JDI	Cemented
Total Femur	K052089	LPH, JDI, LZO, KWY, KWZ	Cemented and non-cemented
<b>Table 1b - Compatible Femoral Stems - 12/14 Tapers</b>			
Taperloc® Femoral Component	510(k) Number	Product Code	Indication
	K043537	LPH	

(b)(4) Trade Secret Process

<sup>4</sup> Submitted under classification 888 3350 JDI

The modular heads in this submission are compatible with the corresponding size of liners, which are compatible with any corresponding size of acetabular system shells listed in the following tables:

Table 2a - All Polyethylene Acetabular Systems			
	510(k) Number	Product Code	Indications
Bio-Clad™ Reinforced All-Poly Acetabular Components	K810120	JDI	Cemented
	K926107	LPH	
All-Poly (Ranawat/Burstein) Acetabular Components	Pre-amendment	N/A	Cemented

Table 2b - Compatible Low Profile Liners and Shells						
	510(k) Number	Product Code	Acetabular System Compatible w/ Liner	510(k) Number	Product Code	Indications
ARCOM® XL RX-90 Low Profile Liners	K052255	LPH	RX-90 Low Profile Acetabular Components	K920639	JDL	Cemented and non-cemented
				K042989	LPH	

Table 2c - Compatible Full Hemispherical Liners and Shells							
	510(k) Number	Product Code	Acetabular System Compatible w/ Liner	510(k) Number	Product Code	Indications	
ARCOM® RingLoc® Liners	K926107	LPH	A-B (Precept®) Acetabular System	K954417	LPH	Cemented and non-cemented	
	K950761	JDI		K030055	LPH, MEH		
	K970501	LPH		Flanged Acetabular Component	K983035	LPH	Cemented and non-cemented
	K023357	LPH			K030055	LPH, MEH	
	K030055	LPH, MEH			K920640	JDL <sup>2</sup>	
ARCOM® RingLoc® Constrained Liner	K021728	KWZ	Full Hemisphere Acetabular Components				
ARCOM® XL RingLoc® Liners	K042051	JDI, LPH	Healy™ Flanged Revision	K921139	JDL <sup>2</sup>	Cemented	
	K051411	LZO					
ARCOM® 36mm RingLoc® Liners	K032396	JDI, LPH	Index® Acetabular Components	K950761	JDI	Cemented and non-cemented	
	K050327	LPH, JDI, LWJ, MAY		K030055	LPH, MEH		
E-Poly Acetabular Liners	K070364	LPH, JDI, LWJ, MAY	Mallory/Head® Acetabular Components	K861114	JDL <sup>3</sup>	Cemented and non-cemented	
	K070399	LPH, JDI, LWJ, MAY		K921181	LZO		
	K073102	LZO, LPH, JDI, LWJ, MAY		K030055	LPH, MEH		

510(k) Number	Product Code	Acetabular System Compatible w/ Liner <sup>5</sup>	510(k) Number	Product Code	Indications
		Mars <sup>®</sup> Modular Acetabular Reconstructive System	K911718	JDI	Cemented
		Par 5 <sup>™</sup> Acetabular Components	K022094	JDI	Cemented and non-cemented
		Quadrant Sparing Acetabular Components	K920640 K050124	JDL <sup>5</sup> KWA	Cemented non-cemented
		Ranawat/Burstein <sup>®</sup> Acetabular Component s	K911685 K921277 K050124	JDI LPH KWA	Cemented and non-cemented (NIDJD only)
		Regenerex <sup>™</sup> Porous Titanium Acetabular Components	K052996	LPH	Cemented and non-cemented
		TRI-SPIKE <sup>™</sup> Pegged Acetabular Components	K970501 K030055	LPH LPH, MEH	Cemented and non-cemented
		Tri-Polar Acetabular System including liners	K991990	KWY	Cemented and non-cemented
		Universal <sup>®</sup> Acetabular Components	K861433 K921301 K030055	JDL <sup>5</sup> LPH LPH, MEH	Cemented and non-cemented
		Vision Acetabular Components	K954417 K030055	LPH/JDI LPH, MEH	Cemented and non-cemented

All acetabular shells with screw holes may be used with Biomet titanium screws cleared under the following 510(k)s as well as any screws contained within the 510(k)s for the acetabular cups:

Table 2d - Biomet Titanium Acetabular Screws		
510(k) number	Product Code	Indications
Titanium Screw LP 5mm	LPH	Cemented and non-cemented
Titanium Screw LP 6.5mm	LPH	Cemented and non-cemented

<sup>5</sup> 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 submissions were for metal on polyethylene systems (JDI).



















































































































































































**Testing of BIOLOX<sup>®</sup> option ball heads 28-16/18 with titanium  
xl (+7)-sleeves 4° type 1 taper for Biomet on titanium and  
CoCr tapers supplied by Biomet**

Content	Seite
Purpose of the test.....	2
Test description.....	2
Results.....	3
Conclusion.....	4
Attachements.....	5ff

Keywords

Project-no. : 28335  
 Object : Option Ball head 28-16/18 (delta)  
 xl- (+7) sleeve with 4° type 1 taper  
 System : Test taper type 1 taper 4°  
 Customer : Biomet  
 Test : BT, PO  
 Material 1 : BIOLOX<sup>®</sup> delta  
 Material 2 : TiAl6V4 (sleeve)  
 Material 3 : CoCrMo (acc. ASTM F799)  
 Material 4 : TiAl6V4 (acc. ASTM F136)  
 Application : Customer information  
 Language : English

*Dr. C. Reinhardt* 11.8.08      *A. Schulz* 11.8.08      *R. Preuss* 17.08.08

Made by: MT-QR      Checked by: MT-Q      Released by: MT-EN  
 Dr. C. Reinhardt      A. Schulz      R. Preuss

Edited on : 29.04.08

Distributed on: 13.8.08

To:	MT	Mr. Billau	MT-E	Mr. G. Griesmayr
	MT-VE	Mr. Silberer	MT-P	Mr. Kemmer
	MT-CS	Mrs. Kober	MT-EN	Mr. Preuss
	Customer	Biomet	MT-EN	Mr. Pallua
			MT-QZ	Mr. Krause









































































































































































































































































# Appendix 1

**Drawings**























# Appendix 2

(b)(4) Trade Secret Process -  
Testing Report



(b)(4)Trade Secret Process - Testing Report

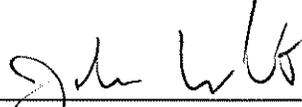




### Declarations Of Conformity With Design Controls

#### Verification Activities

To the best of my knowledge, all verification and validation activities were performed by the designated individual(s) and the result of the activities demonstrated that the predetermined acceptance criteria were met.



\_\_\_\_\_  
John White  
Director of Hip Engineering  
Biomet Manufacturing Corp.

9/15/08

\_\_\_\_\_  
Date

## Declarations Of Conformity With Design Controls

### Manufacturing Facility

The manufacturing facility, Biomet, Inc., is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

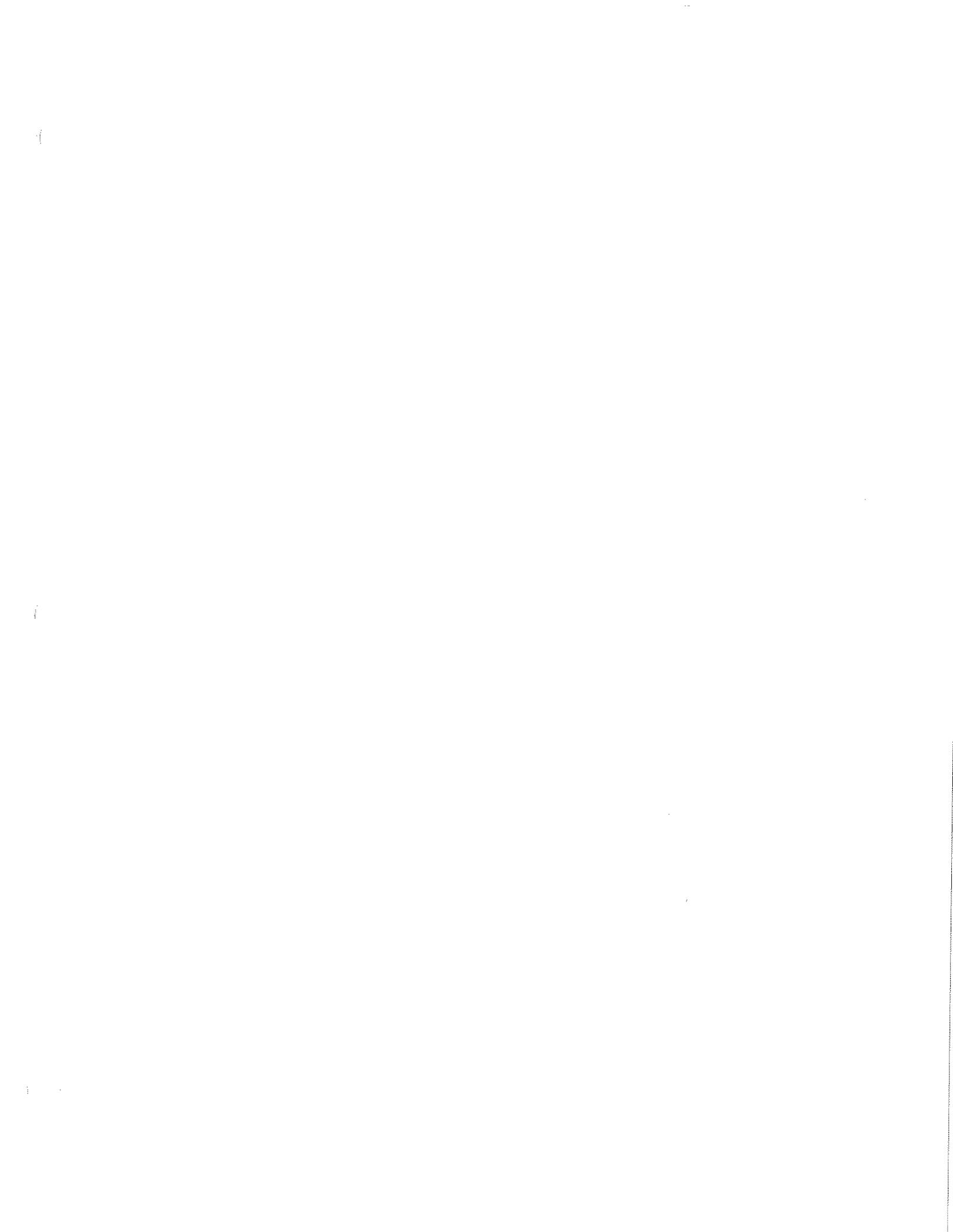


\_\_\_\_\_  
Rex A. White

Vice President, Regulatory Compliance and Quality Assurance  
Biomet Manufacturing Corp.

22 Sept 08

\_\_\_\_\_  
Date



### 510(k) Summary

**Date:** September 10, 2008

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist

**Proprietary Name:** BioloX<sup>®</sup> *delta* Option Ceramic Heads

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

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

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**  
BioloX<sup>®</sup> *delta* Ceramic Heads – K042091, K051411, K061312, K073102

**Device Description:** BioloX<sup>®</sup> *delta* Option Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. A highly polished spherical head in a variety of diameters articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem via a taper adapter. Adapters are available for either Biomet's Type I taper or Biomet's 12/14 taper in a variety of neck lengths.

