Zimmer GmbH
Neha Sreenath
Regulatory Affairs Senior Speicalist
Sulzerallee 8
Winterthur, 8404 Ch

October 1, 2019

Re: K192416
Trade/Device Name: BIOLOX Delta Ceramic Femoral Heads, BIOLOX Option Ceramic Femoral Head System
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: August 30, 2019
Received: September 4, 2019

Dear Neha Sreenath:

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)*

K192416

Device Name

BIOLOX® delta Ceramic Femoral Head

Indications for Use *(Describe)*

The BIOLOX delta Ceramic Femoral Heads are modular components used in total hip arthroplasty and are 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.
• Patients with acute femoral neck fractures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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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)*

K192416

Device Name

BIOLOX® OPTION Ceramic Femoral Head System

Indications for Use *(Describe)*

The BIOLOX OPTION Ceramic Femoral Head System is comprised of modular components used in primary or revision total hip arthroplasty and is 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.
- Patients with acute neck fractures.

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)

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510(k) SUMMARY

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Neha Sreenath Senior Specialist, Regulatory Affairs Telephone: +41 58 85 48814 Fax: + 41 52 244 86 58
Date:	August 30, 2019
Trade Name:	BIOLOX® delta Ceramic Femoral Head BIOLOX® OPTION Ceramic Femoral Head System
Common Name:	Ceramic Femoral Head Prosthesis
Classification Product Code :	LZO
Device Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Regulation Number / Description:	21 CFR § 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Predicate Device:	Biolox Delta Ceramic Femoral Heads, manufactured by Zimmer GmbH, K071535, cleared 11/19/2007 and K130899, cleared 05/01/2013 Biolox Option Ceramic Femoral Head System, manufactured by Zimmer GmbH, K073567, cleared 03/13/2008
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 40mm 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. The BIOLOX OPTION Ceramic Femoral Head System consist of a ceramic head fabricated from an alumina matrix composite available in diameters of 28, 32, 36, and 40 mm and a titanium

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510(K) SUMMARY

adapter for the femoral stem cone with a range of offsets to accommodate various patient anatomies. The system serves as an alternative to both metal and alumina ceramic femoral heads and is for use in both primary and revision total hip arthroplasty.

Indications for Use:

BIOLOX delta Ceramic Femoral Heads:

The BIOLOX delta Ceramic Femoral Heads are modular components used in total hip arthroplasty and are 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.
- Patients with acute femoral neck fractures.

BIOLOX OPTION Ceramic Femoral Head System:

The BIOLOX OPTION Ceramic Femoral Head System is comprised of modular components used in primary or revision total hip arthroplasty and is 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.
- Patients with acute neck fractures.

Comparison to Predicate Device:

The intended use of the modified devices, as described in its labelling, has not changed as a result of the modifications proposed in the present submission. Further, the indications for use, materials, design features and sterilization method of the subject devices remain identical to the predicate devices. The proposed compatibility extension does not alter the fundamental scientific technology shared by both the subject devices and predicate devices.

Performance Data (Nonclinical

Non-Clinical Performance and Conclusions:

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and/or Clinical):

Results from engineering analyses demonstrate that the subject BIOLOX delta and BIOLOX OPTION ceramic femoral heads for which the expansion of product compatibility is proposed remains substantially equivalent to the predicate devices cleared under K071535 and K130899 (BIOLOX delta) and K073567 (BIOLOX OPTION) respectively. This conclusion has been supported by rationales for wear justification (ISO 7206-2), material equivalence (ISO 6474-2, ISO 5832-3/ASTM F136) and Range of Motion according to ISO 21535.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion:

The subject devices have the same intended use and indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labelling and are manufactured and sterilized using the same materials and processes as the predicate devices.

Except for the modifications described in this submission, the subject devices are identical to the predicate devices, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness as established with performance testing; and
- the subject devices are at least as safe and effective as the legally marketed predicate devices.