K093549 #1/2

DEC 16 2009

BIOMET®
MANUFACTURING CORP.

510(k) Summary

Date: November 16, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl
Regulatory Specialist

Proprietary Name: 44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
(**also known as E-Poly™ Acetabular Liners)*

Common or Usual Name: UHMWPE Liners

Classification Name:

- 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: 100 kGy E-Poly™ Acetabular Liners – K070399 and K090103, Biolox® *delta* Option Ceramic Heads – K082996.

Device Description: Biomet Manufacturing Corp. is adding a size 44mm liner to their line of E1™ Acetabular Liners to allow the surgeon more options. Additionally, the 44mm Biolox® *delta* Option Ceramic Head is added to the ceramic option line. The 44mm M²a Magnum™ may be used when a Co-Cr-Mo option is needed. This submission is a line extension of the previously cleared systems.

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

K093549 # 2/2

510(k) Summary
44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
Biomet Manufacturing Corp.
Page 2

Indications For Use: The 44mm E1™ Acetabular Liners are 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 Biolox® *delta* Option Ceramic Head 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)

Summary of Technologies: The 44mm E1™ Liner and 44mm Biolox® *delta* Option Ceramic Head 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

Biolox is a trademark of CeramTec AG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 16 2009

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

Re: K093549
Trade/Device Name: 44mm E1™ Acetabular Liner with 44mm Biolox® delta Option Ceramic Head or 44mm M²a Magnum Modular Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, JDI, LWJ, MAY
Dated: November 16, 2009
Received: November 17, 2009

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

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

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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K093549

Device Name: 44mm E1™ Acetabular Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head

Indications For Use: The 44mm E1™ Acetabuler Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head is 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 44mm Biolox® *delta* Option Ceramic Head 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)

for MXM

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

510(k) Number K093549

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 16 2009

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

Re: K093549
Trade/Device Name: 44mm E1™ Acetabular Liner with 44mm Biolox® delta Option Ceramic Head or 44mm M²a Magnum Modular Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, JDI, LWJ, MAY
Dated: November 16, 2009
Received: November 17, 2009

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

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

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

Sincerely yours,

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

Enclosure

DJA x00003

Indications for Use

510(k) Number (if known): K093549

Device Name: 44mm E1™ Acetabular Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head

Indications For Use: The 44mm E1™ Acetabuler Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head is 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 44mm Biolox® *delta* Option Ceramic Head 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093549

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 17, 2009

BIOMET MANUFACTURING CORP.
PO BOX 587
WARSAW, INDIANA 46581-0587
UNITED STATES
ATTN: BECKY EARL

510k Number: K093549
Received: 11/17/2009
Product: 44MM E1 ACETABULAR LINER WITH

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) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

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

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K093549

BIOMET®
MANUFACTURING CORP.

FDA CDRH DMC
NOV 17 2009
Received

November 16, 2009

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

Reference: "Special" 510(k) – 44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
User Fee ID: MD6045537-956733

Dear Sir or Madam:

Enclosed is a **"Special" 510(k): Device Modifications** submission for the 44mm E1™ Acetabular Liner, which is a line extension of 100 kGy E-Poly™ Acetabular Liners—Additional Profiles, K070399, cleared 05/04/07 and 100 kGy E-Poly™ Acetabular Liners—Additional Profiles: +3 MaxRom™ and +3 Hi-Wall, K090103, cleared 02/11/09.

The E1™ liner may be used with:

- A 44mm Biolox® *delta* Option Ceramic Head, which is a line extension of the Biolox® *delta* Option Ceramic Heads cleared through special 510(k) K082996, 01/15/09.
- A 44 M²a Magnum™ Modular Head, previously cleared in K042037.

We believe this device is substantially equivalent* to cleared devices and warrants a "Special" 510(k).

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

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

Sincerely,

Becky Earl

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

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

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

K42

BIOMET®
MANUFACTURING CORP.

November 16, 2009

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

Reference: "Special" 510(k) – 44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head

User Fee ID: (b)(4)Trade Secret Process

Dear Sir or Madam:

Enclosed is a "**Special" 510(k): Device Modifications** submission for the 44mm E1™ Acetabular Liner, which is a line extension of 100 kGy E-Poly™ Acetabular Liners—Additional Profiles, K070399, cleared 05/04/07 and 100 kGy E-Poly™ Acetabular Liners—Additional Profiles: +3 MaxRom™ and +3 Hi-Wall, K090103, cleared 02/11/09.

The E1™ liner may be used with:

- A 44mm Biolox® *delta* Option Ceramic Head, which is a line extension of the Biolox® *delta* Option Ceramic Heads cleared through special 510(k) K082996, 01/15/09.
- A 44 M²a Magnum™ Modular Head, previously cleared in K042037.

We believe this device is substantially equivalent* to cleared devices and warrants a "Special" 510(k).

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

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

Sincerely,

Becky Earl

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

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

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

BIOMET INC
56 EAST BELL DRIVE
P O BOX 587
WARSAW IN 46581-0587
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)Trade Secret

2. CONTACT NAME
Rebecca Earl
2.1 E-MAIL ADDRESS
becky.earl@biomet.com
2.2 TELEPHONE NUMBER (include Area code)
574-267-6639 1216
2.3 FACSIMILE (FAX) NUMBER (include Area code)
574-372-1683

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER
3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)Trade
06-Oct-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Table of Contents

44mm E1™ Acetabular Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
Special 510(k)

Device Name

Device Trade Name: 44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
(*also known as E-Poly™ Acetabular Liners)
Common Name: 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
(Ceramic Heads)

Sterilization Site:

Contact Information

Name: Becky Earl
Title: Regulatory Specialist
Address: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, IN 46581-0587
Telephone: 574-267-6639
Fax: 574-372-1683
E-mail: becky.earl@biomet.com

Alternate Contact
Name: Tracy B. Johnson
Title: Director, Clinical and Regulatory Affairs
Address: Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, IN 46581-0587
Telephone: 574-267-6639
Fax: 574-372-1683
E-mail: tracy.johnson@biomet.com

Device Classification

Class: II
Product Code/Classification Names:

- 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)[1] No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for highly cross-linked polyethylene liners. There are currently no applicable guidance documents for these implants. 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* Option Ceramic Heads 510(k) K082996, for which the size 44 Biolox® *delta* Option Ceramic Head is a line extension. 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 100 kGy E-Poly™ Acetabular Liners—Additional Profiles: +3 MaxRom™ and +3 Hi-Wall, K090103, cleared 02/11/09; the 10 Degree liners were previously cleared in K070399, 100 kGy E-Poly™ Acetabular Liners—Additional Profiles, cleared 05/04/07. Additionally, bundled with these size 44mm E1™ liners is the 44mm Biolox® *delta* Option Ceramic Head, which is a line extension of the Biolox® *delta* Option Ceramic Heads, cleared through special 510(k) K082996, 01/15/09. The M^2a Magnum™ Modular 44mm Head (Co-Cr-Mo) was previously cleared through K042037.
Labeling and Indications for Use	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. The only change to the package insert for the Biolox® *delta* Option Ceramic Head is a clarification under "Assembly Instructions", involving item 4 and a caution statement. There were several minor changes to update this insert to standard Biomet verbiage in all package inserts. There are no changes to the E1™ liner package insert. Indications for Use The 44mm E1™ Acetabular Liners are for use in total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

[1] This classification was inadvertently left off the clearance letter. It was clearly found in the submission and the 510(k) Summary.

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 is identical to the predicate with the exception of minor grammatical changes.

The indications are identical to those for the Biolox® *delta* Option Ceramic Head cleared in K082996. Specific indications for compatible components that can be used with the Biolox® *delta* Option Ceramic Head 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)

The Indications for Use Statement can be found in Attachment 2.

