510(k) Summary

JUL 1 1 2014

Date: April 4, 2014

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: (512) 834-6313
Email: teffany.hutto@djoglobal.com

Product	Classification	Product Code
Exprt™ Revision Knee	Class II	JWH, OIY

Product Code	Regulation and Classification Name
JWH	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560
OIY	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3560

Description:

The Exprt Revision Knee (ERK) is a tri-compartmental posterior stabilized knee for cemented applications. The system is comprised of three primary components: Femur, Tibial Insert, and Tibial Baseplate. The system is intended to treat patients who are candidates for revision total knee arthroplasty or difficult primary arthroplasty where bone loss may be substantial and the collateral ligaments may be compromised. The design of the knee system is a total condylar design, increasing sagittal conformity and stability. The post and cam of the posterior stabilized design are crucial to inducing femoral rollback and providing resistance to tibial subluxation, substituting the function of the absent PCL. The tibial post, in combination with the femoral cam, provides for greater patient flexion by forcing the femur posteriorly on the tibia.

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.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s). This device may also be indicated in the salvage of previously failed surgical attempts. This system is to be used for cemented applications

Predicate Devices: DJO Surgical Foundation PS Knee System – K933539
DJO Surgical Movation Knee System – K100900, K121727
DJO Surgical e+ FMP Acetabular Liner (Accessory Sterilization) – K130365

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Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same material, indications, surgical implantation technique, and intended use. The same technological characteristics include: same size offerings, same posterior stabilization, same tibial snap lock feature, and same femoral component box width. Differences to the predicate include tibial baseplate dimensions, femoral component dimensions, tibial insert post height, and length of the stem extensions.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected conditions. Testing included static contact area/contact stress testing, static testing in anterior-posterior draw, static testing in rotary laxity, and patella subluxation evaluation. All testing has determined that the device is substantially equivalent to the predicate devices.

Clinical Testing: None provided.

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

July 11, 2014

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

Re: K140830
Trade/Device Name: Exprt™ Revision Knee
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: June 5, 2014
Received: June 6, 2014

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,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K140830

Device Name: Exprt Revision Knee

Indications for Use:

Exprt™ Revision Knee
Indications for Use

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- avascular necrosis of the femoral condyle;
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices