April 26, 2024

Encore Medical, L.P. (dba Enovis)
Trey Thorsen
Regulatory Consultant
9800 Metric Boulevard
Austin, Texas 78758

Re: K240324
Trade/Device Name: EMPOWR Revision Symmetric Knee Cones
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: February 1, 2024
Received: February 2, 2024

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 (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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.04.26 11:12:48 -04'00'

For Lixin Liu, 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)*

K240324

Device Name

EMPOWR Revision Symmetric Knee Cones

Indications for Use *(Describe)*

Total joint replacement is indicated for patients suffering from disability due to:

-degenerative, post-traumatic or rheumatoid arthritis;
-avascular necrosis of the femoral condyle;
-post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
-moderate valgus, varus or flexion deformities;

This device may also be indicated in the salvage of previously failed surgical attempts where bone loss may require the use of augments, sleeves cones or extensions.
The EMPOWR Revision Knee™ Symmetric Cones are indicated for the following conditions:

- EMPOWR™ Revision Knee™ Symmetric Cones are indicated for use in skeletally mature patients with bone defect or poor bone quality (osteoporotic bone) or in case of sclerotic bone that requires supplemental fixation in the clinical judgment of the surgeon.

- EMPOWR™ Revision Knee™ Symmetric Cones are indicated for uncemented fixation to the bone and are fixed to the femoral and tibial implants using bone cement.

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.

510(k) Summary

I. SUBMITTER

Encore Medical, L.P.
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 Revision Knee™ Symmetric Cones
Common or Usual Name: Total Knee Implant
Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis

Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.

Regulation: 21 CFR 888.3560 / 21 CFR 888.3565
Regulatory Class: II
Primary Product Code: JWH
Secondary Product Code: MBH

III. PREDICATE / REFERENCE DEVICES

Predicate: AMF Revision TT Cones, (K200653)
Reference: LINK TrabecuLink® Femoral Cones, (K201364)
3D Metal Diaphyseal Femoral Cones, (K200075)

IV. DEVICE DESCRIPTION

Envois is adding a non-mating modular component accessory to the EMPOWR™ Knee product line and is compatible with the EMPOWR Revision Knee™ Femur (K213793), the EMPOWR PS Knee® Femur (K160342), the EMPOWR™ Universal Tibial Baseplate (K173723), and the EMPOWR™ Knee Cemented Stems and Extender Accessories (K173723, K213793, and K230441).

The EMPOWR Revision Knee™ Symmetric Cone implants (also known as Cones) are an optional accessory in primary or revision Total Knee Arthroplasty. The Cones are sterile, single-use device that are compatible for use with the EMPOWR Revision Knee™ components. The EMPOWR™ Cones are composed of Ti6Al4V alloy per ASTM F1472 and contain a modified surface composed of commercially pure titanium per ASTM F67. This modified surface (i.e. porous coating) is exactly the same as applied to existing FMP™ Porous Coated Acetabular Shells (K072888).

The EMPOWR Revision Knee™ Symmetric Cones are intended to be affixed to the mating femoral and/or tibial component using bone cement. The cones are intended for fixation as an assembled construct in the distal femur and/or proximal tibia, without bone cement.

V. INDICATIONS FOR USE / INTENDED USE

Intended Use

The EMPOWR Revision Knee™ Symmetric Cones are intended for use in skeletally mature patients with bone defect or poor bone quality (osteoporotic bone) or in case of sclerotic bone that requires supplemental fixation in the clinical judgment of the surgeon. The EMPOWR Revision Knee™ Symmetric Cones are intended for uncemented fixation to the bone and are fixed to the femoral and tibial implants using bone cement.

Indications for Use

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The EMPOWR Revision Knee™ :

Total joint replacement indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The EMPOWR Revision Knee™ Symmetric Cones are an optional accessory in primary or revision Total Knee Arthroplasty.

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

Biocompatibility testing
The biocompatibility evaluation for the EMPOWR Cones 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 Revision Knee™ Symmetric Cones are intended for permanent implantation, contacting tissue/bone. Biocompatibility was ensured through the use of qualified materials and contact agents.

Performance Testing
The following testing was performed to FDA recognized standards and internal protocols:

- Dynamic Fatigue Testing: ASTM F1800-19e1 (modified)
- MR Conditional Labeling: ASTM F2052 -21, ASTM F2213-17, ASTM F2119-07(2013), ASTM F2182-10e2, ASTM F2503-20

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.