K061312

JUN - 6 2006

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

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

Common or Usual Name: Ceramic Modular Head

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

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

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

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

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

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

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

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574.267.8137

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biomet@biomet.com

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

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

Non-Clinical Testing: All parameters of the "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" were 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

JUN - 6 2006

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

Re: K061312
Trade/Device Name: 36mm Biolox® *delta* Ceramic Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: May 9, 2006
Received: May 10, 2006

Dear Ms. Beres:

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

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

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

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K061312

Device Name: 36mm Biolox® *delta* Ceramic Heads

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

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2) Rheumatoid arthritis
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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 K061312

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Biomet Manufacturing Corp.
c/o Ms. Patricia Sandborn Beres,
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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.
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Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K061312

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(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 K061312

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

May 11, 2006

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

510(k) Number: K061312
Received: 10-MAY-2006
Product: 36MM BIOLOX DELTA CERAMIC HEADS

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

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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

BIOMET

May 9, 2006

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

Reference: "Special" 510(k) – An electronic copy of this submission is included.
36mm Biolox® *delta* Ceramic Heads
User Fee ID: (b)(4)Trade Secret [redacted]
P

Dear Sir or Madam:

Enclosed is a "**Special" 510(k): Device Modifications** submission for 36mm Biolox® *delta* Ceramic Heads which is a modification of the Biolox® *delta* Ceramic Heads cleared in 510(k) K042091. The modification to this device is a larger diameter, 36mm. We believe this device is substantially equivalent* to cleared devices and warrants a "Special" 510(k).

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

Sincerely,

Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.

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

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Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. 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. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

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

BIOMET INC
P.O. Box 587
Warsaw IN 46581-0587
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)

2. CONTACT NAME
Patricia Beres

2.1 E-MAIL ADDRESS
patty.beres@biometmail.com

2.2 TELEPHONE NUMBER (include Area code)
574-267-6693 1278

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 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. 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, parents, and partner firms
[ ] This biologics application is submitted under secion 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

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4)Trade Secret
27-Feb-2006

Form FDA 3601 (08/2003)

Close Window

Device Name	**Device Trade Name:** 36mm Biolox® *delta* Ceramic Heads **Common Name:** Ceramic Modular Heads
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 [redacted] **Sterilization Site:** [redacted]
Contact Information	**Name:** Patricia Sandborn Beres **Title:** Senior Regulatory Specialist **Address:** Biomet Manufacturing Corp. P.O. Box 587 Warsaw, IN 46581-0587 **Telephone:** 574-267-6639 **Fax:** 574-372-1683 **E-mail:** patty.beres@biometmail.com
Device Classification	**Class:** II **Product Code**: LZO **Classification Names**: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Common Name. The guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" was followed for the preparation of the predicate Biolox® *delta* Ceramic Heads 510(k) K042091. Only those portions which are affected by the modifications required to create the new device will be addressed in this document.
Predicate Device Information	The predicate devices are the Biolox® *delta* Ceramic Heads cleared through 510(k) K042091, March 25, 2005 and K051411, 6/29/05.

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. No changes have been made to the instructions for use.

Indications for Use

The 36mm Biolox® *delta* Ceramic Heads are intended for total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
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Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)

These are the same intended use as previously cleared for the Biolox® *delta* Ceramic Heads (K042091).

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

No specific surgical technique exists for these devices. The surgical technique is based on the femoral and/or acetabular component selected to use with the 36mm Biolox® *delta* Ceramic Heads.

Sterilization and Packaging

Devices are provided sterile by radiation methods as follows:

1. Radiation Type: Gamma
   Radiation Source: (b)(4)Trade [redacted]
   Minimum Dosage: 25 kGy
   Maximum Dosage: 40 kGy
2. Sterility Assurance Level: 10^{-6}
3. Sterility Validation Method: (b)(4)Trade Secret Process [redacted]
4. Pyrogen-Free: no claims will be made
5. Packaging: Each component is placed within a plastic bag between two foam pads. They are then placed in an inner blister pack sealed with a Tyvek® lid which fits into an outer blister pack also sealed with a Tyvek® lid. The entire unit is placed in a cardboard box, shrink wrapped for protection. All labeling will be on the outer Tyvek® lid as well as on the outer cardboard box.
6. Labeling: All packages will display a yellow to red chemical indication dot along with a statement that the device has been sterilized by gamma irradiation, 25 kGy
7. Expiration Date: The 36mm Biolox® *delta* Ceramic Heads 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 36mm Biolox® *delta* Ceramic Heads is as follows:

Sizes

- 36mm [redacted] head diameter
- Neck lengths of -3, 0, +3 and +6mm

Material

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

Specific Characteristics

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

Product Listing/Drawings

- The name and manufacturers model number for each 36mm Biolox® *delta* Ceramic Head may be found in Attachment 3.
- Dimensioned engineering drawings of the 36mm Biolox® *delta* Ceramic Heads may be found in Attachment 3.
- A product listing and engineering drawings of the predicate Biolox® *delta* Ceramic Heads cleared through 510(k) K042091 may also be found in Attachment 3.

