April 24, 2024

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Meenakshi Verma
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K234025
Trade/Device Name: 22.2mm Biolox® delta Ceramic V40 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: December 20, 2023
Received: December 20, 2023

Dear Meenakshi Verma/Gregg Ritter:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234025

Device Name
22.2mm BIOLOX® delta Ceramic V40™ Femoral Heads

Indications for Use *(Describe)*
1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post traumatic arthritis or late-stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

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.

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510(k) Summary

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Date Prepared: 21-December-2023

Proprietary Name: 22.2mm BIOLOX® delta Ceramic V40™ Femoral Heads

Common Name: Total Hip Joint Replacement

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)

Product Codes: LZO

Legally Marketed Primary Predicate Device to Which Substantial Equivalence is Claimed:

- V40^{TM} Biolox® delta Ceramic Femoral Heads – K052718

Reason for 510(k) Submission:
The purpose of this submission is to introduce a line extension to the existing Biolox® delta Ceramic V40^{TM} Femoral Heads device family, specifically 22.2mm Biolox® delta Ceramic V40^{TM} Femoral Heads, with neck length +0mm & +3mm.

Device Description:

The subject 22.2mm Biolox® delta Ceramic V40™ Femoral Heads with neck length +0mm and +3mm are sterile, single-use devices that are manufactured with high-purity alumina matrix with zirconia reinforcement and are compatible with the 22.2mm ID sizes of compatible acetabular inserts and UHMWPE acetabular cups. The Biolox® delta Ceramic V40™ Femoral Heads may be used in conjunction with compatible V40™ taper femoral stems and acetabular shell components to achieve reconstructive replacement of the hip joint.

Intended Use:

The subject device has the same intended use as that specified in the predicate device 510(k) clearance.

Indications:

The indications for use for the subject device are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Summary of Technological Characteristics:

The device comparisons and performance testing show that the 22.2mm Biolox® delta Ceramic V40™ Femoral Heads are substantially equivalent to the cited predicate V40™ Biolox® delta Ceramic Femoral Heads cleared via K052718, based on intended use, indications for use, design, material, technological characteristics, operational principles, and non-clinical performance data. The predicate femoral heads are available in an outer diameter of 28mm, 32mm, and 36mm with various neck lengths. The subject femoral heads add two 22.2mm outer diameter options to the existing Biolox® delta Ceramic V40™ Femoral Heads family.

A new vendor for the titanium coating component of compatible Accolade II hip stems was also notified as part of this submission. Coating characterization information was provided per FDA guidance. The following test standards were followed to assess the titanium coating:

- ISO 13179-1
- ASTM F1160
- ASTM F1147
- ASTM F1044
- ASTM F1978
- ASTM F1580
- ASTM F1854

Non-Clinical Testing:

The following non-clinical laboratory testing and engineering analysis were performed to determine substantial equivalence:

- Burst testing, Fatigue testing and post-fatigue burst testing (ISO 7206-10 and ASTM F2345-21)
- Axial Pull-off testing
- Wear evaluation
- Range of Motion
- Torsional resistance (ISO 7206-13)
- MRI Safety testing

Clinical Testing:
Clinical testing was not required as a basis for demonstrating substantial equivalence.

Conclusion:
Based upon a comparison of the intended use, indications for use, design, material, technological characteristics, operational principles, and non-clinical performance data the subject 22.2mm Biolox® delta Ceramic V40™ Femoral Heads are substantially equivalent to the predicate Biolox® delta Ceramic V40™ Femoral Heads identified in this premarket notification.