May 16, 2025

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

Re: K251184
Trade/Device Name: AltiVate Reverse® Shoulder System; Reverse® Shoulder Prosthesis (RSP®); SMR Shoulder System; PRIMA Humeral System; PRIMA Glenoid System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD, PAO, KWT, MBF
Dated: April 15, 2025
Received: April 16, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.05.16 09:33:00 -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

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)*
K251184

Device Name
AltiVate Reverse® Shoulder System, Reverse® Shoulder Prosthesis (RSP®), SMR Shoulder System, PRIMA Humeral System and PRIMA Glenoid System

Indications for Use *(Describe)*

AltiVate Reverse® Shoulder System:

Indications for RSP® Modular Stem:
The Reverse® Shoulder Prosthesis (RSP®) Humeral Stem and Socket Shell are indicated for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Indications for RSP® Monoblock Stem:
The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus.
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or Cementless use (Cementless use not cleared in the EU).

Indications for AltiVate Reverse® Humeral Stem and Small Shell Humeral Stem (Primary, Short Stem and Revision)

Reverse Total Shoulder Indications:
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.

SMR Shoulder System:
The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement.

The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- revision of a failed primary implant; in case of SMR Short Stems only if sufficient bone stock remains);
- cuff tear arthropathy (CTA Heads only);
- glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR TT Hybrid Glenoid only).

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The SMR TT Hybrid Glenoid Reverse Baseplate must not be used in cases of excessive glenoid bone loss and/or when bone graft is needed.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.

In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.

The Anatomic glenoid construct consists of an all polyethylene glenoid, a polyethylene glenoid with metal peg or a metal back assembled with a liner; the Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.

On the glenoid side, the fixation of all polyethylene glenoid, the polyethylene glenoid with metal peg or the metal back determines if the construct is cemented or uncemented.

System		Components	Material	System Use	
A	R			Cem	Not Cem
●	●	SMR Stem (Cemented, Cemented Revision)	Ti6Al4V	X	
●	●	SMR Stem (Cementless Finned, Cementless Revision)	Ti6Al4V		X
●	●	SMR Short Stem (Cementless Finned)	Ti6Al4V		X
●		SMR Humeral Body (Trauma, Finned)	Ti6Al4V	X	X
●	●	SMR Reverse Humeral Body	Ti6Al4V	X	X
●	●	Humeral Extension	Ti6Al4V	X	X
●		SMR Humeral Head (Standard*, CTA)	CoCrMo	X	X
●		SMR Adaptor Taper (Neutral, Eccentric)	Ti6Al4V	X	X

System		Components	Material	System Use	
A	R			Cem	Not Cem
•		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X
	•	SMR Glenosphere*	CoCrMo		X
	•	SMR Connector*	Ti6Al4V		X
	•	Reverse Liner	UHMWPE	X	X
			LimaVit (Vitamin E highly crosslinked UHMWPE)	X	X
•		SMR Cemented Glenoid	UHMWPE	X	
•		SMR 3 Pegs Cemented Glenoid	UHMWPE	X	
•	• *	SMR TT Hybrid Glenoid	UHMWPE+ Ti6Al4V 3D printed +Ta	X	X
	•	SMR TT Hybrid Glenoid Reverse Baseplate + Screw	Ti6Al4V		X
•	•	SMR Metal Back Glenoid	Ti6Al4V+PoroTi	X*	X*
•	•	SMR TT Baseplate	Ti6Al4V	X*	X*
	•	SMR TT Augmented 360 Baseplate	Ti6Al4V		X
•	•	SMR TT Glenoid Peg	Ti6Al4V 3D printed	X	X
•		SMR Metal Back Liner	UHMWPE	X*	X*
• *	•	SMR Bone screw	Ti6Al4V		X
Material Standards					
Ti6Al4V (ISO 5832-3 - ASTM F1472) – **Ti6Al4V 3D printed** (to meet the mechanical and chemical requirements of ISO 5832-3) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **UHMWPE** (ISO 5834-2 - ASTM F648) - **LimaVit (Vitamin E highly crosslinked UHMWPE)** (ISO 5834-2 - ASTM F648 - ASTM F2695 – ASTM F2565) - **PoroTi Titanium Coating** (ASTM F1580) - **Ta** (ISO13782 - ASTM F560)					

