March 4, 2025

Limacorporate
℅ Alessia Collarini
Regulatory Affairs Specialist
Enovis
9800 Metric Blvd.
Austin, Texas 78758

Re: K243809
Trade/Device Name: Biolox® Delta Revision 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
Dated: December 2, 2024
Received: December 11, 2024

Dear Alessia Collarini:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243809

Device Name
Biolox® Delta Revision Heads

Indications for Use *(Describe)*
LimaCorporate Femoral modular heads are intended to be used in Total Hip arthroplasty with compatible femoral and acetabular components.

- Coupling of femoral modular heads with DELTA Acetabular System is indicated for use for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
• Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
• Rheumatoid arthritis;
• Post-traumatic arthritis,
• Correction of functional deformity;
• Fractures, dislocation of the hip and unsuccessful cup arthroplasty;
• Revisions in cases of good remaining bone stock.
• Revision of previously failed total hip arthroplasty (DELTA Multihole TT Pro only)
The components are intended for use in cementless (press-fit) applications.

- Coupling of femoral modular heads with H-MAX S, Minima S, Master SL, C2, MODULUS femoral stems is indicated for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
• non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
• rheumatoid arthritis;
• osteoarthritis after femoral heads fractures (H-MAX S and Modulus stem);
• treatment of femoral head and neck fractures (Minima S and MasterSL stems)
• correction of functional deformity (MODULUS stems);
• revisions in cases of good remaining femoral bone stock.
The components are intended for use in cementless (press-fit) applications.

- Coupling of femoral modular heads with Revision Femoral Stem is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. The components are intended for use in cementless (press-fit) applications.

- Coupling of femoral modular heads with Cemented Cup is intended for cemented applications in hip arthroplasty where the acetabular socket needs reconstruction.

LimaCorporate Lock Bipolar femoral heads are intended to be used in Partial Hip replacement with compatible femoral components (Minima S, Master SL, C2, MODULUS femoral stems) for cementless applications.
This procedure is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: treatment of non-union, femoral neck fracture and intertrochanteric fractures unmanageable by other techniques.

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
K243809

Date prepared: February 6, 2025

Manufacturer:
LimaCorporate S.p.A.
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Daniele Udine - Italy

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Product	Product Code	Regulation and Classification Name
Biolox® Delta Revision heads	LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
	LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358

Common name: Femoral head with sleeve

Description:

Biolox® Delta Revision heads consist of a Biolox® Delta ball head and a titanium sleeve (Ti6Al4V). The ball heads are made of the Biolox® Delta ceramic material (K141327, K182099) and come in various outer diameters. The ceramic Biolox® Delta ball head is assembled with the corresponding titanium sleeve and is then placed over the taper of an in-situ hip stem prosthesis, during revision of a previously implanted femoral head:

K170473, K112091, K160011, K140975, K151739, K161226, K141327, K143509, K150855

The titanium sleeve has an inner 12/14 taper which fits the dimensions of a metallic hip stem prosthesis, and the Biolox® Delta ball head has a 16/18 taper which fits to the dimensions of the outer diameter of the titanium sleeve. The ball head then articulates against an acetabular insert:

K112898, K141395, K182099, K181491, K191622, K200656

The titanium sleeves are available in sizes -3, 0, +4, and +7 (S, M, L, XL) and the ball heads of the Biolox® Delta Revision heads are available with outer diameters ranging from 28mm - 40 mm.

Indications for Use:

LimaCorporate Femoral modular heads are intended to be used in Total Hip arthroplasty with compatible femoral and acetabular components.

- Coupling of femoral modular heads with DELTA Acetabular System is indicated for use for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
  • Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
  • Rheumatoid arthritis;
  • Post-traumatic arthritis,
  • Correction of functional deformity;
  • Fractures, dislocation of the hip and unsuccessful cup arthroplasty;
  • Revisions in cases of good remaining bone stock.
  • Revision of previously failed total hip arthroplasty (DELTA Multihole TT Pro only)
  The components are intended for use in cementless (press-fit) applications.
- Coupling of femoral modular heads with H-MAX S, Minima S, Master SL, C2, MODULUS femoral stems is indicated for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:
  • non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
  • rheumatoid arthritis;
  • osteoarthritis after femoral heads fractures (H-MAX S and Modulus stem);
  • treatment of femoral head and neck fractures (Minima S and MasterSL stems)
  • correction of functional deformity (MODULUS stems);
  • revisions in cases of good remaining femoral bone stock.
  The components are intended for use in cementless (press-fit) applications.
- Coupling of femoral modular heads with Revision Femoral Stem is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. The components are intended for use in cementless (press-fit) applications.

- Coupling of femoral modular heads with Cemented Cup is intended for cemented applications in hip arthroplasty where the acetabular socket needs reconstruction.

LimaCorporate Lock Bipolar femoral heads are intended to be used in Partial Hip replacement with compatible femoral components (Minima S, Master SL, C2, MODULUS femoral stems) for cementless applications.
This procedure is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: treatment of non-union, femoral neck fracture and intertrochanteric fractures unmanageable by other techniques.

Predicate Devices:

No.	Company	Device name	Cleared via

1 (Primary predicate)	TJO	Biolox Option Ceramic Heads Line Extension	K213580
2 (Additional predicate)	Biomet UK	Biolox® Delta Option Ceramic Heads	K192683
3 (Additional predicate)	Limacorporate	CoCrMo Femoral heads	K112158

Summary of technology comparison:
TJO Biolox® Option Ceramic Heads Line Extension and Biomet UK Biolox® Delta Option Ceramic Heads are provided with the same material, manufacturing, fixation, design, class, regulation number, and contain the same product codes. The mechanical testing for the subject device contains the equivalent testing to TJO Biolox® Option Ceramic Heads Line Extension.

The following stems have the same tapered design for the femoral heads: K170473, K112091, K160011, K140975, K151739, K161226, K141327, K143509, K150855.

Biolox Ceramic heads provided by Ceramtec are cleared with the following acetabular cups: K112898, K141395, K182099, K181491, K191622, K200656.

The design of the subject device uses the same dimensions of the LimaCorporate cleared 510(k) femoral heads. The fitment of the head uses a taper 12/14 press fit and the outer surface of the head to fit into the poly liner.

Non-clinical testing
Mechanical tests demonstrated that device performance fulfilled the intended use and that the devices are substantially equivalent to the predicate devices.
Mechanical testing was performed on worst case components or constructs:

- Burst, fatigue, post fatigue, pull-off (ISO 7206-10)
- Fretting corrosion test (ASTM F1875)
- Pull-off test (ASTM F2009)
- Torque-off test (ISO 7206-13)
- Fatigue test (ISO 7206-4) – mechanical evaluation
- Fatigue-fretting test (ISO 7206-6) – mechanical evaluation

Conclusion
Based upon a comparison of intended use, materials, summary of technological characteristics, and non-Clinical testing, the Biolox® Delta Revision heads components are substantially equivalent to the predicate device components identified in this premarket notification.