Sterilization and Packaging

Devices are provided sterile by radiation methods as follows:
Radiation Type: Gamma
Radiation Source: (b)(4)Trade S t
Minimum Dosage: 25 kGy
Maximum Dosage: 40 kGy
Sterility Assurance Level: 10^{-6}
Sterility Validation Method: (b)(4)Trade Secret Process (b)(4)Trade Secret Process
Pyrogen-Free: no claims will be made
Packaging:

E1™ Components
The E1™ components are vacuum sealed in a barrier film bag and placed in an outer blister with a Tyvek lid®. The blisters are then boxed; shrink wrapped and sent for gamma sterilization.

Biolox® delta Option Ceramic Heads/M²a Magnum™ Head
Each component is placed within a plastic bag between two foam

pads. They are then placed in an inner blister pack, sealed with a Tyvek® lid which fits into an outer blister pack also sealed with a Tyvek® lid. The entire unit is placed in a cardboard box, shrink wrapped for protection.

All labeling will be on the outer Tyvek® lid as well as on the outer cardboard box.
Labeling: All packages will display a yellow to red chemical indication dot along with a statement that the device has been sterilized by gamma irradiation, 25 kGy.
Expiration Date: The E1™ Acetabular Liners have a 3-year shelf life; the Biolox® *delta* Option Heads and the 44mm M²a Magnum™ Modular Head have a 10-year shelf-life. Supporting data is on file at Biomet and can be accessed at any future FDA inspection.

Device Description

The device description of the 44mm 100 kGy E1™ Liners is as follows:

Designs and Sizes

Profile	*ID (mm)*	*Sizes (mm)*
(b)(4)Trade Secret Process		

Material

- 100 kGy E1™ (also known as E-Poly™)

Specific Characteristics

- (b)(4)Trade Secret Process
- The 100 kGy E1 acetabular liners are offered in three profiles: the MaxRom™, the Hi-Wall, and the 10 Degree. The specific characteristics of each profile are identical to those previously cleared (K070399 and K090103). The liners included in this submission are simply line extensions (larger IDs) of previously tested and cleared devices.

Product Listing/Drawings

- The name and manufacturer's model number for each 44mm E1™ Acetabular Liner may be found in Attachment 3A.
- Dimensioned engineering drawings of the 44mm, 100 kGy E1™ Acetabular Liners may be found in Attachment 3B.

The 44mm Biolox® *delta* Option Ceramic Head is part of a series of Biolox® *delta* Option ceramic ball heads that are used in combination with a titanium sleeve.

Sizes

- 44mm head diameter

- Neck lengths Biomet Type 1 Taper: -6, -3, 0, +3 and +6mm
- Neck lengths 12/14 Taper: -3, 0, +4, +7mm

Material

- Transition-Toughened-Platelet Alumina (TTPA)
- 75% Alumina, 24% Zirconia and 1% Platelet

Specific Characteristics

- (b)(4)Trade Secret Process [redacted]

The 44mm M²a Magnum™ Modular Head has been previously cleared for metal-on-metal articulation in K042037. The cobalt-chromium-molybdenum (ASTM F-75) modular head is designed to be assembled (b)(4)Trade Secret Process [redacted] at the time of surgery. The Magnum™ head may be used in conjunction with any cleared Magnum™ taper insert. Except for the articulation surface (metal-on-E1™), the femoral head is identical to the predicate.

Product Listing/Drawings

- The name and manufacturer's model number for the 44mm E1™ Acetabular Liners, as well as the 44mm Biolox® *delta* Option Ceramic Head and 44mm M²a Magnum™ Modular Head may be found in Attachment 3A.
- Dimensioned engineering drawings of the 44mm E1™ Acetabular Liners, the 44mm Biolox® *delta* Option Head and the 44mm M²a Magnum™ Modular Head the may be found in Attachment 3B.
- A product listing of the predicate 44mm E1™ Acetabular Liners cleared through K070399 and K090103 , the Biolox® *delta* Option Ceramic Heads cleared through 510(k) K082996, and the M²a Magnum heads cleared through K042037 can be found in Attachment 3C. An Engineer Drawing of each style of cleared E1™ liner; Engineer Drawings of each cleared Biolox® *delta* Option Head (K082996) and the 44mm M²a Magnum™ Modular Head cleared through K042037 are also included. Predicate clearance letters are located in Attachment 3D.

Compatible Products

- Attachment 4A contains a table of compatible hip stems for use with the 44mm Biolox® *delta* Ceramic Head or M²a Magnum modular heads.
- All of the devices are metallic hip stems with or without porous coating.
- Each stem has a Biomet 12/14 or Biomet Type I trunnion (standard or reduced) for attachment of the modular head. A

sample engineering drawing of a femoral stem with each type of taper is included in Attachment 4B.

- (b)(4)Trade Secret Process [redacted]

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

Device Comparison

The following features of the 44mm E1™ Acetabular Liners have not changed as previously cleared in K070399 and K090103:

- 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.
- Previous liners were cleared for use with either ceramic or Co-Cr-Mo heads.

The only modification to the originally cleared 100 kGy E-Poly™ Acetabular Liners is the additional larger ID, 44 mm.

The following features of the 44mm Biolox® *delta* Option Ceramic head have not changed, as previously described in the predicate device 510(k) K082996:

- Indications statement and intended use are identical to the predicate.
- Material, including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity.
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability
- Use of a titanium taper adapter (sleeve) with

The only modification that was made is expansion of the cleared 28mm – 40mm Biolox® *delta* Option Ceramic head diameter product line to include a 44mm head diameter. The taper adapters are previously cleared but listed with the component. (Attachment 3A)

The previously cleared 44mm M²a Magnum™ Modular Head is identical to the predicate (K042037). The only difference is the articulation surface being expanded from metal-on-metal to include metal-on-polyethylene (E1™). The taper inserts for this head are also listed in Attachment 3A.

Bench/Animal Testing

44mm E1™ Acetabular Liners

Wear testing was completed using a 44mm Co-Cr-Mo modular head (M^2a Magnum) and the 44mm E1™ liner included in this submission. In order for the wear rates to be acceptable, the 44mm E1™ (b)(4)Trade Secret Process (b)(4)Trade Secret Process

The 44mm E1™ Max-Rom+ acetabular liners performed as expected (b)(4)Trade Secret Process (b)(4)Trade Secret acetabular liners currently on the market. (Attachment 5A.)

44mm Biolox® *delta* Ceramic Head

Previous testing serves as verification to new risks. See Engineering Justification, Attachment 5B.

44mm M^2a Magnum™ Modular Head

The only new risk would be wear. The 44mm E1™ liner was tested with the 44mm M^2a Magnum™ head. (See above notes and Attachment 5B.)

Substantial Equivalence

The 44mm E1™ Acetabular Liners have the following similarities to the 100 kGy E-Poly™ Acetabular Liners previously cleared in K070399 and K090103:

- Indications statement and intended use are identical to the predicate.
- Devices are manufactured from the same materials using identical techniques; both predicate and modified device are manufactured from (b)(4)Trade Secret UHMWPE.
- Are packaged and sterilized using the same materials and processes.
- The sterilization method is identical to the predicate.

The 44mm Biolox® *delta* Option Ceramic Head shares these characteristics with the Biolox® *delta* Option Ceramic Heads which previously received 510(k) concurrence (K082996):

- They have identical indication statements
- They incorporate the same basic design
- (b)(4)Trade Secret Process
- They are compatible with new or used Biomet Type I tapers (standard and reduced) and 12/14 Biomet 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.

