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)

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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:

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*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)

Elizabeth L. Frank -S

Division of Orthopedic Devices