Compatible Products

- Attachment 4 contains a table of compatible hip stems for use with the 36mm Biolox® *delta* Ceramic Heads.
- All of the devices are metallic hip stems with or without porous coating.
- Each stem has a Biomet Type I trunion (standard or reduced) for attachment of the modular head. In lieu of a drawing of each hip stem, detailed drawings of the two types of taper trunions are provided in Attachment 4.
- (b)(4)Trade Secret Process [redacted].
- Attachment 4 also contains a list of the compatible acetabular components that may be used with this device.

Device Comparison

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

- Cone design of mating stems
- Material including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity.
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- (b)(4)Trade [redacted]
- Neck lengths
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability

The only modification that was made is expansion of the cleared 28mm and 32mm head diameter product line to include a 36mm head diameter. One of the potential benefits of a large head diameter is an increased range of motion. A 32mm head has a (b)(4)Trade Secret Process [redacted] whereas the 36mm heads has a (b)(4)Trade Secret Process [redacted] Additionally, cobalt alloy modular heads with a 36mm diameter have previously been cleared by the FDA (i.e. K032396 – RingLoc® 36mm Liners and Modular Femoral Heads).

Bench/Animal Testing

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

All testing was conducted in keeping with the FDA guidance document "Guidance Document for the Preparation of PreMarket

Notifications for Ceramic Ball Hip Systems".

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

Static Compression

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

Fatigue Testing

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

Axial Pull-Off

Axial pull-off testing for Biolox® *delta* Ceramic Heads is contained in Attachment 7. (b)(4)Trade Secret Process [redacted]

Wear

The predicate Biolox® *delta* Ceramic Heads have demonstrated superior wear properties as compared to cobalt alloy modular heads. Attachment 8 contains a justification for not conducting additional wear testing for these components.

Substantial Equivalence

The modified device have the following similarities to the Biolox® *delta* Ceramic Heads which previously received 510(k) concurrence (K042091):

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

	In summary, the 36mm Biolox® *delta* Ceramic Heads described in this submission are, in our opinion, substantially equivalent to the predicate device.
Summary of Design Control Activities	The risk assessment has been conducted in accordance with ISO 14971 to determine the impact of the modifications. A discussion of the risks identified is presented in Attachment 9. A declaration of conformity with design control is included in Attachment 10. Evidence of design transfer, as specified in QSR § 820.30(h), is found in Biomet SOP 4.1.7 under QM 4.1. "Final design transfer is conducted upon completion of the final design review pursuant to SOP 4.1.4 Design Review to ensure all transfer activities have been completed." The final design review and the design history file (DHF) have been completed for this project.
510(k) Summary	A 510(k) Summary for the 36mm Biolox® *delta* Ceramic Heads is included in Attachment 11.
Truthful and Accuracy Certification	A certification of the truthfulness and accuracy of the information presented in this submission is provided in Attachment 12.

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

REF. 12-115120 LOT 123123

BIOLOX-DELTA® MODULAR CERAMIC HEAD

36MM HEAD DIAMETER

MINUS 3 NECK TYPE I TAPER

ALUMINA / ZIRCONIA

FOR USE W/TYPE I TAPERS ONLY

Biolox is a registered trademark of CeramTec AG

LOT 123123 QTY. 1

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

STERILE R

2006-04

EXPIRY DATE:
2016-04

Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-0941
Date: 04/06

Biomet® TTPA Ceramic Modular Head Hip Joint Prostheses

Attention Operating Surgeon

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

MATERIALS
TTPA Ceramic

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

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

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

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

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

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

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

PRECAUTIONS

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

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

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

POSSIBLE ADVERSE EFFECTS

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

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

STERILITY

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

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

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

Indications for Use

510(k) Number (if known):_____

Device Name: 36mm Biolox® *delta* Ceramic Heads

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

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

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

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

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

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Modified Component Listing

Biomet

Part Number	Description
12-115120	36mm Biolox® *delta* Ceramic Head, -3
12-115121	36mm Biolox® *delta* Ceramic Head, Std
12-115122	36mm Biolox® *delta* Ceramic Head, +3
12-115123	36mm Biolox® *delta* Ceramic Head, +6

(b)(4)Trade Secret Process

[redacted]

(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 Component Listing – K042091

(b)(4)Trade Secret Process

[redacted]