**Indications For Use:** BioloX<sup>®</sup> *delta* Option 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:

Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.8137  
www.biomet.com

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

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

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

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

**Summary of Technologies:** The Biolox® *delta* Option 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

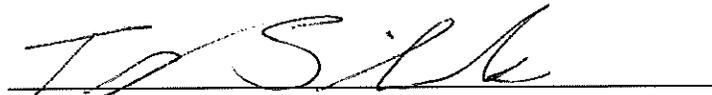
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*Biolox is a trademark of CeramTec AG*



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

I certify, in my capacity as a Development Engineer 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

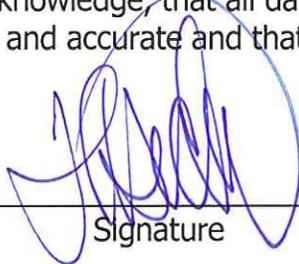
Anthony Siebeneck  
Typed Name

09/10/08  
Date

Biolog<sup>®</sup> delta Option Ceramic Heads  
Device

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

I certify, in my capacity as Director of Clinical and Regulatory Affairs, 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

Tracy B. Johnson  
Typed Name

14 September 2008  
Date

BioloX<sup>®</sup> delta Option Ceramic Heads  
Device





**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Food and Drug Administration

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

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

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Biomet Manufacturing Corp.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Oct 6, 2008
3. ADDRESS (Number, Street, State, and ZIP Code) 56 Bell Drive Warsaw, IN 46582	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 574-267-6639 (Fax) 574-372-1683

**PRODUCT INFORMATION**

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

Device Trade Name: Biolog® delta Option Ceramic Heads

Common Name: Ceramic Modular Heads

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

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

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

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

**CERTIFICATION STATEMENT / INFORMATION**

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

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

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

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

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

NCT Number(s):

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) Patricia S. Beres (Title) Senior Regulatory Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) P.O. Box 587 Warsaw, IN 46581	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 574-267-6639 x1278 (Fax) 574-372-1683
	15. DATE OF CERTIFICATION 08/11/2008



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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 5832-3, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy. 1996

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... NA # (List 017, Item 58)

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 5832-3, IMPLANTS FOR SURGERY -- METALLIC MATERIALS -- PART 3: WROUGHT TITANIUM 6-ALUMINIUM 4-VANADIUM ALLOY, 1996

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*  
None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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

**Paperwork Reduction Act Statement**

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Rockville, MD 20850

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F75-07, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075). 2007

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 018, Item 8-137

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F75-07, STANDARD SPECIFICATION FOR COBALT-28 CHROMIUM-6 MOLYBDENUM ALLOY CASTINGS AND CASTING ALLOY  
JR SURGICAL IMPLANTS (UNS R30075).

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*  
None

DESCRIPTION  
Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

JUSTIFICATION

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

DESCRIPTION

JUSTIFICATION

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

DESCRIPTION

JUSTIFICATION

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

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

**Paperwork Reduction Act Statement**

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

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F136-02a, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications 2002

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA<sup>2</sup>? .....                      

FDA Recognition number<sup>3</sup> ..... # List 017, Item 44

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ASTM F136-02A, STANDARD SPECIFICATION FOR WROUGHT TITANIUM-6 ALUMINUM-4 VANADIUM ELI (EXTRA LOW INTERSTITIAL) ALLOY FOR SURGICAL IMPLANT APPLICATIONS 2002

**CONFORMANCE WITH STANDARD SECTIONS\***

**SECTION NUMBER**

**SECTION TITLE**

**CONFORMANCE?**

Yes  No  N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

**SECTION NUMBER**

**SECTION TITLE**

**CONFORMANCE?**

Yes  No  N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

**SECTION NUMBER**

**SECTION TITLE**

**CONFORMANCE?**

Yes  No  N/A

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

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

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Department of Health and Human Services  
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**STANDARDS DATA REPORT FOR 510(K)S**

*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F648-07, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants. 2007

*Please answer the following questions*

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 018, Item 143

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

3TM F648-07, STANDARD SPECIFICATION FOR ULTRA-HIGH-MOLECULAR-WEIGHT POLYETHYLENE POWDER AND FABRICATED FORM FOR SURGICAL IMPLANTS.

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*  
None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F799-06, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539), 2006

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 17  
# Item 8-131

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F799-06, STANDARD SPECIFICATION FOR COBALT-28 CHROMIUM-6 MOLYBDENUM ALLOY FORGINGS FOR SURGICAL IMPLANTS (UNS R31537, R31538, R31539)

**CONFORMANCE WITH STANDARD SECTIONS\***

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

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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Department of Health and Human Services  
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**STANDARDS DATA REPORT FOR 510(K)S**

*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F1580-01, Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants. 2001

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # List 017, Item 54

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F1580-01, STANDARD SPECIFICATION FOR TITANIUM AND TITANIUM-6 ALUMINUM-4 VANADIUM ALLOY POWDERS FOR COATINGS OF SURGICAL IMPLANTS. 2001

**CONFORMANCE WITH STANDARD SECTIONS\***

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

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

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

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

**Paperwork Reduction Act Statement**

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

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

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

Department of Health and Human Services  
Food and Drug Administration

**STANDARDS DATA REPORT FOR 510(K)S**

*(To be filled in by applicant)*

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 7206-10:2003, Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....  Yes       No

FDA Recognition number<sup>3</sup> ..... # \_\_\_\_\_

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

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes       No

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 7206-10:2003, IMPLANTS FOR SURGERY -- PARTIAL AND TOTAL HIP-JOINT PROSTHESES -- PART 10: DETERMINATION OF RESISTANCE TO STATIC LOAD OF MODULAR FEMORAL HEADS

**CONFORMANCE WITH STANDARD SECTIONS\***

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

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

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

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

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F1875-98(2004), Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA<sup>2</sup>? .....                      

FDA Recognition number<sup>3</sup> ..... List 017,  
# Item 11-183

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

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

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

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

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

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

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

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

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

Title of guidance: Guidance Document for Femoral Stem Prostheses

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

TM F1875-98(2004), STANDARD PRACTICE FOR FRETTING CORROSION TESTING OF MODULAR IMPLANT INTERFACES: HIP  
MEMORAL HEAD-BORE AND CONE TAPER INTERFACE

**CONFORMANCE WITH STANDARD SECTIONS\***

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

DESCRIPTION

JUSTIFICATION

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

DESCRIPTION

JUSTIFICATION

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

DESCRIPTION

JUSTIFICATION

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

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 7206-10:2003, Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes       No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

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

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes       No

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

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

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 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes       No

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

7206-10:2003, IMPLANTS FOR SURGERY -- PARTIAL AND TOTAL HIP-JOINT PROSTHESES -- PART 10: DETERMINATION OF RESISTANCE TO STATIC LOAD OF MODULAR FEMORAL HEADS

**CONFORMANCE WITH STANDARD SECTIONS\***

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

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

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

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## Table of Contents

Cover Letter	
Medical Device User Fee Cover Sheet	
510(k) Body .....	1
Tab 1 Labeling .....	8
Tab 2 Indications for Use Form.....	11
Tab 3 Modified Component Listing and Prints .....	12
Predicate Component Listing and Prints.....	27
Tab 4 Compatible Components .....	45
Sample Drawing – Type I Taper .....	50
Sample Drawing – Type I Reduced Taper.....	51
Sample Drawing – 12/14 Taper .....	52
Tab 5 Risk Analysis Table and Discussion .....	53
Tab A CeramTach’s Testing Protocol .....	62
Tab B Mechanical Testing of 12/14 Taper Sleeves .....	66
Tab C Mechanical Testing of Type I Taper Sleeve .....	121
Tab D Corrosion .....	169
Tab E Wear Testing Justification .....	221
Tab 6 Declarations of Conformity.....	284
Tab 7 510(k) Summary .....	286
Tab 8 Truthful and Accurate Statements .....	288
Tab 9 Clinical Trails Certification.....	290
Tab 10 Standards Data Report For 510(k) .....	291



October 6, 2008

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

Reference: "Special" 510(k) – Biomet® BioloX® *delta* Option Ceramic Heads  
User Fee ID: (b)(4) Trade Secret  
Process

Dear Sir or Madam:

Enclosed is a "**Special**" 510(k): **Device Modifications** submission for BioloX® *delta* Option Ceramic Heads which is a modification of the BioloX® *delta* Ceramic Heads cleared in 510(k) K042091, K061312 and K073102. We believe this device is substantially equivalent\* to cleared devices and warrants a "Special" 510(k).

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. Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Sincerely,

A handwritten signature in cursive script that reads "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)]

Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.8137  
[www.biomet.com](http://www.biomet.com)

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: <b>(b)(4)Trade Secret</b> Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  BIOMET INC P.O. Box 587 Warsaw IN 46581-0587 US		2. CONTACT NAME Patricia Beres 2.1 E-MAIL ADDRESS patty.beres@biometmail.com 2.2 TELEPHONE NUMBER (include Area code) 574-267-6639 1278 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 574-372-1683	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) <b>(b)(4)Trade</b>			
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/dc/mdufma">http://www.fda.gov/dc/mdufma</a> )			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <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 application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION <b>(b)(4)Trade</b>		29-Sep-2008	

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

**Device Name**

---

**Device Trade Name:** BioloX<sup>®</sup> *delta* Option Ceramic Heads  
**Common Name:** Ceramic Modular Heads

---

**Address and Registration #**

**Specification Holder:** Biomet Manufacturing Corp  
56 Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581-0587  
FDA Registration #: 1825034

**Contract Manufacturer:** (b)(4)Trade Secret Process

**Sterilization Site:**

**Contact Information**

---

**Name:** Patricia Sandborn Beres  
**Title:** Senior Regulatory Specialist  
**Address:** Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, IN 46581-0587  
**Telephone:** 574-267-6639  
**Fax:** 574-372-1683  
**E-mail:** [patty.beres@biometmail.com](mailto:patty.beres@biometmail.com)

**Alternate Contact:**

**Name:** Tracy B. Johnson  
**Title:** Director, Clinical and Regulatory Affairs  
**Address:** Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, IN 46581-0587  
**Telephone:** 574-267-6639  
**Fax:** 574-372-1683  
**E-mail:** [tracy.johnson@biometmail.com](mailto:tracy.johnson@biometmail.com)

**Device Classification**

---

**Class:** II  
**Product Code:** LZ0  
**Classification Names:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Common Name.

The guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" was followed

for the preparation of the predicate BioloX<sup>®</sup> *delta* Ceramic Heads 510(k) K042091. Only those portions which are affected by the modifications required to create the new device will be addressed in this document.

**Predicate  
Device  
Information**

The predicate devices are the BioloX<sup>®</sup> *delta* Ceramic Heads cleared through 510(k)s K042091 (March 25, 2005), K051411, (June 29, 2005), 510(k) K061312 (June 6, 2006) and K073102 (November 27, 2007).

(b)(4)Trade Secret Process

**Labeling and  
Indications for  
Use**

Draft labels and Instructions for Use (package insert) can be found in Attachment 1. A new package insert which contains assembly instructions for the components has been developed. A specific surgical technique for the BioloX<sup>®</sup> *delta* Option Ceramic Heads has not been developed at this time. Placement of the head on the femoral stem trunion would be in keeping with the surgical procedure for the femoral stem or acetabular component being used in conjunction with the head.

Indications for Use

The BioloX<sup>®</sup> *delta* Option Ceramic Heads are intended for 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)

These are the same intended use as previously cleared for the predicate BioloX<sup>®</sup> *delta* Ceramic Heads. The Indications for Use Statement can be found in Attachment 2.

## Sterilization and Packaging

Devices are provided sterile by radiation methods as follows:

- Radiation Type: Gamma  
Radiation Source: (b)(4)Trade Secret  
Minimum Dosage: 25 kGy  
Maximum Dosage: 40 kGy
- Sterility Assurance Level: 10<sup>-6</sup>
- Sterility Validation Method: (b)(4)Trade Secret Process
- Pyrogen-Free: no claims will be made
- Packaging: Each component is placed within a plastic bag between two foam pads. They are then placed in an inner blister pack sealed with a Tyvek<sup>®</sup> lid which fits into an outer blister pack also sealed with a Tyvek<sup>®</sup> lid. The entire unit is placed in a cardboard box, shrink wrapped for protection. All labeling will be on the outer Tyvek<sup>®</sup> lid as well as on the outer cardboard box.
- 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, 25 kGy
- Expiration Date: The BioloX<sup>®</sup> *delta* Option Ceramic Heads have a 10-year shelf-life. Supporting data is on file at Biomet and can be accessed at any future FDA inspection.

Note: The BioloX<sup>®</sup> *delta* Option Ceramic Head and Taper Adapter will be packaged separately.

## Device Description

The BioloX<sup>®</sup> *delta* Option Ceramic Heads consist of a series of BioloX<sup>®</sup> *delta* ceramic ball heads in combination with a titanium sleeve. The heads are available in a variety of diameters and taper adapters are available for Biomet's Type I and Biomet 12/14 tapers in a variety of neck lengths.

