BIOMET

510(k) Summary

OCT 10 2013

Preparation Date: October 9, 2013

Sponsor:
Biomet UK Ltd.
Waterton Industrial Estate
Bridgend, South Wales, UNITED KINGDOM CF31 3XA
FDA Registration Number: 9044936
Telephone: +44(0) 1656 655221

Correspondent
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
Establishment Registration Number: 1825034
Telephone: (574) 267-6639

Contact Person:
Becky Earl
Regulatory Specialist

Proprietary Name: Biolox® *delta* Ceramic Heads

Common Name: Femoral Ceramic Head, Monoblock

Classification Name:

LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)

LPH— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)

OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (21 CFR 888.3358)

LWJ—prosthesis, hip, semi-constrained, metal/polymer, uncemented (21 CFR 888.3360)

JDI— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)

OQH—Hip, semi-constrained, cemented, metal/polymer + additive, cemented (21 CFR 888.3350)

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free. 800.348.9500
Office. 574.267.6639
Main Fax: 574 267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

OQI—Hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented (21 CFR 888.3353)

MAY—Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish (21 CFR 888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Biolox® *delta* Ceramic Heads—Biomet—(K042091)

36mm Biolox® *delta* Ceramic Heads—Biomet—(K061312)

Biolox® *delta* Ceramic Head—Zimmer—(K071535)

Device Description:

The Biolox® *delta* component is a traditional, one-piece ceramic head indicated for hip arthroplasty. The material for the device is Transition-Toughened-Platelet Alumina (TTPA) 75% Alumina, 24% Zirconia and 1% Platelet. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. The ceramic heads are available in three sizes, with several offsets.

The scope of this submission is:

- An inner taper change and distal face change requested by CeramTec for the purpose of increased burst strength and increased cost effectiveness.
- The one remaining size is previously cleared through K061312 and K073102. This submission seeks to incorporate all of Biomet's Biolox® *delta* Ceramic Heads (Monobloc) under unified Indications, Contraindications, Instructions for Use and labeling.

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, avascular necrosis and traumatic arthritis.
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)

Summary of Technologies:

The technological characteristics of the proposed device are the same as or similar to the predicates. The Biolox® *delta* Ceramic Heads are similar in design, dimensions, and intended use as their predicates. They are made of the same material as all their predicates, and indications are similar or the same as all the predicates. There have been no changes to the larger size.

Non-Clinical Testing:

New testing to support the argument for substantial equivalence includes the following: Burst testing to assess the worst case and further testing on worst case to include: Fatigue burst test; Post-fatigue burst test; Pull-off test on CoCrMo tapers; and Rotational stability on CoCrMo tapers.

Clinical Testing:

None provided as a basis for substantial equivalence.

Testing demonstrates that the modifications made to the Biolox® *delta* Ceramic Heads (Monoblock) do not introduce any new risks of safety or efficacy, and that the Biolox® *delta* Ceramic Heads (Monoblock) are substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 10, 2013

Biomet UK Limited
% Ms. Becky Earl
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581

Re: K131684
Trade/Device Name: 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, LPH, OQG, LWJ, JDI, OQH
Dated: September 10, 2013
Received: September 12, 2013

Dear Ms. Earl:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Erin I. Keith

for

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

Enclosure

Indications for Use

510(k) Number (if known): K131684

Device Name: Biolox® *delta* Ceramic Heads

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

1. Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and traumatic arthritis.
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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)*

*Note – for the USA only

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)

Elizabeth L. Frank -S

Division of Orthopedic Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 10, 2013

Biomet UK Limited
% Ms. Becky Earl
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, Indiana 46581

Re: K131684
Trade/Device Name: 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, LPH, OQG, LWJ, JDI, OQH
Dated: September 10, 2013
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Sincerely yours,

Erin I. Keith

for

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

Enclosure

Concurrence & Template History Page

Full Submission Number: K131684

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Limin Sun
Branch Chief Sign-Off	Elizabeth Frank Kunkoski 10/9/13
Division Sign-Off	Erin I. Keith 2013.10.10 14:44:51 -04'00'

f/t:LAS:JNJ:10/9/2013:eaf:10/10/13
Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

Indications for Use

510(k) Number (if known): K131684

Device Name: Biolox® *delta* Ceramic Heads

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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)

Elizabeth L. Frank -S

Division of Orthopedic Devices

K131684

BIOMET
MANUFACTURING CORP.

FDA CDRH DMC
JUN 10 2013
Received

June 4, 2013

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

Dear Sir or Madam:

SUBJECT: 510(k) – Biolox® *delta* Ceramic Heads—Taper Change and Global Product Line
(b)(4)Trade Secret
Process

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and relevant amendments thereto, Biomet Orthopedics is submitting the attached premarket notification for the Biolox® *delta* Ceramic Heads (Class II Device, Orthopedics). There are two sizes, 28mm and 32mm, which include a taper change and one size which was previously cleared, 36mm (K061312), that needs to be included in the global numbering and IFU reorganization. There have been no prior submissions for these changes to the Biolox® *delta* Ceramic Heads. This notification is submitted in duplicate: please find enclosed one paper copy and one electronic copy which is an exact duplicate of the paper submission.

The Biomet Biolox® *delta* Ceramic Head is a monoblock, highly polished femoral head, made of Transition-Toughened-Platelet Alumina (TTPA), with a Type I taper. The submission has been prepared following the "Guidance Document for the Preparation of Pre-Market Notifications for Ceramic Ball Hip Systems". Only those portions which are affected by the modifications required to create the new device will be addressed in this document. The Biomet Biolox® *delta* Ceramic Head is a permanent implantable device. The device does not contain software, nor would it be classified as an *in vitro* diagnostic device. It does not require EMC and/or Electrical Safety evaluation.

Biomet considers its intent to market this device to be confidential commercial information under 21 CFR§807.95. To the best of my knowledge, neither Biomet nor anyone else has disclosed through advertising or any other manner Biomet's intent to market the device to anyone except employees of, or paid consultants to Biomet or individuals in an advertising or law firm retained by Biomet. Biomet therefore requests that FDA not disclose the existence of this notification unless and until the Agency finds the device substantially equivalent. Further, this notification contains information that is trade secret or confidential commercial information under 21 CFR§20.61 and therefore, exempt from disclosure under the Freedom of Information Act (FOIA). Biomet requests that FDA consult with the Company as provided in 21 CFR §20.47 prior to public disclosure of information contained herein.

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

Shipping Address:
56 E. Bell Drive
Warsaw, IN 46582

I trust that the enclosed information is adequate to facilitate your review. Please contact me by phone (574-372-1518), fax (574-372-1683) or email (becky.earl@biomet.com) should you require additional information.

Sincerely,

Becky Earl

Becky Earl
Regulatory Specialist
Biomet Manufacturing Corp.

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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]
Write the Payment Identification number on your check.

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

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

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

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

(b) [redacted]

2. CONTACT NAME
Rebecca Earl

2.1 E-MAIL ADDRESS
becky.earl@biomet.com

2.2 TELEPHONE NUMBER (include Area code)
574-372-1518

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
574-372-1683

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

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

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

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

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

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

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

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) [redacted] 04-Apr-2013

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
June 4, 2013	(b)(4)Trade S t P [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Biomet, Inc.	Establishment Registration Number *(if known)*: 9044936		
Division Name *(if applicable)*: Biomet UK Ltd.	Phone Number *(including area code)*: +44 (0) 1656 655221 (US contact # 574-372-1518)		
Street Address: Waterton Industrial Estate	FAX Number *(including area code)*: +44 (0) 1656 645454 (US fax # 574-372-1683)		
City: Bridgend	State / Province: South Wales	ZIP/Postal Code: CF31 3XA	Country: UK
Contact Name: Becky Earl			
Contact Title: Regulatory Affairs Specialist	Contact E-mail Address: becky.earl@biomet.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: Biomet, Inc.			
Division Name *(if applicable)*:	Phone Number *(including area code)*: 574-372-1518		
Street Address: 56 E. Bell Drive, Box 587	FAX Number *(including area code)*: 574-372-1683		
City: Warsaw	State / Province: IN	ZIP Code: 46581	Country: USA
Contact Name: Becky Earl			
Contact Title: Regulatory Affairs Specialist	Contact E-mail Address: becky.earl@biomet.com		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Response to FDA correspondence:

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [x] Additional or Expanded Indications
- [x] Change in Technology

- [x] Other Reason *(specify)*:

Modification to cleared device: Changes recommended by [redacted] ([redacted]

Inclusion of all Biolox delta Ceramic Heads (Monoblock) manufactured by Biomet into one global part number list, labeling system, and IFU.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LZO	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K042091	1	Biolox® delta Ceramic Heads	1	Biomet, Inc.
2	K060312	2	36mm Biolox® delta Ceramic Heads	2	Biomet, Inc.
3	K070535	3	Biolox® delta Ceramic Head	3	Zimmer, Inc.
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Femoral Ceramic Head, Monoblock

	Trade or Proprietary or Model Name for This Device		Model Number
1	Biolox® delta Ceramic Heads	1	650-1157/59; 650-1160/63; 650-0060/63
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 None	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: LZO

C.F.R. Section *(if applicable)*: 888.3353

Classification Panel: Orthopedics

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

See attached

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Biomet, Inc.		Establishment Registration Number: 1825034
Division Name *(if applicable)*		Phone Number *(including area code)*: 574-267-6639
Street Address: 56 East Bell Drive		FAX Number *(including area code)*: 574-372-1683
City: Warsaw		State / Province: IN; ZIP Code: 46580; Country: USA

[redacted]

Rex White	Vice President, Quality Assurance	rex.white@biomet.com

(b)(4)Trade Secret Process

[redacted]

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Biomet UK Ltd.		Establishment Registration Number: 9044936
Division Name *(if applicable)*		Phone Number *(including area code)*: +44 (0) 1656 655221
Street Address: Waterton Industrial Estate		FAX Number *(including area code)*: +44 (0) 1656 645454
City: Bridgend		State / Province: South Wales; ZIP Code: CF31 3XA; Country: UK
Contact Name: Richard Young	Contact Title: Director of QA and RC	Contact E-mail Address: richard.young@biomet.com

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H ***(Continued)***

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	11137-2	ANSI/AAMI/ISO	Sterilization of health care products- Radiation- Part 2: Establishing the Sterilization Dose	2012	
2	ASTM F136	ASTM	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy	2008	
3	AAMI TIR 12:2010	AAMI	Designing, Testing, And Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities	12:2010	12:2010
4	ASTM F799	ASTM	Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	2006	
5	ISO 6474-2	ISO	Implants for Surgery--Ceramic Materials, Part 2: composite materials based on a high-purity alumina matrix with zirconia reinforcement.	2012	04/15/2013
6	ISO 7206-10	ISO	Implants for Surgery, Partial and Total Hip Joint Prostheses, Pt. 10, Determination of resistance to static load of modular femoral heads.	2003	12/01/2003
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

Indications (from labeling)

Device Name: Biolox® *delta* Ceramic Heads

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

1. Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and traumatic arthritis.
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)*

*Note – for the USA only

BIOMET
MANUFACTURING CORP.