The 44mm M^2a Magnum™ Modular Head is identical to the predicate cleared in K042037. The only difference is the

	articulation surface being expanded to include metal-on-polyethylene (E1™). In summary, the 44mm E1™ Acetabular Liners described in this submission are substantially equivalent to the predicate device. The 44mm Biolox® *delta* Option Ceramic Head described in this submission is substantially equivalent to the predicate device. The 44mm M^{2}a Magnum™ Modular Head is identical to the predicate device. The 44mm E1™ Acetabular Liners and the 44mm Biolox® *delta* Option Ceramic Heads are, therefore, found to be substantially equivalent to the predicate devices.
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 6. A declaration of conformity with design controls is included in Attachment 7. 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	A 510(k) Summary for the E1™ 44mm Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M^{2}a Magnum™ Head is included in Attachment 8.
Truthful and Accuracy Certification	A certification of the truthfulness and accuracy of the information presented in this submission is provided in Attachment 9.

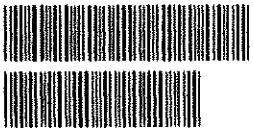
REF 650-1059 LOT 123123

BIOLOX® DELTA OPTION CERAMIC HEAD
44MM HEAD DIAMETER
TYPE 16/18 TAPER

ALUMINA / ZIRCONIA
FOR SINGLE USE WITH BIOLOX OPTION
TAPER ADAPTER ONLY

Biolox is a registered trademark of CeramTec AG

LOT 123123 QTY. 1



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

STERILE R
2009-11
EXPIRY DATE: 2019-11

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. 650-1059
BIOLOX® DELTA OPTION CERAMIC HEAD
44MM HEAD DIAMETER
TYPE 16/18 TAPER
ALUMINA / ZIRCONIA
FOR SINGLE USE WITH BIOLOX OPTION
TAPER ADAPTER ONLY
LOT 123123 EXPIRY DATE: 2019-11
AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. 650-1059
BIOLOX® DELTA OPTION CERAMIC HEAD
44MM HEAD DIAMETER
TYPE 16/18 TAPER
ALUMINA / ZIRCONIA
FOR SINGLE USE WITH BIOLOX OPTION
TAPER ADAPTER ONLY
LOT 123123 EXPIRY DATE: 2019-11
AFFIX TO PATIENT RECORDS

REF. EP-108625 LOT 123123

E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER +3 MAXROM(TM)
SIZE 25
E-POLY(TM) UHMWPE

E-Poly™ H X L P E

LOT 123123 QTY. 1 STERILE R

EXPIRY DATE: 2012-11

2009-11

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

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF EP-108625
E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER +3 MAXROM(TM)
SIZE 25
E-POLY(TM) UHMWPE

LOT 123123 EXPIRY DATE: 2012-11
AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF EP-108625
E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER +3 MAXROM(TM)
SIZE 25
E-POLY(TM) UHMWPE

LOT 123123 EXPIRY DATE: 2012-11
AFFIX TO PATIENT RECORDS

REF. EP-108725

LOT 123123

E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER +3 HI-WALL
SIZE 25
E-POLY(TM) UHMWPE

E-Poly™
H X L P E

LOT 123123 QTY. 1

STERILE R

EXPIRY DATE: 2009-11
2012-11

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

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF EP-108725
E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER +3 HI-WALL
SIZE 25
E-POLY(TM) UHMWPE

LOT 123123 EXPIRY DATE: 2012-11
AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF EP-108725
E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER +3 HI-WALL
SIZE 25
E-POLY(TM) UHMWPE

LOT 123123 EXPIRY DATE: 2012-11
AFFIX TO PATIENT RECORDS

REF. EP-109826 LOT 123123

E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER 10 DEGREE
SIZE 26
E-POLY(TM) UHMWPE

E-Poly™ H X L P E

LOT 123123 QTY. 1 STERILE R

EXPIRY DATE: 2012-11

2009-11

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

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF EP-109826
E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER 10 DEGREE
SIZE 26
E-POLY(TM) UHMWPE

LOT 123123 EXPIRY DATE: 2012-11
AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF EP-109826
E-POLY(TM) 44MM RINGLOC®
ACETABULAR LINER 10 DEGREE
SIZE 26
E-POLY(TM) UHMWPE

LOT 123123 EXPIRY DATE: 2012-11
AFFIX TO PATIENT RECORDS

REF 157444 LOT 123123

M2A MAGNUM(TM) MODULAR HEAD
44MM HEAD DIAMETER

USE M2A MAGNUM TAPER ADAPTER 42-50MM
CO-CR-MO ALLOY/METAL ON METAL

LOT 123123

QTY. 1

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA
STERILE R
2009-11
EXPIRY DATE: 2019-11

CE 0086

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. 157444
M2A MAGNUM(TM) MODULAR HEAD
44MM HEAD DIAMETER
USE M2A MAGNUM TAPER ADAPTER 42-50MM
CO-CR-MO ALLOY/METAL ON METAL

LOT 123123 EXPIRY DATE: 2019-11
AFFIX TO PATIENT RECORDS

BIOMET ORTHOPEDICS
56 EAST BELL DRIVE
P.O. BOX 587 WARSAW, IN 46581 USA
REF. 157444
M2A MAGNUM(TM) MODULAR HEAD
44MM HEAD DIAMETER
USE M2A MAGNUM TAPER ADAPTER 42-50MM
CO-CR-MO ALLOY/METAL ON METAL

LOT 123123 EXPIRY DATE: 2019-11
AFFIX TO PATIENT RECORDS

Biomet Orthopedics
56 East Bell Drive
P.O. Box 587
/arsaw, Indiana 46581 USA

01-50-0967
Date: 09/08

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

ATTENTION OPERATING SURGEON

DESCRIPTION
E-Poly™ Acetabular Liners are composed of UHMWPE and Vitamin E (α-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 α-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.

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, and osteomyelitis.
Relative contraindications include: 1) uncooperative patient or patient with urologic disorders who is 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.
4. In an instance where a liner engages the RingLoc™ locking ring and the liner is subsequently removed or replaced, the RingLoc™ locking ring should be replaced with a new ring.

.omet® 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.

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.

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-3968.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA, U.K.

CE 0086

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

01-50- 0916
Date: 11/09

Biomet® Biolox™ delta Option Modular Head Hip Joint Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION
The Biomet® Biolox™ *delta* Option Ceramic modular head components are a Transition-Toughened-Platelet Alumina Composite ceramic (TTPA) material with highly polished surfaces in a variety of head sizes. The highly polished surface is designed to reduce friction and minimizes wear. The titanium sleeves adapt the ceramic heads to either a Biomet® Type I or a Biomet® 12/14 taper and allows them to be used in both primary and revision total hip arthroplasty.

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

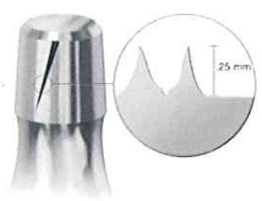
INDICATIONS
1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable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

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, and osteomyelitis.

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

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

1. Use Biomet® Biolox™ delta Option ceramic modular head with Biomet® metallic femoral components. Do not use Biomet® Biolox™ delta Option ceramic modular heads with femoral stems or acetabular components offered by other manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture of ceramic heads.
2. Sleeves labeled "Type I Taper" are to be used with femoral stem components labeled "Type I Taper".
3. Sleeves labeled "12/14" are to be used with femoral stem components labeled "12/14" taper.
4. Use only with Ultra-High Molecular Weight Polyethylene (UHMWPE) or metal-backed UHMWPE acetabular components.
   Do not use ceramic heads that have been dropped, rubbed, scratched, or disfigured. Blemishes can be expected to cause failure.
6. Do not use a metallic hammer when seating the ceramic head. Use a nylon or polyethylene seating instrument. Do not use excessive force. The TTPA ceramic head can fracture with excessive force.
7. The femoral stem trunion, sleeves and the bore of the ceramic head should be dry and free of contamination prior to assembly.
8. During a revision surgery, extraction of the femoral head should be done with suitable extraction instruments to avoid unnecessary damage to the trunion.
9. Biomet® Biolox™ *delta* Option modular head components should not be used on trunnions with scratches or defects greater than 0.25mm in height. The surgeon should inspect the taper for damage prior to placement of the modular head components by measuring, with a measuring device, any scratches or defects, and verifying that the height is less than 0.25mm (see Figure A) . The conditions shown in Figures B, C and D are also considered unsuitable for the use of the Biomet® Biolox™ *delta* Option Ceramic Head and can be expected to cause failure:
10. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.