Biomet

Part Number	Description
12-115109	28mm Biolox® *delta* Ceramic Head, -3
12-115110	28mm Biolox® *delta* Ceramic Head, Std
12-115111	28mm Biolox® *delta* Ceramic Head, +3
12-115112	28mm Biolox® *delta* Ceramic Head, +5
12-115114	32mm Biolox® *delta* Ceramic Head, -3
12-115115	32mm Biolox® *delta* Ceramic Head, Std
12-115116	32mm Biolox® *delta* Ceramic Head, +3
12-115117	32mm Biolox® *delta* Ceramic Head, +6

(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

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

Femoral Component Name	510(k) Number	Product Code	(b)(4)Trade Secret Process	Indication
Answer® Femoral Component	K991987	JDI	[redacted]	Cemented
Co-Cr Answer® Femoral Components	K931194	JDG[1]	[redacted]	Cemented
APF Femoral Component	K852585 K984154 K030055	JDI JDI LPH	[redacted]	Cemented and non-cemented
Balance® Hip System Microplasty® Stems	K050251	KWZ, JDL, KWA, JDI, LZO, MEH, LPH, LZY, KWY	[redacted]	Non-cemented
Bi-Metric® Femoral Components	K921224 K020580 K030055 K052089[2]	LZO LPH LPH LPH, JDI, LZO, KWY, KWZ	[redacted]	Cemented and non-cemented
Bi-Metric® Head/Neck Replacement	K955350 K992058 K983710	LZO JDI JDI	[redacted]	Cemented
HA Bi-Metric® Femoral Component	K023409 K030055	LPH LPH	[redacted]	Non-cemented
Bio-Groove® HAP Hip Components	K912369 K912370	MEH MEH	[redacted]	Non-cemented
Bohn Femoral Component	K000262	LZO, MEH	[redacted]	Non-cemented
Buchalter/Fauser Femoral Component	K952686	LZO	[redacted]	Cemented
Color Buffed Cemented Stem	K992903 K012019	JDI JDI	[redacted]	Cemented
Fenning (Osteocap RS®) Femoral Component	K960303	LPH	[redacted]	Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO	[redacted]	Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734[2]	JDI	[redacted]	Cemented
Gross Femoral Component	K001580	MEH	[redacted]	Non-cemented
Impact® Co-Cr Femoral Components	K942027	JDG[3]	[redacted]	Cemented
Integral® Femoral Component	K921225 K984296 K984408 K030055 K030501 K042029	LZO LPH LPH LPH LPH LPH	[redacted]	Cemented and non-cemented
Integral® Co-Cr Femoral Component	K942479	LZO	[redacted]	Cemented
Interlocking Hip Stems	K990830 K042774	LPH LPH[4]	[redacted]	Non-cemented

[1] Submitted under classification 888.3350 JDI
[2] Reduced Taper Stem
[3] Submitted under classification 888.3350 JDI
[4] 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

Mallory/Head® Total Hip System	K921181 K994007 K000538 K003429 K030055	LZO JDI LPH LPH LPH	(b)(4)Trade Secret Process	Cemented and non-cemented
HA Mallory/Head® Total Hip System	K021403 K030055	LPH, MEH LPH, MEH		Non-cemented
Mallory/Head® Co-Cr Femoral Component	K911684	JDI		Cemented
Mallory/Head® Calcar Femoral Components (including HA)	K945115 K001660 K031693	LPH, LZO LPH LPH		Cemented and non-cemented
Medallion Hip	K041850	LPH		Uncemented
Modular Hip Stems	K912712 K921274 K030055	JDI LPH LPH		Cemented and non-cemented
Orthopedic Salvage System (OSS)	K002757 K052685	JDI JDI		Cemented
OSS™ Les Proximal Femoral Component	K021380	JDI, LPH		Cemented and non-cemented
PMI® Femoral Component	K911802 K923452 K030055	JDI LPH LPH		Cemented and non-cemented
HA PMI® Femoral Stem	K030048	LPH		Non-cemented
Portrait™ Femoral Component	K010560	LZO		Non-cemented
Reach® Femoral Component	K971824 K982367 K000760	LPH LPH LPH		Non-cemented
Modular Reach®	K994038	LPH		Non-cemented
HA Modular Reach®	K022463 K030055	LPH LPH		Non-cemented
Rx-90® Femoral Stems	K942028 K023085	JDG[5] JDI		Cemented
SHP™ Hip System	K960984	JDI		Cemented
Taper2™ Porous Femoral Stem	K050441	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH, KWB, LZY, KWY		Non-cemented
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
Total Femur	K974558	JDI		Cemented

[5] Submitted under classification 888.3350 JDI

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

Acetabular System Name	510(k) number	Product Code	Indications
A-B Acetabular System	K954417 K030055	JDI, LPH LPH	Cemented and non-cemented
ARCOM® Ringloc® Liners	K032396	JDI, LPH	Cemented and non-cemented
ARCOM XL™ Polyethylene Liners	K042051 K051411 K052255	JDI, LPH LZO LPH, LZO, JDI, KWZ, MEH	Cemented and non-cemented
Bio-Clad™ All-Poly	K926107	LPH	Cemented
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
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 submissions were for metal on polyethylene systems (JDI).

