



November 2, 2016

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

Re: K140904

Trade/Device Name: Reverse<sup>®</sup> Shoulder Prosthesis Monoblock  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: PHX, KWS  
Dated: April 9, 2014  
Received: April 9, 2014

Dear Ms. Hutto:

This letter corrects our substantially equivalent letter of May 6, 2014.

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" (21 CFR 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): \_\_\_\_\_ K140904 \_\_\_\_\_

Device Name: Reverse Shoulder Prosthesis Monoblock

Indications for Use:

**Reverse® Shoulder Prosthesis Monoblock  
Indications for Use**

The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus. (For cemented implantation only)
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or cementless use.

Prescription Use   
(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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K140904

**510(k) Summary****MAY 06 2014****Date:** April 9, 2014**Contact Person:****Manufacturer:**

DJO Surgical (Legal Name: Encore Medical, L.P.)  
9800 Metric Blvd  
Austin, TX 78758

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Manager, Regulatory Affairs  
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Product	Classification	Product Code
Reverse® Shoulder Monoblock Stem	Class II	KWS

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

**Description:**

The RSP system is designed so that the "ball" of the articulation fits into the glenoid baseplate, and the "cup" of the articulation fits into a metal cup that is joined to the humeral stem. The RSP Monoblock stem includes a humeral stem with socket attached, and humeral socket insert. This change is to replace the current titanium plasma spray coating with porous coating on the size 6 stem only. There are no changes to the fundamental scientific technology of the RSP Monoblock with the modifications in this 510(k) submission.

**Indications for Use:**

The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus. (For cemented implantation only)
- In cases of bone defect in proximal humerus.

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The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or cementless use.

**Predicate Devices:** RSP Monoblock Humeral Stem, DJO Surgical K100741, K103208, K130048  
RSP Baseplate with Porous Coating, DJO Surgical K112069  
Reverse Shoulder Prosthesis – DJO Surgical K041066

**Comparable Features to Predicate Device(s):** This device is comparable to the current RSP Monoblock Stem in indications, material, dimensions, surgical implantation technique, and intended use. This device will have the same porous coating as cleared with the RSP Baseplate with Porous Coating. This device has the same implant packaging and sterilization as the Reverse Shoulder Prosthesis. There are no features included in this change that are not already cleared in a predicate device listed above.

**Non-Clinical Testing:** Fatigue testing, coating shear strength, coating tensile strength, bead size measurement, pore size measurement, porosity assessment, bead layer assessment, coating thickness assessment. All testing has determined that the device is substantially equivalent to the predicate devices.

**Clinical Testing:** None provided.