K082844 (pg 1/1)

Summary of Safety and Effectiveness

NOV 25 2008

Date: September 25, 2008

Manufacturer:
DJO Surgical (legally 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@djosurgical.com

Product	510(k) Number, Clearance Date/ Classification	Product Code
Biolox® Ceramic Femoral Head	K955563 – August 9, 1996 / Class II	LZO

Product Code	Regulation and Classification Name
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353

Description: The modification consists of a new material used in the manufacture of the Biolox Ceramic Femoral Heads. The femoral heads, manufactured from Biolox® *delta** material, are fabricated from an alumina matrix composite. The standard femoral head will mate with a femoral stem through a taper fit. The Option femoral head includes a sleeve that is inserted into the head and attached to the femoral stem through a taper fit. The heads will be available in sizes 22, 28, 32, 36, 40 and 44mm.

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

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

These devices may also be indicated in the salvage of previously failed surgical attempts.

Intended Use: DJO Surgical hip devices are intended for treatment of patients who are candidates for total hip arthroplasty per the indications for use. While hip 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.

Predicate Devices:

- Zimmer Biolox® *delta* Ceramic Femoral Head – K071535, Cleared November 19, 2007
- Biomet Biolox *delta* Ceramic Head – K042091, Cleared March 25, 2005, K051411, Cleared June 29, 2005, K061312, Cleared June 6, 2006
- DePuy Delta Ceramic Femoral Head – K062748, Cleared November 30, 2006
- Stryker Howmedica Osteonics V40™ Biolox delta Ceramic Femoral Head – K052781, Cleared October 27, 2005
- Stryker Howmedica Osteonics V40™/C-Taper Adapter Sleeve – K003379, Cleared November 30, 2000

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

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

Clinical Testing: None provided.

*Trademark of CeramTec AG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2008

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

Re: K082844
Trade/Device Name: Biolox *delta* Ceramic Femoral Head
Biolox *delta* Ceramic Femoral Head Offset Sleeve
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: October 30, 2008
Received: October 31, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K082844 (pg 1/1)

Device Name: Ceramic Femoral Head

Indications for Use:

Biolox® *delta* Ceramic Femoral Head
Indications for Use

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

- noninflammatory 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.

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 General, Restorative,
and Neurological Devices

510(k) Number K082844