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

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Appendix A

Biomet Mechanical Test Request Form

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

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

Appendix B

Metcut Research Inc. Test Report

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

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Appendix C

Drawing

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

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

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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.

Troy Hershberger
Director of Product Development
Biomet Manufacturing Corp.

4/26/06
Date

Manufacturing Facility

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

Rex A. White
Director of Compliance
Biomet Manufacturing Corp.

1 May '06
Date

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

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

Common or Usual Name: Ceramic Modular Head

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

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

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

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

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

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

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

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Warsaw, IN 46581-0587

SHIPPING ADDRESS
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Warsaw, IN 46582

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574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

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

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

Non-Clinical Testing: All parameters of the "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" were meet 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))

36mm Biolox® *delta* Ceramic Heads

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

Robert E. Durgin

8 MAY 06
Date

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

Aaron Smith

4/26/06
Date

K061312 / OR. / DG RND

BIOMET

May 9, 2006

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

Reference: "Special" 510(k) – An electronic copy of this submission is included.
36mm Biolox® *delta* Ceramic Heads
User Fee ID: (b)(4)Trade Secret [redacted]3

Dear Sir or Madam:

Enclosed is a **"Special" 510(k): Device Modifications** submission for 36mm Biolox® *delta* Ceramic Heads which is a modification of the Biolox® *delta* Ceramic Heads cleared in 510(k) K042091. The modification to this device is a larger diameter, 36mm. We believe this device is substantially equivalent* to cleared devices and warrants a "Special" 510(k).

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

Sincerely,

Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.

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

K4

CLASS II
OR.

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Compatible Acetabular Component Listing

Attachment 5
Verification and Validation Protocol - Mechanical Testing of 36mm Biolox® *delta* Heads

Attachment 6
Verification and/or Validation Report - Component Testing of Biolox® *delta* Heads

Attachment 7
Taper Pulloff Test of 32mm TTPA Heads

Attachment 8
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Attachment 9
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Attachment 12
Truth and Accuracy Statements

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. 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 [redacted]3
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

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

BIOMET INC
P.O. Box 587
Warsaw IN 46581-0587
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b) [redacted]

2. CONTACT NAME
Patricia Beres

2.1 E-MAIL ADDRESS
patty.beres@biometmail.com

2.2 TELEPHONE NUMBER (include Area code)
574-267-6693 1278

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 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. 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, parents, and partner firms
[ ] This biologics application is submitted under secion 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

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b) [redacted]0
27-Feb-2006

Form FDA 8601 (08/2003)

Close Window

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K06:312-/0

Device Name	**Device Trade Name:** 36mm Biolox® *delta* Ceramic Heads **Common Name:** Ceramic Modular Heads
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 [redacted] **Sterilization Site:**
Contact Information	**Name:** Patricia Sandborn Beres **Title:** Senior Regulatory Specialist **Address:** Biomet Manufacturing Corp. P.O. Box 587 Warsaw, IN 46581-0587 **Telephone:** 574-267-6639 **Fax:** 574-372-1683 **E-mail:** patty.beres@biometmail.com
Device Classification	**Class:** II **Product Code**: LZO **Classification Names**: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Common Name. The guidance document "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" was followed for the preparation of the predicate Biolox® *delta* Ceramic Heads 510(k) K042091. Only those portions which are affected by the modifications required to create the new device will be addressed in this document.
Predicate Device Information	The predicate devices are the Biolox® *delta* Ceramic Heads cleared through 510(k) K042091, March 25, 2005 and K051411, 6/29/05.

2

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. No changes have been made to the instructions for use.

Indications for Use

The 36mm Biolox® *delta* Ceramic Heads are intended for total hip replacement with cemented or non-cemented femoral and acetabular components in cases of:

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

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)

These are the same intended use as previously cleared for the Biolox® *delta* Ceramic Heads (K042091).

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

No specific surgical technique exists for these devices. The surgical technique is based on the femoral and/or acetabular component selected to use with the 36mm Biolox® *delta* Ceramic Heads.

