June 3, 2020

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

Re: K193226
Trade/Device Name: AltiVate® Anatomic Canal-Sparing (CS) Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: April 30, 2020
Received: May 1, 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
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193226

Device Name
AltiVate® Anatomic Canal-Sparing (CS) Shoulder

Indications for Use *(Describe)*

The AltiVate® Anatomic CS Shoulder is indicated for severely painful and/or disabled shoulder joint resulting from osteoarthritis or traumatic arthritis.

The humeral components with a porous coated surface are indicated for uncemented (press-fit) 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

Date: May 28, 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 Canal-Sparing (CS) Shoulder | Total Shoulder Implant | Class II | PKC |

| Product Code | Regulation and Classification Name |
|---|---|
| PKC | Shoulder joint metal/polymer semi-constrained cemented prosthesis per CFR 888.3660 |

**Description**:

The AltiVate Anatomic Canal-Sparing (CS) Shoulder is a canal-sparing prothesis intended for use in an anatomic Total Shoulder Arthroplasty (aTSA) application. The canal-sparing prosthesis is a modular humeral component consisting of a metaphyseal humeral stem and humeral neck that are compatible with previously cleared DJO humeral heads and DJO keeled and pegged glenoids.

**AltiVate Anatomic CS Humeral Stem** -
The AltiVate Anatomic CS Humeral Stem component (Ti-6Al-4V per ASTM F1472) is a 3-fin design that extend radially from the central body and are equally spaced at 120°. It has a female Morse taper to accept the humeral neck component. The stem is tapered and has one consistent collar diameter. It has porous coating applied around the outer central body, fins, and bottom of the collar for cementless fixation in the proximal humerus. The stem is offered in three sizes, ranging from 18mm to 24mm in length.

**AltiVate Anatomic CS Humeral Neck** -
The AltiVate Anatomic CS Humeral Neck component (CoCr per ASTM F1537) is a dual Morse taper and is the modular connection between the humeral stem and the humeral head and is offered in one neutral size.

**Indications for Use:**

The AltiVate Anatomic CS Shoulder is indicated for severely painful and/or disabled shoulder joint resulting from osteoarthritis or traumatic arthritis.

The humeral components with a porous coated surface are indicated for uncemented (press-fit) applications. Glenoid components are indicated for cemented use only.

**Predicate Devices:**

| Device | Manufacturer | 510(k) Number |
|---|---|---|
| Simpliciti Shoulder System | Tornier | K143552 |
| AltiVate Anatomic Shoulder System | Encore Medical, L.P. | K162024 |

**Comparable Features to Predicate Device(s):**

- Intended Use and Indications for Use
- Material (Stem and Neck)
- Porous Coating
- Bone Fixation
- Quantity of Fins
- Size Offerings
- Length Offerings

**Key Differences in Subject Device to Predicate:**

- Fin width of subject device increases incrementally
- Collar diameter is smaller than predicate

**Non-Clinical Testing:** Non-clinical testing has demonstrated the device's ability to perform under expected conditions. This testing includes:

- Taper Disassociation Testing
- Humeral Construct Fatigue Testing
- Torque-Out Testing
- Axial Pull-Out Testing
- Humeral Micromotion - Cadaveric Experimental Analysis
- Humeral Micromotion - Finite Element Analysis (FEA)
- Humeral Fit Analysis

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.