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 19, 2016

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

Re: K160342
Trade/Device Name: EMPOWR PS Knee System
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: May 2, 2016
Received: May 3, 2016

Dear Ms. 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. 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 Parts 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" (21CFR 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 yours,

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)*
K160342

Device Name
EMPOWR PS Knee System

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 6, 2016

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: (512) 834-6313
Email: teffany.hutto@djosurgical.com

| Product | Classification | Product Codes |
|---|---|---|
| EMPOWR PS Knee System | Class II | JWH, OIY |

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

**Description**:

The EMPOWR PS Knee System is a line extension to the current EMPOWR system (previously cleared as Rebel 3DKNEE System). It is a total knee system that includes non-porous distal femoral implants made from cast CoCr alloy per ASTM F75 and tibial insert implants made from Highly Cross-Linked with Vitamin E (HXL VE) UHMWPE.

**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;
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**Predicate Devices:** EMPOWR Knee System – K143242
Foundation PS Knee System - K933539
Movation Knee System - K100900 & K121727

**Comparable Features to Predicate Device(s):** This device is comparable to the predicate devices in indications, material, dimensions, surgical implantation technique, and intended use. This device has the same implant packaging and sterilization as the EMPOWR Knee System and there are no different technological characteristics from the predicate device.

**Key Differences in Subject Device to Predicate:** Anterior Cam Position within Intercondylar Housing, Values of Coronal Condylar Radii and Bearing Spacing, Femoral Component PS Housing Profile, Posterior Cam Engagement with Tibial Insert, Post Jump Height, Shape of Tibial Insert Post Section, Tibial Insert Post Coronal Profile, Tibial Insert Articular Geometry Conformity Ratio, and Values of Tibial Post Width.

**Non-Clinical Testing:** FEA assessments for PS femur condyle closing loads, PS femur flange closing loads, and PS femur wedge loading. CAD analysis was completed for range of motion, and testing was completed for post fatigue, contact area, constraint, and lateral subluxation. All testing has determined that the device is substantially equivalent to the predicate devices.

**Clinical Testing:** None provided.