Sterilization and Packaging

Devices are provided sterile by radiation methods as follows:

1. Radiation Type: Gamma
   Radiation Source: (b)(4)Trade [redacted]
   Minimum Dosage: 25 kGy
   Maximum Dosage: 40 kGy
2. Sterility Assurance Level: 10^{-6}
3. Sterility Validation Method: (b)(4)Trade Secret Process [redacted]
4. Pyrogen-Free: no claims will be made
5. Packaging: Each component is placed within a plastic bag between two foam pads. They are then placed in an inner blister pack sealed with a Tyvek® lid which fits into an outer blister pack also sealed with a Tyvek® lid. The entire unit is placed in a cardboard box, shrink wrapped for protection. All labeling will be on the outer Tyvek® lid as well as on the outer cardboard box.
6. Labeling: All packages will display a yellow to red chemical indication dot along with a statement that the device has been sterilized by gamma irradiation, 25 kGy
7. Expiration Date: The 36mm Biolox® *delta* Ceramic Heads 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 36mm Biolox® *delta* Ceramic Heads is as follows:

Sizes

- 36mm (b)(4)Trad [redacted] head diameter
- Neck lengths of -3, 0, +3 and +6mm

Material

- Transition-Toughened-Platelet Alumina (TTPA)
- [redacted]% (b)(4)Trade Secret Process [redacted] [redacted]% [redacted]

Specific Characteristics

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

Product Listing/Drawings

- The name and manufacturers model number for each 36mm Biolox® *delta* Ceramic Head may be found in Attachment 3.
- Dimensioned engineering drawings of the 36mm Biolox® *delta* Ceramic Heads may be found in Attachment 3.
- A product listing and engineering drawings of the predicate Biolox® *delta* Ceramic Heads cleared through 510(k) K042091 may also be found in Attachment 3.

Compatible Products

- Attachment 4 contains a table of compatible hip stems for use with the 36mm Biolox® *delta* Ceramic Heads.
- All of the devices are metallic hip stems with or without porous coating.
- Each stem has a Biomet Type I trunion (standard or reduced) for attachment of the modular head. In lieu of a drawing of each hip stem, detailed drawings of the two types of taper trunions are provided in Attachment 4.
- [redacted] (b)(4)Trade Secr
- Attachment 4 also contains a list of the compatible acetabular components that may be used with this device.

Device Comparison

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

- Cone design of mating stems
- Material including composition, purity, trace elements, phase content, grain size, specific gravity, and microporosity.
- Material properties not dependent on component size including flexural strength, hardness, elastic modulus
- Engraving
- (b)(4)Trade Secret
- Neck lengths
- Surface roughness
- Sphericity
- Allowable defects
- Hydrothermal stability

The only modification that was made is expansion of the cleared 28mm and 32mm head diameter product line to include a 36mm head diameter. One of the potential benefits of a large head diameter is an increased range of motion. A 32mm head has a (b)(4)Trade Secret Process [redacted] whereas the 36mm heads has a (b)(4)Trade Secret Process [redacted]. Additionally, cobalt alloy modular heads with a 36mm diameter have previously been cleared by the FDA (i.e. K032396 – RingLoc® 36mm Liners and Modular Femoral Heads).

Bench/Animal Testing

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

All testing was conducted in keeping with the FDA guidance document "Guidance Document for the Preparation of PreMarket

Notifications for Ceramic Ball Hip Systems".

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

Static Compression

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

Fatigue Testing

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

Axial Pull-Off

Axial pull-off testing for Biolox® *delta* Ceramic Heads is contained in Attachment 7. (b)(4)Trade Secret Process [redacted]

Wear

The predicate Biolox® *delta* Ceramic Heads have demonstrated superior wear properties as compared to cobalt alloy modular heads. Attachment 8 contains a justification for not conducting additional wear testing for these components.

Substantial Equivalence

The modified device have the following similarities to the Biolox® *delta* Ceramic Heads which previously received 510(k) concurrence (K042091):

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

	In summary, the 36mm Biolox® *delta* Ceramic Heads described in this submission are, in our opinion, substantially equivalent to the predicate device.
Summary of Design Control Activities	The risk assessment has been conducted in accordance with ISO 14971 to determine the impact of the modifications. A discussion of the risks identified is presented in Attachment 9. A declaration of conformity with design control is included in Attachment 10. Evidence of design transfer, as specified in QSR § 820.30(h), is found in Biomet SOP 4.1.7 under QM 4.1. "Final design transfer is conducted upon completion of the final design review pursuant to SOP 4.1.4 Design Review to ensure all transfer activities have been completed." The final design review and the design history file (DHF) have been completed for this project.
510(k) Summary	A 510(k) Summary for the 36mm Biolox® *delta* Ceramic Heads is included in Attachment 11.
Truthful and Accuracy Certification	A certification of the truthfulness and accuracy of the information presented in this submission is provided in Attachment 12.

