K122636 (pg. 1 of 2)

510(k) Summary

Date: October 2, 2012

Manufacturer:
Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758

NOV 2 2012

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

Product	Classification	Product Codes
Revelation Porous Coated Hip Stem, Size 8	Class II	LPH, MBL, LZO, KWZ

Product Code	Regulation and Classification Name
LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358
MBL	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. per 2 I CFR 888.3353
KWZ	Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310

Description: This device has an asymmetrical body with an anterior build up that requires right and left components. When a symmetrical implant is used a large amount of cancellous bone often remains in the anterior metaphaseal portion of the femur. The anterior built up provides a more complete fill of the proximal femur. The proximal body is trapezoidal in cross-sectional geometry and tapers proximal to distal and lateral to medial. The distal stem portion is slightly conical in shape. The Revelation stem is collarless and has a Morse type taper to receive modular heads. The purpose of this application is to add an alternate porous coating.

Indications for Use:

Joint replacement is indicated for patients suffering from disability due to:

- non inflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head
- rheumatoid arthritis
- correction of functional deformity
- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for who all other options to constrained acetabular components have been considered.

The device is intended for cementless applications.

Predicate Device: DJO Surgical Revelation Hip Stem, Size 8 – K994070
DJO Surgical Revelation Hip Stem with P^2 Coating – K081679

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same design features, materials, indications, sterilization, packaging and intended use.

Non-Clinical Testing: Fatigue testing, Porous coating characterization, Ceramic burst assessment.

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 20993-002

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

Letter Dated: November 2, 2012

Re: K122636
Trade/Device Name: Revelation Porous Coated Hip Stem, Size 8
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, MBL, LZO, KWZ
Dated: October 2, 2012
Received: October 3, 2012

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

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

Enclosure

510(k) Number (if known): K122636

Device Name: Revelation® Porous Coated Hip Stem, Size 8

Indications for Use:

Revelation® Porous Coated Hip Stem, Size 8
Indications for Use

Joint replacement is indicated for patients suffering from disability due to:

- non inflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head
- rheumatoid arthritis
- correction of functional deformity
- femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts

The constrained acetabular component is indicated for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for who all other options to constrained acetabular components have been considered.

The device is intended for cementless applications.

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)

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

510(k) Number K122636