January 20, 2022

Encore Medical, L.P. dba DJO Surgical
Michael Siano
Sr. Program Manager, RA
9800 Metric Boulevard
Austin, Texas 78758

Re: K212941
Trade/Device Name: Porous Patella
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: December 22, 2021
Received: December 23, 2021

Dear Michael Siano:

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,

Ting Song, Ph.D., R.A.C.
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)*
K212941

Device Name
Porous Patella e+™

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. All devices are intended for cemented applications except for the FOUNDATION® Porous Coated Femur, FOUNDATION® Porous Coated Tibia Stemmed, FK/3DKNEE™ Porous Coated Downsize Tibia, 3DKNEE™ Porous Coated Femur, 3DKNEE™ Porous Coated Tibia, EMPOWR Porous® Knee Femur, EMPOWR Porous® Knee Tibia and Patella – Metal Backed which are intended for cementless applications.

While knee replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

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.

510(k) Summary

I. SUBMITTER

Encore Medical, L.P. (dba DJO Surgical)
9800 Metric Blvd.
Austin, TX 78758

Phone: (737) 207-4857
Fax: (512) 834-6313

Contact Person: Michael A. Siano
Date Prepared: September 9, 2021

II. DEVICE

Name of Device: Porous Patella e+™
Common or Usual Name: Total Knee Prosthesis
Classification Name(s):
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)
Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (888.3565)
Regulatory Class: II

Product Code(s): MBH, JWH

III. PREDICATE DEVICE

Stryker Triathlon Tritanium Metal-Backed Patella, K132624

The following reference devices are used:
Encore Medical Moderately Cross Linked Patella with Vitamin E, K113756
Encore Orthopedics Foundation Metal-Backed Patella, K932246

IV. DEVICE DESCRIPTION

The Porous Patella e+™ is a sterile, single-use, non-modular metal-backed patella that is manufactured from moderately crosslinked UHMWPE blended with Vitamin E and titanium alloy. The device is offered in a symmetric, domed, design available in multiple sizes. The device is intended for cemented or uncemented applications.

Non-sterile surgical instruments are supplied with the implant.

V. 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. All devices are intended for cemented applications except for the 3DKNEE™ Porous Coated Femur, EMPOWR Porous® Knee Femur, and EMPOWR Porous® Knee Tibia, which are intended for cementless applications.

While knee replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial Equivalence is demonstrated to the Stryker Triathlon Tritanium Metal-Backed Patella (K132624). Both subject and predicate device share a common intended use, and have similar technological characteristics. Technological differences were supported through the use of Reference Devices.

Comparable Features to Predicate Device:

- The Porous Patella e+™ is constructed with a similar manufacturing process to the predicate. Both devices consists of a metal backing produced by additive manufacturing.
- The anterior side of both devices is compression overmolded with UHMWPE then machined to final form.
- The Porous Patella e+™ has a similar bone ingrowth surface to the predicate constructed of an additive manufacturing porous lattice integrated into the metal backing.
- The Porous Patella e+™ has a similar articulating surface geometry to the predicate consisting of a symmetric spherical surface.
- The Porous Patella e+™ has the same number of bone fixation pegs (3) as the predicate.

Key Differences in Subject Device to Predicate:

- The material specification of the metal backing used in the Porous Patella e+™ is different from the predicate. The Porous Patella e+™ uses Ti-6Al-4V per ASTM F2924 while the predicate uses commercially pure titanium per ASTM F1580.

- The specific geometry of the porous bone ingrowth surface on the Porous Patella e+™ is different from the predicate. The Porous Patella e+™ uses a proprietary randomized

stochastic lattice structure. The exact geometry of the predicate lattice structure is unknown but is visually different from the Porous Patella e+™.

- The material specification of the articulating surface on the Porous Patella e+™ is different from the predicate. The Porous Patella e+™ uses a moderately crosslinked GUR® 1020-E UHMWPE with Vitamin E per ASTM F648 and ASTM F2695 while the predicate uses conventional, non-crosslinked UHMWPE per ASTM F648.
- The UHMWPE used in the Porous Patella e+™ is crosslinked in two sequential doses.
- The Porous Patella e+™ is offered in five sizes ranging from 29–41mm in diameter and 8-11mm in thickness while the predicate is offered in four sizes ranging from 31–39mm in diameter and 9-11mm in thickness.
- The exact dimensions of the bone fixation pegs and their spacing on the Porous Patella e+™ differ from the predicate.

Biocompatibility Testing
Biocompatibility evaluation for the Porous Patella e+™ was conducted in accordance with FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process",* September 4, 2020, and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,* as recognized by FDA.

The Porous Patella e+™ is intended for permanent implantation, contacting tissue/bone.

Biocompatibility was ensured through the use of qualified materials and contact agents.

Non-clinical Testing
- Chemical Composition & Microstructure of the Bone-apposing Materials (ASTM F2924)
- Stereological Evaluation of the Porous Surface (ASTM F1854)
- Mechanical Properties of the Porous Surface (ASTM F1147, ASTM F1044, ASTM F1160, ISO 13314)
- Abrasion of the Porous Surface
- Initial Implant Stability
- Static tensile, static shear, and shear fatigue strength of UHMWPE/metal interface
- Durability performance of the patellofemoral joint (ISO 14243-5)UHMWPE Material Characterization

Animal Studies
No animal data submitted.

Clinical Studies
Clinical testing was not required.

VIII. CONCLUSIONS

All testing and evaluations demonstrate that the device is substantially equivalent to the predicate identified.