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

REF. 12-115120 LOT 123123

BIOLOX-DELTA® MODULAR CERAMIC HEAD

36MM HEAD DIAMETER

MINUS 3 NECK TYPE I TAPER

ALUMINA / ZIRCONIA

FOR USE W/TYPE I TAPERS ONLY

Biolox is a registered trademark of CeramTec AG

LOT 123123 QTY. 1

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

STERILE R

2006-04

EXPIRY DATE:
2016-04

Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-0941
Date: 04/06

Biomet® TTPA Ceramic Modular Head Hip Joint Prostheses

Attention Operating Surgeon

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

MATERIALS
TTPA Ceramic

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

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

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

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

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

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

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

PRECAUTIONS

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

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

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

POSSIBLE ADVERSE EFFECTS

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

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

STERILITY

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

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

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

Indications for Use

510(k) Number (if known):_____

Device Name: 36mm Biolox® *delta* Ceramic Heads

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

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

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

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

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

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Modified Component Listing

(b)(4)Trade Secret Process

[redacted]

Biomet Part Number	Description
12-115120	36mm Biolox® *delta* Ceramic Head, -3
12-115121	36mm Biolox® *delta* Ceramic Head, Std
12-115122	36mm Biolox® *delta* Ceramic Head, +3
12-115123	36mm Biolox® *delta* Ceramic Head, +6

(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 Component Listing – K042091

Biomet Part Number	Description	(b)(4)Trade Secret Process
12-115109	28mm Biolox® *delta* Ceramic Head, -3	[redacted]
12-115110	28mm Biolox® *delta* Ceramic Head, Std	
12-115111	28mm Biolox® *delta* Ceramic Head, +3	
12-115112	28mm Biolox® *delta* Ceramic Head, +5	
12-115114	32mm Biolox® *delta* Ceramic Head, -3	
12-115115	32mm Biolox® *delta* Ceramic Head, Std	
12-115116	32mm Biolox® *delta* Ceramic Head, +3	
12-115117	32mm Biolox® *delta* Ceramic Head, +6	

(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

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

Femoral Component Name	510(k) Number	Product Code	(b)(4)Trade Secret Process	Indication
Answer® Femoral Component	K991987	JDI		Cemented
Co-Cr Answer® Femoral Components	K931194	JDG[1]		Cemented
APF Femoral Component	K852585 K984154 K030055	JDI JDI LPH		Cemented and non-cemented
Balance® Hip System Microplasty® Stems	K050251	KWZ, JDL, KWA, JDI, LZO, MEH, LPH, LZY, KWY		Non-cemented
Bi-Metric® Femoral Components	K921224 K020580 K030055 K052089[2]	LZO LPH LPH LPH, JDI, LZO, KWY, KWZ		Cemented and non-cemented
Bi-Metric® Head/Neck Replacement	K955350 K992058 K983710	LZO JDI JDI		Cemented
HA Bi-Metric® Femoral Component	K023409 K030055	LPH LPH		Non-cemented
Bio-Groove® HAP Hip Components	K912369 K912370	MEH MEH		Non-cemented
Bohn Femoral Component	K000262	LZO, MEH		Non-cemented
Buchalter/Fauser Femoral Component	K952686	LZO		Cemented
Color Buffed Cemented Stem	K992903 K012019	JDI JDI		Cemented
Fenning (Osteocap RS®) Femoral Component	K960303	LPH		Non-cemented
Fine Grain Cast Cobalt Chromium Hip	K953925	LZO		Cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734[2]	JDI		Cemented
Gross Femoral Component	K001580	MEH		Non-cemented
Impact® Co-Cr Femoral Components	K942027	JDG[3]		Cemented
Integral® Femoral Component	K921225 K984296 K984408 K030055 K030501 K042029	LZO LPH LPH LPH LPH LPH		Cemented and non-cemented
Integral® Co-Cr Femoral Component	K942479	LZO		Cemented
Interlocking Hip Stems	K990830 K042774	LPH LPH[4]		Non-cemented

[1] Submitted under classification 888.3350 JDI
[2] Reduced Taper Stem
[3] Submitted under classification 888.3350 JDI
[4] 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