Taper with scratch/defect at a Height of 0.25mm – Figure A

Taper with Broad Truncation – Figure B

Slanted Taper - Figure C

Crushed Taper - Figure D

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

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

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

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

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

POSSIBLE ADVERSE EFFECTS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative infection and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption, and or excessive, unusual and/or awkward movement and/or activity. The trunnion must also be free of scratches or defects greater than 0.25mm in height, free of slants, free of broad truncations, and free of crushed ends (see warning #9 for clarification).
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.

    Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
13. The TTPA ceramic modular head is composed of ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular components, ceramic balls produce a relatively low amount of particles, the total amount of particulate produced remains undetermined. Because of the limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown.
14. Intraoperative and postoperative bone fracture and/or postoperative pain.
15. Ceramic head fractures have been reported.

ASSEMBLY INSTRUCTIONS

1. The modular head components must be assembled together before positioning them onto the stem.
2. Verify that the appropriate head size and matching tapers are being utilized before assembly.
3. The modular head components are assembled by placing the head onto the sleeve as shown in Figure E and Figure F . Assure that the tapers are clean and dry and that they are aligned axially before applying pressure. The tapers are engaged once resistance is felt.

Figure E

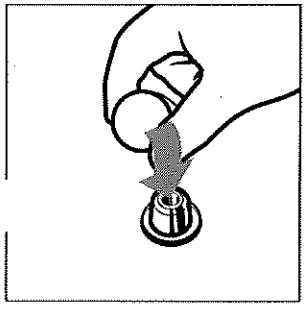
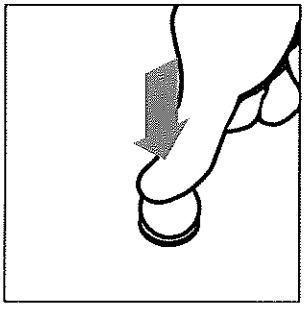


Figure F



4. Impact the modular head components onto the stem with a light tap that firmly and definitively seats the head using a plastic head impactor only. Metal impactors or any other metallic objects may scratch or crack the modular head bearing surface and, therefore, should not be used.
5. If the modular ceramic head becomes scratched or cracked, the head and sleeve must be replaced.

CAUTION: In cases in which the **BIOLOX™ OPTION system** can only be put on the shaft taper using more pressure, because there are scratches or warping of more than 0.25mm, the **BIOLOX™ OPTION system shall not be used.**

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. 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: 574-372-3968.

Symbol Legend

 Manufacturer

 Date of Manufacture

 Do Not Reuse

 Caution

Sterilized using Ethylene Oxide

Sterilized using Irradiation

Sterile

Sterilized using Aseptic Processing Techniques

Sterilized using Steam or Dry Heat

 Use By

 WEEE Device

Catalogue Number

Batch Code

Flammable

Indications for Use

510(k) Number (if known):_____

Device Name: 44mm E1™ Acetabular Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M^2a Magnum™ Modular Head

Indications For Use: The 44mm E1™ Acetabuler Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M^2a Magnum™ Modular Head is 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 44mm Biolox® *delta* Option Ceramic Head 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_ AND/OR Over-The-Counter Use _No_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Modified Component Listing
(Blue Print indicates Previously Cleared Components)

Biomet Part Number	Description	CeramTec Part Number
E1™ Acetabular Liner		
EP-109826	E-Poly 44mm 10 Degree Liner, Size 26	
EP-109827	E-Poly 44mm 10 Degree Liner, Size 27	
EP-109828	E-Poly 44mm 10 Degree Liner, Size 28	
EP-108625	E-Poly 44mm +3 MaxRom Liner, Size 25	
EP-108626	E-Poly 44mm +3 MaxRom Liner, Size 26	
EP-108627	E-Poly 44mm +3 MaxRom Liner, Size 27	
EP-108628	E-Poly 44mm +3 MaxRom Liner, Size 28	
EP-108725	E-Poly 44mm +3 HiWall Liner, Size 25	
EP-108726	E-Poly 44mm +3 HiWall Liner, Size 26	
EP-108727	E-Poly 44mm +3 HiWall Liner, Size 27	
EP-108728	E-Poly 44mm +3 HiWall Liner, Size 28	
Ceramic Head		
650-1059	Biolox® *delta* Option Ceramic Head, Size 44mm	38.39.7179.355.00
Biolox® *delta* Option *Sleeves (Previously Cleared in K082996)*		
650-1060	Biolox® *delta* Option 12/14 Sleeve -3	36.49.7500.018.01
650-1061	Biolox® *delta* Option 12/14 Sleeve 0	36.49.7500.019.01
650-1062	Biolox® *delta* Option 12/14 Sleeve +4	36.49.7500.023.01
650-1063	Biolox® *delta* Option 12/14 Sleeve +7	36.49.7500.021.01
650-1064	Biolox® *delta* Option Type I Sleeve -6	36.49.7500.053.00
650-1066	Biolox® *delta* Option Type I Sleeve 0	36.49.7500.029.00
650-1068	Biolox® *delta* Option Type I Sleeve +6	36.49.7500.031.00
44mm M²a Magnum™ Modular Head (Previously Cleared in K042037)		
157444	M²a Magnum Modular Head, Size 44mm	
M²a Magnum™ Taper Inserts (Previously Cleared in K042037)		
139252	M²a Magnum 42-50mm Taper Insert -6	
139254	M²a Magnum 42-50mm Taper Insert -3	
139256	M²a Magnum 42-50mm Taper Insert Std	
139258	M²a Magnum 42-50mm Taper Insert +3	
139259	M²a Magnum 42-50mm Taper Insert +6	
139261	M²a Magnum 42-50mm Taper Insert +9	
M²a Magnum™ 12/14 Taper Inserts (Previously Cleared in K061423)		
239252	M²a Magnum 12/14 Taper 42-50 Insert -6	
239254	M²a Magnum 12/14 Taper 42-50 Insert -3	
239256	M²a Magnum 12/14 Taper 42-50 Insert Std	

239258	M^2a Magnum 12/14 Taper 42-50 Insert +3
239260	M^2a Magnum 12/14 Taper 42-50 Insert +6
239262	M^2a Magnum 12/14 Taper 42-50 Insert +9

Acetabular Liner Trials

33-109826	Ringloc+ Screw-in Provisional 10 Degree, 44mm, Size 26
33-109827	Ringloc+ Screw-in Provisional 10 Degree, 44mm, Size 27
33-109828	Ringloc+ Screw-in Provisional 10 Degree, 44mm, Size 28
33-108625	Ringloc+ Screw-in Provisional +3, 44mm, Size 25
33-108626	Ringloc+ Screw-in Provisional +3, 44mm, Size 26
33-108627	Ringloc+ Screw-in Provisional +3, 44mm, Size 27
33-108628	Ringloc+ Screw-in Provisional +3, 44mm, Size 28
33-108725	Ringloc+ Screw-in Provisional +3 Hi-Wall ,44mm, Size 25
33-108726	Ringloc+ Screw-in Provisional +3 Hi-Wall ,44mm, Size 26
33-108727	Ringloc+ Screw-in Provisional +3 Hi-Wall ,44mm, Size 27
33-108728	Ringloc+ Screw-in Provisional +3 Hi-Wall ,44mm, Size 28

