Encore Medical, L.P.
Michael A. Siano
Senior Program Manager, Regulatory Affairs
9800 Metric Boulevard
Austin, Texas 78758

July 7, 2022

Re: K213387
Trade/Device Name: AltiVate® Anatomic Shoulder AG e+™ 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: June 2, 2022
Received: June 6, 2022

Dear Michael A. Siano:

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 Jiping Chen, M.D., Ph.D., M.P.H.
Acting Division 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213387

Device Name
AltiVate® Anatomic Shoulder AG e+™ 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

I. SUBMITTER

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

Phone: (864) 322-3801
Fax: (512) 834-6313

Contact Person: Michael A. Siano, Sr. Program Manager, RA
Date Prepared: October 13, 2021

II. DEVICE

Name of Device: AltiVate® Anatomic Shoulder AG e+™ with Markers
Common or Usual Name: Total Shoulder Implant
Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis (888.3660)
Regulatory Class: II
Product Code(s): KWS, PAO

III. PREDICATE DEVICE

Encore Medical, L.P., AltiVate Anatomic Pegged Glenoid with Markers, K203026 (Primary Predicate)
Encore Medical, L.P., AltiVate Anatomic Shoulder, K162024

Reference devices:
Tornier, Inc., Aequalis PerFORM+ Shoulder System, K150583
Encore Orthopedics, Inc., Total Shoulder Prosthesis, K950651

IV. DEVICE DESCRIPTION

This application is to include the AltiVate® Anatomic Shoulder AG e+™ with Markers, as a component of the AltiVate® Anatomic Shoulder System. The AltiVate® Anatomic Shoulder AG e+™ with Markers are 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(s) 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.

V. 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:

- 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparable Elements to Predicate Device(s):

- Intended Use and Indications for Use
- Material
- Articulating surface geometry
- Size Offerings
- Radiographic markers
- Sterilization

Different Elements to Predicate Device(s):

- Augmented back surface geometry

Any noted differences do not raise different questions of safety and effectiveness.

Endotoxin Assessment
DJO Surgical conducts device testing to assure that pyrogen limit specifications are met via the Kinetic Chromogenic method for bacterial endotoxin testing.

Mechanical and acoustic testing
Dynamic evaluation of glenoid loosening or disassociation was performed per ASTM F2028-17.

Animal Study
No animal studies were undertaken.

Clinical Studies
Clinical data was not required.

VII. CONCLUSIONS

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