



MANUFACTURING CORP.

**510(k) Summary****Applicant/Sponsor:** Biomet Manufacturing Corp.

NOV 27 2007

**Contact Person:** Becky Earl  
Regulatory Specialist**Proprietary Name:** BioloX® *delta* Ceramic Heads with 100kGy E-Poly™  
Acetabular Liners**Common or Usual Name:** Ceramic Modular Heads/UHMWPE Liners**Classification Name:** Hip joint/ceramic/polymer semiconstrained cemented or non-cemented prosthesis**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**  
BioloX® *delta* Ceramic Heads – K042091, K051411 and K061312; 100 kGy E-Poly™  
Acetabular Liners—K070364 and K070399.**Device Description:** BioloX® *delta* Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper.The 100 kGy E-Poly™ acetabular liners for the BioloX® *delta* Ceramic Heads are a larger size of the previously cleared 100 kGy E-Poly™ liners, K070364 and K070399.**Indications For Use:** BioloX® *delta* Ceramic Heads are indicated for use in total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

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

Mailing Address:  
 P.O. Box 137  
 Warsaw, IN 46584-0137  
 In: (317) 844-1374  
 Fax: (317) 844-1375  
 E-mail: [usa@biomet.com](mailto:usa@biomet.com)

Shipping Address:  
 501 East B. Chicago  
 Warsaw, IN 46584

## 510(k) Summary

BioloX® *delta* Ceramic Heads with 100kGy E-Poly™ Acetabular Liners

Biomet Manufacturing Corp.

Page 2

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

Salvage/Oncology Hip and Total Femur System components 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.

The 100 kGy E-Poly™ Acetabular Liners are intended for cemented and uncemented applications with the following indications for use:

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

Cemented and Uncemented Applications.

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

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 27 2007

Biomet Manufacturing Corp.  
% Ms. Becky Earl  
Regulatory Specialist  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K073102

Trade/Device Name: Biolox<sup>®</sup> delta Ceramic Heads with 100 kGy E-Poly<sup>™</sup> Acetabular Liners  
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, JDI, LWJ, LPH, MAY  
Dated: November 1, 2007  
Received: November 2, 2007

Dear Ms. Earl:

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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

## Indications for Use

510(k) Number (if known): K073102

Device Name: 100kGy E-Poly™ Acetabular Components

Indications For Use:

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

Cemented and Uncemented Applications

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)



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

510(k) Number

K073102

## Indications for Use

510(k) Number (if known): K073102

Device Name: 38mm BioloX® delta Ceramic Heads

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

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

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

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

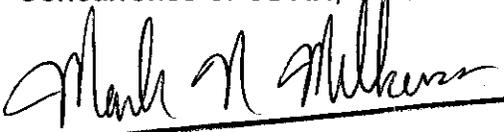
Prescription Use X  
(Part 21 CFR 801 Subpart D)

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

K073102



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

MAR 11 2010

BioMet Manufacturing Corp.  
% Ms. Becky Earl  
Regulatory Specialist  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K073102

Trade/Device Name: 100kGy E-Poly™ Acetabular Components  
38mm Biolox® delta Ceramic Heads

Regulation Number: 21 CFR 888.3353

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

Regulatory Class: II

Product Code: OQI, OQG, OQH, LZO, JDI, LWJ, LPH, MAY

Dated: November 1, 2007

Received: November 2, 2007

Dear Ms. Earl:

This letter corrects our substantially equivalent letter of November 27, 2007.

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

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

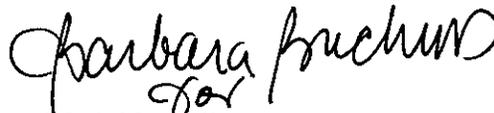
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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

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

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

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic,  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K073102

Device Name: 100kGy E-Poly™ Acetabular Components

Indications For Use:

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

Cemented and Uncemented Applications

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, Prosthetic,  
and Neurological Devices

510(k) Number

K073102

## Indications for Use

510(k) Number (if known): K073102

Device Name: 38mm BioloX® delta Ceramic Heads

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

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
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Specific indications for compatible components that can be used with the above modular heads include:

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

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number

K073102



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 27 2007

Biomet Manufacturing Corp.  
% Ms. Becky Earl  
Regulatory Specialist  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K073102

Trade/Device Name: BioloX<sup>®</sup> delta Ceramic Heads with 100 kGy E-Poly<sup>™</sup> Acetabular Liners  
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, JDI, LWJ, LPH, MAY  
Dated: November 1, 2007  
Received: November 2, 2007

Dear Ms. Earl:

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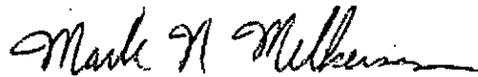
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Sincerely yours,



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): K073102

Device Name: 100kGy E-Poly™ Acetabular Components

### Indications For Use:

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

Cemented and Uncemented Applications

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number

K073102

## Indications for Use

510(k) Number (if known): K073102

Device Name: 38mm BioloX® delta Ceramic Heads

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

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

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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)

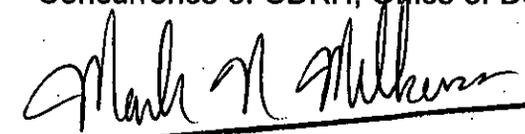
Prescription Use X  
(Part 21 CFR 801 Subpart D)

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 K073102

Page 1 of 1

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

November 05, 2007

BIOMET MANUFACTURING CORP.  
PO BOX 587  
WARSAW, IN 46581  
ATTN: BECKY EARL

510(k) Number: K073102  
Received: 02-NOV-2007  
Product: BIOLOX DELTA CERAMIC  
HEADS WITH 100KG  
E-POLY ACETABULAR  
LINERS

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

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

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at [www.fda.gov/cdrh/mdufma/guidance/1219.html](http://www.fda.gov/cdrh/mdufma/guidance/1219.html).
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at [www.fda.gov/cdrh/ode/guidance/1567.html](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).
- 3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

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

OR/DERND

K073102

**BIOMET**

ORTHOPEDICS, INC.

November 1, 2007

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

FDA CDRH DMC

NOV 2 2007

Received

Reference: "Special" 510(k)—An electronic copy of this submission is enclosed.

BioloX® *delta* Ceramic Heads with  
100kGy E-Poly™ Acetabular Liners

Payment ID Number: (b)(4) Trade Secret

Dear Sir or Madam:

Enclosed is a "Special" 510(k) submission for the BioloX® *delta* Ceramic Heads with 100kGy E-Poly™ Acetabular Liners, which is a modification of the 36mm BioloX® *delta* Ceramic Heads Device cleared in 510(k) K061312. The only modification to this device is the addition of the larger size, 38mm heads. Additionally, the 38mm 100kGy E-Poly™ Acetabular Liners for use with the ceramic heads are included, identical to their predicates, K070364 and K070399, except for the larger size. We believe this device is substantially equivalent\* to the 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 information related to this submission is granted by the Sponsor.

Sincerely,

Becky Earl  
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)]

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

K31

**BIOMET**  
ORTHOPEDICS, INC.

November 1, 2007

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)—An electronic copy of this submission is enclosed.

BioloX® *delta* Ceramic Heads with  
100kGy E-Poly™ Acetabular Liners

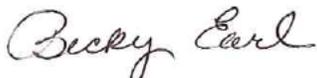
Payment ID Number: (b)(4) Trade Secret  
Process

Dear Sir or Madam:

Enclosed is a "Special" 510(k) submission for the BioloX® *delta* Ceramic Heads with 100kGy E-Poly™ Acetabular Liners, which is a modification of the 36mm BioloX® *delta* Ceramic Heads Device cleared in 510(k) K061312. The only modification to this device is the addition of the larger size, 38mm heads. Additionally, the 38mm 100kGy E-Poly™ Acetabular Liners for use with the ceramic heads are included, identical to their predicates, K070364 and K070399, except for the larger size. We believe this device is substantially equivalent\* to the 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 information related to this submission is granted by the Sponsor.