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

Predicate Component Listing

100 kGy E-Poly™ Acetabular Liners

Device Description	Part Number
K070399	
28mm 10 Degree RingLoc® Size 21	EP-105811
28mm 10 Degree RingLoc® Size 22	EP-105812
28mm 10 Degree RingLoc® Size 23	EP-105813
28mm 10 Degree RingLoc® Size 24	EP-105814
28mm 10 Degree RingLoc® Size 25	EP-105815
28mm 10 Degree RingLoc® Size 26	EP-105816
28mm 10 Degree RingLoc® Size 27	EP-105817
28mm 10 Degree RingLoc® Size 28	EP-105818
32mm 10 Degree RingLoc® Size 23	EP-105833
32mm 10 Degree RingLoc® Size 24	EP-105834
32mm 10 Degree RingLoc® Size 25	EP-105835
32mm 10 Degree RingLoc® Size 26	EP-105836
32mm 10 Degree RingLoc® Size 27	EP-105837
32mm 10 Degree RingLoc® Size 28	EP-105838
36mm 10 Degree RingLoc® Size 24	EP-105894
36mm 10 Degree RingLoc® Size 25	EP-105895
36mm 10 Degree RingLoc® Size 26	EP-105896
36mm 10 Degree RingLoc® Size 27	EP-105897
36mm 10 Degree RingLoc® Size 28	EP-105898
28mm Hi-Wall RingLoc® Size 22	EP-105902
28mm Hi-Wall RingLoc® Size 23	EP-105903
28mm Hi-Wall RingLoc® Size 24	EP-105904
28mm Hi-Wall RingLoc® Size 25	EP-105905
28mm Hi-Wall RingLoc® Size 26	EP-105906
28mm Hi-Wall RingLoc® Size 27	EP-105907
28mm Hi-Wall RingLoc® Size 28	EP-105908
32mm Hi-Wall RingLoc® Size 23	EP-105923
32mm Hi-Wall RingLoc® Size 24	EP-105924
32mm Hi-Wall RingLoc® Size 25	EP-105925
32mm Hi-Wall RingLoc® Size 26	EP-105926
32mm Hi-Wall RingLoc® Size 27	EP-105927
32mm Hi-Wall RingLoc® Size 28	EP-105928

36mm Hi-Wall RingLoc® Size 24	EP-105914
36mm Hi-Wall RingLoc® Size 25	EP-105915
36mm Hi-Wall RingLoc® Size 26	EP-105916
36mm Hi-Wall RingLoc® Size 27	EP-105917
36mm Hi-Wall RingLoc® Size 28	EP-105918
28mm +5mm RingLoc® Size 21	EP-105951
28mm +5mm RingLoc® Size 22	EP-105952
28mm +5mm RingLoc® Size 23	EP-105953
28mm +5mm RingLoc® Size 24	EP-105954
28mm +5mm RingLoc® Size 25	EP-105955
28mm +5mm RingLoc® Size 26	EP-105956
28mm +5mm RingLoc® Size 27	EP-105957
28mm +5mm RingLoc® Size 28	EP-105958
32mm +5mm RingLoc® Size 22	EP-155232
32mm +5mm RingLoc® Size 23	EP-155233
32mm +5mm RingLoc® Size 24	EP-155234
32mm +5mm RingLoc® Size 25	EP-155235
32mm +5mm RingLoc® Size 26	EP-155236
32mm +5mm RingLoc® Size 27	EP-155237
32mm +5mm RingLoc® Size 28	EP-155238
36mm +5mm RingLoc® Size 23	EP-156233
36mm +5mm RingLoc® Size 24	EP-156234
36mm +5mm RingLoc® Size 25	EP-156235
36mm +5mm RingLoc® Size 26	EP-156236
36mm +5mm RingLoc® Size 27	EP-156237
36mm +5mm RingLoc® Size 28	EP-156238
32mm +5mm Hi-Wall RingLoc® Size 22	EP-105780
36mm +5mm Hi-Wall RingLoc® Size 23	EP-105790
38mm Hi-Wall Liner, Size 25	EP-106985
38mm Hi-Wall Liner, Size 26	EP-106986
38mm Hi-Wall Liner, Size 27	EP-106987
38mm Hi-Wall Liner, Size 28	EP-106988
38mm 10 Degree Liner, Size 25	EP-106995
38mm 10 Degree Liner, Size 26	EP-106996
38mm 10 Degree Liner, Size 27	EP-106997
38mm 10 Degree Liner, Size 28	EP-106998
38mm MaxRom Liner, Size 25	EP-106885
38mm MaxRom Liner, Size 26	EP-106886
38mm MaxRom Liner, Size 27	EP-106887

38mm MaxRom Liner, Size 28	EP-106888
38mm (+)5 Hi-Wall Liner, Size 24	EP-195234
38mm (+)5 Hi-Wall Liner, Size 25	EP-195235
38mm (+)5 Hi-Wall Liner, Size 26	EP-195236
38mm (+)5 Hi-Wall Liner, Size 27	EP-195237
38mm (+)5 Hi-Wall Liner, Size 28	EP-195238
38mm (+)5 MaxRom Liner, Size 24	EP-166234
38mm (+)5 MaxRom Liner, Size 25	EP-166235
38mm (+)5 MaxRom Liner, Size 26	EP-166236
38mm (+)5 MaxRom Liner, Size 27	EP-166237
38mm (+)5 MaxRom Liner, Size 28	EP-166238

K090103

28mm Max-Rom™ +3 RingLoc® Size 21	EP-108221
32mm Max-Rom™ +3 RingLoc® Size 22	EP-108222
36mm Max-Rom™ +3 RingLoc® Size 23	EP-108223
38mm Max-Rom™ +3 RingLoc® Size 24	EP-108224
40mm Max-Rom™ +3 RingLoc® Size 24	EP-108424
40mm Max-Rom™ +3 RingLoc® Size 25	EP-108425
40mm Max-Rom™ +3 RingLoc® Size 26	EP-108426
40mm Max-Rom™ +3 RingLoc® Size 27	EP-108427
40mm Max-Rom™ +3 RingLoc® Size 28	EP-108428
28mm Hi-Wall +3 RingLoc® Size 21	EP-108321
32mm Hi-Wall +3 RingLoc® Size 22	EP-108322
36mm Hi-Wall +3 RingLoc® Size 23	EP-108323
38mm Hi-Wall +3 RingLoc® Size 24	EP-108324
40mm Hi-Wall +3 RingLoc® Size 24	EP-108524
40mm Hi-Wall +3 RingLoc® Size 25	EP-108525
40mm Hi-Wall +3 RingLoc® Size 26	EP-108526
40mm Hi-Wall +3 RingLoc® Size 27	EP-108527
40mm Hi-Wall +3 RingLoc® Size 28	EP-108528

Biolox® *delta* Option Ceramic Heads—K082996

Biomet Part Number	Description	CeramTec Part Number
650-1055	Biolox® *delta* Option Ceramic Head 28mm	38.39.7176.335
650-1056	Biolox® *delta* Option Ceramic Head 32mm	38.39.7176.355
650-1057	Biolox® *delta* Option Ceramic Head 36mm	38.39.7176.965
650-1054	Biolox® *delta* Option Ceramic Head 38mm	not assigned
650-1058	Biolox® *delta* Option Ceramic Head 40mm	38.39.7176.795
650-1060	Biolox® *delta* Option 12/14 Sleeve Small	36.49.7500.018.01

650-1061	Biolox® *delta* Option 12/14 Sleeve Medium	36.49.7500.019.01
650-1062	Biolox® *delta* Option 12/14 Sleeve Large	36.49.7500.023.01
650-1063	Biolox® *delta* Option 12/14 Sleeve X-Large	36.49.7500.021.01
650-1064	Biolox® *delta* Option Type I Sleeve X-Small	36.49.7500.053.00
650-1065	Biolox® *delta* Option Type I Sleeve Small	36.49.7500.028.00
650-1066	Biolox® *delta* Option Type I Sleeve Medium	36.49.7500.029.00
650-1067	Biolox® *delta* Option Type I Sleeve Large	36.49.7500.030.00
650-1068	Biolox® *delta* Option Type I Sleeve X-Large	36.49.7500.031.00

Sleeves

650-1060	Biolox® *delta* Option 12/14 Sleeve -3	36.49.7500.018.01
650-1061	Biolox® *delta* Option 12/14 Sleeve 0	36.49.7500.019.01
650-1062	Biolox® *delta* Option 12/14 Sleeve +4	36.49.7500.023.01
650-1063	Biolox® *delta* Option 12/14 Sleeve +7	36.49.7500.021.01
650-1064	Biolox® *delta* Option Type I Sleeve -6	36.49.7500.053.00
650-1066	Biolox® *delta* Option Type I Sleeve 0	36.49.7500.029.00
650-1068	Biolox® *delta* Option Type I Sleeve +6	36.49.7500.031.00

M^2a Magnum ™ System

(Numerous components were cleared in this system, K042037. Only the 44mm M^2a Magnum™ Modular Head is being used as a predicate.)