### Specific Characteristics – Heads

- Material - Transition-Toughened-Platelet Alumina (TTPA) (b)(4)Trade Secret Process (b)(4)T

Head Size	28mm	32mm	36mm	38mm	40mm
(b)(4)Trade Secret Process					

**Specific Characteristics – Biomet Type I Adapter**

- Material -Titanium Alloy (Ti-6Al-4V, ISO 5832-3)
- (b)(4)Trade Secret Process
- Neck Lengths – x-small, small, medium, large, x-large (-6, -3, 0, +3, +6)

(b)(4)Trade Secret Process

Adapter Size	X-small -6	Small -3	Medium 0	Large +3	X-large +6
(b)(4)Trade Secret Process					

**Specific Characteristics – Biomet 12/14 Adapter**

- Material -Titanium Alloy (Ti-6Al-4V, ISO 5832-3)
- (b)(4)Trade Secret Process
- Neck Lengths – small, medium, large, x-large (-3, 0, +4, +7)

(b)(4)Trade Secret Process

Adapter Size	Small -3	Medium 0	Large +4	X-large +7
(b)(4)Trade Secret Process				

### Product Listing/Drawings

- The name and manufacturers model number for each BioloX<sup>®</sup> *delta* Option Ceramic Head may be found in Attachment 3.
- Dimensioned engineering drawings of the BioloX<sup>®</sup> *delta* Option Ceramic Heads and taper adapters may be found in Attachment 3.
- A product listing and engineering drawings of the predicate BioloX<sup>®</sup> *delta* Ceramic Heads may be found in Attachment 3.

### Compatible Products

- Attachment 4 contains a table of compatible hip stems for use with the BioloX<sup>®</sup> *delta* Option Ceramic Heads.
- All of the devices are metallic hip stems with or without porous coating.
- Each stem has a Biomet 12/14 or Biomet Type I trunion (standard or reduced) for attachment of the modular head. A sample engineering drawing of a femoral stem with each type of taper is included in Attachment 4.

(b)(4)Trade Secret Process

- Porous coating material conforms to ASTM F-1580.
- Attachment 4 also contains a list of the compatible acetabular components that may be used with this device.

(b)(4)Trade Secret Process

- Porous coating material conforms to ASTM F-1580.
- Polyethylene liners and all polyethylene cups are manufactured from material conforming to ASTM F-648.
- Screws for use in the acetabular shells are manufactured from titanium alloy conforming to ASTM F-136.

### Device Comparison

The following features have not changed as previously described in the predicate device 510(k) K042091.

- Material including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity.
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability

Modifications from the cleared product are as follows:

(b)(4)Trade Secret Process

- Additional head diameter of 40mm
- Use of a titanium taper adapter (sleeve)

**Substantial  
Equivalence**

---

The modified device have the following similarities to the Biolo<sup>®</sup>*delta* Ceramic Heads which previously received 510(k) concurrence:

- They have identical indications statements
- They are compatible with Biomet femoral stems
- They are manufactured from the same materials
- They are packaged and sterilized using the same materials and processes
- They have the same shelf life
- Mechanical testing shows the modified devices meet the standards put forth in FDA's guidance document or are comparable to the predicate devices.

In summary, the Bolox<sup>®</sup> *delta* Option Ceramic Heads described in this submission are substantially equivalent to the predicate device.

**Summary of  
Design Control  
Activities**

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The risk assessment has been conducted in accordance with ISO 14971 to determine the impact of the modifications. A discussion of the risks identified and supporting data is presented in Attachment 5.

A declaration of conformity with design control is included in Attachment 6.

Evidence of design transfer, as specified in QSR § 820.30(h), is found in Biomet SOP 4.1.7 under QM 4.1. "Final design transfer is conducted upon completion of the final design review pursuant to SOP 4.1.4 Design Review to ensure all transfer activities have been completed." The final design review and the design history file (DHF) have been completed for this project.

**Bench/Animal  
Testing**

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Bench testing is summarized in detail in the risk section presented in Attachment 5. Properties measured include:

(b)(4)Trade Secret Process



Wear: Biolo<sup>®</sup> *delta* Ceramic Heads have demonstrated superior wear properties as compared to cobalt alloy modular heads.

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**510(k)  
Summary**

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A 510(k) Summary for the Biolox<sup>®</sup> *delta* Option Ceramic Heads is included in Attachment 7.

**Truthful and  
Accuracy  
Certification**

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A certification of the truthfulness and accuracy of the information presented in this submission is provided in Attachment 8.

**Additional  
Information**

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Attachment 9 contains a Certificate of Compliance with ClinicalTrials.gov Data Bank.

Standards Data Reports for 510(k)s have been completed for the material and testing standards cited in this submission and are contained in Attachment 10.

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*All trademarks are property of Biomet, Inc. except for the following:  
Biolox is a trademark of CeramTec AG  
Tyvek is a trademark of E.I. duPont de Nemours and Company*

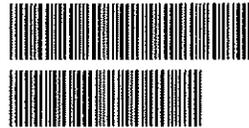


REF. 650-1054 LOT 123123

BIOLOX-DELTA® OPTION CERAMIC HEAD  
38MM HEAD DIAMETER  
TYPE 16/18 TAPER

ALUMINA / ZIRCONIA  
FOR USE W/BIOLOX OPTION -  
TAPER ADAPTER ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

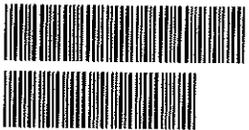
2008-07  
EXPIRY DATE: 2018-07

REF. 650-1068 LOT 123123

BIOLOX® OPTION TAPER ADAPTER  
PLUS 6 NECK  
TYPE I TAPER

TI-6AL-4V ALLOY  
FOR SINGLE USE WITH BIOMET -  
TYPE I TAPERS ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

2008-08  
EXPIRY DATE: 2018-08

BIOMET ORTHOPEDICS, INC.

BIOMET ORTHOPEDICS, INC.

REF. 650-1060 LOT 123123

BIOLOX® OPTION TAPER ADAPTER  
S / MINUS 3 NECK  
TYPE 12/14 TAPER

TI-6AL-4V ALLOY  
FOR SINGLE USE WITH BIOMET -  
12/14 TAPERS ONLY.  
BioloX is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R

2008-08  
EXPIRY DATE: 2018-08

BIOMET ORTHOPEDICS, INC.

BIOMET ORTHOPEDICS, INC.

## Biomet Orthopedics, Inc.

56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581 USA

01-50-0916

Date: 08/08

### Biomet® BioloX™ delta Option Modular Head Hip Joint Prostheses

#### ATTENTION OPERATING SURGEON

#### DESCRIPTION

The Biomet® BioloX™ delta Option Ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces in a variety of head sizes. The highly polished surface is designed to reduce friction and minimize wear. The titanium sleeves adapt the ceramic heads to either a Biomet® Type I or a Biomet® 12/14 taper.

#### MATERIALS

Head - TTPA Ceramic  
Sleeve - Titanium Alloy (Ti-6Al-4V)

#### 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 trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
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 Biomet® BioloX™ delta Option ceramic modular head with Biomet® metallic femoral components. Do not use Biomet® BioloX™ delta Option 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. Sleeves labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Sleeves labeled "12/14" are to be used with femoral stem components labeled "12/14" taper.
4. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal-backed UHMWPE acetabular components.
5. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
6. 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.
7. The femoral stem trunion, sleeves and the bore of the ceramic head should be dry and free of contamination prior to assembly.
8. During a revision surgery, extraction of the femoral head should be done with suitable extraction instruments to avoid unnecessary damage to the trunion.

9. Biomet® BioloX™ delta Option modular head components should not be used on trunions with damage greater than 0.25mm. The surgeon should inspect the taper for damage prior to placement of the sleeve. The following conditions are considered unsuitable for the use of the Biomet® BioloX™ delta Option Ceramic Head:



Slanted Taper



Taper with Scratches/Warping



Taper with Broad Truncation



Crushed Taper

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, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation 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.

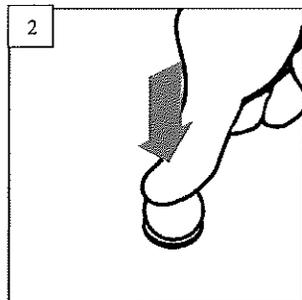
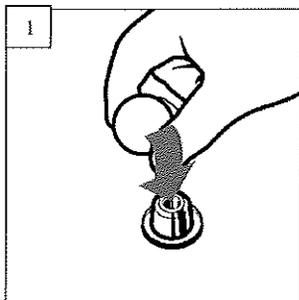
#### POSSIBLE ADVERSE EFFECTS

1. 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.

2. Early or late postoperative infection and allergic reaction.
3. 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.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption, and/or excessive, unusual and/or awkward movement and/or activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
12. 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.
13. 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.
14. Intraoperative and postoperative bone fracture and/or postoperative pain.
15. Ceramic head fractures have been reported.

#### ASSEMBLY INSTRUCTIONS



#### 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, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46582 USA, FAX: 574-372-3968.

Biomet® and all other trademarks herein are the property of Biomet, Inc. or its subsidiaries.



## Indications for Use

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

Device Name: Biolox<sup>®</sup> delta Option Ceramic Heads

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

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

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

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

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

Prescription Use  X   
\_(Part 21 CFR 801 Subpart D)

AND/OR

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



## Modified Component Listing

Biomet

<u>Part Number</u>	<u>Description</u>
650-1055	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 28mm
650-1056	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 32mm
650-1057	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 36mm
650-1054	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 38mm
650-1058	BioloX <sup>®</sup> <i>delta</i> Option Ceramic Head 40mm
650-1060	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Small
650-1061	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Medium
650-1062	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve Large
650-1063	BioloX <sup>®</sup> <i>delta</i> Option 12/14 Sleeve X-Large
650-1064	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve X-Small
650-1065	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Small
650-1066	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Medium
650-1067	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve Large
650-1068	BioloX <sup>®</sup> <i>delta</i> Option Type I Sleeve X-Large

(b)(4)Trade

Part Number

(b)(4)Trade Secret  
Process



























### Predicate Component Listing – K042091 and K051411

Biomet

<u>Part Number</u>	<u>Description</u>
12-115109	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115110	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115111	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115112	28mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +5
12-115114	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115115	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115116	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115117	32mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade  
Secret Process  
Part Number  
(b)(4)Trade Secret Process

### Predicate Component Listing – K061312

Biomet

<u>Part Number</u>	<u>Description</u>
12-115120	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115121	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, Std
12-115122	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115123	36mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade  
Secret Process  
Part Number  
(b)(4)Trade Secret  
Process

### Predicate Component Listing – K073102

Biomet

<u>Part Number</u>	<u>Description</u>
12-115130	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -6
12-115131	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, -3
12-115132	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, STD
12-115133	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +3
12-115134	38mm BioloX <sup>®</sup> <i>delta</i> Ceramic Head, +6

(b)(4)Trade Secret  
Process  
Part Number  
(b)(4)Trade Secret  
Process



































### Compatible Component Listing

In order to complete a total hip replacement surgery, the BioloX<sup>®</sup> delta Option Ceramic Heads require the use of a femoral stem and an acetabular component. Listed below are those Biomet hip components that are compatible with the components that are the subject of this 510(k).