A= Anatomic / R=Reverse

*NOTE:

- When considering the humeral side, SMR Glenosphere Ø42 can be coupled only with PRIMA Humeral System.
- In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.
- The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.
- SMR Lateralized Connectors are not indicated for use with glenoid bone grafting techniques.
- In the US the SMR TT Metal Back Baseplate used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws; while when used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.
- If a SMR TT Hybrid Glenoid is in place and revision to a reverse prosthesis is required, the patient can be revised by removing the polyethylene baseplate, leaving the metal peg in place and by connecting it to the SMR TT Hybrid Glenoid Reverse Baseplate. The SMR TT Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.
- The Dia. 50, 52 and 54mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric). The Dia. 52 and 54mm Humeral Heads with + 2mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).
- The SMR Reverse Humeral System is compatible with the RSP® Glenoid and AltiVate Reverse® Glenoid systems only when a diameter 36 or 40mm SMR Reverse Insert LimaVit are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use.
- The SMR Reverse Glenoid System is compatible with the RSP® Humeral and AltiVate Reverse® Humeral systems only when a diameter 36 or 40mm SMR Glenosphere are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use.

PRIMA Shoulder System:

PRIMA Humeral System

The PRIMA Humeral System is intended for partial or total, primary or revision, shoulder joint replacement in skeletally mature patients. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The PRIMA Short Stem and PRIMA Short Stem Plus are intended for use in cementless and cemented applications, at the discretion of the surgeon.

The PRIMA Anatomic implant is indicated for partial or total, primary or revision shoulder joint replacement, in patients suffering from pain and disability due to:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis),
- Inflammatory arthritis of the glenohumeral join including rheumatoid arthritis,
- Avascular necrosis of the humeral head,
- Traumatic/post-traumatic arthritis,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains,
- Post-fracture deformity with intact rotator cuff, where adequate fixation can be achieved and adequate bone stock remains,
- Cuff tear arthropathy (CTA Heads only).

The PRIMA Reverse implant is indicated for primary reverse total shoulder replacement or for revision when converting an anatomic PRIMA arthroplasty to a reverse total shoulder arthroplasty (i.e. in case of cuff tear arthropathy or in a grossly rotator cuff deficiency joint with severe arthropathy).

Revision surgery with retention of the PRIMA Short Stem and PRIMA Short Stem Plus are intended as conversion surgery from anatomic to reverse, where the stem is stable, well positioned and tissue integrated. Other revisions of the humeral prosthesis part should be treated with traditional shoulder prostheses.

The PRIMA reverse implant is indicated for patients suffering from pain and disability due to:

- Rotator cuff tear arthropathy,
- Osteoarthritis with rotator cuff tear,
- Rheumatoid arthritis with rotator cuff tear,
- Massive irreparable rotator cuff tear,
- Avascular necrosis of the humeral head,
- Correction of functional deformity, where adequate fixation can be achieved and adequate bone stock remains,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains.

The PRIMA Humeral System consists of the following single use components:

- Anatomic configuration:
  - stem
  - adaptor for humeral heads.
- Reverse configuration:
  - stem
  - reverse tray
  - reverse insert.

