SEP 3 0 2008

K081448

Summary of Safety and Effectiveness

Date: September 3, 2008

Manufacturer:
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@encoremed.com

Product	Product Code	Regulation and Classification Name
Encore Shoulder System	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The Encore Metal-Backed Revision Glenoid is a two piece metal backed polyethylene glenoid component for use in total shoulder arthroplasty. It includes a metal baseplate and polyethylene insert.

Metal Baseplate
The metal baseplate component, manufactured from Ti-6Al-4V per ASTM F136, is porous coated with commercially pure titanium (per ASTM F67 grade 2). It has an integrated central screw that provides initial fixation of the glenoid component as well as compression between the baseplate and the glenoid surface. HA porous coating on the surface of the medial side of the baseplate promotes biological fixation. No enhanced claims regarding the calcium phosphate coating will be made for this device. Additional fixation of the baseplate is achieved using four peripheral screws that can lock to the baseplate or have varying angles. All screws are manufactured from Ti-6Al-4V per ASTM F136.

Polyethylene Insert
The polyethylene insert component, molded from Ultra High Molecular Weight Polyethylene (per ASTM F648), snaps into the baseplate and provides a smooth bearing surface with the humeral head.

The Gemini Revision Glenoid is indicated for un-cemented use for the following indications:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable (e.g. revision of a failed primary component);
- cuff tear arthropathy.

Uncemented fixation may be supplemented by optional screw fixation.

Intended Use: Encore Medical shoulder devices are intended for treatment of patients who are candidates for shoulder arthroplasty per the indications for use. While shoulder 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:
Bio-Modular Shoulder System – Biomet Orthopedics, Inc.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same materials, sterilization, 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
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2008

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

Re: K081448
Trade/Device Name: Encore Shoulder system – Metal Backed Revision Glenoid
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/poly-mer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: MBF
Dated: September 03, 2008
Received: September 04, 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): K081448

Device Name: Shoulder System

Indications for Use:

Encore Shoulder System – Metal-Backed Revision Glenoid Indications for Use

The Gemini Revision Glenoid is indicated for un-cemented use for the following indications:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable (e.g. revision of a failed primary component);
- cuff tear arthropathy.

Uncemented fixation may be supplemented by optional screw fixation.

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 K081448