K111735

510(k) Summary

Date: September 27, 2011

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

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
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OCT - 3 2011

Product	510(k) Number, Clearance Date/ Classification	Product Code
Reverse® Shoulder Monoblock Prosthesis	K100741, August 2, 2010, Class II	KWS
Encore (Turon) Shoulder System	K080402, March 28, 2008, Class II	KWS

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

Description: A monoblock humeral stem with socket that is joined with an adapter to mate with a humeral head for use in hemi-arthroplasty applications.

There is no change to the intended use or fundamental scientific technology. This includes no changes to currently cleared devices, packaging or sterilization.

Indications for Use:

The Reverse® Shoulder Prosthesis (RSP) is indicated for treatment of patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or 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.

During primary surgery, after the humerus is prepared for the RSP humeral stem (modular and monoblock), if purchase to the glenoid bone is insufficient to bear the load of the glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP humeral stem adapter can be used to convert the RSP humeral stem to hemiarthroplasty prosthesis as a salvage procedure. During revision surgery of an RSP (modular or monoblock), if the glenoid bone stock appears to be "insufficient" to bear the load of the glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP humeral stem adapter can be used to convert the RSP device to hemiarthroplasty prosthesis as a salvage procedure. For modular RSP stems, the Foundation Shoulder humeral head should be used. For the monoblock stem, the Turon humeral head should be used.

This stem/adapter construct is not approved for use as a surrogate for traditional hemiarthroplasty or anatomic replacement indications.

Predicate Device:

- DJO Surgical Reverse® Shoulder Prosthesis Adapter – K052086

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same design features, materials, indications, sterilization, and intended use.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected conditions. Testing included lever out strength, load cycle, screw torque strength, cycle, and taper tensile.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

OCT - 3 2011

Re: K111735
Trade/Device Name: Reverse® Shoulder Monoblock Stem with Hemi Adapter
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: September 7, 2011
Received: September 8, 2011

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

510(k) Number (if known): K111735

Device Name: Reverse® Shoulder Monoblock Stem with Hemi Adapter

Indications for Use:

Reverse® Shoulder Monoblock Stem with Hemi Adapter
Indications for Use

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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)

Michael Chen for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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