Sincerely,



Becky Earl  
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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**with 100kGy E-Poly™ Acetabular Liners**  
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**Device Name**

**Device Trade Name:** Biolox® *delta* Ceramic Heads with 100kGy E-Poly™ Acetabular Liners

**Common Name:** Ceramic Modular Heads/UHMWPE Liners

**Address and Registration #**

**Specification Holder:** Biomet Manufacturing Corp.  
56 East Bell Drive  
Warsaw, IN 46582  
FDA Registration #: 1825034

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



**Sterilization Site:**

**Contact Information**

**Name:** Becky Earl  
**Title:** Regulatory Specialist  
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**Device Classification**

**Class:** II  
**Product Code:** LZO  
**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® *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 36mm Biolox® *delta* Ceramic Heads cleared through 510(k) K042091, 04/25/05 and special 510(k) K061312, 6/06/06.

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Additionally, the 100 kGy E-Poly™ Acetabular Liners for these heads, 38mm, are additional sizes of previously cleared 100 kGy E-Poly™ liners in the following 510(k)s:

- K070364 – 100 kGy E-Poly™ MaxRom™ Acetabular Liners
- K070399 – 100 kGy E-Poly™ Acetabular Liners – Additional Profiles

The additional sizes were added to the product line via documentation to the existing files as outlined in FDA Guidance Document, "When to File a 510(k) After Change to a Legally Marketed Device".

**Labeling and  
Indications for  
Use**

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Draft labels and Instructions for Use can be found in [Attachment 1](#). No changes have been made to the labels other than the reference to the new size. No changes have been made to the instructions for use.

Indications for Use

The 38mm BioloX® *delta* 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.

The Indications for Use Statement for the 100 kGy E-Poly™ Acetabular Liners is identical to the above statement with the exception of several minor grammatical changes.

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)

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These are the same intended uses as previously cleared for the 36mm BioloX® *delta* Ceramic Heads (K061312).

The Indications for Use Statement can be found in Attachment 2. No specific surgical technique exists for these devices. The surgical technique is based on the femoral and/or acetabular component selected to use with the 38mm BioloX® *delta* Ceramic Heads.

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**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  
(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® 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.
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® *delta* Ceramic Heads have a 10-year shelf-life; the 100 kGy E-Poly™ Acetabular Liners have a 3-year shelf life. Supporting data is on file at Biomet and can be accessed at any future FDA inspection.

**Device Description**

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The device description of the 38mm BioloX® *delta* Ceramic Heads is as follows:

**Sizes**

- 38mm (b) head diameter
- Neck lengths of -6, -3, 0, +3 and +6mm

**Material**

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

**Specific Characteristics**

- (b)(4)Trade Secret Process
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**Product Listing/Drawings**

- The name and manufacturer's model number for each 38mm BioloX® *delta* Ceramic Head may be found in [Attachment 3A](#).
- Dimensioned engineering drawings of the 38mm BioloX® *delta* Ceramic Heads may be found in [Attachment 3B](#).
- A product listing of the predicate BioloX® *delta* Ceramic Heads cleared through 510(k) K042091 and K061312 may be found in [Attachment 3C](#); Engineer Drawings are in [Attachment 3D](#); and predicate clearance letters are located in [Attachment 3E](#).

The device description of the 100 kGy E-Poly™ Liners is as follows:

**Designs and Sizes**

<i>Profile</i>	<i>ID (mm)</i>	<i>Sizes (mm)</i>
<b>(b)(4)Trade Secret Process</b>		

**Material**

- 100 kGy E-Poly™

**Specific Characteristics**

- **(b)(4)Trade Secret Process**
- The 100 kGy E-Poly™ acetabular liners are offered in five profiles: the MaxRom™, the Hi-Wall, the 10 Degree, the (+) 5 MaxRom™, and the (+) 5 Hi-Wall. The specific characteristics of each profile are identical to those previously cleared (K070364 and K070399). The liners included in this submission are simply line extensions (larger sizes) of previously tested and cleared devices.

**Product Listing/Drawings**

- The name and manufacturer's model number for each 38mm 100kGy E-Poly™ Acetabular Liner may be found in [Attachment 3A](#).
- Dimensioned engineering drawings of the 38mm, 100 kGy E-Poly™ Acetabular Liners may be found in [Attachment 3B](#).

**Compatible Products**

- [Attachment 4A](#) contains a table of compatible hip stems for use with the 38mm BioloX® *delta* Ceramic Heads.
  - All of the devices are metallic hip stems with or without porous coating.
  - Each stem has a Biomet Type I trunion (standard or reduced) for attachment of the modular head. In lieu of a drawing of
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each hip stem, detailed drawings of the two types of taper trunions are provided in Attachment 4B.

- (b)(4)Trade Secret Process

Attachment 4C also contains a list of the compatible acetabular components that may be used with this device.

**Device Comparison**

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

- Cone design of mating stems
- 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
- (b)(4)Trade Secret Process
- Surface roughness
- Allowable defects
- Hydrothermal stability

The only modifications that were made is expansion of the cleared 28mm, 32mm (K042091) and 36mm (K061312) head diameter product line to include a 38mm head diameter and one additional neck size, -6mm. One of the potential benefits of a large head diameter is an increased range of motion. A 32mm head has a (b)(4)Trade Secret Process the 36mm heads have a (b)(4)Trade Secret Process and the 38mm heads have a (b)(4)Trade Secret Process

The following features of the 100 kGy E-Poly™ Acetabular Liners have not changed as previously cleared in K070364 and K070399:

- Indications statement and intended use are identical to the predicate.
- Manufactured from the same materials using similar techniques.
- All the liner profiles have been cleared previously.
- Packaging and sterilization processes are identical.
- Large diameter sizes included in this submission were included in the original testing that verified the safety and effectiveness.

The only modification to the originally cleared 100 kGy E-Poly™ Acetabular Liners is the additional larger size, 38 mm.

**Bench/Animal Testing**

The modular heads and taper trunions used for mechanical testing are representative of the design tolerances of the product to be

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shipped for clinical use. The ceramic test specimens have the same composition and structure as those to be marketed.

All testing was conducted in keeping with the FDA guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems".

Justifications for test component selection, test trunion material selection and use of standard Type I tapers, are contained in the Verification and Validation Protocol presented in Attachment 5.

### **Static Compression**

(b)(4)Trade Secret Process



the guidance document. A full test report may be found in Attachment 6A.

### **Fatigue Testing**

(b)(4)Trade Secret Process

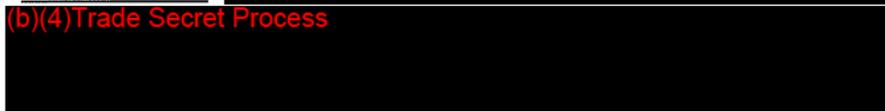


test report may be found in Attachment 6B.

### **Axial Pull-Off**

Axial pull-off testing for Biolox® *delta* Ceramic Heads is contained in Attachment 6C. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process



### **Wear**

The predicate Biolox® *delta* Ceramic Heads have demonstrated superior wear properties as compared to cobalt alloy modular heads. Attachment 7 contains a justification for not conducting additional wear testing for these components.

### **100 kGy E-Poly™ Acetabular Liners**

The 100 kGy E-Poly™ liners incorporated in this submission (38mm) are included in the range of sizes previously tested. **(Attachment 8)**

- (b)(4)Trade Secret Process



(b)(4)Trade Secret Process

**Substantial  
Equivalence**

The modified device has the following similarities to the BioloX® *delta* Ceramic Heads which previously received 510(k) concurrence (K042091 and K061312).