System		Components	Material
A	R		
•	•	PRIMA Short Stem	Ti6Al4V 3d printed
•	•	PRIMA Short Stem Plus	Ti6Al4V 3d printed
•		PRIMA Adaptor with screw	Ti6Al4V
	•	PRIMA Reverse Tray	Ti6Al4V
	•	PRIMA Reverse Insert	LimaVit (Vitamin E highly crosslinked UHMWPE), Ti6Al4V
Material Standards Ti6Al4V (ISO 5832-3 - ASTM F1472), Ti6Al4V 3d printed (ISO 5832-3), LimaVit (Vitamin E highly crosslinked UHMWPE) (ISO 5834-2 - ASTM F648 - ASTM F2695 – ASTM F2565)			
A = Anatomic, R = Reverse			

Table 1 PRIMA Humeral System components materials

The PRIMA Humeral System is intended to be used with all glenoids implants belonging to the SMR Shoulder System and PRIMA Glenoid System.

The PRIMA Humeral System is compatible with the RSP® Glenoid and AltiVate Reverse® Glenoid systems only when a diameter 36 or 40mm PRIMA Reverse Insert LimaVit are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use.

PRIMA Glenoid System

The PRIMA Glenoid System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The PRIMA Glenoid System components are intended for uncemented use with the addition of screw fixation.

510(k) Summary

Manufacturer:	Enovis Corporation 9800 Metric Boulevard Austin, TX 78758 LimaCorporate S.p.A. Via Nazionale, 52 – 33038 Villanova di San Daniele del Friuli (UD) Italy
Contact:	Ms. Patricia Kontoudis Regulatory Program Manager, Surgical Encore Medical, L.P. 9800 Metric Boulevard Austin, TX 78758 Phone: (443) 722-0126 patricia.kontoudis@enovis.com
Date Prepared:	May 15, 2025
Device Trade Name:	AltiVate Reverse® Shoulder System Reverse® Shoulder Prosthesis (RSP®) SMR Shoulder System PRIMA Humeral System PRIMA Glenoid System
Classification:	21 CFR §888.3660 Class II
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Common Name:	Reverse Shoulder Prosthesis
Product Codes:	PHX, KWS, HSD, PAO, KWT, MBF
Primary Predicate Device:	AltiVate Reverse® Glenoid (K233481)

Additional Predicate Devices:

ENCORE REVERSE SHOULDER PROSTHESIS (K051075)
SMR REVERSE SHOULDER SYSTEM (K110598)
RSP HUMERAL SOCKET INSERT (K141006)
SMR 40MM GLENOSPHERE (K142139)
AltiVate Reverse Humeral Stem, AltiVate Reverse Small Spacer, Altivate Reverse, Small Hemi-Adapter, AltiVate Reverse, Small Socket Insert (K172351)
PRIMA Humeral System and SMR Glenosphere Ø42 (K212800)
SMR Reverse Liner (K220792)
PRIMA TT Glenoid (K222427)
PRIMA Humeral System; PRIMA TT Glenoid (K233712)

Indications for Use:

AltiVate Reverse® Shoulder System:

Indications for RSP® Modular Stem:
The Reverse® Shoulder Prosthesis (RSP®) Humeral Stem and Socket Shell are indicated for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Indications for RSP® Monoblock Stem:
The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus.
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or Cementless use (Cementless use not cleared in the EU).

Indications for AltiVate Reverse® Humeral Stem and Small Shell Humeral Stem (Primary, Short Stem and Revision)

Reverse Total Shoulder Indications:
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.

SMR Shoulder System:
The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement.

The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- revision of a failed primary implant; in case of SMR Short Stems only if sufficient bone stock remains);
- cuff tear arthropathy (CTA Heads only);
- glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR TT Hybrid Glenoid only).

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The SMR TT Hybrid Glenoid Reverse Baseplate must not be used in cases of excessive glenoid bone loss and/or when bone graft is needed.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.

In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.

The Anatomic glenoid construct consists of an all polyethylene glenoid, a polyethylene glenoid with metal peg or a metal back assembled with a liner; the Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.

On the glenoid side, the fixation of all polyethylene glenoid, the polyethylene glenoid with metal peg or the metal back determines if the construct is cemented or uncemented.

