DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2015

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

Re: K143242
Trade/Device Name: Rebel 3DKNEE System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: April 10, 2015
Received: April 13, 2015

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" (21CFR 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143242

Device Name
Rebel 3DKNEE System

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. This device is intended to be used for cemented 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.

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510(k) Summary

Date: May 7, 2015

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

Contact Person:
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Manager, Regulatory Affairs
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Product	Classification	Product Codes
Rebel™ 3DKNEE System	Class II	JWH, OIY

Product Code	Regulation and Classification Name
JWH	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 888.3560
OIY	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 888.3560

Description:

The REBEL™ 3DKNEE SYSTEM is a line extension to the current 3DKNEE system. It is a total knee system that includes non-porous distal femoral implants made from cast CoCr alloy per ASTM F75, tibial insert implants made from Highly Cross-Linked with Vitamin E (HXL VE) UHMWPE, and tibial base implants made from cast CoCr alloy per ASTM F75.

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. This device is intended to be used for cemented applications.

Predicate Devices: 3DKNEE System - K020114 & K091956
Foundation Knee System - K923277
Foundation PS Knee System - K933539
Movation Knee System - K100900 & K121727

Comparable Features to Predicate Device(s): This device is comparable to the current 3DKNEE System in indications, material, dimensions, surgical implantation technique, and intended use. This device has the same implant packaging and sterilization as the 3DKNEE System.

Non-Clinical Testing: FEA to assess load conditions, patella subluxation, contact area/contact stress, tibial-femoral contact area, and tibial-femoral subluxation testing. All testing has determined that the device is substantially equivalent to the predicate devices.

Clinical Testing: None provided.