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

December 23, 2020

Re: K203026
Trade/Device Name: AltiVate® Anatomic Pegged Glenoid with Markers
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, PAO
Dated: September 28, 2020
Received: October 2, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K203026

Device Name
AltiVate® Anatomic Pegged Glenoid with Markers

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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: December 10, 2020

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

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
Phone: (512) 834-6255
Fax: (760) 597-3466
Email: teffany.hutto@djoglobal.com

Product	Common Name	Classification	Product Code
AltiVate® Anatomic Pegged Glenoid with Markers	Total Shoulder Implant	Class II	KWS, PAO

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

Description:

This application is to introduce the AltiVate Anatomic Pegged Glenoid with Markers is a component that is manufactured from ultra-high molecular weight polyethylene with vitamin E. The articulating surface has a radius of curvature greater than the compatible humeral heads to allow 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. Radiographic markers are found in all three peripheral pegs. This application also includes a material change from the currently cleared AltiVate Anatomic Pegged Glenoids.

Indications for Use:

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

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Predicate Devices:

Device	Manufacturer	510(k) Number
AltiVate Anatomic Shoulder System*	Encore Medical, L.P.	K162024
Encore Shoulder System (now named Turon)	Encore Medical, L.P.	K080402
Discovery Elbow	Encore Medical L.P.	K013042

*Primary Predicate

Comparable Features to Predicate Device(s):

- Intended Use and Indications for Use
- Material
- Geometry and Features
- Size Offerings
- Radiographic Markers
- Sterilization

There are no differences in the subject device from the predicate device(s)

Non-Clinical Testing: Non-clinical testing has demonstrated the device's ability to perform under expected conditions. This testing was completed and submitted with K162024 and K080402 and determined to be applicable to this device. Applicable analysis included material evaluation and dimensional comparisons.

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.

Clinical Testing: Clinical testing was not required

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