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

February 10, 2021

Re: K203557
Trade/Device Name: EMPOWR Dual Mobility Metal Liner, EMPOWR Dual Mobility Poly Bearing
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
Dated: February 5, 2021
Received: February 8, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K203557

Device Name
EMPOWR Dual Mobility Metal Liner
EMPOWR Dual Mobility Poly Bearing

Indications for Use *(Describe)*
EMPOWR Dual Mobility (Metal Liner and Poly Bearing) is indicated as part of a total hip replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
- Revision of previously failed total hip arthroplasty
- Dislocation risks
- 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: February 9, 2021

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
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| Product | Common Name | Classification | Product Code |
|---|---|---|---|
| EMPOWR Dual Mobility Metal Liner | Total Hip Implant | Class II | LPH |
| EMPOWR Dual Mobility Poly Bearing | | | |

| Product Code | Regulation and Classification Name |
|---|---|
| LPH | Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 888.3358 |

**Description**:

EMPOWR Dual Mobility (Metal Liner and Poly Bearing) introduces a modular dual mobility bearing to the current acetabular system. The benefit of the new system is enhanced stability due to a larger femoral head with more ROM for a given cup size than the previously cleared single articulation liners. Bearings are offered in nominal OD sizes of 38-58mm compatible with previously cleared cups.

The subject bearing includes a Metal Liner made of CoCr alloy that locks to the cup with a modular taper junction and a Poly Bearing (Head) made from highly crossed linked UHMWPE infused with Vitamin E that captures an Inner Head made of ceramic or CoCr. The bearing provides two articulating surfaces. The Poly Bearing component articulates inside the Metal Liner and the permanently captured Inner Head articulates inside the Poly Bearing. The two articulations can occur independently or simultaneously.

**Indications for Use:**

EMPOWR Dual Mobility (Metal Liner and Poly Bearing) is indicated as part of a total hip replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
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- Dislocation risks
- To be used for uncemented applications

**Predicate Devices:**



| Device | Manufacturer | 510(k) Number |
|---|---|---|
| G7 Dual Mobility (Primary) | Biomet | K150522 |
| Trident MDM (Reference) | Stryker | K103233 |
| OR30 Dual Mobility (Reference) | Smith & Nephew | K191002 |
| DJO EMPOWR Acetabular System (Reference) | DJO Surgical | K190057 |
| DJO FMP Acetabular System (Reference) | DJO Surgical | K973119<br>K072888<br>K130365 |
| DJO CoCr Femoral Heads (Reference) | DJO Surgical | K935449 |

**Comparable Features to Predicate Device(s):**

- Intended Use and Indications for Use
- Materials
- Design Features (Bearing Design, Modular Connection, Head/Cup Differential)
- Poly Head/Inner Head Capture Feature
- Bearing Surface
- Size Range

There are no key differences in subject device to predicate

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

- Wear Testing
- Metal Liner Disassembly
- Head Disassembly
- Metal Liner Corrosion
- Impingement Testing
- Range of Motion

Based on the equivalent features, basic design, intended uses, and the comparative assessment included in this application, the EMPOWR Dual Mobility can be considered substantially equivalent to 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.