July 16, 2019

Encore Medical, L.P.
Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Blvd.
Austin, Texas 78758

Re: K191325
Trade/Device Name: EMPOWR Partial Knee
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: May 15, 2019
Received: May 16, 2019

Dear Teffany Hutto:

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191325

Device Name
EMPOWR Partial Knee

Indications for Use *(Describe)*

The EMPOWR Partial Knee System is indicated for patients with:
• Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
• Previous tibial condyle or plateau fractures with loss of anatomy or function.
• Varus or valgus deformities.
• Revision procedures where other treatments or devices have failed.
• These devices are indicated for cemented use only.

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.

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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

Date: July 16, 2019

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

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
Phone: (512) 834-6255
Fax: (760) 597-3466
Email: teffany.hutto@djoglobal.com

Product	Common Name	Classification	Product Code
EMPOWR Partial Knee	Partial Knee Implant	Class II	HSX

Product Code	Regulation and Classification Name
HSX	Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer per 21 CFR 888.3520

Description:

The EMPOWR Partial Knee is a unicompartmental knee system that is unconstrained in the anteroposterior and mediolateral directions, allowing unconstrained internal/external rotation between the femoral and tibial components. This system includes a cobalt chrome femoral component, titanium tibial baseplate, and Vitamin E Polyethylene insert.

Indications for Use:

The EMPOWR Partial Knee System is indicated for patients with:

- Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
- Previous tibial condyle or plateau fractures with loss of anatomy or function.
- Varus or valgus deformities.
- Revision procedures where other treatments or devices have failed.

These devices are indicated for cemented use only.

Predicate Devices:

Device	Manufacturer	510(k) Number	Predicate Type
Zimmer® Unicompartmental Knee	Zimmer Biomet	K033363	Primary
EPIK Knee System	Encore Medical, L.P.	K020741	Reference Device

Comparable Features to Predicate Device(s):

- Indications for Use
- Material of Femoral and Tibial Baseplate components, (Femoral component – Cobalt Chrome, Tibial Baseplate – Titanium)
- Tibial baseplate component sizing and dimensions
- Insert thicknesses
- Femoral Component Size offerings
- 2-peg femoral design
- Keel and 2-peg tibial baseplate design
- Unconstrained tibial insert articulation

Key Differences in Subject Device to Predicate:

- Femoral component profile and articular surface geometry
- Tibial baseplate peg and keel geometry

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected conditions. This testing includes:

- FEA for Femur Component Strength
- Tibial Baseplate Component Strength Testing
- Range of Motion Assessment
- Tibial-femoral Contact Area Testing
- Static Locking Mechanism Disassembly

All testing has determined that the device is substantially equivalent to the predicate devices.

Endotoxin Assessment: DJO Surgical conducts device testing to assure that pyrogen limit specifications are met via the Kinetic Chromogenic method for bacterial endotoxin testing.

Clinical Testing: Clinical testing was not required

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