Encore Medical, L.P.
Sherri Mellingen
Director, Regulatory Affairs
9800 Metric Boulevard
Austin, Texas 78758

May 29, 2024

Re: K233481
Trade/Device Name: AltiVate Reverse® Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: April 12, 2024
Received: April 15, 2024

Dear Sherri Mellingen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2024.05.29 09:35:26 -04'00'

Farzana Sharmin, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233481

Device Name

AltiVate Reverse® Glenoid

Indications for Use *(Describe)*

The AltiVate Reverse® Shoulder Prosthesis is indicated 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 RSP® Monoblock and AltiVate Reverse® 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.

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.
9800 Metric Blvd.
Austin, TX 78758

Phone: (952) 913-6383
Fax: (512) 834-6313

Contact Person: Sherri Mellingen, Director, Regulatory Affairs
Date Prepared: April 11, 2024

II. DEVICE

Name of Device: AltiVate Reverse® Glenoid
Common Name: Reverse Shoulder Prosthesis
Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
Regulatory Class: II
Product Code(s): PHX, KWS

III. PREDICATE DEVICE

Substantial equivalence of the subject AltiVate Reverse® Glenoid is being claimed with the primary predicate device, Encore Reverse Shoulder Prosthesis® (RSP) Glenoid System (K041066, K051075, K092873, and K112069), and the additional predicate Tornier Perform Reversed Augmented Glenoid (K161742).

This predicates have not been subject to a design-related recall.

Reference devices:

SMR Reverse Liner (K220792)

IV. DEVICE DESCRIPTION

The AltiVate Reverse® Glenoid is a line extension to the existing RSP Glenoid System consisting of additional size offerings, modularity, and augment/revision offerings for varying glenoid morphologies for use in reverse Total Shoulder Arthroplasty (TSA) applications. The new implants consist of modular neutral and augmented baseplates, Torx peripheral screws, porous coated pegs, and additional offsets of glenospheres. All of the subject device implants are manufactured from Ti-6Al-4V except the glenospheres, which are manufactured from CoCrMo. New device specific accessories/instruments have been developed and are intended to facilitate proper implantation of the glenoid shoulder system.

For peripheral fixation when using a neutral baseplate, a minimum of two 5.0mm Torx Locking Screws that are 22mm or greater in length are indicated. When using only two peripheral locking screws, the screws should be placed in the superior and inferior holes of the baseplate. For peripheral fixation when using a wedge baseplate, a minimum of two 5.0mm Torx Locking Screws that are 26mm or greater in length are indicated. When using only two peripheral locking screws, the screws should be placed in the

superior and inferior holes of the baseplate. When using more than two locking screws, the screw through the thickest portion of the wedge should be 18mm or greater.

V. INDICATIONS FOR USE

The AltiVate Reverse® Shoulder Prosthesis is indicated 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 RSP® Monoblock and AltiVate Reverse® humeral stems are intended for cemented or cementless use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial equivalence of the subject AltiVate Reverse® Glenoid has been demonstrated with the predicate device, Encore Reverse Shoulder Prosthesis® (RSP) glenoid system with the same materials, indications for use, and intended use.

Non-Clinical Performance Testing

- Glenoid loosening testing per ASTM F2028
- Taper disassociation testing per ASTM F2009
- Screw testing per ASTM F543
- Range of motion evaluation per F1378
- Porous coating characterization
- Corrosion evaluation
- MRI compatibility evaluation

Performance testing demonstrated substantial equivalence between the subject and predicate device and did not raise different questions of safety and effectiveness.

Animal Studies

No animal studies were undertaken.

Clinical Studies

Clinical data was not required.

VIII. CONCLUSIONS

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