System		Components	Material	System Use	
A	R			Cem	Not Cem
•	•	SMR Stem (Cemented, Cemented Revision)	Ti6Al4V	X	
•	•	SMR Stem (Cementless Finned, Cementless Revision)	Ti6Al4V		X
•	•	SMR Short Stem (Cementless Finned)	Ti6Al4V		X
•		SMR Humeral Body (Trauma, Finned)	Ti6Al4V	X	X
•	•	SMR Reverse Humeral Body	Ti6Al4V	X	X
•	•	Humeral Extension	Ti6Al4V	X	X
•		SMR Humeral Head (Standard*, CTA)	CoCrMo	X	X
•		SMR Adaptor Taper (Neutral, Eccentric)	Ti6Al4V	X	X
•		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X
	•	SMR Glenosphere*	CoCrMo		X
	•	SMR Connector*	Ti6Al4V		X
	•	Reverse Liner	UHMWPE	X	X
			LimaVit (Vitamin E highly crosslinked UHMWPE)	X	X
•		SMR Cemented Glenoid	UHMWPE	X	
•		SMR 3 Pegs Cemented Glenoid	UHMWPE	X	
•	• *	SMR TT Hybrid Glenoid	UHMWPE+ Ti6Al4V 3D printed +Ta	X	X
	•	SMR TT Hybrid Glenoid Reverse Baseplate + Screw	Ti6Al4V		X
•	•	SMR Metal Back Glenoid	Ti6Al4V+PoroTi	X *	X *
•	•	SMR TT Baseplate	Ti6Al4V	X *	X *
	•	SMR TT Augmented 360 Baseplate	Ti6Al4V		X
•	•	SMR TT Glenoid Peg	Ti6Al4V 3D printed	X	X
•		SMR Metal Back Liner	UHMWPE	X *	X *

• *	•	SMR Bone screw	Ti6Al4V		X
Material Standards					
Ti6Al4V (ISO 5832-3 - ASTM F1472) – Ti6Al4V 3D printed (to meet the mechanical and chemical requirements of ISO 5832-3) - CoCrMo (ISO 5832-12 - ASTM F1537) – UHMWPE (ISO 5834-2 - ASTM F648) - LimaVit (Vitamin E highly crosslinked UHMWPE) (ISO 5834-2 - ASTM F648 - ASTM F2695 – ASTM F2565) - PoroTi Titanium Coating (ASTM F1580) - Ta (ISO13782 - ASTM F560)					

A= Anatomic / R=Reverse

*NOTE:

- When considering the humeral side, SMR Glenosphere Ø42 can be coupled only with PRIMA Humeral System.
- In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.
- The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.
- SMR Lateralized Connectors are not indicated for use with glenoid bone grafting techniques.
- In the US the SMR TT Metal Back Baseplate used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws; while when used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.
- If a SMR TT Hybrid Glenoid is in place and revision to a reverse prosthesis is required, the patient can be revised by removing the polyethylene baseplate, leaving the metal peg in place and by connecting it to the SMR TT Hybrid Glenoid Reverse Baseplate. The SMR TT Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.
- The Dia. 50, 52 and 54mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric). The Dia. 52 and 54mm Humeral Heads with + 2mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).
- The SMR Reverse Humeral System is compatible with the RSP® Glenoid and AltiVate Reverse® Glenoid systems only when a diameter 36 or 40mm SMR Reverse Insert

LimaVit are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use.

- The SMR Reverse Glenoid System is compatible with the RSP® Humeral and AltiVate Reverse® Humeral systems only when a diameter 36 or 40mm SMR Glenosphere are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use.

PRIMA Shoulder System:

PRIMA Humeral System

The PRIMA Humeral System is intended for partial or total, primary or revision, shoulder joint replacement in skeletally mature patients. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The PRIMA Short Stem and PRIMA Short Stem Plus are intended for use in cementless and cemented applications, at the discretion of the surgeon.