June 4, 2013

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

Dear Sir or Madam:

SUBJECT: 510(k) – Biolox® *delta* Ceramic Heads—Taper Change and Global Product Line
(b)(4)Trade Secret

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and relevant amendments thereto, Biomet Orthopedics is submitting the attached premarket notification for the Biolox® *delta* Ceramic Heads (Class II Device, Orthopedics). There are two sizes, 28mm and 32mm, which include a taper change and one size which was previously cleared, 36mm (K061312), that needs to be included in the global numbering and IFU reorganization. There have been no prior submissions for these changes to the Biolox® *delta* Ceramic Heads. This notification is submitted in duplicate: please find enclosed one paper copy and one electronic copy which is an exact duplicate of the paper submission.

The Biomet Biolox® *delta* Ceramic Head is a monoblock, highly polished femoral head, made of Transition-Toughened-Platelet Alumina (TTPA), with a Type I taper. The submission has been prepared following the "Guidance Document for the Preparation of Pre-Market Notifications for Ceramic Ball Hip Systems". Only those portions which are affected by the modifications required to create the new device will be addressed in this document. The Biomet Biolox® *delta* Ceramic Head is a permanent implantable device. The device does not contain software, nor would it be classified as an *in vitro* diagnostic device. It does not require EMC and/or Electrical Safety evaluation.

Biomet considers its intent to market this device to be confidential commercial information under 21 CFR§807.95. To the best of my knowledge, neither Biomet nor anyone else has disclosed through advertising or any other manner Biomet's intent to market the device to anyone except employees of, or paid consultants to Biomet or individuals in an advertising or law firm retained by Biomet. Biomet therefore requests that FDA not disclose the existence of this notification unless and until the Agency finds the device substantially equivalent. Further, this notification contains information that is trade secret or confidential commercial information under 21 CFR§20.61 and therefore, exempt from disclosure under the Freedom of Information Act (FOIA). Biomet requests that FDA consult with the Company as provided in 21 CFR §20.47 prior to public disclosure of information contained herein.

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

Shipping Address:
56 E. Bell Drive
Warsaw, IN 46582

I trust that the enclosed information is adequate to facilitate your review. Please contact me by phone (574-372-1518), fax (574-372-1683) or email (becky.earl@biomet.com) should you require additional information.

Sincerely,

Becky Earl
Regulatory Specialist
Biomet Manufacturing Corp.

Completed by Biomet Manufacturing Corp. to assist the reviewer – 510(k) submission for Biolox delta Ceramic Heads.

(Location of requested information noted in red.)

Contains Nonbinding Recommendations

Acceptance Checklist
for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	x	
Comments: Coversheet		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	x	
Comments: CDRH		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:	x	

a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.		
Comments: **Not applicable**		
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	x	
Comments: **Coversheet**		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		x
Comments: **No**		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.		x

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

Acceptance Checklist for Traditional 510(k)

If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	x	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	x	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	x	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*x	x	☐
Comments: Coverletter		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. · Any "No" answer will result in a "Refuse to Accept" decision. · Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		x		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		x		☐
		a.	Device trade name or proprietary name	x		☐
		b.	Device common name	x		☐

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

			- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	x		☐
		Comments: Coversheet				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		x		☐
		Comments: Coversheet and Indications for Use Statement				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*		x		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	x	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93		x	☐
		Comments: 510(k) Summary				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		x		☐
		Comments: Appendix				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
			• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
	6.		Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*	☐	x	☐
			Comments: Not Applicable			
	7.		Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐	x	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators*	☐	x	☐
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	x	☐
			Comments: Not Applicable			
	8.		If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*	x	☐	☐

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
			- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
		Comments: Appendix				
	9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*		x		☐
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the	☐	x	☐

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
			Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*			
		Comments: No prior submission—Coversheet and Device Description				
B.	**Device Description**					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		☐	x
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	x	☐	
		Comments: Guidance Document for the Preparation of Pre-Market Notifications for Ceramic Ball Hip Systems". Only those portions which are affected by the modifications required to create the new device will be addressed in this document				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
	11.		Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	x	☐	☐
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	x	☐	☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	x	☐	☐
		Comments: Device Description				
	12.		Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*	x	☐	☐
		Comments: Device Description, Tab B				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
	13.		If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*	x	☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	x	☐	☐
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	x	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*	x	☐	☐
		Comments: Device Description, Tabs C and D				
C.	**Substantial Equivalence Discussion**					
	14.		Submitter has identified a predicate(s) device	x		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan*	x		☐

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Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
			ce/ComplianceActivities/ucm072746.htm).			
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	x		☐
		Comments: Substantial Equivalence Section				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	x		☐
		b.	Technology, including features, materials, and principles of operation	x		☐
		Comments: Substantial Equivalence Section Tab A				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in*		x	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
			- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
			manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.			
			Comments: Substantial Equivalence			
	Proposed Labeling (see also 21 CFR part 801) *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.*				☐	
	17.		Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use	x		☐
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	x		☐
		b.	Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	x		☐
			Comments: Device Description Tab F. No single surgical technique is included with this submission; the procedure will vary according to compatible modular stem selection.			
	18.		If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*	x	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
		Comments: Device Description, Tab F				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	x		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*	x	☐	☐
		Comments: Device Description, Tab F				
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	x	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	x	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	x	☐
		Comments: Not Applicable				
	21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	x	☐
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☐xprovided sterile ☐provided non-sterile but sterilized by the end user ☐non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from*					☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
	the checklist. *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments:					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	X	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	x	☐
		Comments: Device Description, Tab B, List of Sterile Devices (Non-sterile are dependent on system)				
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*				
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	x		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	x		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	☐	x	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
			levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	x		☐
		e.	Sterility Assurance Level (SAL) stated	x		☐
		Comments: Device Description				
	24.	If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*			x	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation is not required.*	☐		☐
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
		d.	Submission includes sterilization instructions for end user	☐		☐
		Comments: Instruments and trials are part of the compatible component systems.				
	25.	a.	If there are requirements regarding sterility, such as special	☐	x	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
			controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	x	☐
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a*		x	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
		special controls document have been addressed should be assessed during the substantive review.			
		Comments: Not Applicable			
F.	**Shelf Life**				
	26.	Proposed shelf life/ expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*	x	☐	☐
		Comments: Device Description			
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*	x	☐	☐
		Comments: Device Description			
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	x		☐
		Comments: Device Description (CeramTec's Master File)			
G.	**Biocompatibility** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*			☐	
	Submission states that there: (*one of the below must be checked*) xare				☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed **Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.** · Any "No" answer will result in a "Refuse to Accept" decision. · Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*				
	Comments:				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	x		☐
		Comments: Device Description			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	x		☐
		Comments: Device Description			
	31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	x		☐
		Comments: Device Description			
H.	**Software**				

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	Submission states that the device: (*one of the below must be checked*) ☐does ☐xdoes not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If*					☐
	Comments: Not Applicable—stated in cover letter					
	32.	Submission includes a statement of software level of concern and rationale for the software level of concern		☐		☐
		Comments:				
	33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).		☐		☐
		Comments:				
I.	**EMC and Electrical Safety**					
	Submission states that the device: (*one of the below must be checked*) ☐does ☐xdoes not require EMC and Electrical Safety evaluation.					☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed **Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.** · Any "No" answer will result in a "Refuse to Accept" decision. · Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				
	Comments: Not Applicable—stated in cover letter				
	34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐		☐
		Comments:			
	35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐		☐
		Comments:			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
			- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
J.	**Performance Data – General** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.*				☐	
	Comments:					
	36.		Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*	x	☐	☐
		Comments: Test Reports were provided by CeramTec—Mechanical Testing Section				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	x	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	☐	x	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
			approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	x	☐
		Comments:				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*			x	
		a.	Legible reprints or a summary of each article	☐		☐
		b.	Discussion of how each article is applicable to support the	☐		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
			substantial equivalence of the subject device to the predicate.			
		Comments:				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*			x	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐		☐
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐		☐
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☐
		Comments: Not Applicable				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐is ☐xis not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
		a.	Precision/reproducibility	☐	☐	☐
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐
		Comments:				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the	☐	☐	☐

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

				Yes	N/A	No
			applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☐	☐
		Comments:				

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

Indications for Use

510(k) Number (if known):_____

Device Name: Biolox® *delta* Ceramic Heads_____

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

1. Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and traumatic arthritis.
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)*

*Note – for the USA only

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Preparation Date:	June 4, 2013
Applicant/Sponsor:	Biomet UK Ltd. Waterton Industrial Estate Bridgend South Wales, UNITED KINGDOM CF31 3XA FDA Registration Number: 9044936 Biomet Manufacturing Corp. 56 East Bell Drive P.O. Box 587 Warsaw, IN 46581-0587 Establishment Registration Number: 1825034
Contact Person:	Becky Earl Regulatory Specialist
Proprietary Name:	Biolox® *delta* Ceramic Heads
Common Name:	Femoral Ceramic Head, Monoblock
Classification Name:	LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Biolox® *delta* Ceramic Heads—Biomet—(K042091)

36mm Biolox® *delta* Ceramic Heads—Biomet—(K061312)

Biolox® *delta* Ceramic Head—Zimmer—(K070535)

Device Description:

The Biolox® *delta* component is a traditional, one-piece ceramic head indicated for primary hip arthroplasty. The material for the device is Transition-Toughened-Platelet Alumina (TTPA) 75% Alumina, 24% Zirconia and 1% Platelet. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. The ceramic heads are available in three sizes, with several offsets.

