



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

October 30, 2017

Re: K172351

Trade/Device Name: AltiVate Reverse Humeral Stem, AltiVate Reverse Small Spacer, AltiVate Reverse, Small Hemi-Adapter, AltiVate Reverse, Small Socket Insert
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PHX
Dated: September 28, 2017
Received: October 2, 2017

Dear Teffany 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 (DICE) 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 (DICE) 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,


Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration**Indications for Use**Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.510(k) Number (if known)
K172351Device Name
AlliVate™ Reverse Shoulder System**Indications for Use (Describe)**

Indications for AlliVate™ Stem:

Anatomic Total Shoulder Indications:

The AlliVate™ 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 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

The all-poly glenoid is intended for cemented use

Hemi Shoulder Indications:

The AlliVate™ 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 AlliVate™ 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date: September 29, 2017

Contact Person:

Manufacturer:

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

Teffany Hutto

Manager, Regulatory Affairs

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Product	Common Name	Classification	Product Code
AltiVate Reverse® Small Shell Shoulder	Total Shoulder Implant	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 CFR 888.3660

Description:

The AltiVate™ Reverse Small Shell Shoulder is a line extension to the AltiVate Reverse System. It consists of four primary components: humeral stem, socket insert, spacer and hemi-adaptor. Device specific instrumentation will also be used. Components are offered for use for either primary or revision surgery applications, in a hemi or total shoulder application.

Indications for Use:

Indications for AltiVate™ Stem:

Anatomic Total Shoulder Indications:

The AltiVate™ 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 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

The all-poly glenoid is intended for cemented use

Hemi Shoulder Indications:

The AltiVate™ 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



The AltiVate™ 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:

- Encore Humeral Shoulder Stem (now called AltiVate Reverse) - K141990
- Reverse® Shoulder Prosthesis Monoblock - K100741, K111061, K111735, K141006
- Zimmer Trabecular Metal Reverse – K052906

Comparable Features to Predicate Device(s):

The AltiVate Reverse Small Shell Shoulder line extension includes a diametrically reduced shell geometry with features comparable to predicate devices including the same material substrate, same porous coating material, surface finishes, size offering, mating interface snap mechanism, sterilization and packaging, indications, intended use, and surgical implantation technique.

Key Differences in Subject Device to Predicate:

Differences to the predicates include a diametrically reduced shell geometry, additional size offerings/thickness and P2 porous coating surface area.

Non-Clinical Testing:

Mechanical testing has demonstrated the device's ability to perform under expected conditions. This testing included assessment of lever out, torsional strength, push-out strength, snap geometry, porous coating, fatigue, tensile strength, and screw strength, All testing has determined that the device is substantially equivalent to the predicate devices.

Endotoxin Assessment:

DJO Surgical conducts device testing to assure that pyrogen limit specifications are met via the Kinetic Chromogenic method for bacterial endotoxin testing. Testing has also been performed to establish product non-pyrogenicity.

Clinical Testing: Clinical testing was not required.

Conclusions: All testing and evaluations demonstrate that the device is substantially equivalent to the predicates identified.