157444 M^2a Magnum™ Modular Head

M^2a Magnum™ Taper Inserts (Previously Cleared in K042037)

139252	M^2a Magnum 42-50mm Taper Insert -6
139254	M^2a Magnum 42-50mm Taper Insert -3
139256	M^2a Magnum 42-50mm Taper Insert Std
139258	M^2a Magnum 42-50mm Taper Insert +3
139259	M^2a Magnum 42-50mm Taper Insert +6
139261	M^2a Magnum 42-50mm Taper Insert +9

M^2a Magnum™ 12/14 Taper Inserts (Previously Cleared in K061423)

239252	M^2a Magnum 12/14 Taper 42-50 Insert -6
239254	M^2a Magnum 12/14 Taper 42-50 Insert -3
239256	M^2a Magnum 12/14 Taper 42-50 Insert Std
239258	M^2a Magnum 12/14 Taper 42-50 Insert +3
239260	M^2a Magnum 12/14 Taper 42-50 Insert +6
239262	M^2a Magnum 12/14 Taper 42-50 Insert +9

SAMPLE PRINTS

Predicate E-Poly Acetabular Liners

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

Predicate Biolox® *delta* Option Heads

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

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 - 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.

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,

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)

Catherine Brechtl MD

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

510(k) Number K070399 Page 1 of 1

K070399 page 1/2

BIOMET

510(k) Summary

MAY - 4 2007

Preparation Date: February 9, 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.

pge 2/2

BIOMET

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet, Inc.
% Ms. Becky Earl
Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581

FEB 11 2009

Re: K090103
Trade/Device Name: 100kGy E-Poly Acetabular Liners – Additional Profiles: +3 MaxRom™ and +3 Hi-Wall
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: Class II
Product Code: MAY, LZO, LWJ, JDI, LPH
Dated: January 13, 2009
Received: January 15, 2009

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

Sincerely yours,

Mark N. Melkerson

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): K090103 (per 1/1)

Device Name: 100kGy E-Poly™ Acetabular Liners—Additional Profiles: +3 MaxRom™ and +3 Hi-Wall

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 (as based on mating shell)

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 K090103

K090103 (pg 1/2)

BIOMET
MANUFACTURING CORP.

FEB 11 2009

510(k) Summary

Preparation Date: January 13, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl

Proprietary Name: 100 kGy E-Poly™Acetabular Liners- Additional Profiles: +3 MaxRom™ and +3 Hi-Wall

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: K070399, 100 kGy E-Poly™ Acetabular Liners—Additional Profiles.

Device Description: Biomet Manufacturing Corp. is adding new +3 MaxRom™ and +3 Hi-Wall profiles to their line of 100 kGy E-Poly™ Acetabular Liners to allow the surgeon an option for achieving more range of motion and joint stability in smaller patients.

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 materials of the subject components remain identical to its predicate counterpart, with the exception of the additional profiles. 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 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

510(K) Notification
Biomet Manufacturing Corp.
100 kGy E-Poly™ Acetabular Liners- Additional Profiles:
+3 MaxRom™ and +3 Hi-Wall

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 15 2009

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

Dear Ms. Beres:

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

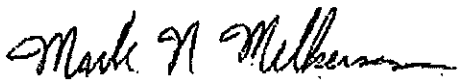
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

Sincerely yours,



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

Enclosure

Indications for Use

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

Device Name: Biolox® *delta* Option 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 K082996

Page 1 of 1

K082996 (pg 1/2)

BIOMET®
MANUFACTURING CORP.

510(k) Summary

Date: December 8, 2008

JAN 15 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Biolox® *delta* Option Ceramic Heads

Common or Usual Name: Ceramic Modular Head

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

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Biolox® *delta* Ceramic Heads – K042091, K051411, K061312, K073102

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

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

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

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

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

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

K082996 (pg 2/2)

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

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

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

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

Clinical Testing: None provided

Biolox is a trademark of CeramTec AG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

Ms. Kacy Arnold, RN, MBA
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K042037
Trade Name: M^{2}a™ Magnum™ System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis
Regulatory Class: III
Product Code: KWA
Dated: July 28, 2004
Received: July 29, 2004

Dear Ms. Arnold:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042037

Device Name: M²a™ Magnum™ Hip System

Indications For Use:

The M²a™ Magnum™ System is indicated for use in patients requiring total hip replacement due to the following:

- Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures and traumatic arthritis.
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
- Revision of previously failed total hip arthroplasty

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

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

510(k) Number K042037

K04 2037

OCT 1 - 2004

BIOMET INC

510(k) Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Kacy Arnold
Regulatory Specialist

Proprietary Name: M^2a™ Magnum™ System

Common Name: Metallic Acetabular Articulation

Classification Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis (888.3330)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The M^2a™ Magnum™ System is substantially equivalent to:

- K011110 M2a™ Acetabular System 38mm *(Biomet)*
- K984028 Bio-Moore Endo Heads *(Biomet)*
- K002106 New Bio-Moore Endo Head, Taper Adapter *(Biomet)*
- K031963 Conserve® Plus Spiked Shell and Conserve® Total 56mm Femoral Head *(Wright Medical)*
- K021249 Metal Transcend® Articulation System (Wright Medical)

Device Description:

The M^2a™ Magnum™ System consists of a CoCrMo monolithic acetabular cup, which articulates with a CoCrMo modular head. The smaller femoral heads, sizes 38mm and 40mm, are a one-piece design with neck length variations ranging from –6mm to +12mm. The larger femoral heads, sizes 42mm to 60mm, are a modular design with neck length variations ranging from -6mm to +9mm, achieved through the use of a titanium adapter assembled with the modular head component at the time of surgery. The femoral heads may be used in conjunction with any of Biomet's commercially available Type I taper femoral component.

Summary of Technologies: The M^2a™ Magnum™ Hip System technological characteristics (material and design) are similar to predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

The acetabular liners and 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 - Product Specs	Indication
Answer® Femoral Component	K991987	JDI		Cemented
Co-Cr Answer® Femoral Components	K931194	JDG[1]		Cemented
Altra Press-Fit Hip Stem (Echo™)	K063002	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY		Uncemented
Altra FX Hip System (Echo™)	K063614	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY		Cemented and non-cemented
APF Femoral Component	K852585 K984154 K030055	JDI JDI LPH		Cemented and non-cemented
Arcos™ Modular Femoral Revision System	K090757	KWA, LPH, JDL, LZO, KWZ, JDI, KWY, MAY, MEH		Uncemented
Balance® Hip System Microplasty® Stems	K050251	KWZ, JDL, KWA, JDI, LZO, MEH, LPH, LZY, KWY		Non-cemented
Bi-Metric® Femoral Components	K921224 K020580 K030055	LZO LPH LPH		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/Fauser Femoral Component	K952686	LZO		Cemented
Color Buffed Cemented Stem	K992903 K012019	JDI JDI		Cemented
Echo B-Metric® Press Fit Stem	K070274	KWA		Non-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 K052639	JDI JDI, LZO, KWZ, MEH, LPH, LZY, KWY, JDG		Cemented
Gross Femoral Component	K001580	MEH		Non-cemented
Impact® Co-Cr Femoral Components	K942027	JDG[2]		Cemented