Table 1a - Compatible Femoral Stems - Type I Tapers			
	510(k) Number	Product Code	Indication
Answer <sup>®</sup> Femoral Component	K991987	JDI	Cemented
Co-Cr Answer <sup>®</sup> Femoral Components	K931194	JDG <sup>1</sup>	Cemented
Altra Press-Fit Hip Stem (Echo <sup>™</sup> )	K063002	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY	Uncemented
Altra FX Hip System (Echo <sup>™</sup> )	K063614	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY	Cemented and non-cemented
APF Femoral Component	K852585 K984154 K030055	JDI JDI LPH	Cemented and non-cemented
Balance <sup>®</sup> Hip System Microplasty <sup>®</sup> Stems	K050251	KWZ, JDL, KWA, JDI, LZO, MEH, LPH, LZY, KWY	Non-cemented
Bi-Metric <sup>®</sup> Femoral Components	K921224 K020580 K030055	LZO LPH LPH	Cemented and non-cemented
Bi-Metric <sup>®</sup> Head/Neck Replacement	K955350 K992058 K983710	LZO JDI JDI	Cemented
HA Bi-Metric <sup>®</sup> Femoral Component	K023409 K030055	LPH LPH	Non-cemented
Bio-Groove <sup>®</sup> HAP Hip Components	K912369 K912370	MEH MEH	Non-cemented
Bohn Femoral Component	K000262	LZO, MEH	Non-cemented
Buchalter/Fausser Femoral Component	K952686	LZO	Cemented
Color Buffered Cemented Stem	K992903 K012019	JDI JDI	Cemented
Echo B-Metric <sup>®</sup> Press Fit Stem	K070274	KWA	Non-cemented
Fenning (Osteocap RS <sup>®</sup> ) Femoral Component	K960303	LPH	Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO	Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734 K052639	JDI JDI, LZO, KWZ, MEH, LPH, LZY, KWY, JDG	Cemented

(b)(4) Trade Secret Process

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

	510(k) Number	Product Code	Indication
Gross Femoral Component	K001580	MEH	Non-cemented
Impact <sup>®</sup> Co-Cr Femoral Components	K942027	JDG <sup>2</sup>	Cemented
Integral <sup>®</sup> Femoral Component	K921225	LZO	Cemented and non-cemented
	K984296	LPH	
	K984408	LPH	
	K030055	LPH	
	K030501	LPH	
	K042029	LPH	
	K942479	LZO	
Integral <sup>®</sup> Co-Cr Femoral Component	K990830	LPH	Cemented
	K042774	LPH <sup>3</sup>	Non-cemented
Interlocking Hip Stems			
Mallory/Head <sup>®</sup> Total Hip System	K921181	LZO	Cemented and non-cemented
	K994007	JDI	
	K000538	LPH	
	K003429	LPH	
	K030055	LPH	
	K021403	LPH, MEH	
HA Mallory/Head <sup>®</sup> Total Hip System	K030055	LPH, MEH	Non-cemented
Mallory/Head <sup>®</sup> Co-Cr Femoral Component	K911684	JDI	Cemented
Mallory/Head <sup>®</sup> Calcar Femoral Components (including HA)	K945115	LPH, LZO	Cemented and non-cemented
	K001660	LPH	
	K031693	LPH	
Medallion Hip	K041850	LPH	Uncemented
Modular Hip Stems	K912712	JDI	Cemented and non-cemented
	K921274	LPH	
	K030055	LPH	
Oncology Salvage System	K002757	JDI	Cemented
OSS <sup>™</sup> Les Proximal Femoral Component	K021380	JDI, LPH	Cemented and non-cemented
PMI <sup>®</sup> Femoral Component	K911802	JDI	Cemented and non-cemented
	K923452	LPH	
	K030055	LPH	
HA PMI <sup>®</sup> Femoral Stem	K030048	LPH	Non-cemented
	K010560	LZO	
Portrait <sup>™</sup> Femoral Component			Non-cemented
			Non-cemented

(b)(4) Trade Secret Process

<sup>2</sup> Submitted under classification 888.3350 JDI

<sup>3</sup> Cleared under product codes JDL, KWA, LPH, LZO, KWZ, JDI and KWY based on available modular head and acetabular components for use with this stem

	510(k) Number	Product Code	Indication
Reach® Femoral Component	K971824	LPH	Non-cemented
	K982367	LPH	
	K000760	LPH	
Modular Reach®	K994038	LPH	Non-cemented
	K022463	LPH	Non-cemented
HA Modular Reach®	K030055	LPH	
	K942028	JDG <sup>4</sup>	Cemented
Rx-90® Femoral Stems	K023085	JDI	
	K960984	JDI	Cemented
SHP™ Hip System	K050441	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH,	Non-cemented
	K062994	KWB, LZY, KWY	
Taper2™ Porous Femoral Stem (Taperloc® Microplasty)	K830313	JDI	Cemented and non-cemented
	K921301	LPH	
	K030055	LPH	
HA Taperloc® Femoral Component	K020963	MEH	Non-cemented
	K030055	LPH	
Total IM Femur	K033871	JDI	Cemented
Total Femur	K974558	JDI	Cemented
XR-Series Bi-Metric Femoral Component	K052089	LPH, JDI, LZO, KWY, KWZ	Cemented and non-cemented
<b>Table 1b - Compatible Femoral Stems - 12/14 Tapers</b>			
	510(k) Number	Product Code	Indication
Taperloc® Femoral Component	K043537	LPH	Cemented and non-cemented

(b)(4) Trade Secret Process

<sup>4</sup> Submitted under classification 888 3350 JDI

The modular heads in this submission are compatible with the corresponding size of liners, which are compatible with any corresponding size of acetabular system shells listed in the following tables:

Table 2a - All Polyethylene Acetabular Systems			
	510(k) Number	Product Code	Indications
Bio-Clad™ Reinforced All-Poly Acetabular Components	K810120	JDI	Cemented
	K926107	LPH	
All-Poly (Ranawat/Burstein) Acetabular Components	Pre-amendment	N/A	Cemented

Table 2b - Compatible Low Profile Liners and Shells						
	510(k) Number	Product Code	Acetabular System Compatible w/ Liner	510(k) Number	Product Code	Indications
ARCOM® XL RX-90 Low Profile Liners	K052255	LPH	RX-90 Low Profile Acetabular Components	K920639	JDL	Cemented and non-cemented
				K042989	LPH	

Table 2c - Compatible Full Hemispherical Liners and Shells							
	510(k) Number	Product Code	Acetabular System Compatible w/ Liner	510(k) Number	Product Code	Indications	
ARCOM® RingLoc® Liners	K926107	LPH	A-B (Precept®) Acetabular System	K954417	LPH	Cemented and non-cemented	
	K950761	JDI		K030055	LPH, MEH		
	K970501	LPH		Flanged Acetabular Component	K983035	LPH	Cemented and non-cemented
	K023357	LPH			K030055	LPH, MEH	
	K030055	LPH, MEH					
ARCOM® RingLoc® Constrained Liner	K021728	KWZ	Full Hemisphere Acetabular Components	K920640	JDL <sup>2</sup>	Cemented	
ARCOM® XL RingLoc® Liners	K042051	JDI, LPH	Healy™ Flanged Revision	K921139	JDL <sup>2</sup>	Cemented	
	K051411	LZO					
ARCOM® 36mm RingLoc® Liners	K032396	JDI, LPH	Index® Acetabular Components	K950761	JDI	Cemented and non-cemented	
E-Poly Acetabular Liners	K050327	LPH, JDI, LWJ, MAY	Mallory/Head® Acetabular Components	K030055	LPH, MEH	Cemented and non-cemented	
				K070364	LPH, JDI, LWJ, MAY		
				K070399	LPH, JDI, LWJ, MAY		
				K073102	LZO, LPH, JDI, LWJ, MAY		
					LPH, MEH		

510(k) Number	Product Code	Acetabular System Compatible w/ Liner <sup>5</sup>	510(k) Number	Product Code	Indications
		Mars <sup>®</sup> Modular Acetabular Reconstructive System	K911718	JDI	Cemented
		Par 5 <sup>™</sup> Acetabular Components	K022094	JDI	Cemented and non-cemented
		Quadrant Sparing Acetabular Components	K920640 K050124	JDL <sup>5</sup> KWA	Cemented non-cemented
		Ranawat/Burstein <sup>®</sup> Acetabular Component s	K911685 K921277 K050124	JDI LPH KWA	Cemented and non-cemented (NIDJD only)
		Regenerex <sup>™</sup> Porous Titanium Acetabular Components	K052996	LPH	Cemented and non-cemented
		TRI-SPIKE <sup>™</sup> Pegged Acetabular Components	K970501 K030055	LPH LPH, MEH	Cemented and non-cemented
		Tri-Polar Acetabular System including liners	K991990	KWY	Cemented and non-cemented
		Universal <sup>®</sup> Acetabular Components	K861433 K921301 K030055	JDL <sup>5</sup> LPH LPH, MEH	Cemented and non-cemented
		Vision Acetabular Components	K954417 K030055	LPH/JDI LPH, MEH	Cemented and non-cemented

All acetabular shells with screw holes may be used with Biomet titanium screws cleared under the following 510(k)s as well as any screws contained within the 510(k)s for the acetabular cups:

Table 2d - Biomet Titanium Acetabular Screws		
510(k) number	Product Code	Indications
Titanium Screw LP 5mm	LPH	Cemented and non-cemented
Titanium Screw LP 6.5mm	LPH	Cemented and non-cemented

<sup>5</sup> 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 submissions were for metal on polyethylene systems (JDI).





























































































































































































































































































































































































































































# Appendix 1

**Drawings**























# Appendix 2

(b)(4) Trade Secret Process - Testing  
Report



(b)(4)Trade Secret Process - Testing Report

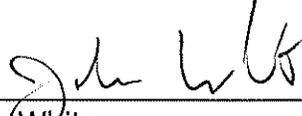




### Declarations Of Conformity With Design Controls

#### Verification Activities

To the best of my knowledge, all verification and validation activities were performed by the designated individual(s) and the result of the activities demonstrated that the predetermined acceptance criteria were met.



\_\_\_\_\_  
John White  
Director of Hip Engineering  
Biomet Manufacturing Corp.

9/15/08

\_\_\_\_\_  
Date

## Declarations Of Conformity With Design Controls

### Manufacturing Facility

The manufacturing facility, Biomet, Inc., is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

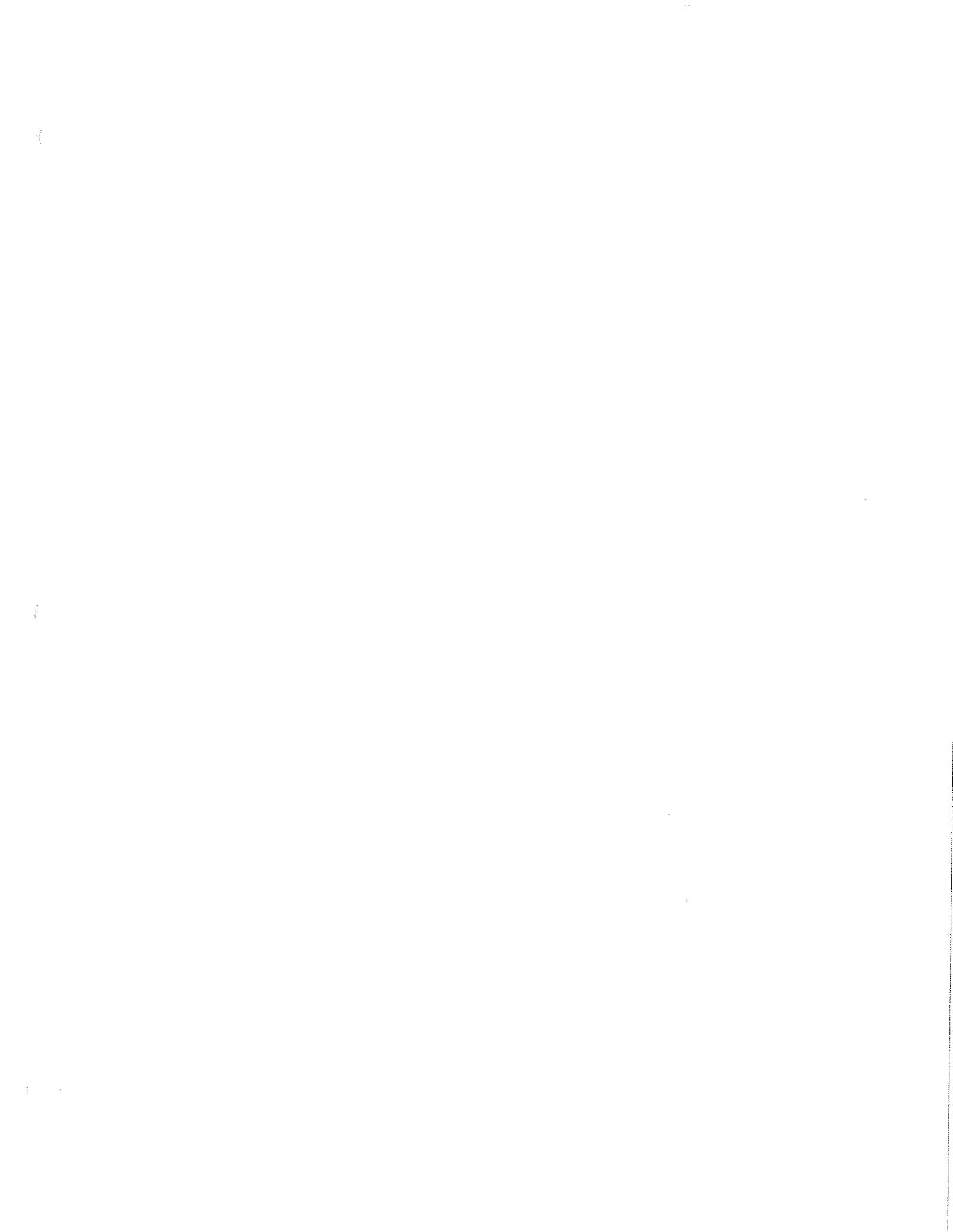


\_\_\_\_\_  
Rex A. White

Vice President, Regulatory Compliance and Quality Assurance  
Biomet Manufacturing Corp.

