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

December 13, 2017

Re: K172651
Trade/Device Name: FMP™ Extended Liners
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: OQG, LPH
Dated: November 28, 2017
Received: November 29, 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)*

K172651

Device Name
FMP™ Extended Liners

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 to be used for uncemented 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.

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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 1 , 2017

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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Email: teffany.hutto@djoglobal.com

Product	Classification	Product Code
FMP Extended Liners	Class II	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:

This Traditional 510(k) is a line extension to the X-alt Highly Cross Linked Acetabular Liner with Vitamin E product line to expand femoral head compatibility within the system by making larger femoral heads compatible with smaller acetabular cups.

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 to be used for uncemented applications.

Predicate Devices:

Device	Manufacturer	510(k) Number	510(k) Type
X-alt Highly Cross Linked Acetabular Liner with Vitamin E	Encore Medical, L.P.	K130365	Primary
Stryker Trident Large Diameter Acetabular Insert	Stryker	K062419	Additional
Foundation® Porous Coated Hemispherical Acetabular Cup	Encore Medical, L.P.	K974093	Reference

Comparable Features to Predicate Device(s):

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

Key Differences in Subject Device to Predicate:

Collar height and liner thickness compared to K130365.

Endotoxin Assessment: Bacterial endotoxin testing conducted based on DJO Surgical's alternative to batch testing plan met the bacterial endotoxin limits defined in USP <161> as evidenced through ongoing monitoring conducted concurrently with dose audits. Testing conducted with the most recent dose audit using the worst case product demonstrated an acceptable BET level. The subject FMP Extended Liners require fewer manufacturing operations and less handling than the worst case product (FMP Shell). Refer to NDPCAW-00085 for new product review.

Non-Clinical Testing: Testing performed includes wear per ISO 14242-2/3, impingement per ASTM F2582-14, push-out, lever-out, torsion per ASTM F1820-13, and range of motion per ISO 21535:2009. All evaluations determined that the devices are substantially equivalent to the applicable predicate devices.

Clinical Testing: Clinical testing is not required.