[1] Submitted under classification 888.3350 JDI
[2] Submitted under classification 888.3350 JDI

Integral® Femoral Component	K921225 K984296 K984408 K030055 K030501 K042029	LZO LPH LPH LPH LPH LPH	(b)(4)Trade Secret Process - Product Specs	Cemented and non-cemented
Integral® Co-Cr Femoral Component	K942479	LZO		Cemented
Interlocking Hip Stems	K990830 K042774	LPH LPH[3]		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
Oncology Salvage System	K002757	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[4] JDI		Cemented
SHP™ Hip System	K960984	JDI		Cemented
Taper2™ Porous Femoral Stem (Taperloc® Microplasty)	K050441 K062994	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH, KWB, LZY, KWY		Non-cemented
Taperloc® Femoral Component	K830313 K921301 K030055 K043537	JDI LPH LPH LPH		Cemented and non-cemented
HA Taperloc® Femoral Component	K020963 K030055	MEH LPH		Non-cemented
Total IM Femur	K033871	JDI		Cemented

[3] 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
[4] Submitted under classification 888.3350 JDI

Total Femur	K974558	JDI	(b)(4)Trade Secret Process - Product	Cemented
XR-Series Bi-Metric Femoral Component	K052089	LPH, JDI, LZO, KWY, KWZ		Cemented and non-cemented

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

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

Acetabular System Name	510(k) number	Product Code	Indications
Flanged Acetabular Component	K983035 K030055	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	
Regenerex™ RingLoc® + Modular Acetabular Shell	K070369	LPH, JDI, JDG, KWZ, LWJ, LZO, MAY, MBL, MEH	Cemented and non-cemented
Ringloc® Bi-Polar Acetabular Components	K051569	KWY, JDI, LPH, LZO, NEH	N/A
Ringloc® Constrained Liner	K021728	KWZ	Indication based on mating shell

RX 90® Low Profile Acetabular Components	K920639 K042989	JDL* LPH, LZO, JDI, KWZ, MEH	Cemented and non-cemented
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 submission were for metal on polyethylene systems (JDI).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

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.

11-11-09

John White
Director of Hip Engineering
Biomet Manufacturing Corp.

Date

Declarations Of Conformity With Design Controls

Manufacturing Facility

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

11Nov'09

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

Date

BIOMET®
MANUFACTURING CORP.

510(k) Summary

Date: November 16, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl
Regulatory Specialist

Proprietary Name: 44mm E1™ Acetabular Liner* with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
(** also known as E-Poly™ Acetabular Liners)*

Common or Usual Name: UHMWPE Liners

Classification Name:

- 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: 100 kGy E-Poly™ Acetabular Liners – K070399 and K090103, Biolox® *delta* Option Ceramic Heads – K082996.

Device Description: Biomet Manufacturing Corp. is adding a size 44mm liner to their line of E1™ Acetabular Liners to allow the surgeon more options. Additionally, the 44mm Biolox® *delta* Option Ceramic Head is added to the ceramic option line. The 44mm M²a Magnum™ may be used when a Co-Cr-Mo option is needed. This submission is a line extension of the previously cleared systems.

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

Indications For Use: The 44mm E1™ Acetabular Liners are 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 Biolox® *delta* Option Ceramic Head 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)

Summary of Technologies: The 44mm E1™ Liner and 44mm Biolox® *delta* Option Ceramic Head 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

Biolox is a trademark of CeramTec AG

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

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

Signature

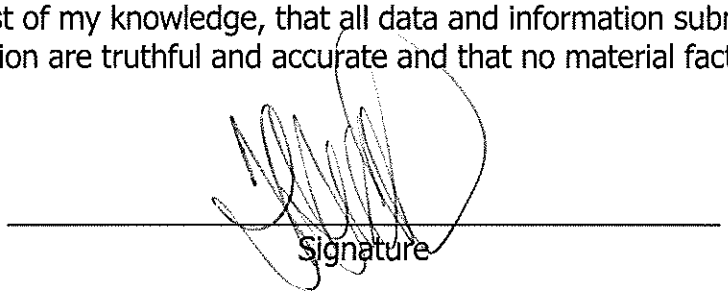
Anthony Siebeneck
Typed Name

11/12/09
Date

44mm E1™ Acetabular Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
Device

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

I certify, in my capacity as Director of Clinical and Regulatory Affairs, Biomet Orthopedics, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Signature

Tracy Bickel Johnson
Typed Name

11/16/09
Date

44mm E1™ Acetabular Liner with 44mm Biolox® *delta* Option Ceramic Head or 44mm M²a Magnum™ Modular Head
Device

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

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

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# List 018, Item 143	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

None

DESCRIPTION

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

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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

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

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

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

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	List 018, # Item 8-137	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
None

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

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

TION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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

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

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

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

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

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# List 017, Item 44	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Is this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   Biomet Manufacturing Corp.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   11-16-09

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   P.O. Box 587
   56 East Bell Drive
   Warsaw, IN 46581

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 574-267-6639
   (Fax) 574-372-1683

PRODUCT INFORMATION

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

   44mm Biolox delta Option Head and E1 Liner

   Ceramic Modular Heads/UHMWPE Liners

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

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

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

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

CERTIFICATION STATEMENT / INFORMATION

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

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

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

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

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

    NCT Number(s):

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
    Becky Earl

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) Becky Earl
    (Title) Regulatory Specialist

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    P.O. Box 587
    56 East Bell Drive
    Warsaw, IN 46581

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 574-267-6639
    (Fax) 574-372-1683

15. DATE OF CERTIFICATION
    Oct 30, 2009

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

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

DJA x00007

To: THE FILE RE: DOCUMENT NUMBER K093549

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.)

   K070399 - 100 kGy E-Poly Acetabular Liners
   K090103 - 100 kGy E-Poly Acetabular Liners
   K082996 – Biolox *delta* Option Ceramic Head
   K042037 - M^2a Magnum Modular Head

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

   The sponsor states on page 3 that the Indications for Use Statement is identical to the predicate with the exception of minor grammatical changes.

   The sponsor also states on page 3 that the indications are identical to those for the Biolox *delta* Option Ceramic Head cleared in K082996. According to the sponsor, specific indications for compatible components that can be used with the Biolox *delta* Option Ceramic Head 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 athrosis. (K974558, K002757, K021380, K033871)

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

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 sponsor states on page 6 that the only modification to the originally cleared 100 kGy E-Poly Acetabular Liners is the additional larger inner diameter, 44 mm.

   The sponsor also states that the only modification to the Biolox *delta* Ceramic Heads is an expansion of the 28mm-40mm head diameter product line to include a 44mm head diameter.

   The previously cleared 44mm M^2a Magnum Modular Head is identical to the predicate (K042037). The only difference is the articulation surface being expanded from metal-on-metal to include metal-on-polyethylene.

   Engineering drawings are provided in Section 3. A list of compatible components is provided in Section 4.

   Comment

   I contacted the sponsor via telephone on 12/14/2009 and asked for confirmation that the list of compatible components is the same as the predicate devices. The sponsor responded via email on 12/14/2009 and confirmed the following:

   - *All the femoral components listed in 4A are correct. The only addition to the predicate submission is the Arcos Revision System, which included the Biolox Delta Option Heads as a compatible component*
   - *With regards to the Acetabular Components, three groups listed should be removed:*

- *Protrusio Cages, K020076*
- *Ringloc Bi-Polar Acetabular Components, K051569*
- *Ringloc Constrained Liner, K021728*

- *Additionally, the Regenerex Augments, K052888, were not previously listed with the Biolox Delta Option Heads, because technically they are only used with shells. However, they have been cleared in previous submissions to be used with the shells listed here.*

- *The Regenerex RingLoc Modular Acetabular Shells was inadvertently not included in the predicate Biolox Delta Option Heads, K082996. These shells, however, listed E-poly liners and Biolox Delta Heads in their compatible component listing.*

In summary, the sponsor states that with the exception of the three listed acetabular component to be removed (Protrusio Cages, Bi-Polar Acetabular Components, and Ring-Loc Constrained Liners), all Compatible Components have been cleared for use with predicate devices.