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

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

The scope of this submission is:

- An inner taper change and distal face change requested by CeramTec for the purpose of increased burst strength and increased cost effectiveness.
- The one remaining size is previously cleared through K061312. This submission seeks to incorporate all of Biomet's Biolox® *delta* Ceramic Heads (Monobloc) under unified Indications, Contraindications, Instructions for Use and labeling.

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, avascular necrosis and traumatic arthritis.
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)*

***Note – for the USA only**

Summary of Technologies:

The technological characteristics of the proposed device are the same as or similar to the predicates. The Biolox® *delta* Ceramic Heads are similar in design, dimensions, and intended use as their predicates. They are made of the same material as all their predicates, and indications are similar or the same as all the predicates. There have been no changes to the larger size.

Non-Clinical Testing:

New testing to support the argument for substantial equivalence includes the following: Burst testing to assess the worst case and further testing on worst case to include: Fatigue burst test; Post-fatigue burst test; Pull-off test on CoCrMo tapers; and Rotational stability on CoCrMo tapers.

Clinical Testing:

None provided as a basis for substantial equivalence.

Testing demonstrates that the modifications made to the Biolox® *delta* Ceramic Heads (Monoblock) do not introduce any new risks of safety or efficacy, and that the Biolox® *delta* Ceramic Heads (Monoblock) are substantially equivalent to the predicates.

Executive Summary

Device Description

The Biolox® *delta* modular femoral head is a traditional, one-piece ceramic head indicated for primary hip arthroplasty. The material for the device is Transition-Toughened-Platelet Alumina (TTPA)(b)(4)Trade Secret Process [redacted]. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. The ceramic heads are available in three sizes, with several offsets.

The scope of this submission is:

- (b)(4)Trade Secret Process [redacted] requested by (b)(4)Trade [redacted] for the purpose of (b)(4)Trade Secret Process [redacted]

- The other remaining size was previously cleared through K061312, which included design features like those above. This submission seeks to incorporate all of Biomet's Biolox® *delta* Ceramic Heads (Monoblock) under unified part numbers, Indications and Contraindications, Instructions for Use, and labeling.

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, avascular necrosis and traumatic arthritis.
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)*

*Note – for the USA only

Basis of Substantial Equivalence

- Identical indications for use, with the addition of specifically including traumatic arthritis, as in Zimmer's K070535
- Incorporated similar design features
- Identical materials
- Identical manufacturing methods
- Similar materials and processes for packaging

The following table provides a comparison of the Biomet Biolox® *delta* Ceramic Heads to the cleared, predicate Biolox® *delta* ceramic femoral heads.

	Biolox® *delta* Ceramic Heads Taper Change and Global Product Line	**Biolox® *delta* Ceramic Heads**	**BIOLOX® *delta* Ceramic Femoral Head**
Sponsor	Biomet	Biomet	Zimmer
510(k) Number	Subject Device	K042091, K061312	K071535
Ceramic Manufacturer	(b)(4)Trade Secret Process [redacted]		
Indications	The 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, avascular necrosis and traumatic arthritis. 2. Rheumatoid arthritis 3. Correction of functional deformity 4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. 5. Revision procedures where other treatments or devices have failed. Specific indications for compatible components that can be used with the above modular heads include: Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrosis. (K974558, K002757, K021380, K033871) Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)	The 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 using other techniques. 5. Revision procedures where other treatments or devices have failed. Specific indications for compatible components that can be used with the above modular heads include: Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrosis. (K974558, K002757, K021380, K033871) Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)	The Biolox® *delta* Ceramic Heads are modular components used in total hip arthroplasty and indicated for the following: Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis, patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.
Product Code	LZO	LZO	LZO
Material	(b)(4)Trade Secret Process [redacted]		
Diameter(s): Neck Lengths	Size 28mm: -3, std, +3, Size 32mm: -3, std, +3, +6mm **Previously Cleared/Global Product Line:** Size 36mm: -3, std, +3, +6mm Size 38mm: -6, -3, std, +3 and +6mm	Size 28mm: -3, std, +3, +5mm Size 32mm: -3, std, +3, +5mm **K061312:** Size 36mm: -3, std, +3, +6mm	Size 28mm: -3.5, std, +3.5mm Size 32 mm: -3.5, std, +3.5, +7.0mm Size 36mm: -3.5, std, +3.5, +7.0mm Size 40mm: -3.5, std, +3.5, +7.0mm
Taper Design	**Internal Taper Changes:**	**K042091, K061312, and K073102**	N/A

Change:	(b)(4)Trade Secret Process [redacted]		
Outer Head Change:	**Outer Head Changes:** Size 28 (b)(4)Trade Secret Process [redacted]	**K042091, K061312, and K073102:** Size 28	N/A

Mechanical Testing

In order to establish that no new issues of safety or effectiveness have been raised by the modified design of the Biomet Biolox® *delta* Ceramic Heads, the following testing was conducted:

- Fatigue Burst Test Post Fatigue Burst Test
- Pull-off Test
- Rotational Stability
- Justification for Range of Motion and Wear

In all cases, the Biomet Biolox® *delta* Ceramic Heads performed at or above expected rates and where applicable, superior to the predicate device.

Clinical Information

No clinical testing is necessary for a determination of substantial equivalence.

Conclusion

The Biomet Biolox® *delta* Ceramic Heads in this submission have been shown to be substantially equivalent to the predicate devices and no new issues of safety or effectiveness have been raised.

Device Description

Introduction

The Biolox *delta*® Ceramic Heads have been part of the Biomet hip product line for over seven years. The contract manufacturer for these parts is (b)(4)Trade Secret [redacted] When Biomet first contracted with (b)(4)Trade Secret [redacted] to provide the ceramic heads, the heads were only available in sizes 28mm and 32mm for Biomet's Type 1 taper. Later, (b)(4)Trade Secret [redacted] added size 36 to its offering, but only with a 12/14 taper. When Biomet expressed interest in adding the size 36 to its line of products, (b)(4)Trade Secret [redacted] reworked the design to make it available in a Type 1 taper. In the process of reworking the design, (b)(4)Trade Secret [redacted] improved the design to (b)(4)Trade Secret Process [redacted] (b)(4)Trade Secret [redacted] then asked Biomet to consider changing the cleared sizes 28 and 32mm Biolox *delta*® Ceramic Heads to include a (b)(4)Trade Secret [redacted]

The scope of this submission is two-fold:

- (b)(4)Trade Secret Process [redacted] requested by (b)(4)Trade Secret [redacted] (sizes 28 and 32mm) for the purpose of (b)(4)Trade Secret Process [redacted].

- The one remaining sizes is currently cleared through K061312 (size 36mm). As Biomet endeavors to become more efficient in its global marketing plan, this submission seeks to incorporate all of Biomet's Biolox *delta* ® Ceramic Heads (Monoblock) under unified part numbers, Instructions for Use and labeling.

Biolox *delta* ® Ceramic Head

The Biolox® *delta* component is a traditional, one-piece ceramic head indicated for primary hip arthroplasty. The material for the device is Transition-Toughened-Platelet Alumina (TTPA) (b)(4)Trade Secret Process [redacted] A full disclosure of the materials used by (b)(4)Trade Secret [redacted] in the manufacturing of the device may be found in their (b)(4)Trade Secret [redacted] A letter granting permission for FDA to examine the contents of the file to complete review of this submission is found in **Tab A**, including the identification of data reference sections. The highly-polished spherical surface articulates with a polyethylene liner acetabular component. (A complete list of compatible components may be found in **Tab C**.) The modular head attaches to any Biomet metallic femoral stem with a Type 1 taper, with the exception of the size 32 +6mm, which may only be used with a titanium stem (Ti-6Al-4V). (**Tab D**)

The sizes included in this submission:

- Size 28mm: -3, std, +3,
- Size 32mm: -3, std, +3, +6mm
- Size 36mm: -3, std, +3, +6mm (cleared in K061312)

A complete listing and description of implants, with accompanying engineering drawings, may be found in this section, **Tab B**. All implants are provided sterile as described below.

Taper Change / Distal Face Change

As stated above, (b)(4)Trade requested the design changes to (b)(4)Trade Secret Process [redacted] (See **Mechanical Testing Section**.)

A visual summary of the design changes for the size 28 +3mm Biolox® *delta* component (as an example) is found in Figures 1 and 2. The features of the design affected by the changes are highlighted in yellow. All changes are noted in the engineering drawings, **Tab B**.

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

Figure 1 – new head design (external)

Figure 1 (b)(4)Trade Secret Process [redacted] (**Mechanical Testing**, **Tab C**).

Figure 2 (b)(4)Trade Secret Process [redacted]

Instruments

There are no device-specific instruments designed for use with the Biolox® *delta* Ceramic Heads; only general instruments are used for the surgical procedure, which are provided non-sterile and have limited patient contact (less than 24 hour duration). Head trials and any other necessary instruments are included with compatible components chosen to complete the system.

Indications

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, avascular necrosis, and traumatic arthritis.
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)*

*Note – for the USA only

Mechanical Testing

A Summary of the testing completed for this submission is found in **Tab E**. Figure 1 is a
(b)(4)Trade Secret Process
[redacted]
These results are summarized in Figure 2. Test reports are included in the **Mechanical Testing** section.

Compatible Components

A list of the stems that are compatible with the Biolox® *delta* Ceramic Heads contained in this submission is provided in **Tab C**. The name of each stem family is presented, as well as the 510(k) number under which they were cleared. Additionally, the stem trunnion material and product codes are listed. In lieu of a drawing of each hip stem, a detailed drawing of the taper trunnion is included in **Tab D**. (b)(4)Trade Secret Process [redacted] All of the devices are metallic hip stems, with or without porous coating. Each stem has a Biomet Type 1 trunnion for attachment to the ceramic head.

Material and Biocompatibility

The materials used in the manufacturing process of the Biolox® *delta* Ceramic Heads have been previously cleared for use in orthopedic implants and are commonly used in the orthopedic industry. Further material biocompatibility information may be found (b)(4)Trade Secret Process [redacted]

Standards Data Reports for 510(k)s have been completed for the material standards cited in this submission and are included in the Appendix.

