March 30, 2021

Encore Medical, L.P.
Christine Chesnutt
Regulatory Affairs Specialist
9800 Metric Blvd.
Austin, Texas 78758

Re: K210308
Trade/Device Name: EMPOWR Porous Femur with HA^{nano} Surface^{TM}
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: February 1, 2021
Received: February 3, 2021

Dear Christine Chesnutt:

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, 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)*
K210308

Device Name
EMPOWR POROUS FEMUR with HAnano Surface™

Indications for Use *(Describe)*

The DJO EMPOWR POROUS FEMUR WITH HAnano Surface™ is indicated for use in total knee arthroplasty patients, receiving total joint replacement because of disability or suffering 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. The device is intended for uncemented 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.

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510(k) Summary

Date: March 28, 2021

Manufacturer:
DJO Surgical (Legal Name: Encore Medical, L.P.)
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Christine Chesnutt
Regulatory Affairs Specialist
Phone: (512) 834-6207
Fax: (760) 597-3466
Email: christine.chesnutt@djoglobal.com

Product	Common Name	Classification	Product Code
EMPOWR POROUS FEMUR with HA*nano* Surface™	Total Knee Implant	Class II	MBH

Product Code	Regulation and Classification Name
MBH	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis per 21 CFR 888.3565

Description:

The EMPOWR Porous Femur with HA*nano* Surface is a line extension to the EMPOWR Knee Platform and EMPOWR Porous Knee Platform (cleared via K143242 and K171991), to include a hydroxyapatite-coated porous femoral component in the system.

The EMPOWR Porous Femur with HA*nano* Surface™ has an adjunct hydroxyapatite (HA) coating on the 3D Matrix® porous coating inside the cement pocket. Since the device is porous coated, it is indicated for cementless use.

Indications for Use:

The DJO EMPOWR POROUS FEMUR WITH HA*nano* Surface™ is indicated for use in total knee arthroplasty patients, receiving total joint replacement because of disability or suffering 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. The device is intended for uncemented 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.

Predicate Devices:

- Empowr Porous Femur (K171991)

Comparable Features to Predicate Device(s):

The EMPOWR Porous Femur with HA*nano* Surface™ line extension includes a modified version of the EMPOWR Porous Femur. The substrate material, articulating geometry, articulating surface roughness, porous coating and bone-facing geometry are identical to the EMPOWR Porous Femur.

Key Differences in Subject Device to Predicate:

The only modification made to the EMPOWR Porous Femur with HA*nano* Surface™ is the addition of a hydroxyapatite coating, the HA*nano* Surface™, to the 3D Matrix® porous coating on the bone-facing side of the femoral component. This HA*nano* coating has been previously utilized in several dental and spinal applications (K101225, K170392, K190025, K201614). The process used to apply the coating to the femur is analogous to those seen in previously cleared product. As the device is porous coated, it is indicated for cementless use.

Non-Clinical Testing: Abrasion testing, pin-on-disk wear testing and cleanability testing was performed on the subject device, demonstrating its ability to perform under expected conditions. As the geometry of the subject device is identical to previously cleared EMPOWR Porous Femur, prior mechanical testing (femur fatigue testing, contact area testing) has demonstrated the device's ability to perform under anticipated clinical conditions. All testing has determined that the device is substantially equivalent to the predicate device.

Endotoxin Assessment: DJO Surgical conducts device testing to assure that pyrogen limit specifications are met via the Kinetic Chromogenic method for bacterial endotoxin testing. Assessments were performed per USP <161> and ANSI/AAMI ST72, with an acceptance criterion of 20 EU/device.

Clinical Testing: Clinical testing was not required

Conclusions: All testing and evaluations demonstrate that the device is substantially equivalent to the predicates identified.