June 07, 2019

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

Re: K190057
Trade/Device Name: DJO Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, OQG
Dated: January 10, 2019
Received: January 11, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
Office of Product Evaluation and Quality
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)*
K190057

Device Name
DJO Acetabular System

Indications for Use *(Describe)*

Joint replacement is indicated for patients suffering from disability due to:
• noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
• rheumatoid arthritis;
• correction of functional deformity;
• femoral fracture.
This device may also be indicated in the salvage of previously failed surgical attempts.
This device is indicated for cementless use.

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:

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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: June 7, 2019

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
DJO Acetabular System	Total Hip Implant	Class II	LPH, OQG

Product Code	Regulation and Classification Name
LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358
OQG	Hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented per 21 CFR 888.3358

Description:

The DJO Acetabular System allows for the total replacement of the acetabulum. The system consists of porous coated titanium acetabular cups, bone screws for use with the cups, and acetabular liners manufactured from highly crossed linked polyethylene with Vitamin E. It is designed for compatibility with currently cleared DJO stems and femoral heads.

Indications for Use:

Joint replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture.

This device may also be indicated in the salvage of previously failed surgical attempts. This device is indicated for cementless use.

Predicate Devices:

System Name	Manufacturer	510(k) Clearance
FMP Hemispherical Acetabular Shells	Encore Medical, L.P.	K072888
FMP HXe+ Acetabular Liner	Encore Medical, L.P.	K130365
FMP HXe+ Extended Acetabular Liner	Encore Medical L.P.	K172651
Cancellous Bone Screws	Encore Medical, L.P.	K931665
G7 Acetabular System	Biomet	K121874
Trident Acetabular System	Stryker	K040412

Comparable Features to Predicate Device(s):

Acetabular Cup: Materials, size offering, style offering, key material thickness, porous coating, outer diameter, internal surface finish, anti-rotation feature, number of internal scallops, dome thread plug, screw hole options, screw hole layout, packaging, sterilization, manufacturing process.

Acetabular Liner: Material, size offering, number of scallops, minimum wall thickness, wear, impingement, poly locking feature, surface finish, sterilization, packaging, manufacturing process.

Bone Screw: Thread form and diameter, screw lengths, self tapping screw tip, surface finish, drive feature, material, sterilization, packaging, manufacturing process.

Implant Relationship: ROM, jump distance, poly liner locking mechanism, poly liner collar, poly liner articulating surface, bone screw angulation, bone screw drill preparation, titanium dome plug cover

Key Differences in Subject Device to Predicate:

There are no key differences between the subject device and predicate devices.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected conditions. This testing includes:

- Range of Motion Analysis
- Impingement Testing
- Push Out, Lever Out, and Torsional Strength

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.