Sterility Information

Devices are provided sterile by radiation methods as follows:

Gamma

Radiation Type: Gamma
Radiation Source: (b)(4)Trade Secret [redacted]
Minimum Dosage: 25 kGy
Maximum Dosage: 40 kGy
Sterility Assurance Level: 10^{-6}
Sterility Validation Method: (b)(4)Trade Secret Process [redacted]

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.

Sterilization Site(s):

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

(b)(4)Trade Secret Process

[redacted]

Packaging validations completed per BS EN ISO 11607-1:2009 "*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems",* section 6.4 confirm that the Biolox® *delta* Ceramic Heads remain sterile and stable for a period of ten (10) years.

Packaging Description

Components will be packaged in a vacuum-sealed, poly-pouch that will be placed in a blister pack, sealed with a Tyvek® lid that is then placed in a cardboard box, covered with a cardboard sleeve. The entire unit is then shrink-wrapped for protection. All labeling will be on the outer Tyvek® lid, as well as on the outer cardboard sleeve.

Shelf Life

A justification for the optimized Biolox® *delta* Heads may be found in the **Mechanical Testing Section, Tab D**. Additionally, (b)(4)Trade has informed us that further information is included in their (b)(4)Trade as follows:

(b)(4)Trade Secret Process

[redacted]

Labeling

A copy of the package insert for the Biolox® *delta* Ceramic Heads may be found behind **Tab F.** As part of the globalization of this product line, all of Biomet's monoblock Biolox® *delta* Ceramic Heads are being brought together under one universal monoblock Biolox® *delta* Ceramic Head package insert. (This includes the 36mm heads, K061312.)

Samples of the outer package label may be found in **Tab F**, as well as a sample generic box.

No single surgical technique is included with this submission; the procedure will vary according to compatible modular stem selection.

Marketing materials have not been developed at this time.

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

Part Number Listing

Biolox® delta Ceramic Heads
Type 1 Taper

28mm Biolox® *delta* Ceramic Head, -3	650-1159
28mm Biolox® *delta* Ceramic Head, STD	650-1158
28mm Biolox® *delta* Ceramic Head, +3	650-1157

32mm Biolox® *delta* Ceramic Head, -3	650-1163
32mm Biolox® *delta* Ceramic Head, STD	650-1162
32mm Biolox® *delta* Ceramic Head, +3	650-1161
32mm Biolox® *delta* Ceramic Head, +6	650-1160

IFU and Part Number Change

Previously Cleared in K061312	New Number	Previously Cleared Number
36mm Biolox® *delta* Ceramic Head, -3	650-0660	12-115120
36mm Biolox® *delta* Ceramic Head, STD	650-0661	12-115121
36mm Biolox® *delta* Ceramic Head, +3	650-0662	12-115122
36mm Biolox® *delta* Ceramic Head, +6	650-0663	12-115123

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

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b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

The Biolox® *delta* Ceramic Monoblock Heads contained in this submission may be used with Biomet femoral components (Type 1) cleared under the following 510(k)s. The size 32 +6mm may only be used with those having Ti-6Al-4V trunnion material.

Femoral Component Name	510(k) Number	Product Code	(b)(4)Trade Secret Process - Product Specs	Indication
Answer® Femoral Component	K991987	JDI	[redacted]	Cemented
Arcos Femoral System	K090757 K100469	KWA, KWZ, JDL, JDI, LZO, MEH, LPH, KWY, MAY (KWA and JDL N/A)	[redacted]	Uncemented
Co-Cr Answer® Femoral Components	K931194	JDG[1]	[redacted]	Cemented
Altra Press-Fit Hip Stem (Echo™)	K063002	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY (KWA and JDL N/A)	[redacted]	Uncemented
Altra FX Hip System (Echo™)	K063614	KWA, JDL, LZO, KWZ, JDI, MAY, MEH, LPH, KWL, LWJ, KWY (KWA and JDL N/A)	[redacted]	Cemented and non-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 (KWA and JDL N/A)	[redacted]	Non-cemented
Bi-Metric® Femoral Components	K921224 K020580 K030055	LZO LPH LPH	[redacted]	Cemented and non-cemented
Bi-Metric® Head/Neck Replacement	K992058 K983710	JDI JDI, LZO	[redacted]	Cemented
HA Bi-Metric® Femoral	K023409	LPH	[redacted]	Non-cemented

[1] Submitted under classification 888.3350 JDI

Component	K030055	LPH	(b)(4)Trade Secret Process - Product Specs	
Bio-Groove® HAP Hip Components	K912369 K912370	MEH MEH		Non-cemented
Bohn Femoral Component	K000262	LZO, MEH		Non-cemented
Color Buffed Cemented Stem	K992903 K012019	JDI JDI		Cemented
Fenning (Osteocap RS®) Femoral Component	K960303	LPH		Non-cemented
Generation 4 Polished Femoral Hip Prosthesis	K031734 K052639	JDI, LZO, KWZ,MEH LPH, LZY, KWY, JDG		Cemented
Gross Femoral Component	K001580	MEH		Non-cemented
Impact® Co-Cr Femoral Components	K942027	JDG[2]		Cemented
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[3]		Non-cemented
Mallory/Head® Total Hip System	K921181 K994007 K000538 K003429 K030055	LZO JDI LPH LPH LPH		Cemented and non-cemented
HA Mallory/Head® Total Hip System	K021403 K030055	LPH, MEH LPH, MEH		Non-cemented
Mallory/Head® Co-Cr Femoral Component	K911684	JDI		Cemented
Mallory/Head® Calcar Femoral Components (including HA)	K945115 K001660 K031693	LPH, LZO LPH LPH		Cemented and non-cemented
Modular Hip Stems	K912712 K921274 K030055	JDI LPH LPH		Cemented and non-cemented

[2] Submitted under classification 888.3350 JDI

[3] Cleared under product codes JDL, KWA, LPH, LZO, KWZ, JDI and KWY based on available modular head and acetabular components for use with this stem. KWA and JDL are not applicable.

OSS™ Les Proximal Femoral Component	K021380	JDI, LPH	(b)(4)Trade Secret Process - Product Specs	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	JDI JDI		Cemented
SHP™ Hip System	K960984	JDI		Cemented
Taper2™ Porous Femoral Stem (Taperloc® Microplasty)	K050441 K062994	LPH, MBL, KWZ, JDL, KWA, JDI, LZO, MEH, KWB, LZY, KWY (KWA and JDL N/A)		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
Taperloc® Complete	K101086 K103755 K110400 K120030	KWA, LZO, KWZ, JDL, JDI, MAY, MEH, LPH, KWL, LWJ, KWY (KWA and JDL N/A)		Non-cemented
XR-Series Bi-Metric Femoral Component	K052089	LPH, JDI, LZO, KWY, KWZ		Cemented and non-cemented

Compatible Component Listing

Acetabular Liners and Shells

Although the Indications for Use for the Biolox® *delta* Ceramic Monoblock Heads are either identical or very similar to the indications for most of the compatible components listed, these Indications for Use are not intended to replace the indications which were previously cleared by FDA for the compatible components.

The Biolox® *delta* Ceramic Monoblock Heads utilize a Biomet Type I taper. As such, they are compatible for use with any Biomet modular femoral stem that has a Biomet Type I mating taper. (The only exception is the size 32 +6mm, which is cleared for use with (b)(4)Trade Secret only.) The poly liners listed below in Table 1 may be used with the Biolox® *delta* Ceramic Monoblock Heads to create a ceramic-on-poly articulation.

The Acetabular Liners listed in **Table 1** all utilize the Biomet RingLoc® locking mechanism and are compatible with Biomet's RingLoc® and RingLoc®+ modular acetabular shells listed in **Table 2** below.

Table 1 **Acetabular Liners**	**510(k) Number**	**Product Code**
ARCOM® RingLoc® Liners	K926107 K950761 K970501 K023357 K030055	LPH JDI LPH LPH LPH
ARCOM® XL RingLoc® Liners	K042051 K051411	JDI, LPH LZO
E1 RingLoc® Liners	K050327 K070364 K070399	LPH JDI JDI
ARCOM® 36mm RingLoc® Liners	K032396	JDI, LPH

All of the Acetabular Liners in **Table 1** utilize the Ringloc® locking mechanism and are compatible with the acetabular shells listed in **Table 2**.

Table 2 **Acetabular System Compatible w/ Liner**	**510(k) Number**	**Product Code**	**Indications**
A-B (Precept®) Acetabular System	K954417 K030055	LPH LPH, MEH	Cemented and non-cemented
Flanged Acetabular Component	K983035 K030055	LPH LPH, MEH	Cemented and non-cemented
Full Hemisphere Acetabular Components	K920640	JDI	Cemented
Healy™ Flanged Revision	K921139	JDI	Cemented
Index® Acetabular Components	K950761 K030055	JDI LPH, MEH	Cemented and non-cemented
Mallory/Head® Acetabular Components	K861114 K921181 K030055	JDI LZO LPH, MEH	Cemented and non-cemented
Mars® Modular Acetabular Reconstructive System	K911718	JDI	Cemented
Par 5™ Acetabular Components	K022094	JDI	Cemented and non-cemented
Quadrant Sparing Acetabular Components	K920640 K050124	KWA,JDI, KWZ, LPH, MAY, MEH (KWA N/A)	Cemented non-cemented

Ranawat/Burstein® Acetabular Components	K911685 K921277 K050124	JDI LPH KWA, JDI, KWZ, LPH, MAY, MEH (KWA N/A)	Cemented and non-cemented (NIDJD only)
Recovery Protrusio Cages	K971890	JDI	Cemented
Regenerex™ Porous Titanium Acetabular Components	K052996	LPH, JDI, KWZ, LZO, MAY, MEH	Cemented and non-cemented
Regenerex™ Ringloc®+ Acetabular Components	K070369	LPH, JDG, JDI, KWZ, LWJ, LZO, MAY, MBL, MEH	Uncemented
RingLoc®+ Limited Hole Acetabular Shells	K093235	KWA, LPH, LZO (KWA N/A)	Uncemented
RingLoc®+ Radial Finned Acetabular Shells			
RingLoc®+ Flared Acetabular Shells			
RingLoc®+ Four-Finned Acetabular Shells			
RingLoc®+ Tri-Spike Acetabular Shells			
RingLoc®+ Solid Acetabular Shells			
TRI-SPIKE™ Pegged Acetabular Components	K970501 K030055	LPH, JDI LPH, MEH	Cemented and non-cemented
Universal® Acetabular Components	K861433 K921301 K030055	JDI LPH LPH, MEH	Cemented and non-cemented
Vision Acetabular Components	K954417 K030055	LPH/JDI LPH, MEH	Cemented and non-cemented

Porous Titanium Acetabular Augments are available if needed. Acetabular shells with screw holes may use the Biomet titanium screws cleared under the following 510(k)s as well as any screws contained within the 510(k)s for the acetabular cups. The augments and screws are listed in **Table 3**.

