October 4, 2017

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

Re: K171991
Trade/Device Name: EMPOWR Porous Knee System
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: June 30, 2017
Received: July 3, 2017

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. 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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -S

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171991

Device Name
EMPOWR Porous 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, EMPOWR 3DKNEE™ Porous Femur, 3DKNEE™ Porous Coated Tibia, and EMPOWR 3DKNEE™ Porous Tibia which are intended for cementless applications.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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: September 29, 2017

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 Porous Knee System	Total Knee Implant	Class II	MBH

Product Code	Regulation and Classification Name
MBH	21 CFR 888.3565, Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis

Description:

The EMPOWR POROUS KNEE System is a line extension to the EMPOWR Knee platform (cleared via K143242), to include porous coated femoral and tibial baseplate implants and instruments, which provide surgeons with comprehensive surgical solutions to address a variety of patient demographics and surgeon preferences.

The EMPOWR 3DKNEE Porous Femur has porous coating applied inside of the cement pocket. The added porous coating allows for long term biological fixation of the device. Therefore, this device is indicated for cementless use.

The EMPOWR Porous Tibia also have a porous coating applied to the backside of the baseplate to allow for long term biological fixation of the device. The distal geometry includes 4 peripheral pegs for initial fixation along with a fully webbed keel to provide rotational stability and initial fixation.

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 3DKNEE™ Porous Tibia which are intended for cementless applications.

Predicate Devices:

- Empowr Knee System (K143242)
- 3DKnee Porous Femur (K032905)
- FMP™ Porous Coated Acetabular Shells (K072888)

Comparable Features to Predicate Device(s):
The EMPOWR POROUS KNEE line extension includes a modified version of the EMPOWR 3DKNEE™ Non-porous Femoral Implants. The material, articulating geometry, and articulating surface roughness are identical to the EMPOWR 3DKNEE™ Non-porous Femoral Implants.

The EMPOWR POROUS KNEE line extension also includes a modified version of the EMPOWR non-porous Tibial Baseplate Implants. The sizing architecture and proximal geometry remains identical to EMPOWR Non-porous Tibial Baseplate Implants.

Key Differences in Subject Device to Predicate:
The only modification made to the EMPOWR POROUS KNEE implants compared to the EMPOWR 3DKNEE non-porous Femoral Implants is the addition of porous coating inside of the cement pocket. The porous coating material and process is identical to the porous coating applied to an existing DJO femoral component, 3D Knee Porous Femur (K032905). The added porous coating allows for long term biological fixation of the device. Therefore, this device is indicated for cementless use.

The distal side of the EMPOWR Porous Tibia was modified to accommodate a cementless indication. The distal geometry includes 4 peripheral pegs for initial fixation along with a fully webbed keel to provide rotational stability and initial fixation. The backside of the baseplate is also coated with porous coating to allow for long term biological fixation of the device. This porous coating is identical to coating applied to existing FMP™ Porous Coated Acetabular Shells (K072888).

Non-Clinical Testing: Mechanical testing (femur fatigue testing, baseplate fatigue 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.