January 22, 2026

Limacorporate S.p.A.
Lilia Maestripieri
Regulatory Affairs Specialist
Via Nazionale, 52
Villanova di San Daniele del Friuli, UD 33038
Italy

Re: K252352
Trade/Device Name: SMR Shoulder System; PRIMA Glenoid System; PRIMA Humeral System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, MBF
Dated: December 22, 2025
Received: December 22, 2025

Dear Lilia Maestripieri:

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

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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252352

Device Name
SMR Shoulder System

Indications for Use *(Describe)*
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
	•		UHMWPE X-Lima + Ti6Al4V		X
	•		LimaVit (Vitamin E highly crosslinked UHMWPE) + Ti6Al4V		X
	•	SMR Connector*	Ti6Al4V		X
	•	Reverse Liner	UHMWPE	X	X
			CoCrMo	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 Dia. 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 Dia. 36 or 40mm SMR Glenosphere CoCrMo are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use.**

- **Glenosphere size must be chosen according to clinical case, considering both joint dimension and soft tissues quality. In case of small shoulder join and/or stiff joint a smaller, surgeon should be prepared to use smaller glenosphere, such as 36 mm CoCrMo one.**
- **In reverse configuration metal glenospheres can be coupled only with polyethylene liners; similarly, the metallic reverse liners can be coupled only with polyethylene glenospheres.**

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.

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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.

510(k) Number *(if known)*
K252352

Device Name
PRIMA Glenoid System

Indications for Use *(Describe)*
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.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252352

Device Name
PRIMA Humeral System

Indications for Use *(Describe)*
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 and polyethylene reverse insert, or
  - metallic 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
			CoCrMo
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) , CoCrMo (ISO 5832-12 / ASTM F1537)			
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 metallic PRIMA Reverse Insert can be used only in combination with SMR Reverse HP and PRIMA Glenosphere in polyethylene LimaVit.

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

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510(k) Summary

Date: January 22, 2026

Manufacturer:
LimaCorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine – Italy

Contact Person:
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LimaCorporate
Telephone: +(39)0432945562

Product	Product Code	Regulation and Classification Name
SMR Shoulder System and PRIMA Glenoid System PRIMA Humeral System	PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660
	MBF	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3670

Common name:

Product	Trade name	Common or usual name of the device
SMR Shoulder System including SMR Reverse HP Glenosphere	SMR Shoulder System	Shoulder Prosthesis
SMR Shoulder System including Reverse HP Liner	SMR Shoulder System	Shoulder Prosthesis
PRIMA Humeral System including PRIMA Reverse Insert	PRIMA Humeral System	Humeral shoulder prosthesis
PRIMA Glenoid System including PRIMA TT Glenoid Glenosphere	PRIMA Glenoid System	Glenoid shoulder prosthesis

Description:

The subject devices consist of a line extension of the SMR Shoulder System and the PRIMA Shoulder System. The new devices introduced with this 510(k) are SMR and

PRIMA Glenospheres with diam. 40 and 44mm made of Vitamin E crosslinked UHMWPE (LimaVit) and corresponding CoCrMo humeral liners.

Indications for 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
	●		UHMWPE X-Lima + Ti6Al4V		X
	●		LimaVit (Vitamin E highly crosslinked UHMWPE) + Ti6Al4V		X

	•	SMR Connector*	Ti6Al4V		X
	•	Reverse Liner	UHMWPE	X	X
			CoCrMo	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 Dia. 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 Dia. 36 or 40mm SMR Glenosphere CoCrMo are used. Instructions for use of the Enovis Reverse Shoulder System should be consulted prior to use.**
- **Glenosphere size must be chosen according to clinical case, considering both joint dimension and soft tissues quality. In case of small shoulder join and/or stiff joint a smaller, surgeon should be prepared to**

use smaller glenosphere, such as 36 mm CoCrMo one.

- **In reverse configuration metal glenospheres can be coupled only with polyethylene liners; similarly, the metallic reverse liners can be coupled only with polyethylene glenospheres.**

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.

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 and polyethylene reverse insert, or
  - metallic 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
			CoCrMo
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), CoCrMo (ISO 5832-12 / ASTM F1537)			
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 metallic PRIMA Reverse Insert can be used only in combination with SMR Reverse HP and PRIMA Glenosphere in polyethylene LimaVit.

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

Predicate Devices:

No.	Company	Device name	Cleared via
1 (Primary Predicate)	LimaCorporate S.p.A.	SMR Reverse HP Shoulder System	K243826
2 (Reference device)	Exatech, INC.	Exactech Equinoxe Reverse Shoulder 46x21mm Glenosphere	K150458
3 (Reference device)	LimaCorporate S.p.A.	PRIMA Glenoid system	K222427
4 (Reference device)	LimaCorporate S.p.A.	PRIMA Humeral System	K212800

Summary of technology comparison:

The subject SMR Shoulder System and PRIMA Shoulder System are substantially equivalent to the primary predicate device (K243826), with respect to intended use, indication for use, principle of operation and performance features that are the same of the predicate. The subject devices feature an inversion of material, polyethene glenospheres articulating against a CoCrMo reverse liner, consistent with the primary

predicate device (K243826). In contrast to the primary predicate (K243826), the subject devices are provided in a wider range of sizes, lateralization, eccentricity and angulation. Reference devices provide supporting safety and effectiveness evidence for diameters greater than 40mm (K150458), lateralization (K222427), eccentricity (K150458) and angulation (K212800).

Non-clinical testing:

Mechanical tests demonstrated that device performance fulfilled the intended use and that the devices are substantially equivalent to the predicate devices.
Mechanical testing was performed on worst case components or constructs:

- Fatigue test
- Push-Out test
- Wear test
- Particle Analysis
- Range of Motion
- Liner push-out, lever-out and torque-out test

An evaluation of glenoid loosening in accordance with ASTM F2028 was performed. Based on this assessment, the subject devices are not considered a worst-case configuration with respect to initial glenoid component stability when compared to the predicate devices. A biological safety evaluation was conducted per FDA Guidance and ISO 10993-1. Previously completed sterility, packaging, shelf life and reprocessing validations from the predicate system were leveraged for the subject devices

Clinical testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the subject devices to the predicate devices.

Conclusion:

Based upon a comparison of intended use, summary of technological characteristics, and preclinical testing, the subject devices are substantially equivalent to the predicate device identified in this premarket notification.