22 Sept 08

\_\_\_\_\_  
Date



### 510(k) Summary

**Date:** September 10, 2008

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist

**Proprietary Name:** BioloX<sup>®</sup> *delta* Option Ceramic Heads

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

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

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**  
BioloX<sup>®</sup> *delta* Ceramic Heads – K042091, K051411, K061312, K073102

**Device Description:** BioloX<sup>®</sup> *delta* Option Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. A highly polished spherical head in a variety of diameters articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem via a taper adapter. Adapters are available for either Biomet's Type I taper or Biomet's 12/14 taper in a variety of neck lengths.

**Indications For Use:** BioloX<sup>®</sup> *delta* Option 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:

Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.6639  
Main Fax: 574.267.8137  
www.biomet.com

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

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

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

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

**Summary of Technologies:** The Biolox® *delta* Option 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

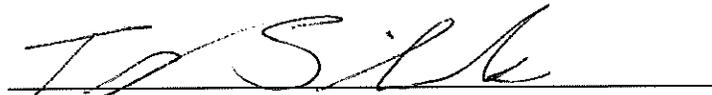
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*Biolox is a trademark of CeramTec AG*



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

I certify, in my capacity as a Development Engineer 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

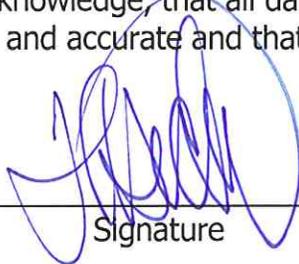
Anthony Siebeneck  
Typed Name

09/10/08  
Date

Biolog<sup>®</sup> delta Option Ceramic Heads  
Device

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

I certify, in my capacity as Director of Clinical and Regulatory Affairs, 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

Tracy B. Johnson  
Typed Name

14 September 2008  
Date

BioloX<sup>®</sup> delta Option Ceramic Heads  
Device





**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Food and Drug Administration

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

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

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Biomet Manufacturing Corp.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Oct 6, 2008
3. ADDRESS (Number, Street, State, and ZIP Code) 56 Bell Drive Warsaw, IN 46582	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 574-267-6639 (Fax) 574-372-1683

**PRODUCT INFORMATION**

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

Device Trade Name: BioloX® delta Option Ceramic Heads

Common Name: Ceramic Modular Heads

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

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

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

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

**CERTIFICATION STATEMENT / INFORMATION**

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

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

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

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

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

NCT Number(s):

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)  Patricia S Beres	12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) Patricia S. Beres (Title) Senior Regulatory Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) P.O. Box 587 Warsaw, IN 46581	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 574-267-6639 x1278 (Fax) 574-372-1683
	15. DATE OF CERTIFICATION 08/11/2008



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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 5832-3, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy. 1996

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... NA # (List 017, Item 58)

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 5832-3, IMPLANTS FOR SURGERY -- METALLIC MATERIALS -- PART 3: WROUGHT TITANIUM 6-ALUMINIUM 4-VANADIUM ALLOY, 1996

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED\*  
None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED\*

**DESCRIPTION**

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED\*

**DESCRIPTION**

**JUSTIFICATION**

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

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

**Paperwork Reduction Act Statement**

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

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

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

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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F75-07, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075). 2007

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 018, Item 8-137

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

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

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

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

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

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

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

Were there any exclusions from the standard? .....         
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 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F75-07, STANDARD SPECIFICATION FOR COBALT-28 CHROMIUM-6 MOLYBDENUM ALLOY CASTINGS AND CASTING ALLOY  
JR SURGICAL IMPLANTS (UNS R30075).

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED\*  
None

DESCRIPTION  
Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

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

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

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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F136-02a, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications 2002

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 017, Item 44

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ASTM F136-02A, STANDARD SPECIFICATION FOR WROUGHT TITANIUM-6 ALUMINUM-4 VANADIUM ELI (EXTRA LOW INTERSTITIAL) ALLOY FOR SURGICAL IMPLANT APPLICATIONS 2002

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes  No  N/A

TYPE OF DEVIATION OR OPTION SELECTED\*

None

DESCRIPTION

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes  No  N/A

TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes  No  N/A

TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

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

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

**Paperwork Reduction Act Statement**

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Department of Health and Human Services  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F648-07, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants. 2007

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 018, Item 143

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

3TM F648-07, STANDARD SPECIFICATION FOR ULTRA-HIGH-MOLECULAR-WEIGHT POLYETHYLENE POWDER AND FABRICATED FORM FOR SURGICAL IMPLANTS.

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED\*  
None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED\*

**DESCRIPTION**

**JUSTIFICATION**

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F799-06, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539), 2006

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # List 17  
# Item 8-131

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F799-06, STANDARD SPECIFICATION FOR COBALT-28 CHROMIUM-6 MOLYBDENUM ALLOY FORGINGS FOR SURGICAL IMPLANTS (UNS R31537, R31538, R31539)

**CONFORMANCE WITH STANDARD SECTIONS\***

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

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F1580-01, Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants. 2001

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # List 017, Item 54

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

STM F1580-01, STANDARD SPECIFICATION FOR TITANIUM AND TITANIUM-6 ALUMINUM-4 VANADIUM ALLOY POWDERS FOR COATINGS OF SURGICAL IMPLANTS. 2001

**CONFORMANCE WITH STANDARD SECTIONS\***

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

None

**DESCRIPTION**

Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

**DESCRIPTION**

**JUSTIFICATION**

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

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 7206-10:2003, Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....  Yes       No

FDA Recognition number<sup>3</sup> ..... # \_\_\_\_\_

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

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes       No

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

ISO 7206-10:2003, IMPLANTS FOR SURGERY -- PARTIAL AND TOTAL HIP-JOINT PROSTHESES -- PART 10: DETERMINATION OF RESISTANCE TO STATIC LOAD OF MODULAR FEMORAL HEADS

**CONFORMANCE WITH STANDARD SECTIONS\***

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

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

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F1875-98(2004), Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA<sup>2</sup>? .....                      

FDA Recognition number<sup>3</sup> ..... List 017,  
# Item 11-183

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

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

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

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

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

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

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

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

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

Title of guidance: Guidance Document for Femoral Stem Prostheses

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

TM F1875-98(2004), STANDARD PRACTICE FOR FRETTING CORROSION TESTING OF MODULAR IMPLANT INTERFACES: HIP  
MEMORAL HEAD-BORE AND CONE TAPER INTERFACE

**CONFORMANCE WITH STANDARD SECTIONS\***

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

TYPE OF DEVIATION OR OPTION SELECTED\*

DESCRIPTION

JUSTIFICATION

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

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

**Paperwork Reduction Act Statement**

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

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

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

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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 7206-10:2003, Implants for surgery -- Partial and total hip-joint prostheses -- Part 10: Determination of resistance to static load of modular femoral heads

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

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

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

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

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

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

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

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

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

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

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

7206-10:2003, IMPLANTS FOR SURGERY -- PARTIAL AND TOTAL HIP-JOINT PROSTHESES -- PART 10: DETERMINATION OF RESISTANCE TO STATIC LOAD OF MODULAR FEMORAL HEADS

**CONFORMANCE WITH STANDARD SECTIONS\***

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	----------------------	--

**TYPE OF DEVIATION OR OPTION SELECTED\***

**DESCRIPTION**

**JUSTIFICATION**

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

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

**Paperwork Reduction Act Statement**

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

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

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



**COVER SHEET MEMORANDUM**

From: Reviewer Name Tara Shepherd  
Subject: 510(k) Number K082996/S  
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%20202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			✓
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank?</i> (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Is this device subject to Section 522 Postmarket Surveillance?  
(Postmarket Surveillance Guidance,  
<http://www.fda.gov/cdrh/osb/guidance/316.html>)

Contact OSB.



Is this device subject to the Tracking Regulation? (Medical Device Tracking  
Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC.



Regulation Number

Class\*

Product Code

880.3353

II

L70

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

Additional Product Codes:

Review:

*[Signature]*  
(Branch Chief)

OTDB  
(Branch Code)

1/14/09  
(Date)

Final Review:

*[Signature]*  
(Division Director)

*[Signature]*  
Def. Dir. 1/15/09

(Date)

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

To: THE FILE

RE: DOCUMENT NUMBER

K082996 S001

Date: January 13, 2009

TNS 1/13/09

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

Division: DGRND/OJDB

Device Name: BioloX Delta Option Ceramic Heads

Classification: 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; LZ0

Company: Biomet, Inc.  
56 East Bell Dr.  
P.O. Box 587  
Warsaw, IN 46581

*Chen  
PAC  
1/15/09*

Contact: Patricia Beres  
Senior Regulatory Specialist  
Phone: (574) 267 – 6639; Fax: (574) 372 – 1683; Email: [patty.beres@biometmail.com](mailto:patty.beres@biometmail.com)

Tracy B. Johnson (Alternate)  
Director, Clinical and Regulatory Affairs  
Phone: (574) 267 – 6639; Fax: (574) 372 – 1683; Email: [tracy.johnson@biometmail.com](mailto:tracy.johnson@biometmail.com)

**Recommendation:** Based on the information provided, I recommend the BioloX Delta Option Ceramic Heads be found **Substantially Equivalent (SE)** to legally marketed predicate devices.

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

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
  - BioloX *delta* Ceramic Head (K042091, K051411, K061312, K073102)
  - BioloX Option Heads (K073567; Zimmer Inc)

(b)(4)Trade Secret Process

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

The BioloX *delta* Option Ceramic Heads are intended for total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity

- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
- Revision procedures where other treatment or devices have failed

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

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

*Reviewer's Comments:* Adequate. (b)(4)Trade Secret Process

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

**This change was for**

- (b)(4)Trade Secret Process
- Additional head diameter of 40mm
- Use of a titanium taper adapter sleeve

Femoral Head	12/14 Sleeve	Type I Sleeve
28mm	Small (-3)	X-Small (-6)
32mm	Medium (0)	Small (-3)
36mm	Large (+3)	Medium (0)
38mm	X-Large (+6)	Large (+3)
40mm		X-Large (+6)-Small (-6)

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

The Biolox *delta* Option Ceramic Heads consist of a series of Biolox *delta* ceramic ball heads in combination with a titanium sleeve. The heads are available in a variety of diameters and taper adapters are available for Biomet's Type I and Biomet 12/14 tapers in a variety of neck lengths.