- They have identical indication statements
- They incorporate the same basic design
- (b)(4)Trade Secret Process
- They are compatible with Biomet Type I tapers
- They are manufactured from the same materials
- They are packaged and sterilized using the same materials and processes.
- Mechanical testing shows the modified devices meet the standards put forth in FDA's guidance document.

In summary, the 38mm BioloX® *delta* Ceramic Heads described in this submission are substantially equivalent to the predicate device.

The 100 kGy E-Poly™ liners are identical in every way to the predicate liners with the exception of the added larger 38mm size. The liners are identical in every way to the predicate liners and 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 is presented in Attachment 9.

A declaration of conformity with design controls is included in Attachment 10.

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.

**510(k)  
Summary  
Truthful and  
Accuracy  
Certification**

A 510(k) Summary for the BioloX® *delta* Ceramic Heads with 100 kGy E-Poly™ Acetabular Liners is included in Attachment 11.

A certification of the truthfulness and accuracy of the information presented in this submission is provided in Attachment 12.

All trademarks are property of Biomet, Inc. except for the following:

(b)(4)Trade Secret Process

Tyvek is a trademark of E.I. duPont de Nemours and Company

REF. 12-115130 LOT 123123

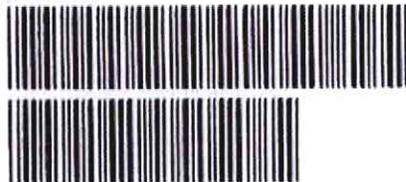
BIOLOX-DELTA® MODULAR CERAMIC HEAD  
38MM HEAD DIAMETER

MINUS 6 NECK TYPE I TAPER

ALUMINA / ZIRCONIA  
FOR USE W/TYPE I TAPERS ONLY

Biolog 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

2007-09  
EXPIRY DATE:  
2017-09

BIOMET ORTHOPEDICS, INC.

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

REF. 12-115130

BIOLOX-DELTA® MODULAR CERAMIC HEAD  
38MM HEAD DIAMETER

MINUS 6 NECK TYPE I TAPER  
ALUMINA / ZIRCONIA  
FOR USE W/TYPE I TAPERS ONLY

LOT 123123 EXPIRY DATE: 2017-09

AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS, INC.

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

REF. 12-115130

BIOLOX-DELTA® MODULAR CERAMIC HEAD  
38MM HEAD DIAMETER

MINUS 6 NECK TYPE I TAPER  
ALUMINA / ZIRCONIA  
FOR USE W/TYPE I TAPERS ONLY

LOT 123123 EXPIRY DATE: 2017-09

AFFIX TO PATIENT RECORDS



**REF.** EP-106985

**LOT** 123123

**E-POLY(TM) 38MM RINGLOC®**

**ACETABULAR LINER HI-WALL**

**SIZE 25**

**E-POLY UHMWPE**



**LOT** 123123

**QTY.** 1

**STERILE | R**

2007-07

**EXPIRY DATE:**  
2010-07



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**REF EP-106985**

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**ACETABULAR LINER HI-WALL**

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**REF EP-106985**

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**ACETABULAR LINER HI-WALL**

**SIZE 25**

**E-POLY UHMWPE**

**LOT 123123 EXPIRY DATE: 2010-07**

**AFFIX TO PATIENT RECORDS**

**LOT 123123 EXPIRY DATE: 2010-07**

**AFFIX TO PATIENT RECORDS**

**Biomet® TTPA Ceramic Modular Head Hip Joint Prostheses****ATTENTION OPERATING SURGEON****DESCRIPTION**

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

**Materials**

TTPA Ceramic

**INDICATIONS**

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and throchanteric fractures of the proximal femur with head involvement, unmanageable 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 TTPA ceramic modular head with Biomet® metallic femoral components. Do not use Biomet® TTPA ceramic modular heads with femoral stems or acetabular components offered by other manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture of ceramic heads.
2. Ceramic heads labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal backed UHMWPE acetabular components.
4. Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
5. Do not use a metallic hammer when seating the ceramic head. Use a nylon or polyethylene seating instrument. Do not use excessive force. The TTPA ceramic head can fracture with excessive force.
6. The femoral stem trunion and the bore of the ceramic head should be dry and free of contamination prior to assembly.

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

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

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

#### **PRECAUTIONS**

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

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

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

#### **POSSIBLE ADVERSE EFFECTS**

Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.

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

#### **STERILITY**

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

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

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



**Biomet Orthopedics, Inc.**  
P.O. Box 587  
56 East Bell Drive  
Warsaw, Indiana 46581 USA

01-50-0967  
Date: 12/06

## **Biomet® Hip Joint Replacement Prostheses E-Poly™ Acetabular Liners**

### **ATTENTION OPERATING SURGEON**

#### **DESCRIPTION**

E-Poly™ Acetabular Liners are composed of UHMWPE and Vitamin E ( $\alpha$ -tocopherol) and are manufactured into various designs and sizes. The acetabular liners are utilized with other hip prostheses as part of a total joint system. Total hip joint prostheses include: femoral stems, femoral heads, acetabular shells, and acetabular liners. Components are available in numerous designs and sizes intended for primary and/or revision applications. Specialty components that can be added to the total hip system include: acetabular screws, centering sleeves, and canal plugs.

#### **Materials**

Acetabular Liners E-Poly™, highly cross-linked Ultra High Molecular Weight Polyethylene (UHMWPE) and  $\alpha$ -tocopherol

#### **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 using other techniques.
5. Revision of previously failed total hip arthroplasty.

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 level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

#### **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, and/or 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

#### **WARNINGS**

Improper selection, placement, positioning, alignment and/or 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. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery.

1. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
2. Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

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

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

#### **PRECAUTIONS**

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear, and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that 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 placed, even momentarily, in a different patient.

#### **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. Further, there has been a report regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement.
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 or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive 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 and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, and/or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.

13. 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.
14. Postoperative bone fracture and pain.

**STERILITY**

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

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-1683.

## Indications for Use

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

Device Name: 38mm BioloX® delta Ceramic Heads

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

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

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

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

## Indications for Use

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

Device Name: 100kGy E-Poly™ Acetabular Components

Indications For Use:

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

Cemented and Uncemented Applications

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

### 38mm BioloX® *delta* Ceramic Heads

Biomet <u>Part Number</u>	<u>Description</u>	CeramTec <u>Part Number</u>
12-115130	38mm BioloX® <i>delta</i> Ceramic Head, -6	99.39.1.06.807.50
12-115131	38mm BioloX® <i>delta</i> Ceramic Head, -3	99.39.1.06.807.30
12-115132	38mm BioloX® <i>delta</i> Ceramic Head, STD	99.39.1.06.807.10
12-115133	38mm BioloX® <i>delta</i> Ceramic Head, +3	99.39.1.06.807.40
12-115134	38mm BioloX® <i>delta</i> Ceramic Head, +6	99.39.1.06.807.20

### 38mm 100 kGy E-Poly™ Acetabular Liners

Biomet <u>Part Number</u>	<u>Description</u>
EP-106985	E-Poly 38mm Hi-Wall Liner, Size 25
EP-106986	E-Poly 38mm Hi-Wall Liner, Size 26
EP-106987	E-Poly 38mm Hi-Wall Liner, Size 27
EP-106988	E-Poly 38mm Hi-Wall Liner, Size 28
EP-106995	E-Poly 38mm 10 Degree Liner, Size 25
EP-106996	E-Poly 38mm 10 Degree Liner, Size 26
EP-106997	E-Poly 38mm 10 Degree Liner, Size 27
EP-106998	E-Poly 38mm 10 Degree Liner, Size 28
EP-106885	E-Poly 38mm MaxRom Liner, Size 25
EP-106886	E-Poly 38mm MaxRom Liner, Size 26
EP-106887	E-Poly 38mm MaxRom Liner, Size 27
EP-106888	E-Poly 38mm MaxRom Liner, Size 28
EP-195234	E-Poly 38mm (+)5 Hi-Wall Liner, Size 24
EP-195235	E-Poly 38mm (+)5 Hi-Wall Liner, Size 25
EP-195236	E-Poly 38mm (+)5 Hi-Wall Liner, Size 26
EP-195237	E-Poly 38mm (+)5 Hi-Wall Liner, Size 27
EP-195238	E-Poly 38mm (+)5 Hi-Wall Liner, Size 28
EP-166234	E-Poly 38mm (+)5 MaxRom Liner, Size 24
EP-166235	E-Poly 38mm (+)5 MaxRom Liner, Size 25
EP-166236	E-Poly 38mm (+)5 MaxRom Liner, Size 26
EP-166237	E-Poly 38mm (+)5 MaxRom Liner, Size 27
EP-166238	E-Poly 38mm (+)5 MaxRom Liner, Size 28























