Biomet UK Ltd.
Lisa Ingram
Regulatory Affairs Specialist
Waterton Industrial Estate
Bridgend, CF31 3XA Gb

February 27, 2020

Re: K192683
Trade/Device Name: Biolox® delta Ceramic Heads, Biolox® delta Option Ceramic Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, OQG, LWJ, JDI, OQH, OQI, MAY
Dated: January 28, 2020
Received: January 29, 2020

Dear Lisa Ingram:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FOR Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192683

Device Name
Biolox® delta Ceramic Heads and Biolox® Delta Option Ceramic Heads

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

1. Non-inflammatory degenerative joint disease including osteoarthritis, 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the **Biolox® delta Ceramic Heads and Biolox® delta Option Ceramic Heads** 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

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|---|---|
| **Sponsor:** | Biomet UK Limited<br>Waterton Industrial Estate<br>Bridgend, South Wales, UNITED KINGDOM, CF31 3XA<br>Establishment Registration Number: 3002806535<br>Telephone: +44(0) 1656 655221 |
| **Correspondent** | Biomet UK Limited<br>Waterton Industrial Estate<br>Bridgend, South Wales, UNITED KINGDOM, CF31 3XA<br>Establishment Registration Number: 3002806535<br>Telephone: +44(0) 1656 655221 |
| **Contact Person**: | Lisa Ingram<br>Regulatory Affairs Specialist<br>Telephone: +44 1656 761608<br>Fax: +44 1656 645454 |
| **Date:** | 21 January 2020 |
| **Subject Device:** | **Trade Name:** Biolox® delta Ceramic Heads and Biolox® delta Option Ceramic Heads<br><br>**Common Name:** Femoral Ceramic Head, Monoblock and Femoral Modular Ceramic Head<br><br>**Classification Name:**<br>LZO—Prosthesis, Hip, Semi□Constrained, Metal/Ceramic/Polymer, Cemented or Non□Porous, Uncemented (21 CFR 888.3353)<br>LPH— Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)<br><br>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)

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:**

**Primary Predicates**

K131684 - Biolox® delta Ceramic Heads – Biomet UK Limited
K141653 - Biolox® delta Option Ceramic Heads – Biomet UK Limited

**Reference Device (Reference item for Packaging only)**

K181761 – Zimmer Biomet Select Ceramic Heads – Zimmer Inc.

**Purpose and Device Description:**

Biolox® delta Ceramic Heads
The Biolox® delta component is a traditional, one□piece ceramic head indicated for primary hip arthroplasty. The material for the device is Zirconia-Platelet Toughened Alumina (ZPTA) 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.

Biolox® delta Option Ceramic Heads
The Biolox® delta Option component is a modular ceramic head with a Type I or 12/14 adapter sleeve, indicated for primary or revision hip arthroplasty. The material for the device is Zirconia-Platelet Toughened Alumina (ZPTA) 75% Alumina, 24% Zirconia and 1% Platelet. The highly polished spherical surface articulates with a polyethylene liner acetabular component. The

modular head attaches to any Biomet metallic femoral stem with a Type 1 taper or a 12/14 taper, using the associated adapter sleeve.

The scope of this submission is to notify the FDA of the cumulative changes to the Biolox® delta Ceramic Heads and Biolox® delta Option Ceramic Heads relating to:

- A manufacturing site transfer of Biolox® delta Ceramic Heads and Biolox® delta Option Ceramic Heads
- Change of sterilization sub-contractor
- Labeling changes (including changes to IFU and labels)
- Packaging changes following the manufacturing site transfer
- Device compatibility (Inclusion of additional compatible products)

The subject devices are the same as the ones previously cleared as Biolox® delta Ceramic Heads (K131684) and Biolox® delta Option Ceramic Heads (K141653).

This traditional 510(k) submission is to highlight device changes as described in scope above. There have been no design changes since the last 510(k) clearance.

**Indications for Use:**

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

1. Non□inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and traumatic arthritis.
2. Rheumatoid arthritis.
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*Note – for the USA only

**Summary of Technological Characteristics:**

The technological characteristics of the proposed devices are the same as the predicates, K131684 and K141653. The Biolox® delta Ceramic Heads and Biolox® delta Option Ceramic Heads are similar in technology, design and dimensions as their predicates.
The intended use, indications for use, material and design features of the proposed devices are the same as the predicates.
There have been no design changes to the design of the devices or the technology since the latest clearance, K131684 and K141653.

**Summary of Performance Data:**

**Non-Clinical Testing**

New testing to support the changes to the device and the argument for substantial equivalence includes the following:

- Product Compatibility Testing – Compatibility testing and/or engineering evaluations were completed to assure paired products can safely be used in combination.
- Pyrogenicity Testing - Limulus amebocyte lysate (LAL) Test

Results from the compatibility testing have been provided under Section 18 (Performance Testing – Bench) of this Traditional 510(k) submission.
Further information on the Pyrogenicity Testing is provided under Section 14 - Biocompatibility

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

**Substantial Equivalence Conclusion**
Evaluation of impact of changes and the testing conducted in support of substantial equivalence demonstrate that the changes made to the Biolox® delta Ceramic Heads and Biolox® delta Option Ceramic Heads do not introduce any new safety or effectiveness risks.
All possible impact of the changes to products has been thoroughly tested/verified.
The proposed devices have the same intended use and indications for use as the predicate(s).
The proposed devices have similar technological characteristics to the predicate(s), and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate device(s).

Biomet UK Limited therefore concludes that the Biomet Biolox® delta Ceramic Heads and Biolox® delta Option 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.