April 6, 2023

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

Re: K230169
Trade/Device Name: EMPOWR Revision VVC+ (Varus / Valgus Constrained), e+ Tibial Insert
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, OIY
Dated: January 20, 2023
Received: January 20, 2023

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2023.04.06 17:15:52 -04'00'

For: [Vacant]
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)*
K230169

Device Name
EMPOWR Revision VVC +(VARUS / VALGUS CONSTRAINED), e + TIBIAL INSERT

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, 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.

The EMPOWR Revision VVC+, e+ Tibial Insert should be considered for use in total knee arthroplasty for patients under the following indications:

- absence or loss of both cruciate ligaments
- moderate varus-valgus or flexion instability that requires a bearing surface with increased constraint in the clinical judgement of the surgeon
- bone loss that requires supplemental fixation in the clinical judgement of the surgeon

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. (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 VVC+ (Varus / Valgus Constrained), e+ Tibial Insert
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
Secondary Product Code: OIY

III. PREDICATE DEVICE

DJO EMPOWR Revision Varus / Valgus Constrained Tibial Insert, K180930

IV. DEVICE DESCRIPTION

EMPOWR Revision VVC+ (Varus / Valgus Constrained) e+ Tibial Insert

The EMPOWR Revision VVC+ (Varus / Valgus Constrained) e+ Tibial Insert Implant is a line extension that offers an increased level of femoral / tibial constraint over the EMPOWR VVC Tibial Insert. This tibial insert implant provides additional internal / external and varus / valgus rotational stability.

The sizing architecture for the insert includes 14 sizes (2-11, 4BU, 5BU, 6BD, 7BD) and thicknesses of 10mm, 12mm, 14mm, 16mm, 19mm, 22mm and 25mm with post medial/lateral width of 0.5520 inches for sizes 2-5 and 0.7080 inches for sizes 6 – 11. Along with the post width, the articulating geometry of the proximal side of the tibial insert accommodates an additional amount of internal / external (I/E), varus / valgus (V/V) constraint, and tibial post / femoral cam jump height when interfacing with the EMPOWR Revision Femoral implant. The material (highly crosslinked 75kGy UHMWPE with vitamin E per ASTM F2695/F2565) and distal locking mechanism geometry with the mating tibial baseplate are identical to the predicate.

All tibial insert thickness options are configured to interface with a reinforcement pin accessory made of Wrought CoCr per ASTM F1537. This accessory is configured with a taper interface on the distal end to mate with the EMPOWR UNIVERSAL TIBIAL BASEPLATE, has a diameter and length configured to reinforce the post and thickness for the EMPOWR Revision VVC+ e+ tibial insert, and contains barbs to

prevent the pin from backout when fully seated within the post of the EMPOWR Revision VVC+, e+ tibial insert.

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;
- moderate valgus, varus or flexion deformities;
- treatment of fractures that are unmanageable using other techniques.

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- bone loss that requires supplemental fixation in the clinical judgement of the surgeon

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The EMPOWR Revision VVC+, e+ Tibial Insert and accessories are a line extension to the predicate EMPOWR Varus / Valgus Constrained Tibial Insert (cleared via K180930).

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

Biocompatibility testing

The biocompatibility evaluation for the EMPOWR Revision VVC+, e+ Tibial Insert 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 VVC+, e+ Tibial Insert is 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:

- CAD Based Range of Motion (ROM)
- Femoral – Tibial Contact Area Assessment - ASTM F2083-21
- Femur – Tibial Intrinsic Stability - ASTM F2083-21, ASTM F1223-20
- Femur – Tibial Varus / Valgus Constraint Testing- ASTM F2083-21, ASTM F1223-20
- 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 device is substantially equivalent to the predicate.