DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 7, 2014

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

Re: K141990
Trade/Device Name: Encore Humeral Shoulder Stem
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD
Dated: October 16, 2014
Received: October 17, 2014

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

for

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

Enclosure

510(k) Number (if known): K141990

Device Name: Encore Humeral Shoulder Stem

Indications for Use:

Encore Humeral Shoulder Stem
Indications for Use

Anatomic Total Shoulder Indications:
The Encore® Shoulder Prosthesis Stem is indicated as an Anatomic shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral join including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;
- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity

The all-poly glenoid is intended for cemented use

Hemi Shoulder Indications:
The Encore® Shoulder Prosthesis Stem is indicated as a hemi shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral joint including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;
- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity;
- Rotator cuff tear arthropathy;
- Humeral fracture.
- Failed previous shoulder surgery

Reverse Total Shoulder Indications:
The Encore® Shoulder Prosthesis Stem is as a reverse shoulder replacement for patients with a functional deltoid muscle and a grossly deficient rotator cuff joint suffering from pain and dysfunction due to:

- Severe arthropathy with a grossly deficient rotator cuff;
- Previously failed joint replacement with a grossly deficient rotator cuff;
- Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head fracture, displaced 3- or 4-part fractures of proximal humerus, or reconstruction after tumor resection;
- Bone defect in proximal humerus;
- Non-inflammatory degenerative disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- Inflammatory arthritis including rheumatoid arthritis;
- Correction of functional deformity.

The glenoid baseplate is intended for cementless application with addition of screws for fixation. This device may also be indicated in the salvage of previously failed surgical attempts for anatomic and hemi procedures

All humeral stems are intended for cemented or cementless use.

510(k) Number (if known): K141990
Device Name: Encore Humeral Shoulder Stem

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)

510(k) Summary

Date: November 6, 2014

Manufacturer:
DJO Surgical (Legal Name: 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@djoglobal.com

Product	Classification	Product Code
Encore Humeral Shoulder Stem	Class II	KWS, HSD, PHX

Product Code	Regulation and Classification Name
KWS	Shoulder joint metal/polymer semi-constrained prosthesis per 21 CFR 888.3660
HSD	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per CFR 888.3690
PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The Encore® Shoulder humeral stem is a single component manufactured from wrought/forged titanium alloy. The stem distal body is cylindrical with four flutes. The stem's body flares proximally to a trapezoidal cross-sectional midbody, and a hemispherical shell is most superior. The stem has porous coating applied on, and around, the outer spherical diameter of the shell. Porous coating is applied, under the shell, to the stem's medial, anterior, and posterior surfaces. Two fins are located in symmetry on the stem's antero-lateral and medio-lateral midbody corners to promote shoulder humeral fracture tuberosity reduction in addition to providing rotational stability. The fins protrude at 45^{o} from the frontal plane. Each fin has two suture holes for reattachment of soft tissue or bone fragments in cases of proximal humeral fracture. A larger hole is located under the stem's shell which traverses the stem body through the medial-lateral plane to allow through a cerclage wire or suture anchorage point. Four suture holes are located through the stem's shell to aid in soft tissue reattachment and fractured shoulder tuberosity reduction. A larger hole spans the stem's midbody within the medial-lateral plane. The hole is tapered to maintain constant stem wall thickness without compromising fatigue strength. This hole can be used for temporary or long-term bone graft fixation in addition to soft-tissue reattachment. Three slots are located through the stem's shell: anterior, posterior, and medial. These slots allow surgical access by osteotome, or other instruments, for stem removal and separation from bone during revision surgery. A central screw thread within the stem's shell allows mating interface with other surgical instruments or implants.

Indications for Use:

Anatomic Total Shoulder Indications:
The Encore® Shoulder Prosthesis Stem is indicated as an Anatomic shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral join including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;
- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity

The all-poly glenoid is intended for cemented use

Hemi Shoulder Indications:
The Encore® Shoulder Prosthesis Stem is indicated as a hemi shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Noninflammatory degenerative joint disease including osteoarthritis;
- Inflammatory arthritis of the glenohumeral joint including rheumatoid arthritis;
- Post-traumatic arthritis of the glenohumeral joint;

- Avascular necrosis of the humeral head with and without involvement of the glenoid;
- Correction of functional deformity;
- Rotator cuff tear arthropathy;
- Humeral fracture.
- Failed previous shoulder surgery

Reverse Total Shoulder Indications:
The Encore® Shoulder Prosthesis Stem is as a reverse shoulder replacement for patients with a functional deltoid muscle and a grossly deficient rotator cuff joint suffering from pain and dysfunction due to:

- Severe arthropathy with a grossly deficient rotator cuff;
- Previously failed joint replacement with a grossly deficient rotator cuff;
- Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head fracture, displaced 3- or 4-part fractures of proximal humerus, or reconstruction after tumor resection;
- Bone defect in proximal humerus;
- Non-inflammatory degenerative disease including osteoarthritis and avascular necrosis of the natural humeral head and/or glenoid;
- Inflammatory arthritis including rheumatoid arthritis;
- Correction of functional deformity.

The glenoid baseplate is intended for cementless application with addition of screws for fixation. This device may also be indicated in the salvage of previously failed surgical attempts for anatomic and hemi procedures

All humeral stems are intended for cemented or cementless use.

Predicate Devices:

- Reverse® Shoulder Prosthesis Monoblock – K100741, K111735, K130048, K103208, K140904
- Encore® Shoulder System – K080402
- Foundation Shoulder System - K950651
- Encore® Hemi Shoulder – K950594
- Torneir Aequalis® Reversed Fracture Shoulder Prosthesis – K082120
- Tornier Aequalis® Flex Shoulder System – K122698

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same material substrate, same porous coating material, surface finishes, size offering, mating interface snap mechanism, sterilization and packaging, and surgical implantation technique. Differences to the predicates include additional size offerings, location of fins, location and quantity of suture holes, P2 porous coating surface area, and mid-body cross-sectional shape, and metaphysis window shape and orientation.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected conditions. Testing included snap mechanism verification tolerance analysis, statistical modal analysis and fatigue testing. All testing has determined that the device is substantially equivalent to the predicate devices.

Clinical Testing: None provided.