DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 31, 2017

Encore Medical, L.P.
Desiree Wells
Regulatory Affairs Specialist
9800 Metric Blvd.
Austin, Texas 78758

Re: K170573
Trade/Device Name: Empowr CR Knee 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: February 24, 2017
Received: February 27, 2017

Dear Desiree Wells:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K170573

Device Name
Empowr CR Knee™ 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 3DKNEE™ Porous Coated Femur which is 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

Date: May 24, 2017

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

Contact Person:
Desireé Wells
Regulatory Affairs Specialist
Phone: (512) 834-6302
Fax: (760) 597-3466
Email: desiree.wells@djoglobal.com

Product	Common Name	Classification	Product Code
Empowr CR Knee™ Tibial Insert	Cruciate-retaining tibial insert	Class II	JWH

Product Code	Regulation and Classification Name
JWH	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560
OIY	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per CFR 888.3560

Description:

The Empowr CR Knee™ Tibial Insert is a line extension to the EMPOWR platform, to include Cruciate Retaining Knee implants and instruments, which provides surgeons with comprehensive surgical solutions to address a variety of patient demographics and surgeon preferences. The Empowr CR Knee™ Tibial Insert utilizes a PCL (posterior cruciate ligament) retaining TKA (total knee arthroplasty) procedure.

The tibial insert implants made from Highly Cross-Linked with Vitamin E (HXL VE) UHMWPE. The tibial inserts are intended to mate with tibial base implants made from cast CoCr alloy per ASTM F75. The Empowr CR Knee™ Tibial Insert implants provide a kinematically relevant bearing geometry for the knee's primary articulating surfaces, replacing the medial and lateral tibial compartments. The articular geometry features a less conforming asymmetric condylar surfaces to match the highly polished Empowr 3D distal femoral implant's asymmetric condylar surfaces. The distal side of the implant includes a precisely machined coupling designed to interface and lock with the EMPOWR tibial base implant. The tibial insert implant also offers soft tissue relief sections in the anterior region for the patellar tendon and the posterior region for the PCL in PCL retaining procedures.

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 which is 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.

Predicate Devices:

Primary Predicate Device: Empowr Knee System - K143242

Reference Devices:

- Foundation PS Knee – K933539
- Movation Knee System – K100900
- Foundation Ultra Congruent - K963028
- 3DKnee System - K020114

Comparable Features to Predicate Device(s): This device is comparable to the predicate devices in implant material, manufacturing process, snap lock interface, design of the tibial insert, indications, intended use, packaging and sterilization.

Key Differences in Subject Device to Predicate: Offers an additional intermediate thickness, a higher anterior lip geometry and lower posterior lip geometry, asymmetric condyle geometries and a different coronal conformity ratio.

Non-Clinical Testing: Mechanical testing (Constraint testing, contact area testing, and locking mechanism testing) has demonstrated the device's ability to perform under expected conditions. 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.