This is adequate.

The Regenerex Ringloc Modular Acetabular Shells were cleared in K070369

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

The sponsor has provided a device comparison on page 6.

According to the sponsor the following features of the 44mm E1 Acetabular Liners have not changes as previously cleared in K070399 and K090103:

- 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
- Previous liners were cleared for use with either ceramic or CoCrMo heads

The sponsor states that the only modification to the originally cleared 100 kGy E-Poly Acetabular Liners is the additional larger inner diameter, 44 mm.

According to the sponsor, rhe following features of the 44mm Biolox *delta* Option Ceramic head have not changed, as previously described in the predicate device 510(k) K082996:

- Indications statement and intended use are identical to the predicate
- Material, including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity
- Material properties not dependent on component size including flexural strength, hardnessm elastic modulu
- Engraving
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability
- Use of a titanium taper adapter (sleeve)

The sponsor also states that the only modification to the Biolox *delta* Ceramic Heads is an expansion of the 28mm-40mm head diameter product line to include a 44mm head diameter.

The previously cleared 44mm M^{2}a Magnum Modular Head is identical to the predicate (K042037). The only difference is the articulation surface being expanded from metal-on-metal to include metal-on-polyethylene.

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

According to the sponsor, the risk assessment has been conducted in accordance with ISO 14971 to determine the impact of the modifications.

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

The sponsor provided the following design control summary table:

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

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

Comment

The sponsor also provided test reports in this submission. However, they were not reviewed as part of the decision making process. Since this is a special 510(k), the design control summary table was reviewed in order to make a determination of substantial equivalence.

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 signed documents are provided in Section 7.

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).

The Truthful and Accurate Statement, a 510(k) Summary, and the Indications for Use Statement are provided in Section 9, Section 8, and Section 2.

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.

Reviewer — Date 12/16/09

Branch Chief — Date 12/16/09

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

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

5. Explain how descriptive characteristics are not precise enough:

Descriptive characteristics alone are not enough to demonstrate substantial equivalence for this product type. The modifications proposed require adequate pre-clinical testing (e.g., wear testing, disassembly testing, burst strength testing...etc.) to determine substantial equivalence as well as safety and effectiveness.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The sponsor completed testing, as summarized in the Design Controls Activity Summary, to demonstrate substantial equivalence to their own legally marketed predicates. The results met the sponsor's acceptance criteria.

Owens, Michael C (CDRH)

From: Earl, Becky [becky.earl@biomet.com]
Sent: Monday, December 14, 2009 12:54 PM
To: Owens, Michael C (CDRH)
Cc: Johnson, Tracy
Subject: (b)(4)Trade Secret Process [redacted]
Importance: High

Dear Mr. Owens:

In response to our phone call this morning regarding Compatible Components for this submission, a detailed review produced a couple minor changes to our listing:

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

Sincerely,

Becky Earl

Becky Earl | Regulatory Specialist | Biomet Orthopedics, Inc.
☎: 574-267-6639, Ext. 1216 | Fax: 574-372-1683 |
✉: becky.earl@biomet.com

COVER SHEET MEMORANDUM

DJA x00004

From: Reviewer Name Michael Owens

Subject: 510(k) Number K093549

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/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

DJA x00005

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old).			✓
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
21 CFR 888.3353	II	LZO

(If unclassified, see 510(k) Staff)

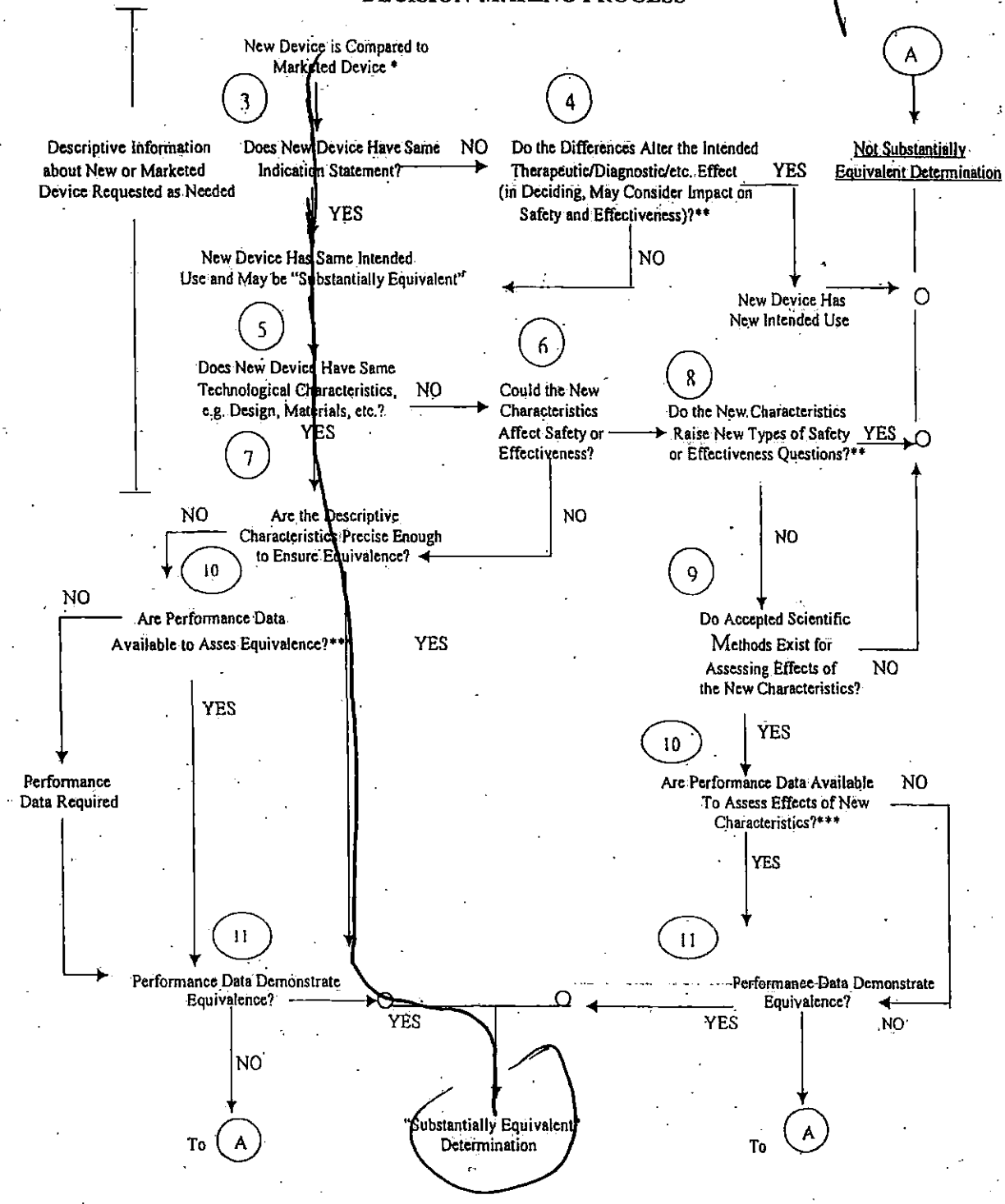
Additional Product Codes: LPH, JDE, LWS, MAY

Review: _____ (Branch Chief) OTDB (Branch Code) 12/15/09 (Date)

Final Review: _____ (Division Director) 12/15/09 (Date)

JG

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



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

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

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