Feburary 7, 2025

Encore Medical, L.P.
Katrina Dombovari
Regulatory Affairs Coordinator
9800 Metric Boulevard
Austin, Texas 78758

Re: K241483
Trade/Device Name: ceramys™ 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: May 24, 2024
Received: January 6, 2025

Dear Katrina Dombovari:

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)*
K241483

Device Name
ceramys™ femoral head system

Indications for Use *(Describe)*
Joint replacement is indicated for patients suffering from disability due to:
• Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
• Rheumatoid arthritis;
• Correction of functional deformity;
• Femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.
The EMPOWR Dual Mobility™ system has the additional indication of joint replacement due to dislocation risks.

The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for who all other options to constrained acetabular components have been considered.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

February 4th, 2025

510(k) Summary

I. SUBMITTER

Encore Medical, L.P.
9800 Metric Blvd.
Austin, TX 78758

Contact Person: Katrina Dombovari
Email: katrina.dombovari@enovis.com
Phone: +49 172 6718181

II. DEVICE

Name of Device: ceramys™ femoral head system

Common or Usual Name: Ceramic Femoral Head Prosthesis

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

Regulatory Class: II

Primary Product Code: LZO

III. PREDICATE DEVICE

Primary Predicate: BIOLOX® *delta* Ceramic Femoral Head (K082844)

Reference Predicate(s): Foundation Unipolar Femoral Head with Modular Neck Length Sleeves (K973614) and Foundation (FMP) Porous Coated Spiked Acetabular System (K072154)

IV. DEVICE DESCRIPTION

The ceramys™ femoral head system represents the latest generation of prosthetic femoral heads used in hip arthroplasty.
The ceramys™ femoral head system is applicable for use in total hip arthroplasty and the prosthetic replacement of femoral neck fractures. It offers a femoral head design with a reproducible surgical technique carefully developed to enable consistent and accurate implantation.
The ceramys™ femoral head system is composed of ceramys™ femoral heads, ceramys™ choice sleeved femoral heads, and ceramys™ choice sleeves. The ceramys™ femoral head system consists of alumina toughened zirconia ceramic heads and titanium adapter sleeves that connect to femoral stems using a 12/14 taper. The ceramys™ choice femoral heads and sleeves can be used with a well fixed stem in revision hip arthroplasty. The femoral head spherical diameter will be offered as 28, 32, 36, 40, and 44 mm and the femoral head center is offered in 4 increments ranging from -4 to +8 mm.

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V. INTENDED USE/INDICATIONS FOR USE

Intended Use:

The ceramys™ femoral head system is intended for treatment of patients who are candidates for total hip arthroplasty, as per the indications for use. While hip replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

Indications for Use:

Joint replacement is indicated for patients suffering from disability due to:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

The EMPOWR Dual Mobility™ system has the additional indication of joint replacement due to dislocation risks.

The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for who all other options to constrained acetabular components have been considered.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject ceramys™ femoral head system and the predicate BIOLOX® *delta* Ceramic Heads and Sleeves (cleared via K082844) are offered in the same diameters and offsets, but the formulation of the subject ceramic material is different. Comparative testing demonstrates substantial equivalence between the subject and predicate device.

Biocompatibility testing

The biocompatibility evaluation for the ceramys™ femoral head system was conducted in accordance with the FDA guidance, *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, May 1, 1995, and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*, as recognized by FDA. Complete test reports are provided as attachments in the Biocompatibility section in the eSTAR.

The ceramys™ femoral head system is intended for permanent implantation, contacting tissue/bone. Biocompatibility was ensured through the use of qualified materials and contact agents.

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Performance Testing

Performance testing was completed on the subject ceramys™ femoral head system and is detailed in the Performance Testing section. The following testing was performed to FDA recognized standards and internal protocols that are specific to the ceramys™ femoral head system:

- Axial pull-off disassembly per ISO 7206-10:2018
- Composition per ISO 13356:2015
- Crystalline phase per ISO 13356:2015
- Cyclic fatigue per ISO 22214:2006
- Density per ISO 13356:2015
- Elastic modulus per DIN EN 843-2:2007
- Flexure strength per ASTM C674-13(2018)
- Fretting corrosion per ASTM F1875-14
- Frictional torque per ASTM F3143-20
- Grain Size per ISO 13383-1:2012
- Hardness per ISO 14705:2016
- Impact resistance per ISO 11491:2017
- MRI compatibility per ASTM F2052-21, F2213-17, F2119-13, and F2182-19e2
- Post-fatigue static compression per ASTM F2345-21
- Radioactivity per ISO 13356:2015
- SEVNB fracture toughness per ISO 23146:2016
- Static compression per ASTM F2345-21
- Torsion disassembly per ISO 7206-13:2016
- Wear rate per ISO 14242-1:2014
- Weibull modulus per ISO 13356:2015

Animal Studies

No animal data submitted.

Clinical Studies

No clinical data submitted.

VIII. CONCLUSIONS

All testing and evaluations demonstrate that the subject device is substantially equivalent to the predicate devices.