**Predicate Component Listing—BioloX® *delta* Ceramic Heads**

K061312

<u>Biomet</u> <u>Part Number</u>	<u>Description</u>	<u>CeramTec</u> <u>Part Number</u>
12-115120	36mm BioloX® <i>delta</i> Ceramic Head, -3	99.39.1.05.825.30
12-115121	36mm BioloX® <i>delta</i> Ceramic Head, Std	99.39.1.05.825.10
12-115122	36mm BioloX® <i>delta</i> Ceramic Head, +3	99.39.1.05.825.40
12-115123	36mm BioloX® <i>delta</i> Ceramic Head, +6	99.39.1.05.825.20

K042091

<u>Biomet</u> <u>Part Number</u>	<u>Description</u>	<u>CeramTec</u> <u>Part Number</u>
12-115109	28mm BioloX® <i>delta</i> Ceramic Head, -3	99.39.1018.826.10
12-115110	28mm BioloX® <i>delta</i> Ceramic Head, Std	99.39.1018.826.20
12-115111	28mm BioloX® <i>delta</i> Ceramic Head, +3	99.39.1018.826.30
12-115112	28mm BioloX® <i>delta</i> Ceramic Head, +5	99.39.1018.826.40
12-115114	32mm BioloX® <i>delta</i> Ceramic Head, -3	99.39.0058.412.00
12-115115	32mm BioloX® <i>delta</i> Ceramic Head, Std	99.39.0058.412.10
12-115116	32mm BioloX® <i>delta</i> Ceramic Head, +3	99.39.0058.412.20
12-115117	32mm BioloX® <i>delta</i> Ceramic Head, +6	99.39.0058.412.30

**Predicate Component Listing—  
100kGy E-Poly™ MaxRom™ Acetabular Liners**

K070364

<u>Biomet</u> <u>Part Number</u>	<u>Description</u>
EP-105882	E-Poly 28mm RingLoc® Liner, MaxRom™, Size 22
EP-105883	E-Poly 28mm RingLoc® Liner, MaxRom™, Size 23
EP-105884	E-Poly 28mm RingLoc® Liner, MaxRom™, Size 24
EP-105885	E-Poly 28mm RingLoc® Liner, MaxRom™, Size 25
EP-105886	E-Poly 28mm RingLoc® Liner, MaxRom™, Size 26
EP-105887	E-Poly 28mm RingLoc® Liner, MaxRom™, Size 27
EP-105888	E-Poly 28mm RingLoc® Liner, MaxRom™, Size 28
EP-105933	E-Poly 32mm RingLoc® Liner, MaxRom™, Size 23
EP-105934	E-Poly 32mm RingLoc® Liner, MaxRom™, Size 24

K070364 (Continued)

<u>Part Number</u>	<u>Description</u>
EP-105935	E-Poly 32mm RingLoc® Liner, MaxRom™, Size 25
EP-105936	E-Poly 32mm RingLoc® Liner, MaxRom™, Size 26
EP-105937	E-Poly 32mm RingLoc® Liner, MaxRom™, Size 27
EP-105938	E-Poly 32mm RingLoc® Liner, MaxRom™, Size 28
EP-105994	E-Poly 36mm RingLoc® Liner, MaxRom™, Size 24
EP-105995	E-Poly 36mm RingLoc® Liner, MaxRom™, Size 25
EP-105996	E-Poly 36mm RingLoc® Liner, MaxRom™, Size 26
EP-105997	E-Poly 36mm RingLoc® Liner, MaxRom™, Size 27
EP-105998	E-Poly 36mm RingLoc® Liner, MaxRom™, Size 28

K070399

<u>Part Number</u>	<u>Description</u>
EP-105811	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 21
EP-105812	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 22
EP-105813	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 23
EP-105814	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 24
EP-105815	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 25
EP-105816	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 26
EP-105817	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 27
EP-105818	E-Poly 28mm RingLoc® Liner, 10 Degree, Size 28
EP-105833	E-Poly 32mm RingLoc® Liner, 10 Degree, Size 23
EP-105834	E-Poly 32mm RingLoc® Liner, 10 Degree, Size 24
EP-105835	E-Poly 32mm RingLoc® Liner, 10 Degree, Size 25
EP-105836	E-Poly 32mm RingLoc® Liner, 10 Degree, Size 26
EP-105837	E-Poly 32mm RingLoc® Liner, 10 Degree, Size 27
EP-105838	E-Poly 32mm RingLoc® Liner, 10 Degree, Size 28
EP-105894	E-Poly 36mm RingLoc® Liner, 10 Degree, Size 24
EP-105895	E-Poly 36mm RingLoc® Liner, 10 Degree, Size 25
EP-105896	E-Poly 36mm RingLoc® Liner, 10 Degree, Size 26
EP-105897	E-Poly 36mm RingLoc® Liner, 10 Degree, Size 27
EP-105898	E-Poly 36mm RingLoc® Liner, 10 Degree, Size 28
EP-105902	E-Poly 28mm RingLoc® Liner, Hi-Wall, Size 22
EP-105903	E-Poly 28mm RingLoc® Liner, Hi-Wall, Size 23
EP-105904	E-Poly 28mm RingLoc® Liner, Hi-Wall, Size 24
EP-105905	E-Poly 28mm RingLoc® Liner, Hi-Wall, Size 25
EP-105906	E-Poly 28mm RingLoc® Liner, Hi-Wall, Size 26
EP-105907	E-Poly 28mm RingLoc® Liner, Hi-Wall, Size 27
EP-105908	E-Poly 28mm RingLoc® Liner, Hi-Wall, Size 28