The following features have not changed as previously described in the predicate device K042091:

- Material including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- Surface roughness
- Sphericity

- Allowable defects
- Hydrothermal stability

#### Sterilization

Method: Gamma radiation  
 Source: (b) [REDACTED]  
 Minimum Dosage: (b)(4)Trade Secret Process 25kGy  
 Maximum Dosage: 40kGy  
 Sterility Assurance Level: 10-6  
 Validation Method: (b)(4)Trade Secret Process [REDACTED]  
 Pyrogen Free: no claims  
 Packaging: inner and outer blister pack sealed with Tyvek lid  
 Expiration Date: 10 years (supporting data is on file at Biomet)

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

4. A **Design Control Activities Summary** which includes:
- 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
  - Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

Change	Risk	Verification Activity	Acceptance Criteria	Results
(b)(4)Trade Secret Process [REDACTED]				





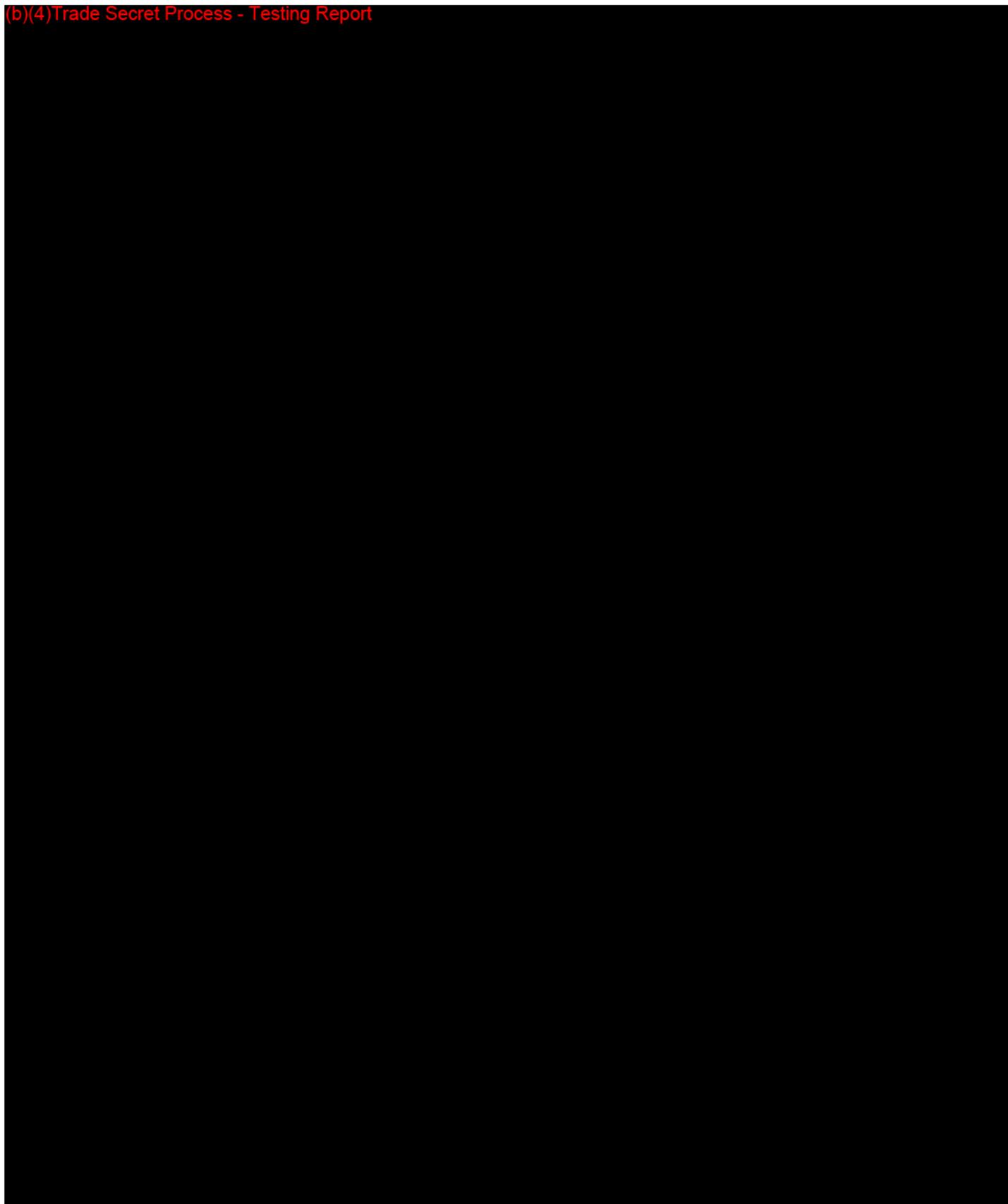








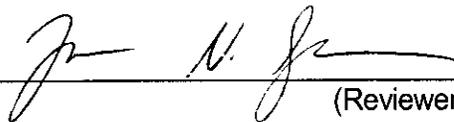
(b)(4)Trade Secret Process - Testing Report



Reviewer's Comments: Adequate.

**5. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

Reviewer's Comments: Adequate. Provided in Sections 2, 7, 8 of original submission

  
\_\_\_\_\_  
(Reviewer's Signature)

Jan 13, 2009  
(Date)

Comments \_\_\_\_\_  
\_\_\_\_\_  1/14/09  
\_\_\_\_\_  
\_\_\_\_\_

revised:8/1/03

## "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

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

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



### COVER SHEET MEMORANDUM

**From:** Reviewer Name Tara Shepherd  
**Subject:** 510(k) Number K082996  
**To:** The Record

Please list CTS decision code AI

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ?			
(If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

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

Regulation Number	Class*	Product Code
8008.3353	II	L20

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

Additional Product Codes: \_\_\_\_\_

Review: *Jmeter* (Branch Chief)      0JDB (Branch Code)      11/13/08 (Date)

Final Review: *Jmeter* (Division Director)      11/13/08 (Date)

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

**To:** THE FILE

**RE:** DOCUMENT NUMBER

K082996

---

**Date:** November 10, 2008

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

**Division:** DGRND/OJDB

**Device Name:** BioloX Delta Option Ceramic Heads  
TNS 11/10/08

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

**Company:** Biomet, Inc.  
56 East Bell Dr.  
P.O. Box 587  
Warsaw, IN 46581

**Contact:** Patricia Beres  
Senior Regulatory Specialist  
Phone: (574) 267 – 6639; Fax: (574) 372 – 1683; Email: [patty.beres@biometmail.com](mailto:patty.beres@biometmail.com)

Tracy B. Johnson (Alternate)  
Director, Clinical and Regulatory Affairs  
Phone: (574) 267 – 6639; Fax: (574) 372 – 1683; Email: [tracy.johnson@biometmail.com](mailto:tracy.johnson@biometmail.com)

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**Recommendation:** Based on the information provided, I recommend **Additional Information (AI)** be requested and the submission be placed on hold.

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

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
  - BioloX *delta* Ceramic Head (K042091, K051411, K061312, K073102)
  - BioloX Option Heads (K073567; Zimmer Inc)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

The BioloX *delta* Option Ceramic Heads are intended for total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

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

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

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

*Reviewer's Comments:* Adequate. (b)(4)Trade Secret Process

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

**This change was for**

- (b)(4)Trade Secret Process
- Additional head diameter of 40mm
- Use of a titanium taper adapter sleeve

Femoral Head	12/14 Sleeve	Type I Sleeve
28mm	Small (-3)	X-Small (-6)
32mm	Medium (0)	Small (-3)
36mm	Large (+3)	Medium (0)
38mm	X-Large (+6)	Large (+3)
40mm		X-Large (+6)-Small (-6)

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

The Biolox *delta* Option Ceramic Heads consist of a series of Biolox *delta* ceramic ball heads in combination with a titanium sleeve. The heads are available in a variety of diameters and taper adapters are available for Biomet's Type I and Biomet 12/14 tapers in a variety of neck lengths.

The following features have not changed as previously described in the predicate device K042091:

- Material including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability

Sterilization

Method: Gamma radiation  
 Source: (b) [REDACTED]  
 Minimum Dosage: (b) (4) Trade Secret Process 25kGy  
 Maximum Dosage: 40kGy  
 Sterility Assurance Level: 10-6  
 Validation Method: (b) (4) Trade Secret Process [REDACTED]  
 Pyrogen Free: no claims  
 Packaging: inner and outer blister pack sealed with Tyvek lid  
 Expiration Date: 10 years (supporting data is on file at Biomet)

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

4. A **Design Control Activities Summary** which includes:
- 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
  - Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

Change	Risk	Verification Activity	Acceptance Criteria	Results
(b) (4) Trade Secret Process [REDACTED]				















**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION**

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

5. Explain how descriptive characteristics are not precise enough:  
*Performance testing necessary*
8. Explain what performance data is needed:  
*Further testing of Biolox option head*
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

K082996/S'

**BIOMET**<sup>®</sup>  
MANUFACTURING CORP.

December 15, 2008

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

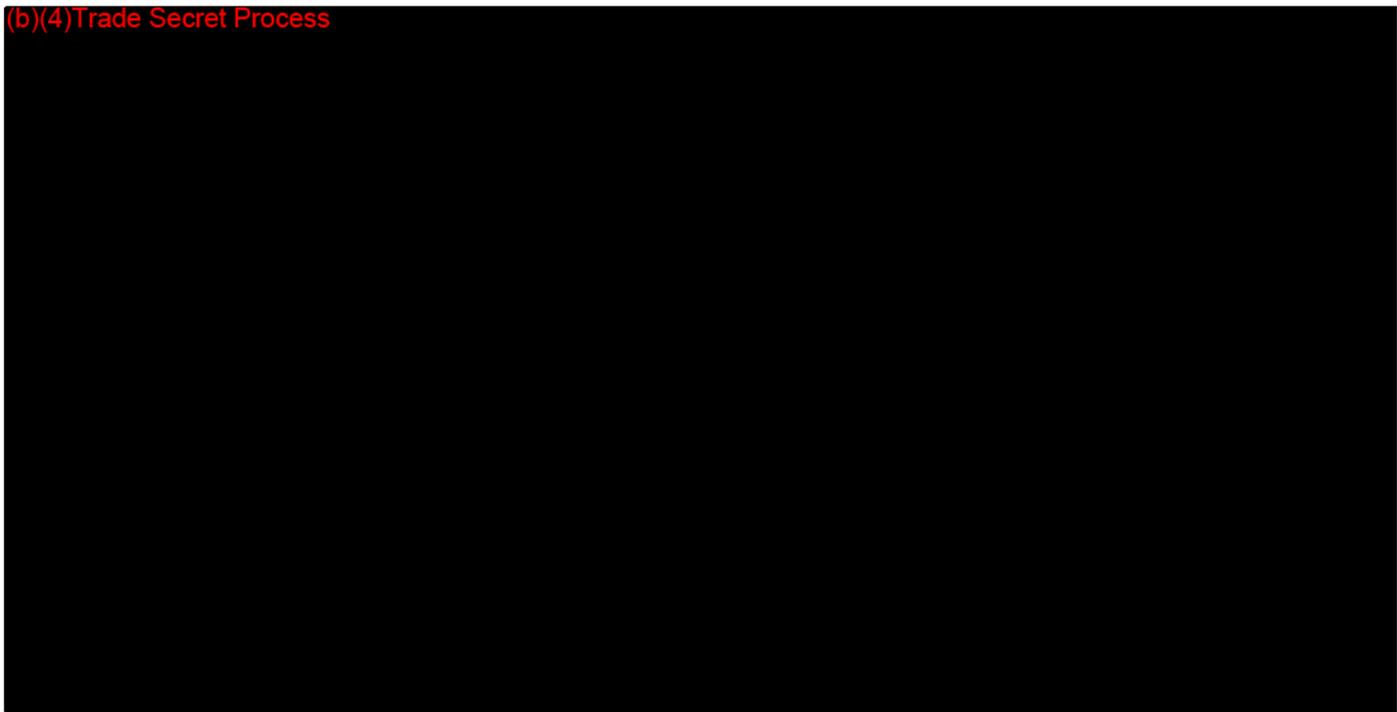
FDA CDRH DMC  
DEC 17 2008  
Received

Re: K082996  
Bilox *delta* Option Ceramic Heads  
Reviewer: Tara Shepherd

Dear Ms. Shepherd,

Enclosed is Biomet's response to your November 14, 2008 request for additional information on our submission for the Bilox *delta* Option Ceramic Heads.

