March 5, 2018

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

Re: K173723
Trade/Device Name: EMPOWR Universal Tibial Baseplate
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
Dated: December 1, 2017
Received: December 5, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173723

Device Name
EMPOWR Universal Tibial Baseplate

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, and EMPOWR 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.

510(k) Summary

Date: March 5, 2018

Manufacturer:
DJO Surgical (legally 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	Classification	Product Code
EMPOWR Universal Tibial Baseplate	Class II	JWH

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

Description:
The EMPOWR Universal Tibial Baseplate Implant is a line extension to the EMPOWR Knee platform to include a tibial baseplate implant with accessories (stem extensions and augments) and instruments, which provide surgeons with comprehensive surgical solutions to address a variety of patient demographics and surgeon preferences.

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, and EMPOWR POROUS Tibia which are intended for cementless applications.

Predicate Devices:

- DJO Surgical EMPOWR Knee System - K143242
- DJO Surgical Foundation Modular Tibial Baseplate - K932425
- DJO Surgical Movation Knee - K100900

Comparable Features and Differences to Predicate Device(s):

Features Exactly the Same as Predicate to Subject Device	• Size offerings • Material • Locking Mechanism geometry and surface finish of the Tibial Baseplate • Distal keel profile and surface finish • Intended Use

Features Similar as Predicate to Subject Device	• Stem length is the same once a modular stem plug is threaded onto the distal end of the tibial base • Cement grooves on the side of the stem extension • Threaded bolt assembly to distal side of tibial base implant
Features Different from Predicate to Subject Device	• Stem boss height is common 25mm for all tibia sizes • Size specific modular stem plug that restores the height of the tibial baseplate; stem plug may be removed intra-operatively to facilitate assembly with a stem extension accessory or may be left as assembled and implanted • threaded holes added to the distal (bone interface) side to use as an attachment means for a bolt to assemble augment accessories • Female taper in the proximal (mating tibial insert locking mechanism) to facilitate assembly with a thicker and more constrained posterior stabilized tibial insert • Threaded connection to distal side of tibial baseplate • Augment accessories are stackable up to 15mm and flip-able so they may be used in either medial or lateral compartment • Augment accessories have pockets and through slots to help facilitate cement flow between augments as added fixation to the tibial baseplate implant

Non-Clinical Testing: Testing has been performed for baseplate/stem extension fatigue testing, baseplate strength FEA, augment screw characterization, and locking mechanism disassembly. This testing has determined that the subject device is similar to the evaluated predicate device.

Endotoxin Assessment: Bacterial endotoxin testing was conducted and was found to meet the expected endotoxin limits.

Clinical Testing: Clinical testing was not required / performed.

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