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 21, 2016

Encore Medical, L.P.
Desiree Wells
Regulatory Affairs Specialist
9800 Metric Blvd.
Austin, Texas 78758

Re: K162024
Trade/Device Name: AltiVate Anatomic™ Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PAO
Dated: October 20, 2016
Received: October 21, 2016

Dear Ms. Desiree Wells:

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,

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)*
K162024

Device Name
AltiVate Anatomic™ Shoulder System

Indications for Use *(Describe)*
The AltiVate Anatomic™ Shoulder System is indicated as an anatomic shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis of the natural humeral head and/or glenoid, and post traumatic arthritis
- Rheumatoid and other inflammatory arthritis
- Correction of functional deformity, including fracture malunion
- Humeral head fracture
- Revision of other devices if sufficient bone stock remains

The AltiVate Anatomic™ Shoulder System is a hemiarthroplasty shoulder replacement for patients with a functional deltoid muscle suffering from pain and dysfunction due to:

- Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis of the natural humeral head and/or glenoid, and post traumatic arthritis
- Rheumatoid and other inflammatory arthritis
- Correction of functional deformity, including fracture malunion
- Humeral head fracture
- Rotator cuff tear arthropathy
- Revision of other devices if sufficient bone stock remains

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for a total shoulder arthroplasty.

Humeral components with a porous coated surface are indicated for either cemented or uncemented applications. Glenoid components are indicated for cemented use only.

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.

510(k) Summary

Date: November 16, 2016

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

Contact Person:
Desireé Wells
Regulatory Affairs Specialist
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Product	Classification	Product Code
AltiVate Anatomic™ Shoulder System	Class II	KWS, HSD, PAO

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
PAO	Shoulder joint metal/polymer semi-constrained cemented prosthesis per CFR 888.3660

Description:

The AltiVate Anatomic™ Shoulder System consists of four primary components: humeral stem, neck, head and glenoid. Components are offered for use for either primary or revision surgery applications, in a hemi or total shoulder application.

The proximal body of the stem is rectangular in cross-sectional geometry and tapers proximal to distal. The distal stem is cylindrical. Anterior and posterior fins are located on the proximal body to help provide rotational stability. The anterior and posterior fins have suture holes to allow reattachment of soft tissue and bone fragments in the case of humeral head fracture.

The humeral neck has two male Morse type tapers that differ in size to prevent incorrect installation. The smaller Morse type taper interfaces with the female Morse type taper in the humeral stem, while the larger Morse type taper interfaces with the female Morse type taper in the humeral head.

The humeral heads are available in standard and offset configurations. In the offset configuration, the male Morse type taper on the humeral heads is offset from the center that makes it possible to orient the head in asymmetric positions on the symmetric stem, thus allowing the surgeon to intraoperatively select the position of the humeral head to recreate the anatomy of the individual patient.

The glenoid components are fabricated from vitamin E ultra-high molecular weight polyethylene and ultra-high molecular weight polyethylene. The articulating surface has a radius of curvature greater than the corresponding humeral head. This allows translation in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has four pegs for fixation in the glenoid. The central peg has three annular barbs and the peripheral pegs have machined fixation features, referred to as Tri-lobes, to provide immediate fixation to the patient's glenoid when inserted.

Indications for Use:

AltiVate Anatomic™ Total Shoulder Indications:
The AltiVate Anatomic™ Shoulder System is indicated as an anatomic shoulder joint replacement for patients suffering from pain and dysfunction due to:

- Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis of the natural humeral head and/or glenoid, and post traumatic arthritis
- Rheumatoid and other inflammatory arthritis
- Correction of functional deformity, including fracture malunion
- Humeral head fracture
- Revision of other devices if sufficient bone stock remains

The AltiVate Anatomic™ Shoulder System is a hemiarthroplasty shoulder replacement for patients with a functional deltoid muscle suffering from pain and dysfunction due to:

- Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis of the natural humeral head and/or glenoid, and post traumatic arthritis
- Rheumatoid and other inflammatory arthritis
- Correction of functional deformity, including fracture malunion
- Humeral head fracture
- Rotator cuff tear arthropathy
- Revision of other devices if sufficient bone stock remains

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for a total shoulder arthroplasty.

Humeral components with a porous coated surface are indicated for either cemented or uncemented applications. Glenoid components are indicated for cemented use only.

Predicate Devices:

- Encore® Shoulder System (now called Turon) - K080402, K123982
- RSP Monoblock Stem with P2 - K140904
- Tornier™ Aequalis Ascend Flex – K113413

Comparable Features to Predicate Device(s): This device is comparable to the predicate devices in implant material, basic design of shoulder components, indications, intended use, packaging and sterilization.

Key Differences in Subject Device to Predicate: Shorter humeral stem and modified proximal body geometry, one additional humeral head size offering, collarless neck and fixation features (Tri-Lobe) added to peripheral pegs on the glenoid.

Non-Clinical Testing: Mechanical testing (Rocking Horse, Stem/Head Fatigue and Humeral Head Disassociation) has demonstrated the device's ability to perform under expected conditions. All testing has determined that the device is substantially equivalent to the predicate devices.
Endotoxin Assessment: Bacterial endotoxin testing was conducted and was found to meet the expected endotoxin limits.

Clinical Testing: Clinical testing was not required.