(b)(4)Trade Secret Process

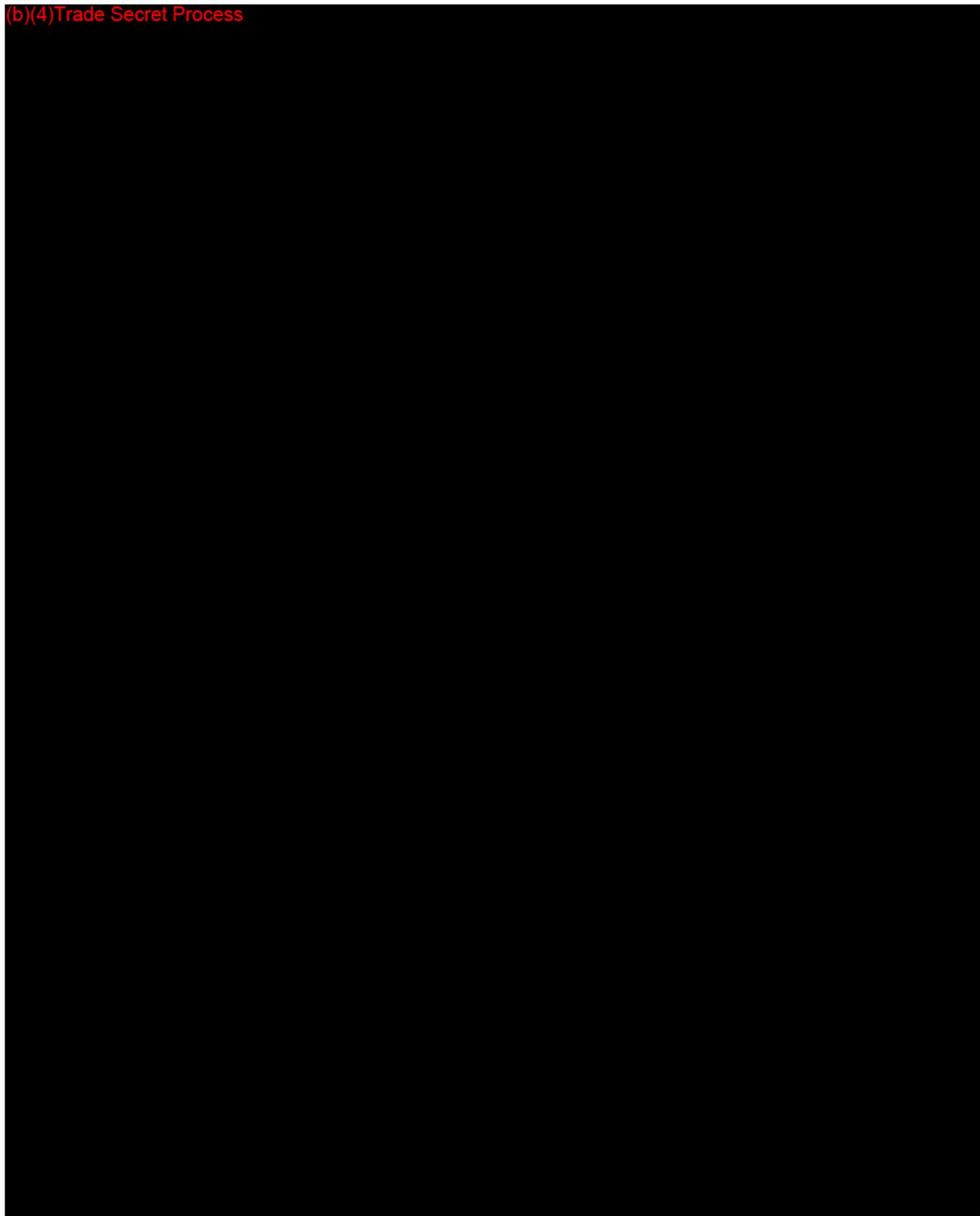


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K27

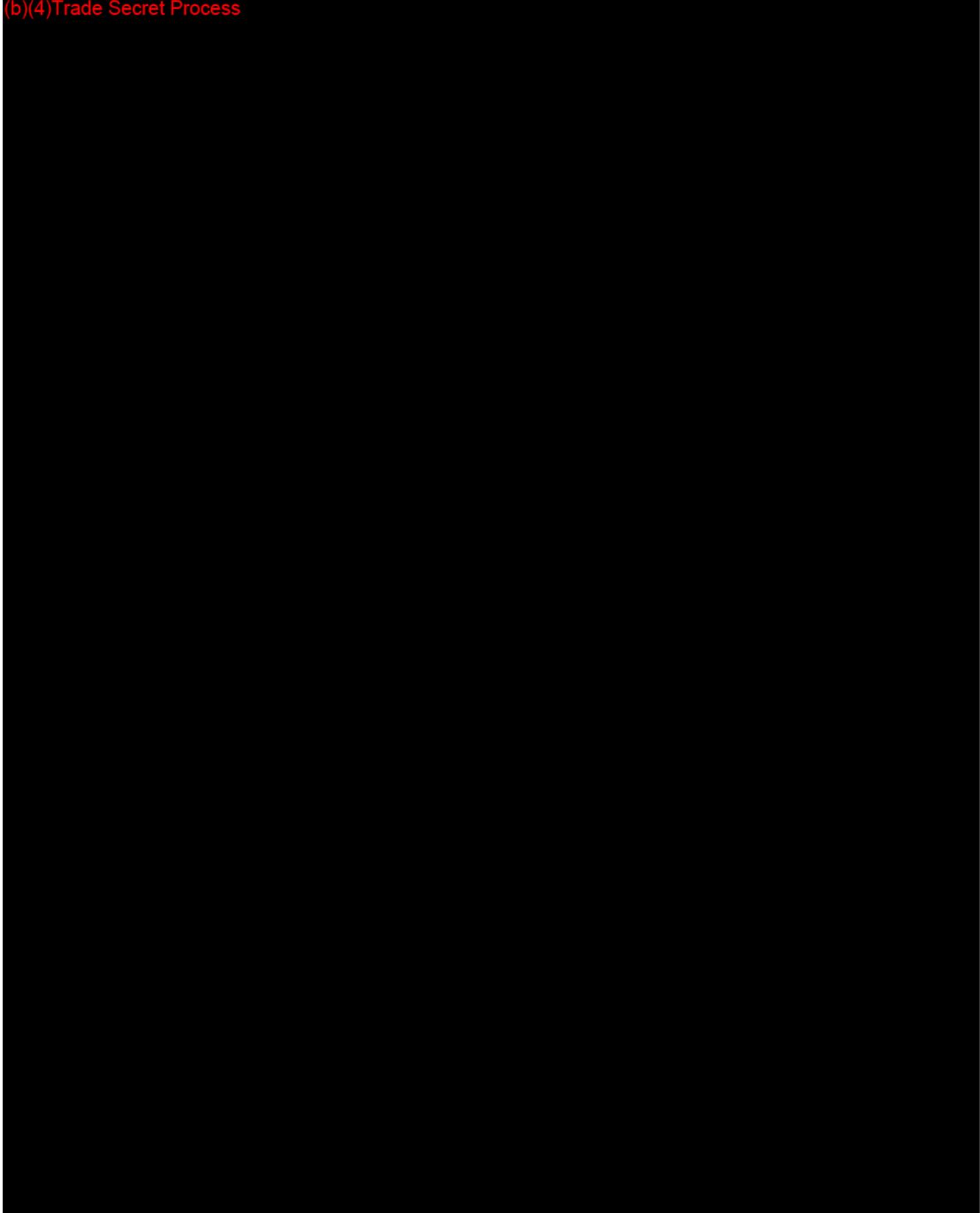
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December 12, 2008

Page 3

(b)(4)Trade Secret Process



December 12, 2008

Page 4

(b)(4)Trade Secret Process



Sincerely,



Patricia Sandborn Beres

Senior Regulatory Specialist

Biomet Manufacturing Corp.

**BIOMET**<sup>®</sup>  
MANUFACTURING CORP.

December 15, 2008

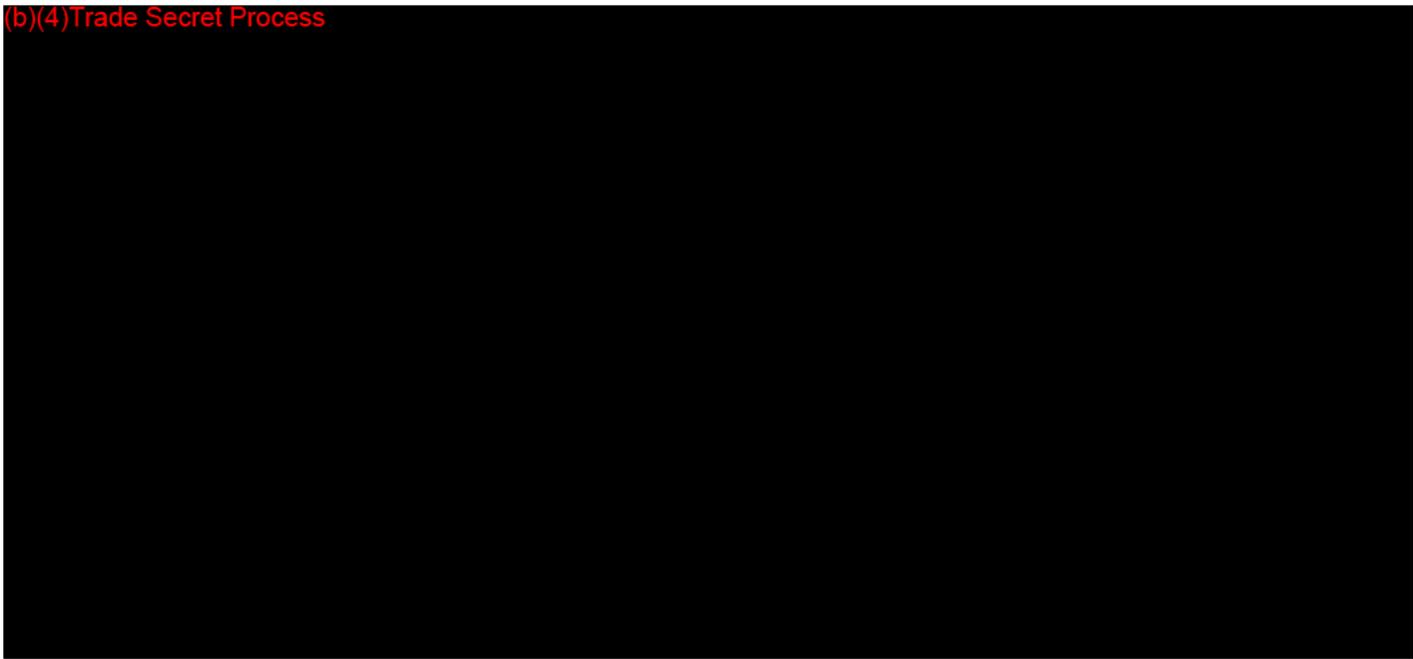
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Re: K082996  
Biolog *delta* Option Ceramic Heads  
Reviewer: Tara Shepherd

Dear Ms. Shepherd,

Enclosed is Biomet's response to your November 14, 2008 request for additional information on our submission for the Biolog *delta* Option Ceramic Heads.

(b)(4)Trade Secret Process



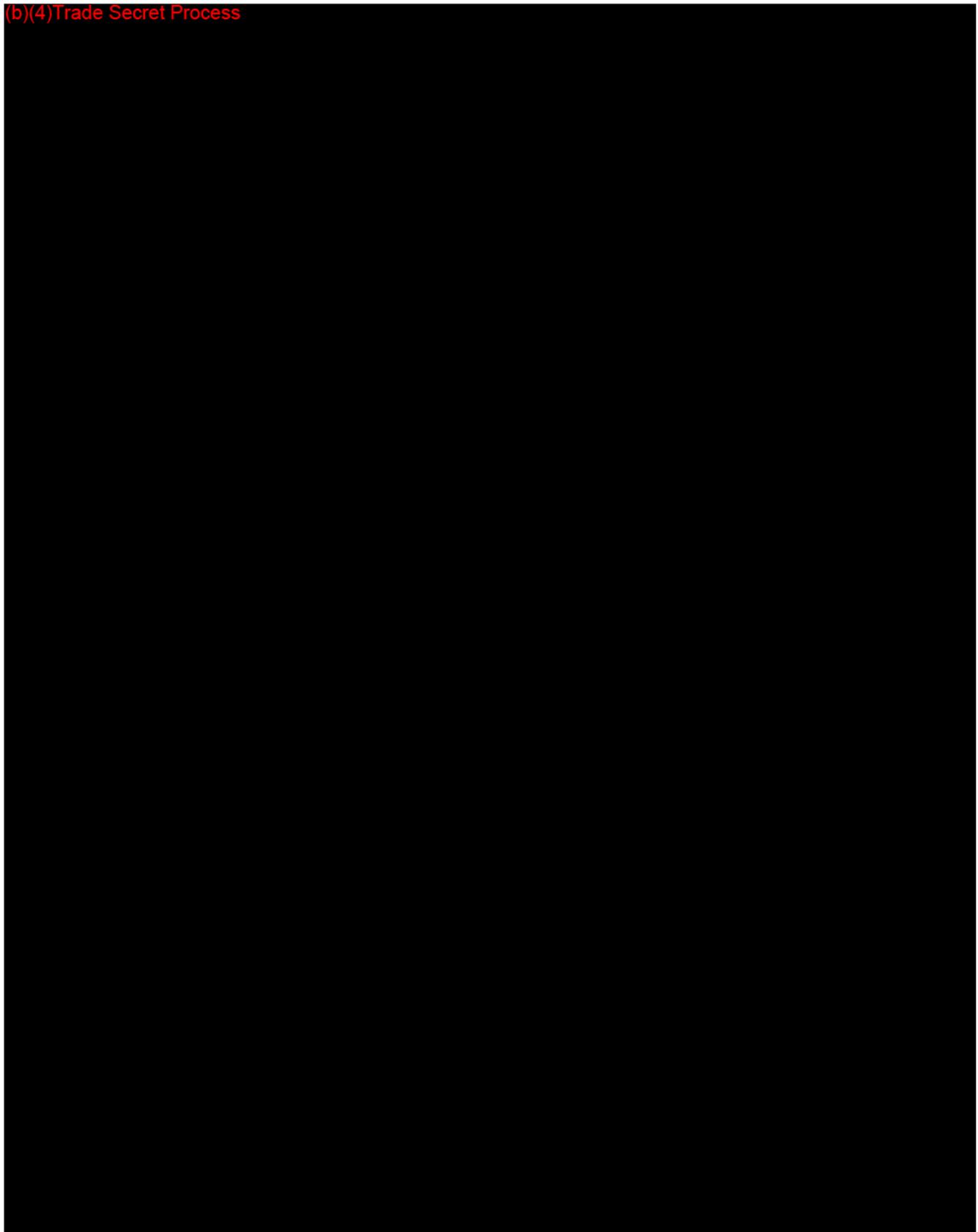
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December 12, 2008

