



August 5, 2025

Encore Medical L.P.  
Patricia Kontoudis  
Regulatory Program Manager, Surgical  
9800 Metric Boulevard  
Austin, Texas 78758

Re: K252141

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  
Dated: July 8, 2025  
Received: July 8, 2025

Dear Patricia Kontoudis:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Farzana**  
**Sharmin -S**

A large, light blue watermark of the letters 'FDA' is visible behind the signature text.

Digitally signed by Farzana  
Sharmin -S  
Date: 2025.08.05 18:13:28  
-04'00'

Farzana Sharmin, PhD  
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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252141

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Please provide the device trade name(s).

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AltiVate Reverse® Glenoid

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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## 510(k) Summary

<b>Manufacturer:</b>	Encore Medical, L.P. 9800 Metric Boulevard Austin, TX 78758
<b>Contact:</b>	Ms. Patricia Kontoudis Regulatory Program Manager, Surgical Encore Medical, L.P. 9800 Metric Boulevard Austin, TX 78758 Phone: (443) 722-0126 <a href="mailto:patricia.kontoudis@enovis.com">patricia.kontoudis@enovis.com</a>
<b>Date Prepared:</b>	August 5, 2025
<b>Device Trade Name:</b>	AltiVate Reverse® Glenoid
<b>Classification:</b>	21 CFR §888.3660 Class II
<b>Classification Name:</b>	Shoulder joint metal/polymer semi- constrained cemented prosthesis
<b>Common Name:</b>	Reverse Shoulder Prosthesis
<b>Product Code:</b>	PHX
<b>Predicate:</b>	AltiVate Reverse® Glenoid (K233481)
<b>Indications for Use:</b>	<p>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:</p> <ul style="list-style-type: none"><li>• Severe arthropathy with a grossly deficient rotator cuff;</li><li>• Previously failed joint replacement with a grossly deficient rotator cuff;</li><li>• Fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder including humeral head</li></ul>

- 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.

**Device Description:**

This 510(k) submission proposes updated Surgical Technique within labeling, to reflect alternative reaming method to prepare the glenoid surface for the AltiVate Reverse Glenoid wedge baseplate. The alternative technique does not replace the original technique; it adds a secondary method for the user. There are no changes to the design, materials, function, or intended use of the devices, and no new implants or instruments are introduced.

**Performance Testing:**

Design Control and Verification and Validation Activities performed, demonstrates substantial equivalence between the subject and predicate devices and did not raise different questions of safety and effectiveness.

**Substantial Equivalence:**

There is no difference in intended use, design, material, manufacturing process, sterilization, packaging and principle of operation of the devices, or the instruments required to implant the devices.

**Conclusion:**

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