July 29, 2020

Biomet UK Ltd.
Caleb Barylski
Regulatory Affairs Specialist
Waterton Industrial Estate
Brigend, South Wales CF31 3XA
United Kingdom

Re: K200959
Trade/Device Name: Biolox® delta Ceramic Head, Biolox® delta Option Ceramic Head (MR Labeling)

Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, LPH, LWJ, MAY, OQG, OQH, OQI
Dated: April 9, 2020
Received: April 10, 2020

Dear Caleb Barylski:

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
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)*

K200959

Device Name

Biolox® *delta* Ceramic Heads, Biolox® *delta* Option Ceramic Heads MR Labeling

Indications for Use *(Describe)*

The 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)

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.

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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) MR Labeling premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s,' issued on September 13, 2019.

Sponsor:

Biomet UK Ltd.
Waterton Industrial Estate
Bridgend, South Wales, United Kingdom CF31 3XA
FDA Registration Number: 3002806535

Contact Person:

Caleb Barylski
Regulatory Affairs Specialist
Telephone: (574-371-0250)

Date:

28 July 2020

Subject Device:

Trade Name: Biolox® *delta* Ceramic Heads, Biolox® *delta* Option Ceramic Heads MR Labeling

Common Name: Femoral Ceramic Head, Monoblock and Femoral Modular Ceramic Head

Classification Name:
Primary Product Code:

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

Additional Product Codes:

- JDI – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)
- LPH – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358)
- LWJ – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (21 CFR 888.3360)
- MAY – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous Cemented, Osteophilic Finish (21 CFR 888.3353)

- OQG – Prosthesis, Hip, Semi-Constrained, Metal/Polymer + Additive, Porous Uncemented (21 CFR 888.3358)
- 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)

Predicate Device(s):

Primary Predicate	K192683	Biolox Delta Ceramic Heads, Biolox Delta Option Ceramic Heads	Biomet UK Ltd.
Secondary Predicate/ Reference Device	K182678	Zimmer M/L Taper Hip Prosthesis With Kinectiv Technology MR Labeling	Zimmer, Inc.

Purpose and Device Description:

The purpose of this submission is the addition of MR Conditional language to the Instructions for Use and MR Conditional symbol to the device package label for the Biolox delta ceramic heads and Biolox delta option ceramic heads. The addition of MR labeling to the subject devices does not impact indications, materials, design features, packaging, or sterilization.

The Biolox® delta component is a traditional, one-piece, ceramic head 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 Type 1 taper. The ceramic heads are available in three sizes, with several offsets. There have been no changes in design or part numbers since their previous clearance in K192683.

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 either a 12/14 or Type 1 taper, using the associated adapter sleeve. There have been no changes in design or part numbers since their previous clearance in K192683.

Intended Use and Indications for Use:

The 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.
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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)

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Identical
- **Indications for Use:** Identical
- **Materials:** Identical

- **Design Features:** Identical
- **Sterilization:** Identical

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  Zimmer has performed non-clinical Magnetic Resonance Imaging (MRI) studies on implants which are determined to be MR Conditional in accordance to ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Tests included the following:
    - RF-induced heating (ASTM F2182-11a)
    - Image Artifact (ASTM F2119-07)
    - Magnetic Displacement (ASTM 2052-14)
- **Clinical Tests:**
    - No additional testing was conducted since there are no design changes to the subject device since clearance in K192683.

Substantial Equivalence Conclusion

Non-clinical tests provided in this Traditional 510(k) establish the conditional safety and compatibility of the implants in a magnetic resonance (MR) environment. The subject device and predicate devices are identical with no design changes since their previous clearance. The subject devices are substantially equivalent to the legally marketed predicate devices.