July 8, 2025

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

Re: K251776
Trade/Device Name: EMPOWR Revision Knee™ (EMPOWR Revision VVC+, 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: June 10, 2025
Received: June 10, 2025

Dear Morgan Paronish:

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,

Lixin Liu -S

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

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.

510(k) Number *(if known)*
K251776

Device Name
EMPOWR Revision Knee™ (EMPOWR Revision VVC+, 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 EMPOWR Porous® Knee Femur, EMPOWR Porous® Knee Tibia, and Porous Patella 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 judgment of the surgeon
• Bone loss that requires supplemental fixation in the clinical judgment 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.
9800 Metric Blvd.
Austin, TX 78758

Contact Person: Morgan Paronish
Email: morgan.paronish@enovis.com
Phone: 317-519-5611
Date: July 8, 2025

II. DEVICE

Name of Device: EMPOWR Revision Knee™ (EMPOWR Revision VVC+, e+ Tibial Insert)
Common or Usual Name: Total Knee Prosthesis
Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis.
Regulation: 21 CFR 888.3560
Regulatory Class: II
Product Codes: JWH
Secondary Product Code: OIY

III. PREDICATE DEVICE

EMPOWR Revision VVC+, e+ Tibial Insert (K230169)

IV. DEVICE DESCRIPTION

The EMPOWR Revision Knee™ system is intended for use in total knee arthroplasty. The system includes femoral components, tibial components, tibial inserts, cones, stems, stem extenders, and augments. Components are available in various sizes and configurations to accommodate a range of patient anatomies and surgeon preferences.

The purpose of this submission is to obtain clearance for using vaporized hydrogen peroxide (VHP) as a sterilization method for the EMPOWR VVC+, e+ Tibial Insert component. The subject device is identical in design, materials, and intended use to the predicate.

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.

This device may also be indicated in the salvage of previously failed surgical attempts. All devices are intended for cemented applications except for the EMPOWR Porous® Knee Femur, EMPOWR Porous® Knee Tibia, and Porous Patella 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 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 judgment of the surgeon
- Bone loss that requires supplemental fixation in the clinical judgment of the surgeon

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no changes to technological characteristics being introduced with this submission except for the change in sterilization method. The addition of the VHP sterilization method for use with the EMPOWR Revision VVC+, e+ Tibial Insert does not affect the materials, design features, indications, or packaging of the implant. Verification and validation activities demonstrate substantial equivalence between the subject and predicate devices.

Verification and Validation

Risks were identified based on the proposed sterilization method and testing was conducted to mitigate those risks. Based on the risk analysis, the following tests were conducted.

- Sterilization Validation
- Shelf-Life Study
- Packaging Testing
- Cytotoxicity
- Material Characterization
- Pin-on-disk Wear
- Lock Detail Fatigue
- Tibial Post Fatigue

Animal Studies

No animal data submitted.

Clinical Studies

No clinical data submitted.

VII. CONCLUSIONS

Based on the intended use, indications for use, and the technological differences supported by the verification and validation activities, the EMPOWR Revision Knee™ system with the VHP sterilized EMPOWR Revision VVC+, e+ Tibial Insert is substantially equivalent to the predicate system with the Hydrogen Peroxide Gas Plasma (HPGP) sterilized components.