The PRIMA Anatomic implant is indicated for partial or total, primary or revision shoulder joint replacement, in patients suffering from pain and disability due to:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis),
- Inflammatory arthritis of the glenohumeral join including rheumatoid arthritis,
- Avascular necrosis of the humeral head,
- Traumatic/post-traumatic arthritis,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains,
- Post-fracture deformity with intact rotator cuff, where adequate fixation can be achieved and adequate bone stock remains,
- Cuff tear arthropathy (CTA Heads only).

The PRIMA Reverse implant is indicated for primary reverse total shoulder replacement or for revision when converting an anatomic PRIMA arthroplasty to a reverse total shoulder arthroplasty (i.e. in case of cuff tear arthropathy or in a grossly rotator cuff deficiency joint with severe arthropathy).

Revision surgery with retention of the PRIMA Short Stem and PRIMA Short Stem Plus are intended as conversion surgery

from anatomic to reverse, where the stem is stable, well positioned and tissue integrated. Other revisions of the humeral prosthesis part should be treated with traditional shoulder prostheses.

The PRIMA reverse implant is indicated for patients suffering from pain and disability due to:

- Rotator cuff tear arthropathy,
- Osteoarthritis with rotator cuff tear,
- Rheumatoid arthritis with rotator cuff tear,
- Massive irreparable rotator cuff tear,
- Avascular necrosis of the humeral head,
- Correction of functional deformity, where adequate fixation can be achieved and adequate bone stock remains,
- Fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains.

The PRIMA Humeral System consists of the following single use components:

- Anatomic configuration:
  - stem
  - adaptor for humeral heads.
- Reverse configuration:
  - stem
  - reverse tray
  - reverse insert.

System		Components	Material
A	R		
•	•	PRIMA Short Stem	Ti6Al4V 3d printed
•	•	PRIMA Short Stem Plus	Ti6Al4V 3d printed
•		PRIMA Adaptor with screw	Ti6Al4V
	•	PRIMA Reverse Tray	Ti6Al4V
	•	PRIMA Reverse Insert	LimaVit (Vitamin E highly crosslinked UHMWPE), Ti6Al4V
Material Standards Ti6Al4V (ISO 5832-3 - ASTM F1472), Ti6Al4V 3d printed (ISO 5832-3), LimaVit (Vitamin E highly crosslinked UHMWPE) (ISO 5834-2 - ASTM F648 - ASTM F2695 – ASTM F2565)			
A = Anatomic, R = Reverse			

Table 1 PRIMA Humeral System components materials

	The PRIMA Humeral System is intended to be used with all glenoids implants belonging to the SMR Shoulder System and PRIMA Glenoid System. The PRIMA Humeral System is compatible with the RSP® Glenoid and AltiVate Reverse® Glenoid systems only when a diameter 36 or 40mm PRIMA Reverse Insert LimaVit are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use. <u>PRIMA Glenoid System</u> The PRIMA Glenoid System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The PRIMA Glenoid System components are intended for uncemented use with the addition of screw fixation.
Device Description:	This 510(k) submission proposes updated labeling to reflect additional compatibility between previously cleared shoulder systems from Encore Medical, L.P. (AltiVate Reverse® Shoulder System) and LimaCorporate S.p.A. (SMR and PRIMA Shoulder Systems). The update allows for cross-system use of humeral and glenoid components for reverse total shoulder arthroplasty, where compatible sizes exist. There are no changes to the design, materials, function, or intended use of the devices, and no new implants or instruments are introduced. The proposed configurations include using an AltiVate Reverse® humeral stem and insert with SMR or PRIMA glenoid components, and vice versa.
Substantial Equivalence:	There has been no change to the previously cleared devices in respect to design, intended use, materials, instrumentation, method of use, manufacturing process, sterilization, or packaging.
Performance testing	Performance testing, including Wear Testing and Range of Motion Analysis, demonstrates substantial equivalence between

	the subject and predicate devices and did not raise different questions of safety and effectiveness.
Conclusion	All testing and evaluations demonstrate that the subject device is substantially equivalent to the predicate device identified.