Table 3 **Biomet Titanium Acetabular Screws and Augments**	**510(k) number**	**Product Code**	**Indications**
Titanium Screw LP 5mm	K991807	LPH	Cemented and non-cemented
Titanium Screw LP 6.5mm	K991807	LPH	Cemented and non-cemented
Porous Titanium Acetabular Augments	K052888	KWA, JDI, JDL, KWZ, LPH, LZO, MAY, MEH	Cemented

Additionally, the Biolox® *delta* Ceramic Monoblock Heads are compatible with the G7 Acetabular System (**Table 4**) in appropriate corresponding sizes.

Table 4 **G7 Acetabular System**	**510(k) number**	**Product Code**	**Indications**
G7 Acetabular System	K121874	LPH, LZO, OQG, KWZ, JDI, OQH, OQI PBI	Non-cemented

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

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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

Figure 1 Mechanical Testing Summary

Test/Evaluation	Test Summary	Acceptance Criteria	Biolox® *delta* Results
(b)(4)Trade Secret Process - Testing Report	[redacted]		

Figure 2 Mechanical Testing Summary (Continued)

Test/Evaluation	Test Summary	Acceptance Criteria	Biolox® *delta* Results
(b)(4)Trade Secret Process - Testing Report	[redacted]		

BIOMET Biolox® *delta* (TTPA)_ CERAMIC MODULAR HEAD HIP JOINT PROSTHESES

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INFORMATION FÜR DEN OPERIERENDEN CHIRURGEN

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REF: 5401000274
REVISION: 0
DATE: May 2013
Change Control No: 226074

BIOMET Biolox® *delta* (TTPA) CERAMIC MODULAR HEAD HIP JOINT PROSTHESES

ATTENTION OPERATING SURGEON

IMPORTANT INFORMATION FOR USERS IN THE U.S.: CERAMIC MODULAR FEMORAL HEADS ARE NOT CLEARED FOR USE WITH CERAMIC LINERS.

DESCRIPTION
Biomet ceramic modular head components are available in a variety of head sizes and neck length variations. The highly polished surface is designed to reduce friction and minimize wear. Biomet modular femoral heads are available with Type 1 and Type 12/14 tapers (where available) with various neck lengths and are compatible with any of Biomet's modular femoral stems of the correct taper type. (Note: Size 32 +6mm Biolox® *delta* head may only be used with Biomet's Ti-6Al-4V Type 1 taper stems.) The modular femoral heads are utilized in conjunction with other hip prosthetic components to form part of a total joint replacement system. Total hip joint prostheses may include: acetabular shells, liners, femoral stems, femoral heads, and accessories.

Biomet ceramic modular head components are indicated to be used either with ceramic acetabular inserts (liners) for ceramic- on -ceramic articulation, in countries where currently licensed/cleared for such use, or with Biomet's range of ultra high molecular weight polyethylene (UHMWPE) acetabular liners and cups.

MATERIALS
Transition-Toughened-Platelet Alumina Composite Ceramic (TTPA Ceramic)

INDICATIONS
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, avascular necrosis and traumatic arthritis.
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, tumour 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)*

* Note- for the USA only

CONTRAINDICATIONS

Absolute contraindications**:**

1. Infection
2. Sepsis
3. 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. Local and 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
8. Skeletal immaturity.
9. Morbid obesity.
10. Foreign body sensitivity; where suspected or unknown, material sensitivity tests are to be made prior to implantation.
11. Any condition that may interfere with the survival of the implants such as Paget's disease, Charcot's disease, sickle cell anaemia or traits, lower extremity muscular atrophy or neuromuscular disease.

PATIENT SELECTION FACTORS

Patient selection factors which should be considered include:

1. Primary need to obtain pain relief.
2. Primary need to improve function.
3. Ability of the patient to follow instructions, including control of weight and activity levels, and a willingness to undergo rehabilitation.
4. A good nutritional state of the patient.
5. Whether the patient has reached full skeletal maturity.

WARNINGS

1. 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.
2. Mal-alignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure.
3. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

4. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
5. Use clean gloves when handling implants.
6. 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.
7. Do not modify implants.
8. The surgeon is to be thoroughly familiar with the implants, surgical technique and instruments, prior to performing surgery.
9. 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 non-Biomet manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture of ceramic heads.
10. Ceramic heads labelled “Type I Taper” are to be used with femoral stem components labelled “Type I Taper”.
11. Ceramic heads labelled “12/14 Taper” are to be used with femoral stem components labelled “12/14 Taper”.
12. Use only with UHMWPE or metal-backed UHMWPE acetabular components. May be used with other acetabular ceramic inserts (liners) that are currently licensed/cleared for marketing in the country of use.
13. Do not use ceramic heads that have been dropped, rubbed, scratched, disfigured, nicked, chipped or otherwise altered. Blemishes can be expected to cause failure.
14. All modular components must be accurately seated to prevent disassociation.
15. 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.
16. The femoral stem trunnion and the bore of the ceramic head should be dry and free of contamination prior to assembly, to minimize the risk of crevice corrosion and improper seating.
17. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
18. Once ceramic components have been seated, do not remove and reuse.
19. Modular delta ceramic head size (32+6mm) Type 1 taper is used ONLY with Biomet’s Ti-6Al-4V Type 1 taper stems.
20. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
21. The appropriate surgical technique will be determined by compatible components used to complete the system. Deviations from the recommended technique could result in early loosening/failure of the device, or other adverse events as outlined in the following section- ‘POSSIBLE ADVERSE EFFECTS’.
22. Please refer to the suggested operative technique guide available from your Biomet representative for suggested operative technique.
23. 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.

24. Firmly seat modular head components to prevent dissociation and/or micro-motion. Micro- motion may contribute to difficult head removal.

    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 in advance of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician, including follow-up visits. The patient must be warned that the device does not replace normal healthy bone, and that the implant can break or be damaged as a result of excessive load bearing or trauma. The patient must be warned to inform any other medical practitioner who may treat him in the future of the presence of the implant.

PRECAUTIONS

1. Specialized instruments are designed for specific Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. Use only with compatible instrumentation to avoid inaccurate fit, sizing, and/or excessive wear and device failure.
2. While rare, 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 prior for surgery.
3. 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. Furthermore, reusing an implant, could cause patient contamination.

MRI INFORMATION

1. This device has not been evaluated by the U.S. FDA for MR safety or compatibility.
2. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artefacts at or near the implant site.

POSSIBLE ADVERSE EFFECTS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and

fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. Further, there has been a report dated March 2010, titled “Advice from the CSD Expert Advisory Group on the biological effects of metal wear debris generated from hip implants,” regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement. 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, mal-alignment, 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 or leg length discrepancy.
7. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
8. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, mal-alignment, trauma, non-union, and/or excessive weight.
9. Fretting and crevice corrosion can occur at interfaces between components.
10. Wear and/or deformation of articulating surfaces.
11. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
12. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
13. The TTPA ceramic modular head is composed of ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular components, ceramic balls produce a relatively low amount of particles, the total amount of particulate produced remains undetermined. Because of the limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown.
14. Intraoperative and postoperative bone fracture and/or postoperative pain.
15. Peripheral neuropathies have been reported following total joint replacement surgery. Subclinical nerve damage occurs more frequently, possibly as a result of surgical trauma.

16. Cardiovascular reactions: venous thrombosis, pulmonary embolism or myocardial infarction.
17. Haematoma.
18. Delayed wound healing.
19. Bursitis.
20. Non-malignant, non-infective soft tissue masses, sometimes referred to as pseudotumours.
21. Gastrointestinal or genitourinary complications.
22. Pulmonary embolism.
23. Death.
24. Effusion.
25. Altered gait / limp

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. Rx symbol

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Biolox® is a registered name of CeramTec.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

REF	CATALOGUE NUMBER
LOT	BATCH CODE
	USE BY
STERILE R	STERILIZED USING IRRADIATION
	CONSULT INSTRUCTIONS FOR USE (OPTIONAL)
	DO NOT REUSE
	DO NOT RESTERILIZE

	MANUFACTURER
	DATE OF MANUFACTURE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DO NOT USE IF PACKAGE IS DAMAGED
MR	MR CONDITIONAL

Catalogue Number
REF **650-1159**

Lot Number
LOT **1234567**

Biolox Delta Modular Ceramic Head
Ø28mm -3mm Neck
Type 1 Taper
Warning Do Not Resterilise
CERAMIC

