November 12, 2025

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

Re: K251833
Trade/Device Name: EMPOWR Acetabular® Liner Extension
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, OQG
Dated: August 14, 2025
Received: August 14, 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,

RYAN TROMBETTA -S

For: 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.

Submission Number *(if known)*

K251833

Device Name

EMPOWR Acetabular® Liner Extension

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.

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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: +1-250-713-6196

II. DEVICE

Trade Name: EMPOWR Acetabular® Liner Extension

Common Name: Total Hip Implant

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulation Number: 21 CFR 888.3358

Regulatory Class: II

Primary Product Code: LPH

Secondary Product Code: OQG

III. PREDICATE DEVICE

Primary Predicate: EMPOWR Acetabular® System (K190057)

Additional Predicates: FMP Extended Liners (K172651); Delta Multihole TT Pro Acetabular System (K191622); ceramys™ femoral head system (K241483); Trident Large Diameter Acetabular Inserts (K062419).

IV. DEVICE DESCRIPTION

The subject device is a family of highly crosslinked (HXL), ultra-high molecular weight polyethylene (UHMWPE) acetabular liners infused with Vitamin E (VE) (also referred to as Encore Medical, L.P. HXe+, GUR 1020e/150kGy) manufactured per ASTM 648. Configurations include Neutral, 10° Hooded, +4mm Offset, and +4mm/10° (Face Changing).

The subject device is a line extension of the cleared liners from the EMPOWR Acetabular® System (K190057) that allows for a 12mm differential between acetabular cup size and femoral head size. The currently cleared liners from the EMPOWR Acetabular® System (K190057) allow for a minimum 14mm differential between acetabular cup size and femoral head size. The subject device allows for the use of a 32mm femoral head with a 44mm acetabular cup, a 36mm femoral head with a 48mm acetabular cup, a 40mm femoral head with a 52mm acetabular cup, and a 44mm femoral head with a 56/58mm acetabular cup. The subject liners are compatible with all the same previously cleared femoral heads compatible with the predicate EMPOWR Acetabular® System (K190057).

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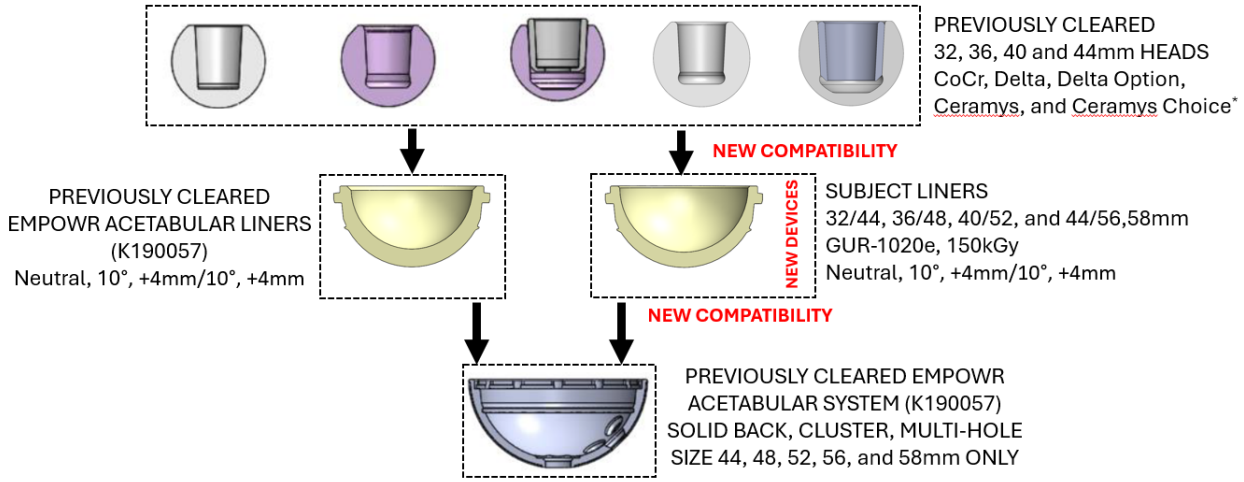

*See Comprehensive Device Description for full list of relevant K numbers

V. INTENDED USE/INDICATIONS FOR USE

Intended Use:

Encore hip devices are intended for treatment of patients who are candidates for total hip arthroplasty 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.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject EMPOWR Acetabular® Liner Extension has the same technological characteristics as the predicate EMPOWR Acetabular® System (K190057).

The subject and the predicate have the same substrate material, sterilization method, packaging configuration, indications for use, and manufacturing process. The subject differs from the predicate as the liners are designed to allow for a 12mm differential between acetabular cup size and femoral head size.

Performance testing demonstrates substantial equivalence between the subject and predicate device.

Biocompatibility

The biocompatibility assessment for the subject device 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. The subject device is intended for permanent implantation, contacting tissue/bone. Biocompatibility was ensured through the use of qualified materials and contact agents.

Performance Testing

Performance testing was completed on the subject EMPOWR Acetabular® Liner Extension and is detailed in the Verification and Validation Summary section. The following testing was performed to FDA recognized standards and internal protocols that are specific to the EMPOWR Acetabular® Liner Extension:

- CAD Based Range of Motion (ROM) – ISO 21535:2023
- Impingement Testing – ASTM F2582-20
- Disassembly Testing – ASTM F1820-22
- Cup Deformation per ISO 7206-12
- Wear Testing per ISO 14242-1 and ISO 14242-2

Performance testing demonstrated substantial equivalence between the subject and predicate device and did not raise new questions of safety and effectiveness.

Animal Studies

No animal data is required to support a determination of substantial equivalence.

Clinical Studies

No clinical data is required to support a determination of substantial equivalence.

VIII. CONCLUSIONS

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