Mallory/Head® Total Hip System	K921181 K994007 K000538 K003429 K030055	LZO JDI LPH LPH LPH	(b)(4)Trade Secret Process	Cemented and non-cemented
HA Mallory/Head® Total Hip System	K021403 K030055	LPH, MEH LPH, MEH		Non-cemented
Mallory/Head® Co-Cr Femoral Component	K911684	JDI		Cemented
Mallory/Head® Calcar Femoral Components (including HA)	K945115 K001660 K031693	LPH, LZO LPH LPH		Cemented and non-cemented
Medallion Hip	K041850	LPH		Uncemented
Modular Hip Stems	K912712 K921274 K030055	JDI LPH LPH		Cemented and non-cemented
Orthopedic Salvage System (OSS)	K002757 K052685	JDI JDI		Cemented
OSS™ Les Proximal Femoral Component	K021380	JDI, LPH		Cemented and non-cemented
PMI® Femoral Component	K911802 K923452 K030055	JDI LPH LPH		Cemented and non-cemented
HA PMI® Femoral Stem	K030048	LPH		Non-cemented
Portrait™ Femoral Component	K010560	LZO		Non-cemented
Reach® Femoral Component	K971824 K982367 K000760	LPH LPH LPH		Non-cemented
Modular Reach®	K994038	LPH		Non-cemented
HA Modular Reach®	K022463 K030055	LPH LPH		Non-cemented
Rx-90® Femoral Stems	K942028 K023085	JDG[5] JDI		Cemented
SHP™ Hip System	K960984	JDI		Cemented
Taper2™ Porous Femoral Stem	K050441	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH, KWB, LZY, KWY		Non-cemented
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
Total Femur	K974558	JDI		Cemented

[5] Submitted under classification 888.3350 JDI

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

Acetabular System Name	510(k) number	Product Code	Indications
A-B Acetabular System	K954417 K030055	JDI, LPH LPH	Cemented and non-cemented
ARCOM® Ringloc® Liners	K032396	JDI, LPH	Cemented and non-cemented
ARCOM XL™ Polyethylene Liners	K042051 K051411 K052255	JDI, LPH LZO LPH, LZO, JDI, KWZ, MEH	Cemented and non-cemented
Bio-Clad™ All-Poly	K926107	LPH	Cemented
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
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 submissions were for metal on polyethylene systems (JDI).

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

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

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Appendix A

Biomet Mechanical Test Request Form

(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

Appendix C

Drawing

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

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

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

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

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

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

Declarations Of Conformity With Design Controls

Verification Activities

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

Troy Hershberger
Director of Product Development
Biomet Manufacturing Corp.

4/26/06
Date

Manufacturing Facility

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

Rex A. White
Director of Compliance
Biomet Manufacturing Corp.

1 May '06
Date

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BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

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

Common or Usual Name: Ceramic Modular Head

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

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

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

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

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

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

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

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

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE 574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL biomet@biomet.com

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

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

Non-Clinical Testing: All parameters of the "Guidance Document for the Preparation of PreMarket Notifications for Ceramic Ball Hip Systems" were meet 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))

36mm Biolox® *delta* Ceramic Heads

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

Robert E. Durgin

8 MAY 06
Date

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

Aaron Smith

4/26/06
Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number K061312

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

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

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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

NA ☒ The required certification and summary for class III devices

☑ The indication for use form

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

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: LZO, 888.3353, II

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

Review: [signature] (Branch Chief) 0503 (Branch Code) 6-5-06 (Date)

Final Review: _____ (Division Director) (Date)

Revised:4/2/03

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: K061312	**RE:** 36mm Biolox *delta* Ceramic Heads	**Sponsor:** Biomet, Inc
Procode: LZO	**Predicates:** K042091, K051411, K032396	**Classification:** Class II; 888.3353

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(s) of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
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.
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**.

   These changes are for a design modification to the currently available Biolox *delta* Ceramic Heads, which consists of adding a larger diameter 36mm head. The predicates are available in diameters of 28mm and 32mm.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics (geometry, materials, etc.), method of fixation, sterilization, static burst strength (ultimate compressive strength), fatigue strength, post-fatigue burst strength, axial pull-off strength, and wear properties.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
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 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.

Peter G. Allen
(Reviewer's Signature)

June 1, 2006
(Date)

Comments: These are standard (b) [redacted] 36mm Biolox *delta* heads that have been cleared for use with numerous competitors' hip systems. They incorporate the standard Biomet Type I taper bore and come in neck lengths of -3mm, 0mm, +3mm, and +6mm. The

material is identical to the predicate 28mm and 32mm Biolox *delta* heads cleared for use with Biomet hip systems. Biomet also has 36mm CoCr heads cleared for use through K032396 – Ringloc 36mm Liners and Modular Femoral Heads. The 36mm heads give a (b)(4)Trade Secret Process [redacted] requirement). A rationale was provided as to why axial pull-off and wear testing of the predicates was sufficient to characterize these properties of the subject components. No matter what the outer diameter of the head is, (b)(4)Trade Secret Process [redacted] strength, testing of (b)(4)Trade Secret Process [redacted], provided in Attachment 7, is applicable. The predicate 32mm Biolox *delta* Ceramic Heads have demonstrated superior wear characteristics as compared to 32mm CoCr heads (Attachment 8), therefore it is expected that the 36mm Biolox delta Ceramic Heads will also perform as well or better than the 36mm CoCr heads. These rationales are acceptable.