Qty
1

Caution Consult Instructions for use Do Not Reuse Use by

Sterilized using Irradiation
STERILE R

CE 0086

(01) 0 50 19279 45695 6

(10) 1234567 (17) 00

Biomet UK Limited
Bridgend
CF31 3XA
UK

Made in Germany

STERILE UNLESS PACK DAMAGED

Keram. modulární hlavice Biolox Delta **Ø28mm -3mm krcek** **Kužel typu 1** *** Pozor, znovu nesterilizujte*** (CZ)	**Biolox Delta Modularer Keramikkopf** **Ø28mm -3mm Hals** **Typ 1 Konus** ***Warnung: Nicht sterilisieren*** (DE)
Biolox Delta modulkeramikhoved **Ø28mm -3mm hals** **Type 1 konus** ***Advarsel: må ikke resteriliseres*** (DK)	**Cabeza modular de cerámica Biolox Delta** **Cuello de Ø28mm -3mm** **Cono de tipo 1** ***Aviso: No reesterilizar *** (ES)
Tête modulaire en céramique Biolox Delta **Ø28mm col -3mm** **Cône type 1** ***Attention : ne pas restériliser*** (FR)	**Biolox Delta -keraamiset modulaaripäät** **Ø28mm -3mm kaula** **Tyypin 1 kartio** ***Varoitus: ei saa steriloida uudelleen*** (FI)
Biolox Delta Modular Ceramic Head **Ø28mm -3mm Neck** **Type 1 Taper** ***Warning Do Not Resterilise*** (UK)	**Biolox Delta modulärt keramikhuvud** **Ø28mm -3mm hals** **Typ 1 konisk** *** Varning får ej omsteriliseras *** (SE)
Testa modulare in ceramica Biolox Delta **Ø28mm -3mm collo** **Cono tipo 1** ***Avvertenza non risterilizzare*** (IT)	**Biolox Delta modulært keramisk hode** **Ø28mm -3mm hals** **Type 1 taper** ***Advarsel Må ikke resteriliseres*** (NO)
Biolox Delta keramische modulaire kop **Ø28mm -3mm hals** **Conus type 1** ***Waarschuwing: niet hersteriliseren*** (NL)	**Cabeça cerâmica modular Biolox Delta** **Colo Ø28mm -3mm** **Cone tipo 1** ***Aviso: não reesterilizar*** (PT)

ΠΡΟΣΑΡΜΟ□ΟΜ ΚΕΡΑΜΙΚΗ ΚΕΦΑΛΗ Βιολοξ Δελτα
¬28μμ, ΑΥΧΕΝΑΣ –3μμ
ΚΩΝΟΣ ΤΥΠΟΥ 1 (EL)

REF
650-1159

LOT
1234567

Catalogue Number
REF 650-1159
Biolox Delta Modular Ceramic Head
Ø28mm -3mm Neck
Type 1 Taper
Warning Do Not Resterilise
CERAMIC

Qty: 1

Caution Consult Instructions for use Do Not Reuse Use by

Sterilized using Irradiation

STERILE R

STERILE UNLESS PACK DAMAGED

Lot Number
LOT 1234567

CE 0086 BIOMET

Biomet UK Limited
Bridgend
CF31 3XA
UK

Made in Germany

Catalogue Number
REF **650-1160**

Lot Number
LOT **1234567**

Biolox Delta Modular Ceramic Head
Ø32mm +6mm Neck Type 1 Taper
Type 1 Taper
Warning Use With Ti6Al4V T1 Taper Only
CERAMIC

Qty	Caution	Consult Instructions for use	Do Not Reuse	Use by	Sterilized using Irradiation	
1					STERILE R	CE 0086

(01) 0 50 19279 45697 0

(10) 1234567 (17) 00

Biomet UK Limited
Bridgend
CF31 3XA
UK

Made in Germany

STERILE UNLESS PACK DAMAGED

Keram. modulární hlavice Biolox Delta **Ø32mm +6mm krcek, kužel typu 1** **Kužel typu 1** ***Pozor, použít jen s T1 kuželem Ti6Al4V*** (CZ)	**Biolox Delta Modularer Keramikkopf** **Ø32mm +6mm Hals Typ 1 Konus** **Typ 1 Konus** ***Warnung: Nur mit Ti6Al4V T1 Konus*** (DE)
Biolox Delta modulkeramikhoved **Ø32mm +6mm hals type 1 konus** **Type 1 konus** ***Adv.må kun bruges med Ti6Al4V T1 konus*** (DK)	**Cabeza modular de cerámica Biolox Delta** **Ø32mm +6mm cuello con cono de tipo 1** **Cono de tipo 1** ***Aviso: Usar sólo con Ti6Al4Vcono T1*** (ES)
Tête modulaire en céramique Biolox Delta **Ø32mm +6mm col +6 cône Type 1** **Cône type 1** ***Pour cône Ti6Al4V T1 seulement*** (FR)	**Biolox Delta -keraamiset modulaaripäät** **Ø32mm +6mm kaula tyypin 1 kartio** **Tyypin 1 kartio** ***Varoitus: vain Ti6Al4V T1-kartioille*** (FI)
Biolox Delta Modular Ceramic Head **Ø32mm +6mm Neck Type 1 Taper** **Type 1 Taper** ***Warning Use With Ti6Al4V T1 Taper Only*** (UK)	**Biolox Delta modulärt keramikhuvud** **Ø32mm +6mm hals typ 1 konisk** **Typ 1 konisk** ***Varning anv endast m Ti6Al4V T1 konisk*** (SE)
Testa modulare in ceramica Biolox Delta **Ø32mm +6mm collo cono tipo 1** **Cono tipo 1** ***Avv. usare solo con cono Ti6Al4V T1*** (IT)	**Biolox Delta modulært keramisk hode** **Ø32mm +6mm hals type 1 taper** **Type 1 taper** ***Advarsel Bruk kun med Ti6Al4V T1 taper*** (NO)
Biolox Delta keramische modulaire kop **Ø32mm +6mm hals conus type 1** **Conus type 1** ***Let op: alleen met Ti6Al4V T1 conus*** (NL)	**Cabeça cerâmica modular Biolox Delta** **Colo Ø32mm +6mm com cone tipo 1** **Cone tipo 1** ***Aviso: use apenas c/ Ti6Al4V cone T1*** (PT)

ΠΡΟΣΑΡΜΟ□ΟΜ ΚΕΡΑΜΙΚΗ ΚΕΦΑΛΗ Βιολοξ Δελτα
¬32μμ, ΑΥΧΕΝΑΣ +6μμ ΚΩΝΟΥ ΤΥΠΟΥ 1
ΚΩΝΟΣ ΤΥΠΟΥ 1 (EL)

REF
650-1160

LOT
1234567

Catalogue Number
REF 650-1160

Biolox Delta Modular Ceramic Head
Ø32mm +6mm Neck Type 1 Taper
Type 1 Taper
Warning Use With Ti6Al4V T1 Taper Only
CERAMIC

Qty: 1

Caution Consult Instructions for use Do Not Reuse Use by

STERILE UNLESS PACK DAMAGED

Sterilized using Irradiation
STERILE R

Lot Number
LOT 1234567

CE 0086 BIOMET

Biomet UK Limited
Bridgend
CF31 3XA
UK

Made in Germany

Sample Outer Package

Substantial Equivalence

Introduction

The Biolox *delta*® Ceramic Heads are substantially equivalent to femoral heads cleared through the following 510(k)s:

Biolox *delta*® Ceramic Heads —Biomet—(K042091)
36mm Biolox *delta*® Ceramic Heads —Biomet—(K060312)
Biolox *delta*® Ceramic Head —Zimmer—(K070535)

A table comparing the monoblock Biolox *delta*® Ceramic Heads to the predicates can be found in **Attachment A** of this section, and clearance letters for the predicate devices may be found in **Attachment B**.

Indications for Use

1. Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, and traumatic arthritis.
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 indications for use as cleared in the Biomet Biolox *delta*® Ceramic Heads, K042091 and K060312, with the addition of specifically naming traumatic arthritis, which is also included in the Zimmer predicate, K070535, indications. The monoblock Biolox® *delta* Ceramic Heads are intended for use in total hip arthroplasty and may be used with either cemented or uncemented compatible components.

Materials

The Biolox® *delta* Ceramic Heads are made from the same material as all the predicates,i.e., Transition-Toughened-Platelet Alumina (TTPA) (b)(4)Trade Secret Process - Product Specs [redacted] This material is a common ceramic material in widespread use in the orthopedic industry. Details regarding the material may be found in (b)(4)Trade Secret Process - [redacted]

Design and Technological Characteristics

The changes to the Size 28 and Size 32 variation of the heads, have only (b)(4)Trade Secret Process - Product Specs [redacted] performance of the previously cleared heads. (See Mechanical Testing below. The Predicate Device Comparison Table in this section, **Tab A,** makes a comparison of the design change in detail.) The design of the 36mm heads has not changed and this size is only included to standardize part numbers and a global package insert (**Device Description**, **Attachment F**). There are a few variations between the UK prints and the US prints for the Size 36. However, the parts remain identical and the raw material part received from (b)(4)Trade Secret is to the same part number and print. (See Engineer's Justification, **this section**, **Tab C**.)

Packaging / Sterilization / Labeling

The packaging and sterilization methods are similar to those of the predicate devices. Both packaging and sterilization processes have been validated to support a ten (10) year shelf-life, and support the claim of substantial equivalence.

The package insert is found in the **Device Description**, **Attachment F.**

Mechanical Testing

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

[redacted]

Summaries of the testing are shown on the charts below:

Test/Evaluation	Test Summary	Acceptance Criteria	Biolox® *delta* Results
(b)(4)Trade Secret Process - Product Specs	[redacted]		

Test/Evaluation	Test Summary	Acceptance Criteria	Biolox® *delta* Results
(b)(4)Trade Secret Process - Product Specs	[redacted]		

Summary Statement

In summary, based on the similarity of design features and dimensional specifications, as well as the use of identical materials and similar indications for use and intended use, combined with successful testing results, the Biolox *delta*® Ceramic Heads described in this submission are substantially equivalent to the predicate devices and raise no new issues of safety or efficacy.

