DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 9, 2016

DJO Surgical (Legal Name: Encore Medical, L.P.)
Ms. Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Boulevard
Austin, Texas 78758

Re: K161610
Trade/Device Name: EXPRT™ Revision Hip System
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip Joint Metal/Polymer Constrained Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWZ, LZO, LWJ
Dated: October 6, 2016
Received: October 13, 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 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 yours,

Lori A. Wiggins -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)*
K161610

Device Name
EXPRT™ Revision Hip System

Indications for Use *(Describe)*
Exprt™ Revision Hip System is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. It is intended for cementless revision hip arthroplasty on both uncemented and cemented femoral implants.

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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510(k) Summary

Date: November 9, 2016

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

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
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Product	Classification	Product Codes
EXPRT™ Revision Hip System	Class II	KWZ, LZO, LWJ

Product Code	Regulation and Classification Name
KWZ	Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
LWJ	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis per 21 CFR 888.3360

Description:

The EXPRT™ Revision Hip System includes non-porous distal femoral stem implants and non-porous proximal body implants, with bolt, all made from titanium alloy (Ti6Al4V) per ASTM F1472. System specific instrumentation allows the surgeon to prepare the bone to accept the EXPRT™ Revision Hip System implants.

Indications for Use:

Exprt™ Revision Hip System is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. It is intended for cementless revision hip arthroplasty on both uncemented and cemented femoral implants.

Predicate Devices: DJO Modular Revision Hip System – K092331
DJO TaperFill Hip Stem – K130099
Stryker Restoration Modular Revision Hip System – K050138

Comparable Features to Predicate Device(s): This device is 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: The subject hip stem features different dimensions and a distal-anterior relief at the bottom taper of the stem that is not present on the cleared predicates referenced in this 510(k).

Non-Clinical Testing: ROM testing and distal fatigue testing. All testing has determined that the device is substantially equivalent to the predicate devices.

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

Clinical Testing: Clinical testing was not required

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