## K070399 (Continued)

Biomet

<u>Part Number</u>	<u>Description</u>
EP-105923	E-Poly 32mm RingLoc® Liner, Hi-Wall, Size 23
EP-105924	E-Poly 32mm RingLoc® Liner, Hi-Wall, Size 24
EP-105925	E-Poly 32mm RingLoc® Liner, Hi-Wall, Size 25
EP-105926	E-Poly 32mm RingLoc® Liner, Hi-Wall, Size 26
EP-105927	E-Poly 32mm RingLoc® Liner, Hi-Wall, Size 27
EP-105928	E-Poly 32mm RingLoc® Liner, Hi-Wall, Size 28
EP-105914	E-Poly 36mm RingLoc® Liner, Hi-Wall, Size 24
EP-105915	E-Poly 36mm RingLoc® Liner, Hi-Wall, Size 25
EP-105916	E-Poly 36mm RingLoc® Liner, Hi-Wall, Size 26
EP-105917	E-Poly 36mm RingLoc® Liner, Hi-Wall, Size 27
EP-105918	E-Poly 36mm RingLoc® Liner, Hi-Wall, Size 28
EP-105951	E-Poly 28mm RingLoc® Liner, +5mm, Size 21
EP-105952	E-Poly 28mm RingLoc® Liner, +5mm, Size 22
EP-105953	E-Poly 28mm RingLoc® Liner, +5mm, Size 23
EP-105954	E-Poly 28mm RingLoc® Liner, +5mm, Size 24
EP-105955	E-Poly 28mm RingLoc® Liner, +5mm, Size 25
EP-105956	E-Poly 28mm RingLoc® Liner, +5mm, Size 26
EP-105957	E-Poly 28mm RingLoc® Liner, +5mm, Size 27
EP-105958	E-Poly 28mm RingLoc® Liner, +5mm, Size 28
EP-155232	E-Poly 32mm RingLoc® Liner, +5mm, Size 22
EP-155233	E-Poly 32mm RingLoc® Liner, +5mm, Size 23
EP-155234	E-Poly 32mm RingLoc® Liner, +5mm, Size 24
EP-155235	E-Poly 32mm RingLoc® Liner, +5mm, Size 25
EP-155236	E-Poly 32mm RingLoc® Liner, +5mm, Size 26
EP-155237	E-Poly 32mm RingLoc® Liner, +5mm, Size 27
EP-155238	E-Poly 32mm RingLoc® Liner, +5mm, Size 28
EP-156233	E-Poly 36mm RingLoc® Liner, +5mm, Size 23
EP-156234	E-Poly 36mm RingLoc® Liner, +5mm, Size 24
EP-156235	E-Poly 36mm RingLoc® Liner, +5mm, Size 25
EP-156236	E-Poly 36mm RingLoc® Liner, +5mm, Size 26
EP-156237	E-Poly 36mm RingLoc® Liner, +5mm, Size 27
EP-156238	E-Poly 36mm RingLoc® Liner, +5mm, Size 28
EP-105780	E-Poly 32mm RingLoc® Liner, +5mm Hi-Wall, Size 22
EP-105790	E-Poly 36mm RingLoc® Liner, +5mm Hi-Wall, Size 23



















































































































































































DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 6 2006

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

Re: K061312

Trade/Device Name: 36mm BioloX<sup>®</sup> delta Ceramic Heads  
Regulation Number: 21 CFR 888.3353  
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis  
Regulatory Class: Class II  
Product Code: LZO  
Dated: May 9, 2006  
Received: May 10, 2006

Dear Ms. Beres:

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

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

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

Page 2 – Ms. Patricia Sandborn Beres

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

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

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

Sincerely yours,



*for* Mark N. Melkerson

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

Enclosure

## Indications for Use

510(k) Number (if known): K061312

Device Name: 36mm BioloX® delta Ceramic Heads

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

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

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

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

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

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

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

Page 1 of 1

510(k) Number K061312

K061312

JUN - 6 2006



### 510(k) Summary

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

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

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

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

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

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

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

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

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

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

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

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

SHIPPING ADDRESS  
56 E. Bell Drive  
Warsaw, IN 46582

OFFICE  
574.267.6639

FAX  
574.267.8137

E-MAIL  
biomet@biomet.com

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

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

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

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

**Clinical Testing:** None provided





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 25 2005

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

Re: K042091

Trade/Device Name: BioloX<sup>®</sup> delta Ceramic Heads  
Regulation Numbers: 21 CFR 888.3353  
Regulation Names: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous  
uncemented prosthesis  
Regulatory Class: II  
Product Codes: LZO  
Dated: January 27, 2005  
Received: January 28, 2005

Dear Ms. Beres:

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

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

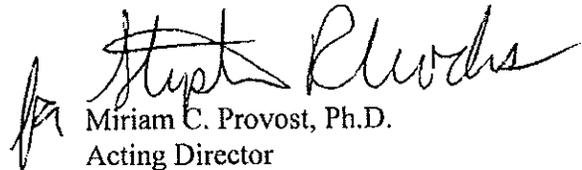
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Patricia Sandborn Beres

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

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost". The signature is written in a cursive style with a large initial "M".

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

Enclosure

## Indications for Use

510(k) Number (if known): K042091

Device Name: BioloX® delta Ceramic Heads

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

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

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

Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or 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  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Page 1 of 1

510(k) Number K042091

K042091

1/2

MAR 25 2005

### 510(k) Summary

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

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

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

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

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

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

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

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

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

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

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

K042091

2/2

510(k) Summary  
BioloX<sup>®</sup> delta Ceramic Heads  
Biomet Manufacturing Corp.  
Page 2

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

**Summary of Technologies:** The BioloX<sup>®</sup> delta Ceramic Heads are technologically similar to the predicate devices.

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

**Clinical Testing:** None provided





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet Manufacturing Corp.  
% Ms. Tracy Bickel Johnson, RAC  
Manager, Regulatory Affairs  
P.O. Box 587  
Warsaw, Indiana 46581-0587

MAY - 3 2007

Re: K070364

Trade/Device Name: 100kGy E-Poly™ MaxRom™ Acetabular Liners  
Regulation Number: 21 CFR 888.3350  
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: II  
Product Code: JDI, LWJ, LPH, MAY  
Dated: April 3, 2007  
Received: April 4, 2007

Dear Ms. Johnson:

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

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

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

Page 2 – Ms. Tracy Bickel Johnson, RAC

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a small "for" written below the main name.

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): K070364

Device Name: 100kGy E-Poly™ MaxRom™ Acetabular Components

**Indications For Use:**

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

Cemented and Uncemented Applications

Prescription Use YES  
(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)

Barbara Pruchins

(Division Sign-Off)

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

510(k) Number K070364

Page 1 of 1



**510(k) Summary**

**Preparation Date:** February 5, 2007

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

MAY - 3 2007

**Contact Person:** Tracy Bickel Johnson, RAC

**Proprietary Name:** 100 kGy E-Poly™ MaxRom™ Acetabular Liners

**Common Name:** UHMWPE Liners

**Classification Name(s):**

- LPH- prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (888.3358);
- JDI- prosthesis, hip, semi-constrained, metal/polymer, cemented (888.3350);
- LWJ- prosthesis, hip, semi-constrained, metal/polymer, uncemented (888.3360);
- MAY- prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish (888.3353)
- LZO- prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (888.3353)

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:** K050327- E-Poly™ (Vitamin E) Acetabular Liners

**Device Description:** Biomet Manufacturing Corp. is modifying the manufacturing process of ultra-high molecular weight polyethylene (UHMWPE) used in the fabrication of polyethylene acetabular components. The modified manufacturing process results in a higher cross-linked polyethylene. The highly cross-linked UHMWPE is infused with medical grade Vitamin E.

**Intended Use:**

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

**Cemented and Uncemented Applications**

**Summary of Technologies:** The intended use, indications, contraindications, and design specifications of the subject components remain identical to its predicate counterpart, with the exception of a manufacturing change. The raw material being utilized in the manufacture of both the subject and the predicate devices remains a ultra-high molecular weight polyethylene (UHMWPE) per ASTM F-648. The modifications to the manufacturing process of this polyethylene will be introduced in order to create a higher cross-linked polyethylene. The safety and effectiveness of this cross-linked polyethylene in acetabular applications are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

**510(K) Notification**  
**Biomet Manufacturing Corp.**  
**100 kGy E-Poly™ MaxRom™ Acetabular Liners**  
**Page 2 of 2**

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

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

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*All trademarks are property of Biomet, Inc.*





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomct Manufacturing Corp.  
% Ms. Tracy Bickel Johnson, RAC  
Manager, Regulatory Affairs  
P.O. Box 587  
Warsaw, Indiana 46581-0587

MAY - 4 2007

Re: K070399

Trade/Device Name: 100kGy E-Poly™ Acetabular Liners – Additional Profiles  
Regulation Number: 21 CFR 888.3350  
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: II  
Product Code: JDI, LWJ, LPH, MAY  
Dated: April 4, 2007  
Received: April 5, 2007

Dear Ms. Johnson:

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

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

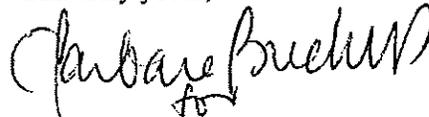
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Tracy Bickel Johnson, RAC

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

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with the first name being the most prominent.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

K070399

**Indications for Use**

510(k) Number (if known):

Device Name: 100kGy E-Poly™ Acetabular Components- Additional Profiles

Indications For Use:

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

Cemented and Uncemented Applications

Prescription Use YES  
(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 K070399 Page 1 of 1



**510(k) Summary**

**Preparation Date:** February 9, 2007

MAY - 4 2007

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

**Contact Person:** Tracy Bickel Johnson, RAC

**Proprietary Name:** 100 kGy E-Poly™ Acetabular Liners- Additional Profiles

**Common Name:** UHMWPE Liners

**Classification Name(s):**

- LPH- prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (888.3358);
- JDI- prosthesis, hip, semi-constrained, metal/polymer, cemented (888.3350);
- LWJ- prosthesis, hip, semi-constrained, metal/polymer, uncemented (888.3360);
- MAY- prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish (888.3353)
- LZO- prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (888.3353)

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:** K050327- E-Poly™ (Vitamin E) Acetabular Liners

**Device Description:** Biomet Manufacturing Corp. is modifying the manufacturing process of ultra-high molecular weight polyethylene (UHMWPE) used in the fabrication of polyethylene acetabular components and adding additional profiles. The modified manufacturing process results in a higher cross-linked polyethylene. The highly cross-linked UHMWPE is infused with medical grade Vitamin E.

**Intended Use:**

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

Cemented and Uncemented Applications

**Summary of Technologies:** The intended use, indications, contraindications, and design specifications of the subject components remain identical to its predicate counterpart, with the exception of a manufacturing change. The raw material being utilized in the manufacture of both the subject and the predicate devices remains a ultra-high molecular weight polyethylene (UHMWPE) per ASTM F-648. The modifications to the manufacturing process of this polyethylene will be introduced in order to create a higher cross-linked polyethylene. The safety and effectiveness of this cross-linked polyethylene in acetabular applications are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

MAILING ADDRESS P.O. Box 1300 Warrenton, OR 97146	SHIPPING ADDRESS 300 E. 10th Street Warrenton, OR 97146
PHONE 503-863-0000	FAX 503-863-0001
E-MAIL info@biomet.com	E-MAIL tracy.bickel@biomet.com

page 2/2



**510(K) Notification**  
**Biomet Manufacturing Corp.**  
**100 kGy E-Poly™ Acetabular Liners- Additional Profiles**  
**Page 2 of 2**

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

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

*All trademarks are property of Biomet, Inc.*

MAILING ADDRESS  
P.O. Box 247  
Warsaw, IN 46584-0247

SHIPPING ADDRESS  
c/o P. 10110-0000  
Warsaw, IN 46584

OFFICE  
Tel: 773-348-7000

FAX  
Tel: 773-348-7000

E-MAIL  
mailto:biomet@biomet.com

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

Femoral Component Name	510(k) Number	Product Code	(b)(4) Trade Secret Process	Indication
Answer® Femoral Component	K991987	JDI	<div style="background-color: black; color: red; padding: 5px;">(b)(4) Trade Secret Process</div>	Cemented
Co-Cr Answer® Femoral Components	K931194	JDG <sup>1</sup>		Cemented
Altra Press-Fit Hip Stem (Echo™)	K063002	KWA, JDI, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY		Uncemented
Altra FX Hip System (Echo™)	K063614	KWA, JDI, 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® Hip System Microplasty® Stems	K050251	KWZ, JDI, KWA, JDI, LZO, MEH, LPH, LZY, KWY		Non-cemented
Bi-Metric® Femoral Components	K921224 K020580 K030055 K052089 <sup>2</sup>	LZO LPH LPH LPH, JDI, LZO, KWY, KWZ		Cemented and non-cemented
Bi-Metric® Head/Neck Replacement	K955350 K992058 K983710	LZO JDI JDI		Cemented
HA Bi-Metric® Femoral Component	K023409 K030055	LPH LPH		Non-cemented
Bio-Groove® 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 Buffed Cemented Stem	K992903 K012019	JDI JDI		Cemented
Fenning (Osteocap RS®) Femoral Component	K960303	LPH		Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO		Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734 <sup>2</sup>	JDI		Cemented
Gross Femoral Component	K001580	MEH		Non-cemented

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

<sup>2</sup> Reduced Taper Stem

Impact® Co-Cr Femoral Components	K942027	JDG <sup>3</sup>	(b)(4)Trade Secret Process	Cemented
Integral® Femoral Component	K921225 K984296 K984408 K030055 K030501 K042029	LZO LPH LPH LPH LPH LPH		Cemented and non-cemented
Integral® Co-Cr Femoral Component	K942479	LZO		Cemented
Interlocking Hip Stems	K990830 K042774	LPH LPH <sup>4</sup>		Non-cemented
Mallory/Head® Total Hip System	K921181 K994007 K000538 K003429 K030055	LZO JDI LPH LPH LPH		Cemented and non-cemented
HA Mallory/Head® Total Hip System	K021403 K030055	LPH, MEH LPH, MEH		Non-cemented
Mallory/Head® Co-Cr Femoral Component	K911684	JDI		Cemented
Mallory/Head® Calcar Femoral Components (including HA)	K945115 K001660 K031693	LPH, LZO LPH LPH		Cemented and non-cemented
Medallion Hip	K041850	LPH		Uncemented
Modular Hip Stems	K912712 K921274 K030055	JDI LPH LPH		Cemented and non-cemented
Orthopedic Salvage System (OSS)	K002757 K052685	JDI JDI		Cemented
OSS™ Les Proximal Femoral Component	K021380	JDI, LPH		Cemented and non-cemented
PMI® Femoral Component	K911802 K923452 K030055	JDI LPH LPH		Cemented and non-cemented
HA PMI® Femoral Stem	K030048	LPH		Non-cemented
Portrait™ Femoral Component	K010560	LZO		Non-cemented
Reach® Femoral Component	K971824 K982367 K000760	LPH LPH LPH		Non-cemented
Modular Reach®	K994038	LPH		Non-cemented
HA Modular Reach®	K022463 K030055	LPH LPH		Non-cemented
Rx-90® Femoral Stems	K942028 K023085	JDG <sup>5</sup> JDI		Cemented
SHP™ Hip System	K960984	JDI		Cemented
Taper2™ Porous Femoral Stem	K050441	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH, KWB, LZY, KWY		Non-cemented

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

<sup>4</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

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

Taperloc® Femoral Component	K830313 K921301 K030055 K043537	JDI LPH LPH LPH	(b)(4) Trade Secret Process	Cemented and non-cemented
HA Taperloc® Femoral Component	K020963 K030055	MEH LPH		Non-cemented
Total IM Femur	K033871	JDI		Cemented
Total Femur	K974558	JDI		Cemented





The 100 kGy E-Poly™ Acetabular Liners contained in this submission may be used with Biomet acetabular components cleared under the following 510(k)s:

Acetabular System Name	510(k) number	Product Code	Indications
A-B Acetabular System	K954417 K030055	JDI, LPH LPH	Cemented and non-cemented
Full Hemisphere Acetabular Components	K920640 K050124	JDL* KWA, KWZ, LPH, MAY, MEH, JDI	Cemented and non-cemented
Healy™ Flanged Revision	K921139	JDL*	Cemented
Index® Acetabular Components	K950761 K030055	JDI LPH	Cemented and non-cemented
Mallory/Head® Acetabular Components	K861114 K921181 K030055	JDL* LZO LPH	Cemented and non-cemented
Mars® Modular Acetabular Reconstructive System	K911718	JDI	Cemented
McLaughlin™ +5 Acetabular Components	K050124	KWA, KWZ, LPH, MAY, MEH, JDI	Cemented and non-cemented
Par 5™ Acetabular Components	K022094	JDI	Cemented and non-cemented
Pegged (TRI-SPIKE™) Acetabular Components	K970501 K030055	JDI, LPH LPH	Cemented and non-cemented
Protrusio Cages	K971890 K020076	JDI JDI	Cemented
Quadrant Sparing™ Acetabular Components	K050124	KWA, KWZ, LPH, MAY, MEH, JDI	Cemented and non-cemented
Ranawat/Burstein® Acetabular Components	K911685 K921277 K050124	JDI LPH KWA, KWZ, LPH, MAY, MEH, JDI	Cemented and non-cemented
Regenerex Porous Titanium Acetabular Shells	K052996	LPH, LZO, JDI, KWZ, MEH, MAY	Cemented and non-cemented
Regenerex™ Porous Titanium Acetabular Augments	K052888	KWA, JDI, JDL, KWZ, LPH, LZO, MAY, MEH	
Tri-Polar Acetabular System including liners	K991990	KWY	Cemented and non-cemented
Universal® Acetabular Components	K861433 K921301 K030055	JDL* LPH LPH	Cemented and non-cemented

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



























































































































# Appendix 1

**Drawings**























# Appendix 2

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





















**ATTACHMENT 1**







































**ATTACHMENT 2**









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**ATTACHMENT 3**









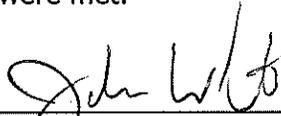




## Declarations Of Conformity With Design Controls

### 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.

10/24/07  
Date

### 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 of Regulatory Compliance and  
Quality Assurance  
Biomet Manufacturing Corp.

3/06/07  
Date

## 510(k) Summary

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

**Contact Person:** Becky Earl  
Regulatory Specialist

**Proprietary Name:** BioloX® *delta* Ceramic Heads with 100kGy E-Poly™  
Acetabular Liners

**Common or Usual Name:** Ceramic Modular Heads/UHMWPE Liners

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

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**  
BioloX® *delta* Ceramic Heads – K042091, K051411 and K061312; 100 kGy E-Poly™  
Acetabular Liners—K070364 and K070399.

**Device Description:** BioloX® *delta* Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper.

The 100 kGy E-Poly™ acetabular liners for the BioloX® *delta* Ceramic Heads are a larger size of the previously cleared 100 kGy E-Poly™ liners, K070364 and K070399.

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

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

510(k) Summary

BioloX® *delta* Ceramic Heads with 100kGy E-Poly™ Acetabular Liners

Biomet Manufacturing Corp.

Page 2

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

Salvage/Oncology Hip and Total Femur System components 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.

The Indications for Use Statement for the 100 kGy E-Poly™ Acetabular Liners is identical to the above statement.

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

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

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

**Biolog<sup>®</sup> *delta* Ceramic Heads with 100kGy E-Poly<sup>™</sup> Acetabular Liners**

I certify, in my capacity as Vice President, Quality, 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.

  
\_\_\_\_\_  
Lynnette Whitaker

10-24-07  
Date

I certify, in my capacity as a Development Engineer, 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.

  
\_\_\_\_\_  
Aaron Smith

10/23/07  
Date



**COVER SHEET MEMORANDUM**

From: Reviewer Name Ronald P. Jean  
Subject: 510(k) Number K073102  
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/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
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://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB-REVIATED-STANDARDS-DATA-FORM.DOC">http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB-REVIATED-STANDARDS-DATA-FORM.DOC</a> )			✓
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReg/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)?			✓
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, <a href="http://www.fda.gov/cdrh/osbguidance/316.html">http://www.fda.gov/cdrh/osbguidance/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 888.3353 Class\* II Product Code LZO  
(\*If unclassified, see 510(k) Staff)

Additional Product Codes: JDI, LWJ, LPH, MAY

Review: [Signature] (Branch Chief) OJDB (Branch Code) 11/26/09 (Date)

Final Review: [Signature] (Division Director) 11/26/09 (Date)

## PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

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

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

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

**To:** THE FILE

**RE:** DOCUMENT NUMBER K073102

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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.)

**K042091, K061312    36 mm BioloX delta Ceramic Heads**  
**K070364, K070399    100 kGy E-Poly Acetabular Liners**

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).

38mm BioloX delta Ceramic Heads

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

- 1) non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- 2) rheumatoid arthritis.
- 3) correction of functional deformity.
- 4) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- 5) revision procedures where other treatments 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)

100kGy E-Poly Acetabular Liners

- 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 of previously failed total hip arthroplasty.

Cemented and Uncemented Applications

*The Indications for Use Statements are identical to those cleared under K061312 and K070399.*

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**.

The purpose of this 510(k) submission is for the following modifications to the Biolox delta Ceramic Heads and 100kGy E-Poly Acetabular Liners:

- Addition of a 38 mm head diameter (along with an additional -6 mm neck size)
- Addition of a 38 mm acetabular liner

The design, materials, intended use, engraving and surface properties of the proposed components will remain the same as the predicate device components.

A parts listing is provided in Attachment 3A, while engineering drawings are provided in Attachment 3B. The sponsor has also included a parts listing and engineering drawings for the predicate device components in Attachments 3C and 3D, respectively.

Compatible Products:

The sponsor provided a list of compatible components in Attachment 4. Each compatible component has a Biomet Type I trunion (standard or reduced), and all stems are manufactured from Ti-6Al-4V (ASTM F136) or CoCr (ASTM F75 or F799).

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device.

38mm Biolox delta Ceramic Head:

The Biolox delta Ceramic Head proposed in this Special 510(k) submission is made of the same Biolox delta ceramic material (b) (4) and has the same intended use as the predicate ceramic heads cleared under K061312. (b) (4) The sponsor is proposing this larger sized head (38mm from 36mm) which will allow a slightly greater theoretical range of motion (b) (4) Trade Secret Process. The 38mm heads will be offered in neck length offsets of -6, -3, 0, +3 and +6 mm with the following specific characteristics:

Biomet Type I taper bore

(b) (4) Trade Secret Process

100 kGy E-Poly Acetabular Liners:

The proposed 38mm inner diameter (ID) acetabular liners are made of the same 100 kGy E-Poly UHMWPE material as the predicate acetabular liners cleared under K070364 and K070399. The following designs (the same as the predicate) are proposed: MaxRom (38mm ID; 25-28mm sizes), Hi-Wall (38mm ID; 25-28mm sizes), 10 degree (38mm ID; 25-28mm sizes), +5 MaxRom (38mm ID; 24-28mm sizes), and +5 Hi-Wall (38mm ID; 24-28mm sizes). (b) (4) Trade Secret Process

