



July 3, 2025

LimaCorporate S.p.A.
% Sarah Pleaugh
Director Regulatory Affairs
Mcra, LLC
803 7th Street NW, Third Floor
Washington, District of Columbia 20001

Re: K243826

Trade/Device Name: SMR Reverse HP Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: June 4, 2025
Received: June 4, 2025

Dear Sarah Pleaugh:

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: 2025.07.03 12:02:14 -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

510(k) Number (if known)
K243826

Device Name
SMR Reverse HP Shoulder System

Indications for Use (Describe)

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 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 Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.

System	Components	Material	System Use		
			Cem	Not Cem	
R	• SMR Stem (Cemented Revision)	Ti6Al4V	X		
	• SMR Stem (Cementless Revision)	Ti6Al4V		X	
	• SMR Short Stem (Cementless Finned)	Ti6Al4V		X	
	• SMR Reverse Humeral Body	Ti6Al4V	X	X	
	• Humeral Extension	Ti6Al4V	X	X	
	• SMR Glenosphere*	CoCrMo		X	
		UHMWPE X-Lima + Ti6Al4V		X	
	• SMR Connector*	Ti6Al4V		X	
	• Reverse Liner		UHMWPE	X	X
			CoCrMo	X	X
			LimaVit™ (Vitamin E highly crosslinked UHMWPE)	X	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*	
• SMR TT Baseplate	Ti6Al4V	X*	X*		
• SMR TT Augmented 360 Baseplate	Ti6Al4V		X		
• SMR TT Glenoid Peg	Ti6Al4V 3D printed	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)					

*NOTE:

- When considering the humeral side, SMR Glenosphere Ø42 can be coupled only with PRIMA Humeral System.
- 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 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.
- Glenosphere size must be chose 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.

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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510(k) Summary

K243826

Device Trade Name: SMR Reverse HP Shoulder System

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

Contact: Marco Talerico
Regulatory Geographical Expansion Lead
39-043-294-5500
marco.talerico@enovis.com

Prepared by: MCRA, LLC
803 7th Street, NW
Washington, DC 20001
Office: 202.552.5800

Date Prepared: July 2, 2025

Classifications: 21 CFR 888.3660; Shoulder joint metal/polymer, semi-constrained, cemented prosthesis

Class: II

Product Codes: PHX

Primary Predicate: LimaCorporate SMR Shoulder System (K223876)

Reference Devices: LimaCorporate SMR Reverse System (K100858/K110598/K142139)
LimaCorporate Delta TT Acetabular System (K112898)

Device Description:

The subject SMR Reverse HP Shoulder System is a line extension to the predicate SMR Shoulder System (K223876) consisting of Reverse HP crosslinked UHMWPE glenospheres and Co-Cr-Mo liners. The components are available in one diameter with various options to accommodate varying patient anatomy.

Indications For Use:

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 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 Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.

System	Components	Material	System Use		
			Cem	Not Cem	
R	• SMR Stem (Cemented Revision)	Ti6Al4V	X		
	• SMR Stem (Cementless Revision)	Ti6Al4V		X	
	• SMR Short Stem (Cementless Finned)	Ti6Al4V		X	
	• SMR Reverse Humeral Body	Ti6Al4V	X	X	
	• Humeral Extension	Ti6Al4V	X	X	
	• SMR Glenosphere*	CoCrMo			X
		UHMWPE X-Lima + Ti6Al4V			X
	• SMR Connector*	Ti6Al4V			X
	• Reverse Liner	UHMWPE		X	X
		CoCrMo		X	X
		LimaVit™ (Vitamin E highly crosslinked UHMWPE)		X	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*
	• SMR TT Baseplate	Ti6Al4V		X*	X*
	• SMR TT Augmented 360 Baseplate	Ti6Al4V			X
	• SMR TT Glenoid Peg	Ti6Al4V 3D printed		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)					

R=Reverse

***NOTE:**

- **When considering the humeral side, SMR Glenosphere Ø42 can be coupled only with PRIMA Humeral System.**
- **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 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.**
- **Glenosphere size must be chose 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.**

Performance Testing Summary:

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
- Creep and Deformation test
- Micromotion test
- Clean and Abrasive Wear test
- Particle Analysis
- Range of Motion

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 Summary:

Post-market clinical data from outside the United States on the subject and predicate device were provided in this submission, including patient-level radiographs, outcome measures, and safety data. The data supported a determination of substantial equivalence.

Predicate Devices:

LimaCorporate submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject SMR Reverse HP Shoulder System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

- Primary Predicate: LimaCorporate SMR Shoulder System (K223876)
- Reference Device: LimaCorporate SMR Reverse System (K100858/K110598/K142139)
- Reference Device: LimaCorporate Delta TT Acetabular System (K112898)

Substantial Equivalence:

The intended use, design, and materials of the SMR Reverse HP System are substantially equivalent to the ones of the manufacturer's own, legally marketed predicate devices. The primary predicate is the same intended use, overall design and fundamental technology as the subject system. In contrast to the primary predicate SMR Shoulder System (K223876), which uses a glenosphere component manufactured of CoCrMo alloy and a humeral liner manufactured from UHMWPE, the subject SMR Reverse HP Shoulder System utilizes a glenosphere component manufactured from crosslinked UHMWPE and a humeral liner manufactured from CoCrMo alloy. Reference devices provide supporting safety and effectiveness evidence for mechanical and clinical performance, UHMWPE material (K112898) and UHMWPE / CoCrMo bearing surface (K100858).

Conclusion:

Based upon comparison of intended use, materials, summary of technological characteristics, non-clinical testing, and clinical testing, the SMR Reverse HP Shoulder System is substantially equivalent to the predicate device identified in this premarket notification.