December 19, 2025

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

Re: K252974
Trade/Device Name: EMPOWR Knee
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, OIY
Dated: September 17, 2025
Received: September 17, 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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252974

Please provide the device trade name(s).

EMPOWR Knee

Please provide your Indications for Use below.

When a mechanical alignment approach is utilized, these devices are 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.

These devices may also be indicated in the salvage of previously failed surgical attempts.

When the EMPOWR® Dynamic Natural Alignment (DNA) approach is utilized, these devices are indicated for patients with disability due to:
• degenerative, post-traumatic or rheumatoid arthritis;
• avascular necrosis of the femoral condyle;
• moderate valgus, varus or flexion deformities.

All EMPOWR devices except for the EMPOWR Revision Knee™, EMPOWR PS Knee™, and EMPOWR Partial Knee™ may be implanted using the EMPOWR® Dynamic Natural Alignment (DNA) surgical technique.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: December 3, 2025

II. DEVICE

Name of Device: EMPOWR Knee
Common or Usual Name: Total Knee Prosthesis
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
Product Codes: JWH, MBH, OIY

III. PREDICATE / REFERENCE DEVICES

Predicates	EMPOWR 3D Knee - Primary Predicate	K143242
	EMPOWR CR Tibial Insert	K170573
	EMPOWR Porous Knee	K171991
	EMPOWR Universal Tibial Baseplate	K173723
	EMPOWR Porous Femur with HAnano Surface	K210308
	Domed Tri-Peg Patella, Highly Cross Linked Domed Tri-Peg Patella With VE	K121835
	Porous Patella	K212941
References	Medacta GMK Sphere – Kinematic Alignment	K173890
	Zimmer Persona Personalized Knee System	K172524

IV. DEVICE DESCRIPTION

The purpose of this submission is to obtain clearance for the EMPOWR® Dynamic Natural Alignment (DNA) surgical technique. The proposed technique is a kinematic alignment (KA) strategy, providing an alternative alignment approach to the current mechanical alignment (MA) strategy. The purpose of the KA technique is to restore normal knee function by preserving the patient's native joint line. The technique may be used to implant all EMPOWR devices except for the EMPOWR Revision Knee™ and the EMOWR PS Knee™. This is a labeling change only. No design changes are being introduced to the implant systems.

V. INDICATIONS FOR USE / INTENDED USE

Intended Use:

Enovis™ knee devices are intended for treatment of patients who are candidates for knee arthroplasty per the Indication for use. While total 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.

Indications for Use:

When a mechanical alignment approach is utilized, these devices are 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.

These devices may also be indicated in the salvage of previously failed surgical attempts.

When the EMPOWR® Dynamic Natural Alignment (DNA) approach is utilized, these devices are indicated for patients with disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- Moderate valgus, varus, or flexion deformities.

All EMPOWR devices except for the EMPOWR Revision Knee™, EMPOWR PS Knee™, and EMPOWR Partial Knee™ may be implanted using the EMPOWR® DNA surgical technique.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

No design changes are being introduced with this submission. Thus, there are no differences in technological characteristics between the subject and predicate devices. The addition of a kinematic alignment surgical technique for use with existing devices does not affect the materials, design features, packaging, or sterilization of the implant systems. Performance testing demonstrates substantial equivalence between the subject and predicate devices.

Performance Testing

Risks were identified based on the proposed surgical technique and testing was conducted to mitigate those risks. Based on the risk analysis, the following test was conducted according to internal protocols.

- initial stability (micromotion) testing
- cadaveric assessment of the kinematic surgical technique

Animal Studies

No animal data submitted.

Clinical Studies

No clinical data submitted.

VIII. CONCLUSIONS

Performance testing demonstrates that the devices implanted using the EMPOWR® DNA surgical technique are substantially equivalent to the predicate devices.