Summary of Safety and Effectiveness

MAR 2 8 2008

Date: March 28, 2008

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

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
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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 Shoulder System consists of a humeral stem, neck and head and a glenoid component. Components are offered for use for either primary or revision surgery applications.

The humeral stem consists of proximal body that is rectangular in cross-sectional geometry and tapers proximal to distal. The distal stem is cylindrical with four flutes. Anterior and posterior fins are located on the proximal body to help provide rotational stability. The anterior and posterior fins have suture holes to allow reattachment of soft tissue and bone fragments in the case of proximal humeral fracture. A suture hole is also placed medially through the proximal body just below the collar. A collar is present on the anterior, posterior and medial faces of the proximal body to resist stem subsidence. A neck stem angle is incorporated. The stem has a female Morse type taper to receive modular humeral necks. Also present is a female locating scallop utilized to orient the modular humeral neck and provide additional rotational stability of the neck and head.

The humeral neck has two male Morse type tapers that differ in size to prevent incorrect installation. The smaller Morse type taper interfaces with the female Morse type taper in the humeral stem, the larger Morse type taper interfaces with the female Morse type taper in the humeral head. A scalloped collar between the two male tapers interfaces with the female locating scallop in the humeral stem to provide orientation when using the angled neck and to provide additional rotational stability of the neck and head

The humeral heads are available in standard and offset configurations. In the offset configuration, the male Morse type taper on the humeral heads is offset from the center that makes it possible to orient the head in asymmetric positions on the symmetric stem, thus allowing the surgeon to intraoperatively select the position of the humeral head to recreate the anatomy of the individual patient.

The glenoid components are fabricated from ultra-high molecular weight polyethylene. The articulating surface has a radius of curvature greater than the corresponding humeral head. This

allows translation in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has either a keel or four pegs for fixation in the glenoid. The central peg has three annular barbs to provide immediate fixation to the patient's glenoid when inserted.

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

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- rheumatoid arthritis;
- correction of functional deformity;
- humeral fracture.

This device may also be indicated in the salvage of previously failed surgical attempts. The glenoid components are indicated for cemented use only.

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 Choice Shoulder System – Biomet Orthopedics, Inc.
Global Advantage – DePuy

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same indications, 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

MAR 28 2008

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

Re: K080402
Trade/Device Name: Encore Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: February 13, 2008
Received: February 14, 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): K080402

Device Name: Shoulder System

Indications for Use:

Encore Shoulder System
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 humeral head and/or glenoid;
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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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080402