Internal Administrative Form

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

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

510(k) Number: K061312

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

☒ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

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

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

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

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

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

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

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

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

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

Passed Screening ✓ Yes ___ No

Reviewer: Peter Allen

Concurrence by Review Branch: ___

Date: 6/1/06

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

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 061312

Reviewer: Peter Allen

Division/Branch: DGRND/OJDB

Device Name: 36 mm Biolox delta Ceramic Heads

Product To Which Compared (510(K) Number If Known): K042091, K051411

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation. Questions 4, 6, and 8 are not applicable. See checklist above.

1. Intended Use: See menu, Indications page, or 510k Summary.

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

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough: Burst testing is required for Ceramic Femoral Heads

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

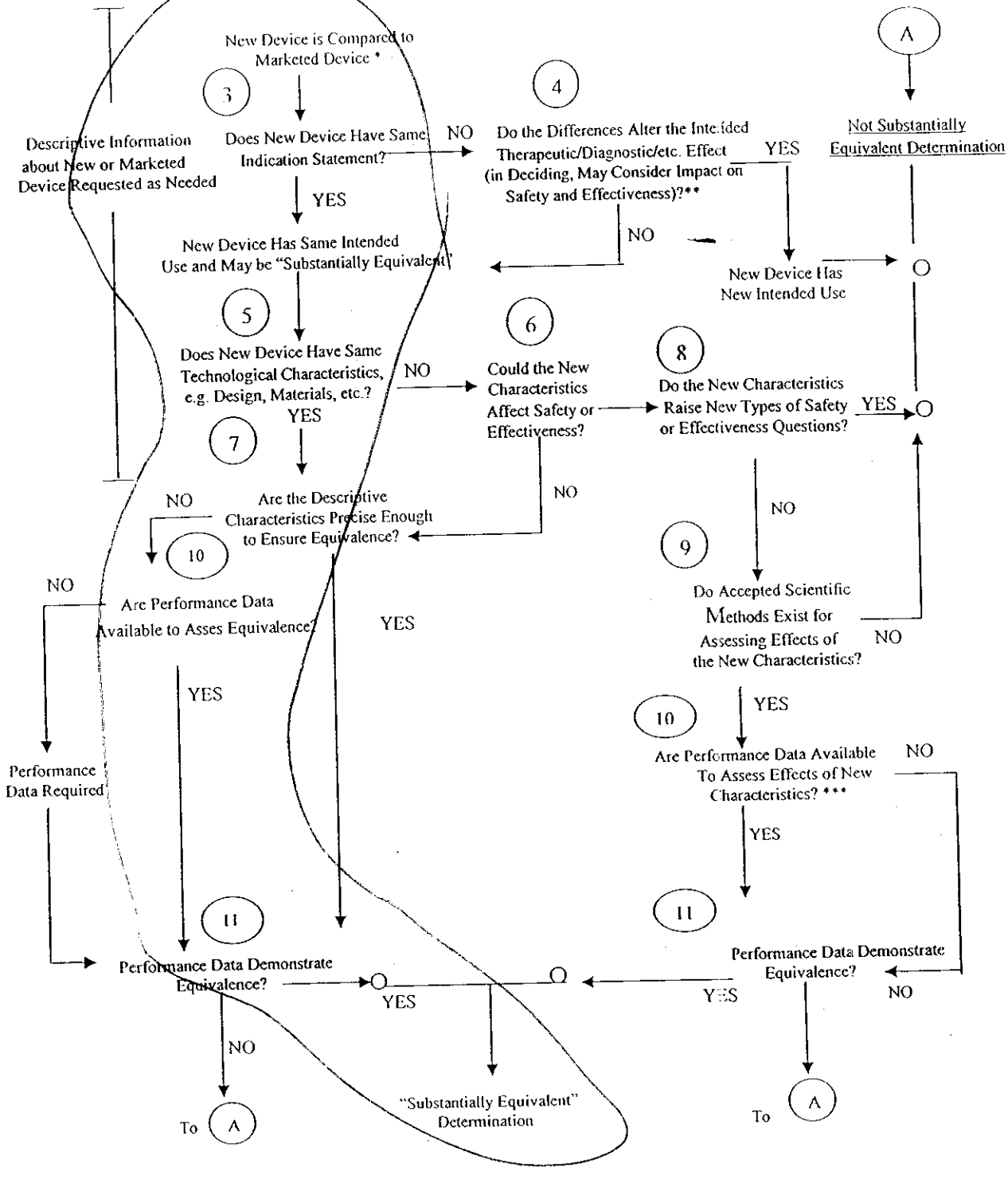
9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: Burst testing results show device is SE to other ceramic heads.

ATTACH ADDITIONAL SUPPORTING INFORMATION

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.