K092331 #1/1

MAR - 3 2010

Summary of Safety and Effectiveness

Date: March 2, 2010

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

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
Phone: (512) 834-6255
Fax: (512) 834-6313
Email: teffany.hutto@djosurgical.com

Product	Product Codes	Regulation and Classification Name
Modular Revision Hip Stem	KWA, LWJ, KWZ, LZO	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis per 21 CFR 888.3330

Description:
The Modular Revision Hip stem is made up of a modular stem coupled with a proper neck by means of a "Morse" taper stabilized during the implantation phase by a safety screw.

This system is particularly indicated for revision surgery on both uncemented and cemented femoral implants, when there is significant bone loss and an abnormal meta-epiphyseal anatomy of the femur. The modular system allows achievement of the required stability and the good distal fit of the stem within the femoral canal, regardless of the bone loss or the changes of the femur anatomy. In some particular cases the stem fixation can be enhanced by using bone cement.

The stems are made of titanium alloy (ASTM F1472). The stem has a 1°50' tapered profile, with round finned section and typical diameters ranging from 14 to 24 mm. The diameter increases by 2 mm.

The neck design, made of titanium alloy (ASTM F1472), includes a single CCD configuration of 135°, thus performing a unique offset of 35mm. An additional neck offset of 40mm of 131°C of CCD configuration is also available. Both the neck versions are available in 7 different lengths from 50 to 110 mm, in 10 mm increments.

The correct length of the final implant can thus be obtained by coupling the stem to a modular neck.

Intended Use: The Modular Revision Femoral Hip Stem is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. It is intended for cementless revision hip arthroplasty on both uncemented and cemented femoral implants.

Predicate Devices:
ZMR™ Hip System - Revision Taper – Zimmer - K992667, K031572
Modular REACH Hip – Biomet - K994038
Modular Femoral Revision System – Biomet - K090757
Modular-Plus Revision System - Plus Orthopedics - K994126, K032709

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, and indications for use.

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

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

MAR - 3 2010

Re: K092331
Trade/Device Name: DJO Surgical Revision Femoral Hip System, 428-14/24-140/20
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LWJ, KWZ, LZO
Dated: February 25, 2010
Received: February 26, 2010

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.

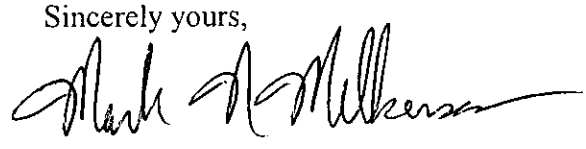
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K092331

Device Name: Modular Revision Femoral Hip Stems

Indications for Use:

Modular Revision Hip Stem
Indications for Use

The Modular Revision Femoral Hip Stem is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. It is intended for cementless revision hip arthroplasty on both uncemented and cemented femoral implants.

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)

for mxn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092331