Predicate Device Comparison Table

	Biolox® *delta* Ceramic Heads Taper Change and Global Product Line	Biolox® *delta* Ceramic Heads	BIOLOX® *delta* Ceramic Femoral Head
Sponsor	Biomet	Biomet	Zimmer
510(k) Number	Subject Device	K042091, K061312	K071535
Ceramic Manufacturer	(b)(4)Trade Secret Process - Product Specs		
Indications	The 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, avascular necrosis and traumatic arthritis. 2. Rheumatoid arthritis 3. Correction of functional deformity 4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. 5. Revision procedures where other treatments or devices have failed. Specific indications for compatible components that can be used with the above modular heads include: Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrosis. (K974558, K002757, K021380, K033871) Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)	The 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 using other techniques. 5. Revision procedures where other treatments or devices have failed. Specific indications for compatible components that can be used with the above modular heads include: Salvage/Oncology Hip and Total Femur System components are also indicated for cases of ligament deficiency, tumor resection, trauma and revision of unsuccessful osteotomy or arthrosis. (K974558, K002757, K021380, K033871) Interlocking hip stems are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis. (K990830, K042774)	The Biolox® *delta* Ceramic Heads are modular components used in total hip arthroplasty and indicated for the following: Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis, patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Predicate Device Comparison Table

	Biolox® *delta* Ceramic Heads Taper Change and Global Product Line	Biolox® *delta* Ceramic Heads	Biolox® *delta* Ceramic Femoral Head
Sponsor	Biomet	Biomet	Zimmer
Product Code	LZO	LZO	LZO
Materials			
Material	(b)(4)Trade Secret Process - Product Specs [redacted]		
Design/Geometry			
Diameter(s): Neck Lengths	**Taper Change:** Size 28mm: -3, std, +3, Size 32mm: -3, std, +3, +6mm **Previously Cleared/Global Product Line:** Size 36mm: -3, std, +3, +6mm	**K040291:** Size 28mm: -3, std, +3, +5mm Size 32mm: -3, std, +3, +5mm **K061312:** Size 36mm: -3, std, +3, +6mm	Size 28mm: -3.5, std, +3.5mm Size 32 mm: -3.5, std, +3.5, +7.0mm Size 36mm: -3.5, std, +3.5, +7.0mm Size 40mm: -3.5, std, +3.5, +7.0mm
Taper Design Change:	**Internal Taper Changes:** (b)(4)Trade Secret Process - Product Specs [redacted]	**K042091:** (b)(4)Trade Secret Process - Product Specs [redacted]	N/A
Outer Head Change:	**Outer Head Changes:** [redacted] [redacted] (	**K042091** (b)(4)Trade Secret Process - Product Specs [redacted]	N/A

K042091 1/2

MAR 2 5 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Biolox® *delta* Ceramic Heads

Common or Usual Name: Ceramic Modular Head

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

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

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

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

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

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

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

K042041 2/2

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

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

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

Clinical Testing: None provided

Biolox is a trademark of Feldmuhle Anlager und Produktions – GHBH Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

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

Re: K042091
Trade/Device Name: Biolox® *delta* Ceramic Heads
Regulation Numbers: 21 CFR 888.3353
Regulation Names: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Codes: LZO
Dated: January 27, 2005
Received: January 28, 2005

Dear Ms. Beres:

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

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

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

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

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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K042091

Device Name: Biolox® *delta* Ceramic Heads

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

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

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

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

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K042091

K071535

Summary of Safety and Effectiveness

NOV 1 9 2007

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Patricia Jenks Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8354 Fax: (574) 372-4605
Date:	June 4, 2007
Trade Name:	BIOLOX® *delta** Ceramic Femoral Head
Common Name:	Ceramic Femoral Head Prosthesis
Classification Name and Reference:	Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis 21 CFR § 888.3353
Predicate Device(s):	36mm Biolox *delta* Ceramic Heads, manufactured by Biomet, K061312, cleared June 6, 2006 DePuy Delta Ceramic Femoral Head, manufactured by DePuy, K062748, cleared November 30, 2006 V40™ Biolox delta Ceramic Femoral Heads, manufactured by Howmedica Osteonics, K052718, cleared October 27, 2005
Device Description:	The BIOLOX *delta* Ceramic Femoral Heads are fabricated from an alumina matrix composite and are available in diameters of 28, 32, 36, and 40 mm with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic femoral heads for use in total hip arthroplasty.

* Trademark of CeramTec AG

Intended Use:	The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following: Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.
Comparison to Predicate Device(s):	The BIOLOX *delta* Ceramic Femoral Heads are substantially equivalent to the femoral heads listed above as predicate devices. Both the proposed and predicate designs are intended to function as a modular femoral head component in total hip arthroplasty and are manufactured from the same materials.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Mechanical testing was performed and results indicate that the BIOLOX *delta* Ceramic Femoral Heads are equivalent to devices currently on the market and capable of withstanding *in vivo* loading. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2007

Zimmer, Inc.
c/o Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K071535
Trade/Device Name: Biolox® *delta* Ceramic Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: October 25, 2007
Received: October 26, 2007

Dear Ms. Jenks:

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

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

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

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

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

Sincerely yours,

Mark N. Melkerson

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

Enclosure

K071535

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX* *delta** Ceramic Femoral Head

Indications for Use:

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

*Trademark of CeramTec AG

510(k) Number K071535

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

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

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

Figure 1

Test/Evaluation	Test Summary	Acceptance Criteria	Biolox® *delta* Results

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

[redacted]

Figure 2

Test/Evaluation	Test Summary	Acceptance Criteria	Biolox® *delta* Results
(b)(4)Trade Secret Process - Testing Report	[redacted]		

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

[redacted]

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

[redacted]

As noted previously under **Substantial Equivalence, Tab C**, the previously cleared size 36mm (K061312) is included in the globalization process, but no design changes have been made. A global part number will be assigned and the new global IFU (with the inclusion of traumatic arthritis in the indications) will be adopted.

Conclusion

The testing reports summarized above, with reports and justifications following, support the evidence that the Biomet Biolox® *delta* Ceramic Heads are substantially equivalent to other predicate monoblock ceramic heads on the market.

(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

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

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

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

Signature

Jenny Bruce
Typed Name

1 May 2013
Date

Biolox® *delta* Ceramic Heads
Device

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

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

Becky Earl
Signature

Becky Earl
Typed Name

5-1-13
Date

Biolox® *delta* Ceramic Heads
Device

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
AAMI/ANSI/ ISO 11137-2:2012 Sterilization of health care products- Radiation- Part 2: Establishing the Sterilization Dose

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-364	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

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

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

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 11137-2:2006 STERILIZATION OF HEALTH CARE PRODUCTS- RADIATION- PART 2: ESTABLISHING THE STERILIZATION DOSE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Definition and maintenance of product families for dose setting, dose substantiation, and sterilization dose auditing	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Option Selected: Use of Product Families

DESCRIPTION
Designation of product to represent a product family for performance of a verification dose experiment or sterilization dose audit

JUSTIFICATION
Biomet utilizes common/standardized manufacturing operation which lend themselves to the use of product families for sterilization validation.

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

TYPE OF DEVIATION OR OPTION SELECTED❖
Option selected: Method VDmax25

DESCRIPTION
Substantiation of 25 kGy as the sterilization dose

JUSTIFICATION
Provides a 10^-6 sterility assurance level

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

TYPE OF DEVIATION OR OPTION SELECTED❖

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F136-08e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-164	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F136-08e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖
None

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

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI TIR 12:2010 Designing, Testing, And Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities

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

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI TIR 12:2010 Designing, Testing, And Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F799-06, Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-131	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F799-06, Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ◆
None

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

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 6474-2 Implants for Surgery--Ceramic Materials, Part 2: composite materials, based on a high-purity alumina matrix w/zirconia

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#List 025, 8-194	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 6474-2 Implants for Surgery--Ceramic Materials, Part 2: composite materials, based on a high-purity alumina matrix w/zirconia

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ◆
Materials are required to conform to this standard when purchased from the vendor. No deviations from the standard are allowed.

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 7206-10 Implants for Surgery, Partial and Total Hip, Part 10, Determination of resistance to static load of modular femoral head

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

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 7206-10 Implants for Surgery, Partial and Total Hip, Part 10, Determination of resistance to static load of modular femoral head

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ◆
None

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Biomet, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
6-4-13

3. ADDRESS *(Number, Street, State, and ZIP Code)*
56 E. Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 574-372-1518
(Fax) 574-372-1683

PRODUCT INFORMATION

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

Biolox delta Ceramic Heads (Femoral Ceramic Head, Monoblock)

LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

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

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

CERTIFICATION STATEMENT / INFORMATION

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

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

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

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

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

NCT Number(s):

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

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

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

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
56 E. Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 574-372-1518
(Fax) 574-372-1683

15. DATE OF CERTIFICATION
6/7/13

PSC Publishing Services (301) 443-6740 EF

Barlow, Lenny *

From:	Barlow, Lenny *
Sent:	Friday, October 18, 2013 10:26 AM
To:	becky.earl@biomet.com
Cc:	DCCLetters
Subject:	k131684 Correspondence
Attachments:	k131684.pdf

5

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Limin Sun

Subject: 510(k) Number K131684/S001

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	21 CFR 888.3353
Class:	II
Product Code:	LZO
Additional Product Codes:	LPH, OQG, LWJ, JDI, OQH

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Elizabeth L. Frank -S 2013.10.09 12:32:58 -04'00'
Division Sign-Off	Erin I. Keith 2013.10.10 14:42:37 -04'00'

K131684/S001

FDA CDRH DMC

SEP 12 2013

Received

BIOMET

MANUFACTURING CORP.

September 10, 2013

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

Attn: Limin Sun, Ph.D.

RE: Additional Information Request for K131684, Biolox delta Ceramic Heads

Dear Dr. Sun:

Following is Biomet's response to your request for additional information dated August 8, 2013 for the Biolox delta Ceramic Heads, K131684. This notification is submitted in duplicate: please find enclosed one paper copy and one electronic copy which is an exact duplicate of the paper submission. The response follows each request.

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

[redacted]

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.6500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

38

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

[redacted]

A 510(k) Summary is provided on page 40 of the submission. For *applicant/sponsor*, you have listed two separate names with different addresses and FDA registration numbers, i.e.,

Biomet UK Ltd.
Waterton Industrial Estate
Bridgend South Wales, UNITED KINGDOM CF31 3XA
FDA Registration Number: 9044936

Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
Establishment Registration Number: 1825034

We understand that Biomet UK Ltd. is part of Biomet Manufacturing Corp., but only one applicant/sponsor should be listed in a 510(k) Summary. Therefore, please clarify which one is the applicant/sponsor for this 510(k) and remove the other one accordingly. Please provide an updated 510(k) Summary.

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

[redacted]

I trust this information will help in making a final determination for the Biolox delta Ceramic Heads, K131684. Please contact me at (574) 372-1518 or at becky.earl@biomet.com, if you have additional questions or require further information. An alternate contact is Laura Williams, at laura.williams@biomet.com or 574-372-6661.

Sincerely,

Becky Earl

Becky Earl
Regulatory Affairs
Biomet Manufacturing Corp.

BIOMET
MANUFACTURING CORP.

September 10, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
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[redacted]

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Sincerely,

Becky Earl

Becky Earl
Regulatory Affairs
Biomet Manufacturing Corp.

