



November 2, 2016

Encore Medical, L.P.
Ms. Christine Chesnutt
Department Coordinator- 1
9800 Metric Boulevard
Austin, Texas 78758

Re: K141006

Trade/Device Name: Reverse[®] Shoulder Prosthesis, Reverse[®] 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: May 5, 2014

Received: May 6, 2014

Dear Ms. Chesnutt:

This letter corrects our substantially equivalent letter of June 5, 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): K141006

Device Name: Reverse Shoulder Prosthesis

Indications for Use:

**Reverse® Shoulder Prosthesis
Indications for Use**

The Reverse® Shoulder Prosthesis (RSP®) is indicated for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy, a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

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

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) Number (if known): K141006

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 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 ofCDRH, Office ofDevice Evaluation (ODE)

K141006

510(k) Summary

Date: May 27, 2014

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

Contact Person:
 Christine Chesnutt
 Department Coordinator-1
 Phone: (512) 834-6207
 Fax: (512) 834-6313
 Email: Christine.Chesnutt@djosurgical.com

| Product | Classification | Product Code |
|------------------------------|----------------|--------------|
| Reverse® Shoulder Prosthesis | Class II | KWS |
| Reverse® Shoulder Monoblock | 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 components included in this system are a glenoid head, a humeral socket joined with humeral stem, a glenoid baseplate, and baseplate screws. The standard RSP system consists of a modular components which include a humeral stem, humeral socket, humeral socket insert, glenoid baseplate, glenoid head, and bone screws. The RSP Monoblock stem includes a humeral stem with socket attached, and humeral socket insert.

The modification outlined in this application consists of an addition of a humeral socket insert infused with pure liquid pharmaceutical grade alpha-tocopherol into the material.

Indications for Use:

The Reverse® Shoulder Prosthesis (RSP®) is indicated for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy, a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient’s joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

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.

Predicate Devices: RSP Shoulder System, DJO Surgical, K041066, K051075, K092873
RSP Monoblock Humeral Stem, DJO Surgical K100741, K103208
FMP Acetabular Liner, DJO Surgical, K130365
RSP Monoblock Accessories, DJO Surgical, K130048

Comparable Features to Predicate Device(s): Features comparable to the RSP Shoulder System insert include the same dimensions and sizing. Features comparable to the RSP Monoblock include the same indications and surgical implantation technique, and intended use. Features comparable to the FMP Acetabular Liner are materials, packaging, and sterilization. There are no features included in this change that are not already cleared in a predicate device listed above.

Non-Clinical Testing: Axial Push Out, Lever Out, Torsion, Izod Impact, Small Punch, Tensile, FTIR Analysis, Animal Implant, Cytotoxicity, and Fatigue. All testing has determined that the device is substantially equivalent to the predicate devices.

Clinical Testing: None provided.