DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 23, 2016

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

Re: K161945
Trade/Device Name: EXPRT Knee Femoral Augment(5mm), EXPRT Revision Knee Stem Extension(40mm)
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: August 22, 2016
Received: August 24, 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,

Vincent J. Devlin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161945

Device Name
EXPRT Revision Knee Femoral Augment (5mm) EXPRT Revision Knee Stem Extension (40mm)

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. This system is to be used for cemented applications.

Exprt Revision Knee Femoral Augments are also to be attached to the femoral component with bone cement.

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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Paperwork Reduction Act (PRA) Staff
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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: September 23, 2016

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

Contact Person:
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Manager, Regulatory Affairs
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Product	Classification	Product Code
Exprt Revision Knee Femoral Augment (5mm) Exprt Revision Knee Stem Extension (40mm)	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

Description:

This Special 510(k) is to add additional components to the currently cleared Exprt Revision Knee. These components are as described as follows:

A 5mm thick, machined, Ti alloy, distal femoral augment which will be available in 4 sizes. The augment covers either the posterior femoral resection in a horizontal orientation or the distal femoral resection in a vertical orientation and fits within the cement pocket of the femoral component.

A shorter cemented stem extension for use with both the tibial base plate and the femoral component. The stem, made from CoCrMo alloy, is fluted along its length for rotational constraint when cemented. The stem is available in a 40mm long, straight configuration.

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. This system is to be used for cemented applications.

Exprt Revision Knee Femoral Augments are also to be attached to the femoral component with bone cement.

Predicate Devices: DJO Surgical Foundation Knee Augment Blocks - K941306
DJO Surgical Exprt Revision Knee - K140830

Comparable Features to Predicate Device(s):

These components are comparable to the predicate devices in indications, material, design features, surgical implantation technique, intended use, packaging, and sterilization.

Key Differences in Subject Device to Predicate: **Femoral stem augments:** Different method of fixation to predicate. **Stem extension**: Shorter length than predicate.

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

Non-Clinical Testing: Analyses were performed which included drawing review with tolerance stack ups and anatomic bone model evaluation. All evaluations have determined that the devices are substantially equivalent to the applicable predicate devices.

Clinical Testing: Clinical testing was not required.