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b)(4)Trade Secret Process - Engineering Drawing

b)(4)Trade Secret Process - Engineering Drawing

510(k) Summary

Preparation Date:	August 22, 2013
Sponsor:	Biomet UK Ltd. Waterton Industrial Estate Bridgend, South Wales, UNITED KINGDOM CF31 3XA FDA Registration Number: 9044936 Telephone: +44(0) 1656 655221
Correspondent	Biomet Manufacturing Corp. 56 East Bell Drive P.O. Box 587 Warsaw, IN 46581-0587 Establishment Registration Number: 1825034 Telephone: (574) 267-6639
Contact Person:	Becky Earl Regulatory Specialist
Proprietary Name:	Biolox® *delta* Ceramic Heads
Common Name:	Femoral Ceramic Head, Monoblock
Classification Name:	LZO—Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented (21 CFR 888.3353) LPH— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358) OQG—Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (21 CFR 888.3358) LWJ—prosthesis, hip, semi-constrained, metal/polymer, uncemented (21 CFR 888.3360) JDI— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350) OQH—Hip, semi-constrained, cemented, metal/polymer + additive, cemented (21 CFR 888.3350)

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Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

OQI—Hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented (21 CFR 888.3353)

MAY—Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish (21 CFR 888.3353)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Biolox® *delta* Ceramic Heads—Biomet—(K042091)

36mm Biolox® *delta* Ceramic Heads—Biomet—(K061312)

Biolox® *delta* Ceramic Head—Zimmer—(K070535)

Device Description:

The Biolox® *delta* component is a traditional, one-piece ceramic head indicated for primary hip arthroplasty. The material for the device is Transition-Toughened-Platelet Alumina (TTPA) 75% Alumina, 24% Zirconia and 1% Platelet. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The modular head attaches to a metallic femoral stem with a Biomet Type I taper. The ceramic heads are available in three sizes, with several offsets.

The scope of this submission is:

- An inner taper change and distal face change requested by CeramTec for the purpose of increased burst strength and increased cost effectiveness.
- The one remaining size is previously cleared through K061312 and K073102. This submission seeks to incorporate all of Biomet's Biolox® *delta* Ceramic Heads (Monobloc) under unified Indications, Contraindications, Instructions for Use and labeling.

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, avascular necrosis and traumatic arthritis.
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)

Summary of Technologies:

The technological characteristics of the proposed device are the same as or similar to the predicates. The Biolox® *delta* Ceramic Heads are similar in design, dimensions, and intended use as their predicates. They are made of the same material as all their predicates, and indications are similar or the same as all the predicates. The slight changes to the Type 1 taper for ease and savings in manufacturing, have only increased the burst strength. There have been no changes to the larger size.

Non-Clinical Testing:

New testing to support the argument for substantial equivalence includes the following: Burst testing to assess the worst case and further testing on worst case to include: Fatigue burst test; Post-fatigue burst test; Pull-off test on CoCrMo tapers; and Rotational stability on CoCrMo tapers.

Clinical Testing:

None provided as a basis for substantial equivalence.

Testing demonstrates that the modifications made to the Biolox® *delta* Ceramic Heads (Monoblock) do not introduce any new risks of safety or efficacy, and that the Biolox® *delta* Ceramic Heads (Monoblock) are substantially equivalent to the predicates.

BIOMET Biolox® *delta* (TTPA)_ CERAMIC MODULAR HEAD HIP JOINT PROSTHESES

UK
ATTENTION OPERATING SURGEON

CZ
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UPOZORNĚNÍ PRO OPERUJÍCÍHO CHIRURGA

DE
FPO
INFORMATION FÜR DEN OPERIERENDEN CHIRURGEN

DK
FPO
BEMÆRKNING TIL OP ERERENDE KIRURG

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FPO
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FPO
主刀外科医生需注意

CE 0086

BIOMET UK LTD.
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For additional information please see
www.biomet.com and www.orthoteers.com

REF: 5401000274
REVISION: 0
DATE: May 2013
Change Control No: 226074

BIOMET Biolox® *delta* (TTPA) CERAMIC MODULAR HEAD HIP JOINT PROSTHESES

ATTENTION OPERATING SURGEON

IMPORTANT INFORMATION FOR USERS IN THE U.S.: CERAMIC MODULAR FEMORAL HEADS ARE NOT CLEARED FOR USE WITH CERAMIC LINERS.

DESCRIPTION
Biomet ceramic modular head components are available in a variety of head sizes and neck length variations. The highly polished surface is designed to reduce friction and minimize wear. Biomet modular femoral heads are available with Type 1 and Type 12/14 tapers (where available) with various neck lengths and are compatible with any of Biomet's modular femoral stems of the correct taper type. (Note: Size 32 +6mm Biolox® *delta* head may only be used with Biomet's Ti-6Al-4V Type 1 taper stems.) The modular femoral heads are utilized in conjunction with other hip prosthetic components to form part of a total joint replacement system. Total hip joint prostheses may include: acetabular shells, liners, femoral stems, femoral heads, and accessories.

Biomet ceramic modular head components are indicated to be used either with ceramic acetabular inserts (liners) for ceramic- on -ceramic articulation, in countries where currently licensed/cleared for such use, or with Biomet's range of ultra high molecular weight polyethylene (UHMWPE) acetabular liners and cups.

MATERIALS
Transition-Toughened-Platelet Alumina Composite Ceramic (TTPA Ceramic)

INDICATIONS
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, avascular necrosis and traumatic arthritis.
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)
* Note- for the USA only

CONTRAINDICATIONS
Absolute contraindications**:**

1. Infection
2. Sepsis
3. 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. Local and 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
8. Skeletal immaturity.
9. Morbid obesity.
10. Foreign body sensitivity; where suspected or unknown, material sensitivity tests are to be made prior to implantation.
11. Any condition that may interfere with the survival of the implants such as Paget's disease, Charcot's disease, sickle cell anaemia or traits, lower extremity muscular atrophy or neuromuscular disease.

PATIENT SELECTION FACTORS
Patient selection factors which should be considered include:

1. Primary need to obtain pain relief.
2. Primary need to improve function.
3. Ability of the patient to follow instructions, including control of weight and activity levels, and a willingness to undergo rehabilitation.
4. A good nutritional state of the patient.
5. Whether the patient has reached full skeletal maturity.

WARNINGS

1. 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.
2. Mal-alignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure.
3. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.
4. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.

5. Use clean gloves when handling implants.
6. 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.
7. Do not modify implants.
8. The surgeon is to be thoroughly familiar with the implants, surgical technique and instruments, prior to performing surgery.
9. 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 non-Biomet manufacturers. Mismatching of components or taper sizes can be expected to cause intraoperative or postoperative fracture of ceramic heads.
10. Ceramic heads labelled “Type I Taper” are to be used with femoral stem components labelled “Type I Taper”.
11. Ceramic heads labelled “12/14 Taper” are to be used with femoral stem components labelled “12/14 Taper”.
12. Use only with UHMWPE or metal-backed UHMWPE acetabular components. May be used with other acetabular ceramic inserts (liners) that are currently licensed/cleared for marketing in the country of use.
13. Do not use ceramic heads that have been dropped, rubbed, scratched, disfigured, nicked, chipped or otherwise altered. Blemishes can be expected to cause failure.
14. All modular components must be accurately seated to prevent disassociation.
15. 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.
16. The femoral stem trunnion and the bore of the ceramic head should be dry and free of contamination prior to assembly, to minimize the risk of crevice corrosion and improper seating.
17. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
18. Once ceramic components have been seated, do not remove and reuse.
19. Modular delta ceramic head size (32+6mm) Type 1 taper is used ONLY with Biomet’s Ti-6Al-4V Type 1 taper stems.
20. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
21. The appropriate surgical technique will be determined by compatible components used to complete the system. Deviations from the recommended technique could result in early loosening/failure of the device, or other adverse events as outlined in the following section- ‘POSSIBLE ADVERSE EFFECTS’.
22. Please refer to the suggested operative technique guide available from your Biomet representative for suggested operative technique.
23. 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.
24. Firmly seat modular head components to prevent dissociation and/or micro-motion. Micro- motion may contribute to difficult head removal.

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 in advance of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician, including follow-up visits. The patient must be warned that the device does not replace normal healthy bone, and that the implant can break or be damaged as a result of excessive load bearing or trauma. The patient must be warned to inform any other medical practitioner who may treat him in the future of the presence of the implant.

PRECAUTIONS

1. Specialized instruments are designed for specific Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. Use only with compatible instrumentation to avoid inaccurate fit, sizing, and/or excessive wear and device failure.
2. While rare, 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 prior for surgery.
3. 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. Furthermore, reusing an implant, could cause patient contamination.

MRI INFORMATION

1. The Biolox® delta Ceramic Heads have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artefacts at or near the implant site.

POSSIBLE ADVERSE EFFECTS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint

implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. Further, there has been a report dated March 2010, titled “Advice from the CSD Expert Advisory Group on the biological effects of metal wear debris generated from hip implants,” regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement.

2. Early or late postoperative infection and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, mal-alignment, non-union, bone resorption, and excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb or leg length discrepancy.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, mal-alignment, trauma, non-union, and/or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. 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.
15. Intraoperative and postoperative bone fracture and/or postoperative pain.
16. Peripheral neuropathies have been reported following total joint replacement surgery. Subclinical nerve damage occurs more frequently, possibly as a result of surgical trauma.
17. Cardiovascular reactions: venous thrombosis, pulmonary embolism or myocardial infarction.
18. Haematoma.
19. Delayed wound healing.

20. Bursitis.
21. Non-malignant, non-infective soft tissue masses, sometimes referred to as pseudotumours.
22. Gastrointestinal or genitourinary complications.
23. Pulmonary embolism.
24. Death.
25. Effusion.
26. Altered gait / limp

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. Rx symbol

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Biolox® is a registered name of CeramTec.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

REF	CATALOGUE NUMBER
LOT	BATCH CODE

	USE BY
STERILE R	STERILIZED USING IRRADIATION
	CONSULT INSTRUCTIONS FOR USE (OPTIONAL)
	DO NOT REUSE
	DO NOT RESTERILIZE
	MANUFACTURER
	DATE OF MANUFACTURE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DO NOT USE IF PACKAGE IS DAMAGED
MR	MR CONDITIONAL