February 13, 2023

Encore Medical LLC
Trey Thorsen
Regulatory Affairs
9800 Metric Blvd
Ste 200
Austin, Texas 78758

Re: K223779
Trade/Device Name: EMPOWR™ blade stem
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, LZO, KWY, KWZ
Dated: December 15, 2022
Received: December 16, 2022

Dear Trey Thorsen:

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,

Christopher Ferreira -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223779

Device Name
EMPOWR™ blade stem

Indications for Use *(Describe)*
The hip joint metal uncemented prosthesis is intended to replace a hip joint. The device is intended 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 intraoperative instability and for whom all other options to constrained acetabular components have been considered.

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; and
- revision procedures where other treatments or devices have failed.

This stem is to be press-fit. This stem is intended for cementless use.

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.

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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."

510(k) Summary

14DEC2022

I. SUBMITTER

Encore® Medical, L.P. (dba Enovis™)
9800 Metric Blvd.
Austin, TX 78758

Contact Person: Trey Thorsen
Email: trey.thorsen@enovis.com
Phone: 850-450-3932

II. DEVICE

Name of Device: EMPOWR™ blade stem
Common or Usual Name: Total Hip Implant
Classification Name: *Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis – 21 CFR 888.3358*
Regulatory Class: II
Primary Product Code: LPH
Secondary Product Code: LZO, KWY, KWZ

III. PREDICATE DEVICE

Primary Predicate: Enovis™ Linear® Hip Stem, K120241
Reference Predicate: Zimmer Biomet™ TaperLoc® Complete Stem, K120030

IV. DEVICE DESCRIPTION

The EMPOWR™ blade stem represents the latest generation of a press-fit, porous coated, wedge style femoral stem. Building on the design principles of its predicate, Linear® Hip Stem, the EMPOWR™ blade stem system features enhancements such as addition of coxa vara offset, neck angle update, and distal angle reduction for wider application.

The EMPOWR™ blade stem is applicable for use in total hip arthroplasty and the prosthetic replacement of femoral neck fractures in all age groups. It offers a stem design with a reproducible surgical technique carefully developed to enable consistent and accurate implantation. The EMPOWR™ blade stem features streamlined and accurate instrumentation that is highly adaptable to any surgical approach.

V. INTENDED USE/INDICATIONS FOR USE

Intended Use:

Enovis™ 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:

The hip joint metal uncemented prosthesis is intended to replace a hip joint. The device is intended 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 intraoperative instability and for whom all other options to constrained acetabular components have been considered.

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; and
- revision procedures where other treatments or devices have failed.

This stem is to be press-fit. This stem is intended for cementless use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The EMPOWR™ blade stem and accessories are technologically the same when compared to the predicate Linear Hip Stem (cleared via K120241). Comparative testing demonstrates substantial equivalence between the subject and predicate device. The stem trunnions and the porous titanium coating are identical between the subject and predicate device.

There is a slight difference between the subject device ("EMPOWR™ blade stem") indications for use and the predicate device, Linear® stem ("Linear®") (K120241) indications for use statement. The added statements are for clarity and do not change the overall intent of the indications.

The subject EMPOWR™ blade stem has one size smaller and one size larger than the predicate Enovis™ Linear® stem. The subject EMPOWR™ blade stem has two fewer sizes than the predicate Biomet® TaperLoc® Complete stem. The smallest size is equivalent between the two systems. The largest subject stem is not larger than the largest Biomet® TaperLoc® Complete stem. The size offering for the subject device is within the size offering of the predicate Biomet® TaperLoc® Complete stem offering.

The component compatibility of the EMPOWR™ blade stem is identical to the Linear® stem (K120241) as femoral stems are compatible with all Enovis™ femoral heads and acetabular systems, including Encore® previously cleared FMP® and EMPOWR™ semi constrained acetabular shells, previously cleared femoral heads, previously cleared unipolar heads/sleeves, EMPOWR™ dual mobility and modular dual mobility system, bipolar systems, and FMP® constrained system.

Biocompatibility testing

The biocompatibility evaluation for the EMPOWR™ blade stem 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 EMPOWR™ blade stem 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™ blade stem and is detailed in the Performance Testing section. The following testing was performed to FDA recognized standards and internal protocols that is specific to the EMPOWR™ blade stem:

- CAD Based Range of Motion (ROM) – ISO 21535:2007
- Distal Stem Fatigue Testing – ISO 7206-4:2010
- Neck Stem Fatigue Testing – ISO 7206-6:2013

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.