March 17, 2023

Encore Medical, L.P DBA Enovis
Thorsen Trey
Regulatory Affairs Consultant
9800 Metric Boulevard
Austin, Texas 78758

Re: K230441
Trade/Device Name: EMPOWR™ Stem Extender, 50mm
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
Dated: February 17, 2023
Received: February 21, 2023

Dear Thorsen Trey:

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,

Ting Song -S

Ting Song, 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)*
K230441

Device Name
EMPOWR™ Stem Extender, 50mm

Indications for Use *(Describe)*
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;
- treatment of fractures that are unmanageable using other techniques.

This device may also be indicated in the salvage of previously failed surgical attempts. All devices are intended for cemented applications except for the 3DKNEE™ Porous Coated Femur, EMPOWR 3DKNEE™ POROUS Femur, 3DKNEE™ Porous Coated Tibia, and EMPOWR POROUS Tibia which are intended for cementless applications.

While knee 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.

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
February 16, 2023

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 Revision Knee Stem Extender, 50mm
Common or Usual Name: Total Knee Implant
Classification Name: *Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per* 21 CFR 888.3560
Regulatory Class: II
Primary Product Code: JWH

III. PREDICATE DEVICE

EMPOWR Revision Knee (K213793)

IV. DEVICE DESCRIPTION

The EMPOWR Stem Extender, 50mm implant is a modular accessory of the EMPOWR Revision Knee (K213793). When coupled with the EMPOWR Revision Knee, the Stem Extender is intended to be fixed to the bone by cement. The extender is connected to the mating implant, Revision Femur, by 7/16-20 UNF-2A male threaded connection on the implant, and 7/16-20 UNF-2B female threaded connection on the other side that is used to “extend” the length of cemented stem accessories (K173723) in an identical way as the EMPOWR Stem Extender, 25mm (K213793).

The Stem Extender is also compatible with the EMPOWR Universal Tibial Baseplate (K173723) and will be offered for use as an accessory with the baseplate.

The EMPOWR Stem 50mm Extender comes in a single diameter of 15mm and is offered a length of 50mm (Refer to Figure 1). The EMPOWR Stem Extender, 50mm is made of wrought CoCr alloy per ASTM F1537, which is identical to the material used in the 25mm extender included in the EMPOWR Revision Knee (K213793).

V. INDICATIONS FOR USE

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;
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While knee 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The EMPOWR Revision Stem Extender, 50mm is a line extension to the EMPOWR Revision Knee (cleared via K213793), that adds the 50mm extender option to the product. The EMPOWR Revision Knee (K213793) was originally cleared with a 25mm extender only.

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

Biocompatibility testing
The EMPOWR Revision Stem Extender, 50mm uses the same materials, manufacturing and sterilization process as the EMPOWR Revision Knee (K213793). There is no impact to biocompatibility.

The EMPOWR Revision Stem Extender, 50mm is intended for permanent implantation, contacting tissue/bone. This is identical to the predicate 25mm Stem Extender.

Performance Testing
An evaluation was performed against the recommended consensus standards for knee implants per the product codes assigned to the subject device. Of those standards, it was determined for this line extension that these additional components should be evaluated against ASTM F2083-21 (Standard Specification for Knee Replacement Prosthesis).

Animal Studies
No animal data submitted.

Clinical Studies
No clinical data submitted.

VIII. CONCLUSIONS

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