April 1, 2022

Encore Medical, L.P.
Michael Siano
Sr. Program Manager, RA
9800 Metric Blvd.
Austin, Texas 78758

Re: K213793
Trade/Device Name: EMPOWR Revision 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
Dated: February 28, 2022
Received: March 1, 2022

Dear Michael Siano:

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,

For Ting Song, Ph.D., R.A.C.
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)*
K213793

Device Name
EMPOWR Revision Knee™

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Encore Medical, L.P. (dba DJO Surgical)
9800 Metric Blvd.
Austin, TX 78758

Phone: 864-3223801
Fax: (512) 834-6313

Contact Person: Michael A. Siano
Date Prepared: December 3, 2021

II. DEVICE

Name of Device: EMPOWR Revision Knee™
Common or Usual Name: Knee prosthesis
Classification Name: *Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis* (21 CFR 888.3560)
Regulatory Class: II
Product Code: JWH

III. PREDICATE DEVICE

DJO EMPOWR PS Knee®, K160342
DJO EMPOWR® Universal Tibial Baseplate, K173723
DJO EXPRT® Femoral Augment, K140830

Several reference devices are used to support minor differences in technological features.

IV. DEVICE DESCRIPTION

EMPOWR Revision Knee™ is intended for total knee prosthesis. The system consists of the sterile implants; EMPOWR Revision Femur, EMPOWR Stem Extender, and EMPOWR Femoral Augments (Distal and Posterior)- Universal. Non-sterile reusable instruments and trials are included as accessories.

The femur component can optionally be used with a stem extender and/or augments to suit a variety of surgeon preferences and patient anatomies.

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 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..

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial equivalence is claimed to three separate predicates for the EMPOWR Revision Femur, EMPOWR Stem Extender, and EMPOWR Femoral Augments (Distal and Posterior)- Universal.

Several additional reference devices are used to support minor technological differences and for comparison testing.

In each case, the intended use is the same between the subject and predicate. Comparative testing demonstrates substantial equivalence between the subject and predicate devices.

Biocompatibility testing
The biocompatibility evaluation for the EMPOWR Revision Knee™ 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™ 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)
- Femur – PS Insert; Contact Area Assessment - ASTM F2083-12
- Femur – VVC Insert; Contact Area Assessment - ASTM F2083-12
- Femur – Insert; Varus / Valgus Constraint - ASTM F1223-14
- Locking Mechanism Disassembly for Total Condylar Knee - ASTM F2083-12
- Post Fatigue Strength
- Femur-Stem Extender-Stem Fatigue Testing
- Femur Finite Element Analysis (FEA)
- Augment Screw Characterization
- Baseplate / Stem Extension Fatigue Testing
- Patella Subluxation Test - ASTM F1672
- Static Patella Contact Area Stress Testing - ASTM F1672
- Intrinsic Stability (Constraint Testing) - ASTM F1223-14

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.