Page 2

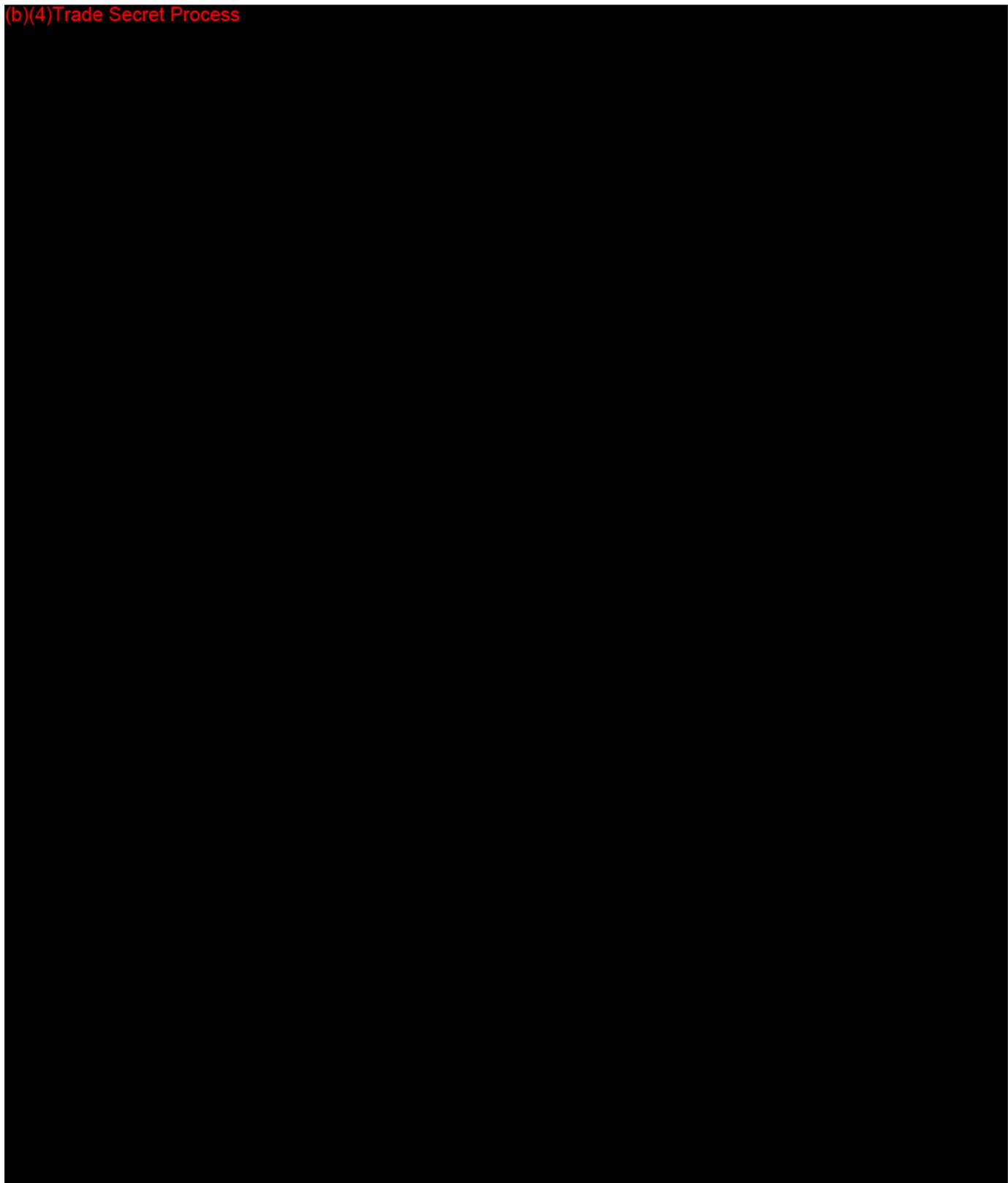
(b)(4)Trade Secret Process



December 12, 2008

Page 3

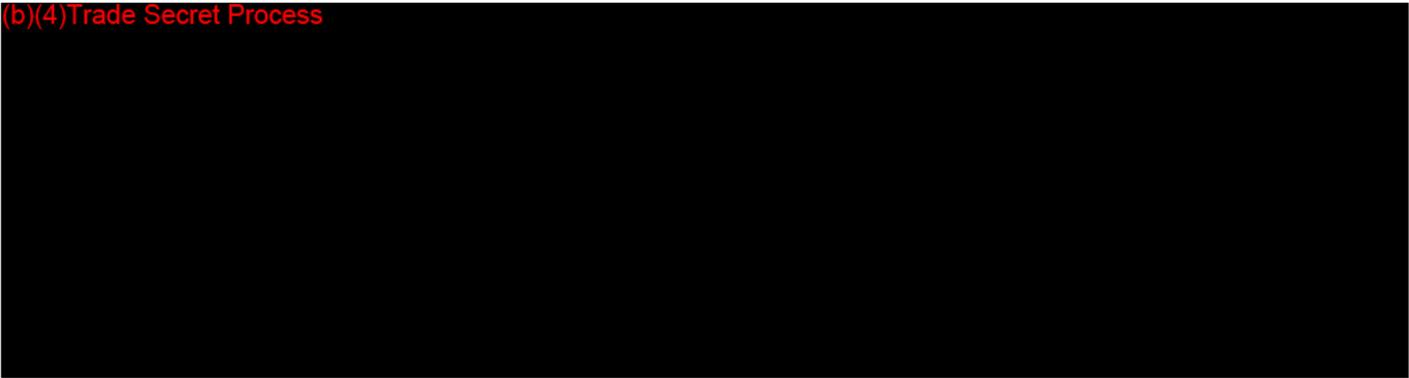
(b)(4)Trade Secret Process



December 12, 2008

Page 4

(b)(4) Trade Secret Process



Sincerely,



Patricia Sandborn Beres

Senior Regulatory Specialist

Biomet Manufacturing Corp.

**510(k) Summary**

**Date:** December 8, 2008

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist

**Proprietary Name:** BioloX<sup>®</sup> *delta* Option 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:**  
BioloX<sup>®</sup> *delta* Ceramic Heads – K042091, K051411, K061312, K073102

**Device Description:** BioloX<sup>®</sup> *delta* Option Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. A highly polished spherical head in a variety of diameters articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem via a taper adapter. Adapters are available for either Biomet's Type I taper or Biomet's 12/14 taper in a variety of neck lengths.

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

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

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

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

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

**Summary of Technologies:** The BioloX® *delta* Option 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

**Biomet® BioloX™ delta Option Modular Head Hip Joint  
Prostheses**

**ATTENTION OPERATING SURGEON**

**DESCRIPTION**

The Biomet® BioloX™ delta Option Ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces in a variety of head sizes. The highly polished surface is designed to reduce friction and minimizes wear. The titanium sleeves adapt the ceramic heads to either a Biomet® Type I or a Biomet® 12/14 taper and allows them to be used in both primary and revision total hip arthroplasty.

**MATERIALS**

Head - TTPA Ceramic  
Sleeve - Titanium Alloy (Ti-6Al-4V)

**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 trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5. Revision procedures where other devices or treatments have failed.

**CONTRAINDICATIONS**

Absolute contraindications include: infection, sepsis, and osteomyelitis.

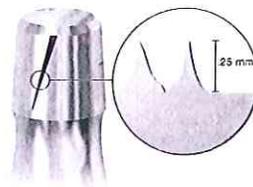
Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) 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 Biomet® BioloX™ delta Option ceramic modular head with Biomet® metallic femoral components. Do not use Biomet® BioloX™ delta Option 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. Sleeves labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Sleeves labeled "12/14" are to be used with femoral stem components labeled "12/14" taper.
4. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal-backed UHMWPE acetabular components.
5. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
6. 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.  
The femoral stem trunion, sleeves and the bore of the ceramic head should be dry and free of contamination prior to assembly.
8. During a revision surgery, extraction of the femoral head should be done with suitable extraction instruments to avoid unnecessary damage to the trunion.

9. Biomet® BioloX™ delta Option modular head components should not be used on trunnions with scratches or defects greater than 0.25mm in height. The surgeon should inspect the taper for damage prior to placement of the modular head components by measuring, with a measuring device, any scratches or defects, and verifying that the height is less than 0.25mm (see Figure A). The conditions shown in Figures B, C and D are also considered unsuitable for the use of the Biomet® BioloX™ delta Option Ceramic Head and can be expected to cause failure:



Taper with scratch/defect at a Height of 0.25mm – Figure A



Taper with Broad Truncation – Figure B



Slanted Taper - Figure C



Crushed Taper - Figure D

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, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation 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.

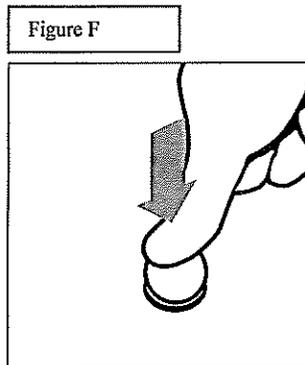
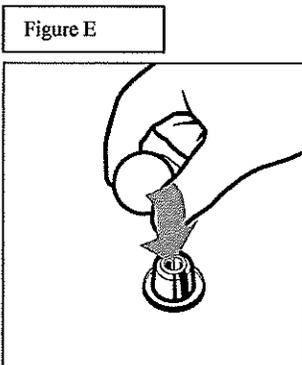
Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, 3) a good nutritional state of the patient, and 4) the patient must have reached full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

## POSSIBLE ADVERSE EFFECTS

1. 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.
2. Early or late postoperative infection and allergic reaction.
3. 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.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption, and or excessive, unusual and/or awkward movement and/or activity. The trunnion must also be free of scratches or defects greater than 0.25mm in height, free of slants, free of broad truncations, and free of crushed ends (see warning #9 for clarification).
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
12. 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.
13. 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.
14. Intraoperative and postoperative bone fracture and/or postoperative pain.
15. Ceramic head fractures have been reported.

## ASSEMBLY INSTRUCTIONS

1. The modular head components must be assembled together before positioning them onto the stem.
2. Verify that the appropriate head size and matching tapers are being utilized before assembly.
3. The modular head components are assembled by placing the head onto the sleeve as shown in Figure E and Figure F. Assure that the tapers are clean and dry and that they are aligned axially before applying pressure. The tapers are engaged once resistance is felt.



Impact the modular head components onto the stem with several brisk mallet strikes using a plastic head impactor only. Metal impactors or any other metallic objects may scratch or crack the modular head bearing surface and, therefore, should not be used.

5. If the modular ceramic head becomes scratched or cracked, the head and sleeve must be replaced.

## 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, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46582 USA, FAX: 574-372-3968.

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