(b)(4)Trade Secret Process

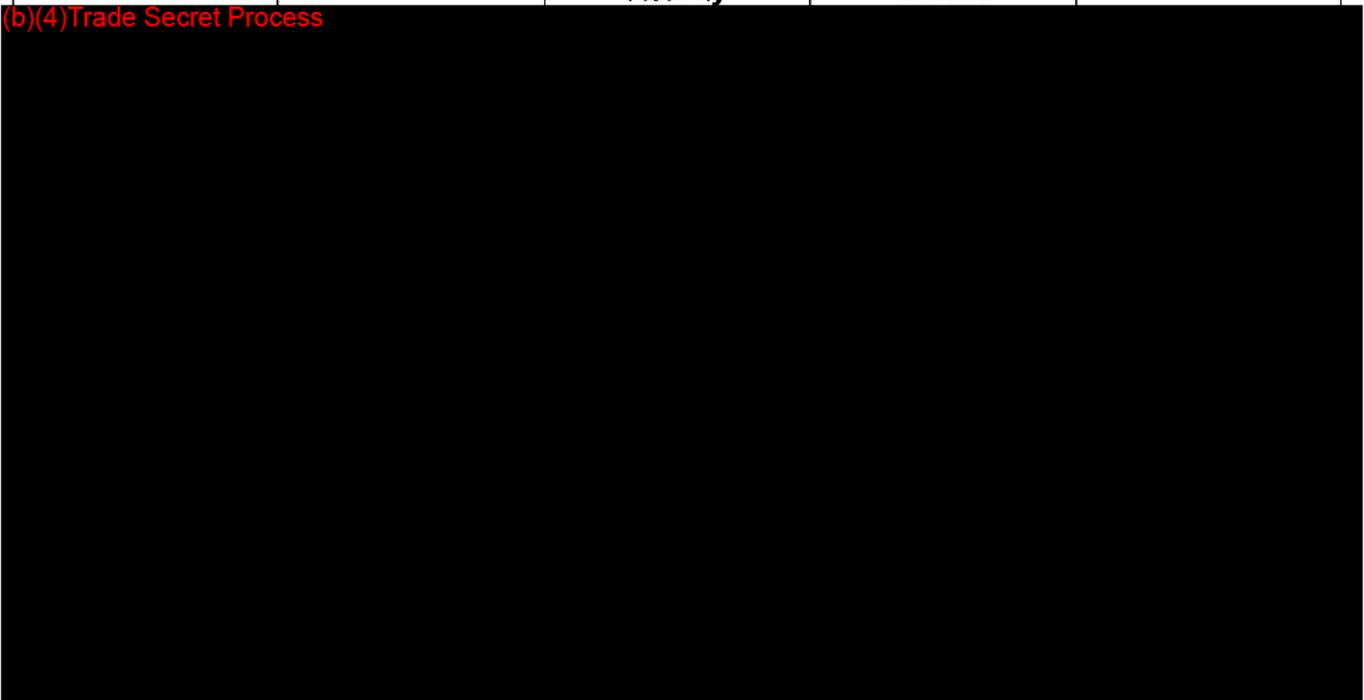
These liners are simply larger versions to accommodate the 38 mm ceramic heads.

5. A **Design Control Activities Summary** which includes:
  - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
  - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
  - c) A declaration of conformity with design controls. The declaration of conformity should include:
    - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
    - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The sponsor provided the required declaration of conformity with design controls pertaining to the risk analysis and manufacturing facility in Attachment 10 for the following Design Control Activities Summary Table (Attachment 9):

Change	Risk	Verification Activity	Acceptance Criteria	Results
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(b)(4)Trade Secret Process



**6. 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).**

In accordance with 21 CFR 807.87(k), the sponsor provided a truthful and accurate statement in Attachment 12.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices

demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

[Signature]  
11/26/07 (Reviewer's Signature)

11/26/2007  
(Date)

Comments:

The sponsor has provided acceptable pre-clinical test results in support of the safety and effectiveness of the proposed 38 mm femoral heads and acetabular liners. The test results for the subject femoral heads are acceptable. In evaluating the engineering drawings, the 38 mm acetabular liners appear to have the same outer dimensional profile as the predicate acetabular liners, suggesting that there is no increased risk of disassembly from the acetabular shell. The wear testing alluded to in the sponsor's Design Control Activities Summary Table for the acetabular liners was provided in the current 510(k) submission in Attachment 8, and indicates that a (b)(4) Trade

(b)(4) Trade Secret Process

Lastly,

[Redacted] sponsor that there are no increased risks posed by the subject acetabular liners.

(b) [Redacted] Therefore, I agree with the Tr

K073102

Reviewer: Ronald P. Jean

Division/Branch: DGRND/OJDB

Device Name: Biomet Biolox delta Ceramic Heads with 100 kGy E-Poly Acetabular Liners

Product To Which Compared (510(K) Number If Known): K042091, K061312, K070364, K070399

	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

Note: See

[http://erom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://erom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: n/a
2. Explain why there is or is not a new effect or safety or effectiveness issue: n/a
3. Describe the new technological characteristics: n/a
4. Explain how new characteristics could or could not affect safety or effectiveness: n/a
5. Explain how descriptive characteristics are not precise enough: need mechanical testing on ceramic femoral heads.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: n/a
7. Explain why existing scientific methods can not be used: n/a
8. Explain what performance data is needed: need performance testing on ceramic femoral heads.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: the test results on the ceramic femoral heads are acceptable per our Ceramic Ball Guidance.

**Jean, Ronald P**

---

**From:** Jean, Ronald P.  
**Sent:** Monday, November 26, 2007 12:29 PM  
**To:** 'becky.earl@biometmail.com'  
**Subject:** K073102 - request for revised 510(k) Summary

Dear Ms. Earl,

Thank you very much for taking the time to go over your 510(k) Summary for K073102. As discussed, you may replace the statement on page 2 of your 510(k) Summary, "The Indications for Use Statement for the 100 kGy E-Poly Acetabular Liners is identical to the above statement" with:

The 100 kGy E-Poly Acetabular Liners are intended for cemented and uncemented applications with the following indications for use:

- 1) non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- 2) rheumatoid arthritis.
- 3) correction of functional deformity.
- 4) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- 5) revision of previously failed total hip arthroplasty.

**Cemented and Uncemented Applications**

Once I receive your revised 510(k) Summary, I will put forth my recommendation. If any questions arise, please feel free to contact me.

Thank you very much.

Ronald

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**Ronald P. Jean, Ph.D.**                      ronald.jean@fda.hhs.gov  
Executive Secretary, Orthopaedic & Rehabilitation Devices Panel  
Scientific Reviewer, Orthopedic Joint Devices Branch  
U.S. Food & Drug Administration  
Tel: (240) 276-3676 **NEW!**              Fax: (240) 276-3602 **NEW!**

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**Jean, Ronald P**

---

**From:** Becky.Earl@Biometmail.com  
**Sent:** Monday, November 26, 2007 1:05 PM  
**To:** Jean, Ronald P  
**Subject:** Re: K073102 - request for revised 510(k) Summary  
**Importance:** High  
**Attachments:** 20071126130115674.pdf

Dear Mr. Jean,

Thank you so much for your call and e-mail. Attached is a revised 510(k) Summary for K073102. Hopefully this will satisfy your request. Please let me know if anything further is needed.

Becky

Becky Earl  
Regulatory Specialist

Biomet, Inc.  
56 E. Bell Drive  
P O. Box 587  
Muncie, IN 46581  
Phone: (574) 267-6639 Ext.1216  
Fax: (574) 372-1683  
Email:becky.earl@biometmail.com



MANUFACTURING CORP.

### 510(k) Summary

**Applicant/Sponsor:** Biomet Manufacturing Corp.  
**Contact Person:** Becky Earl  
Regulatory Specialist  
**Proprietary Name:** BioloX® *delta* Ceramic Heads with 100kGy E-Poly™  
Acetabular Liners

**Common or Usual Name:** Ceramic Modular Heads/UHMWPE Liners

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

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**  
BioloX® *delta* Ceramic Heads – K042091, K051411 and K061312; 100 kGy E-Poly™  
Acetabular Liners—K070364 and K070399.

**Device Description:** BioloX® *delta* Ceramic Heads are designed to be the bearing surface of a total hip joint replacement. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper.

The 100 kGy E-Poly™ acetabular liners for the BioloX® *delta* Ceramic Heads are a larger size of the previously cleared 100 kGy E-Poly™ liners, K070364 and K070399.

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

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

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510(k) Summary

Biolox® *delta* Ceramic Heads with 100kGy E-Poly™ Acetabular Liners

Biomet Manufacturing Corp.

Page 2

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

Salvage/Oncology Hip and Total Femur System components 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.

The 100 kGy E-Poly™ Acetabular Liners are intended for cemented and uncemented applications with the following indications for use:

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

Cemented and Uncemented Applications.

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

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