



LimaCorporate S.p.A.
% Kenneth Newman
Regulatory Affairs Associate
Lima USA Inc.
2001 NE Green Oaks Blvd. Ste 100
Arlington, Texas 76006

December 21, 2023

Re: K231099

Trade/Device Name: SMR Hybrid Glenoid System

Regulation Number: 21 CFR 888.3670

Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

Regulatory Class: Class II

Product Code: MBF, KWT, KWS, PHX, PAO

Dated: October 23, 2023

Received: November 17, 2023

Dear Kenneth Newman:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph P. Russell

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Digitally signed by Joseph P.
Russell -S
Date: 2023.12.21 08:27:50 -05'00'

for: 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

K231099

Device Name

SMR Hybrid Glenoid 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	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).

☒ 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: 19-December-2023

Manufacturer:

Limacorporate S.p.A.
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33038 – Villanova di San Daniele
Udine - Italy

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Product	Product Code	Regulation and Classification Name
SMR Hybrid Glenoid System	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660
	KWT	Shoulder joint metal/polymer non-constrained cemented prosthesis per 21 CFR 888.3650
	MBF	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3670
	PAO	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660
	PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR Hybrid Glenoid System (K223876) is a modular shoulder system intended to be used in combination with previously cleared devices of the SMR Shoulder System. The system consists of a SMR Hybrid Glenoid component to be used in anatomical shoulder configuration and a reverse baseplate with screws and glenosphere that are used in reverse shoulders.

The SMR Hybrid Glenoid is a cemented glenoid component composed of a polyethylene baseplate connected to a central peg made of Trabecular Titanium. The baseplate has two peripheral pegs intended to be cemented into the native glenoid with the central peg being uncemented. The SMR Hybrid Glenoid is available in different sizes of baseplate and peg.

If a SMR Hybrid Glenoid is in place and revision to a reverse prosthesis is required, the patient can be revised by removing the anatomic polyethylene baseplate and leaving the metal peg in place. A metal SMR Hybrid Glenoid Reverse Baseplate is then connected to the central peg and a SMR Glenosphere coupled to the metal SMR Hybrid Glenoid Reverse Baseplate to articulate with a SMR Reverse Shoulder humeral liner, body and stem assembly on the humeral side. The metal SMR Hybrid Glenoid Reverse Baseplate and central porous peg assembly is intended for uncemented use with the addition of screws for fixation in reverse shoulder reconstructions.

This 510(k) is to introduce Selective Laser Melting (SLM) as a manufacturing option for central peg comprised of Trabecular Titanium. The subject device peg, made by SLM, has the same design of the predicate SMR Hybrid Glenoid System (K223876) and features the same net on the external surface.

Indications for Use:

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);
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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.

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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	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

System		Components	Material	Use	
A	R			Cem	Not Cem
	•	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.
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Predicate Devices:

No.	Company	Device name	Cleared via
1 (Primary Predicate)	LimaCorporate S.p.A	SMR Hybrid Glenoid System	K223876
2	Exactech, Inc.	Exactech® Equinox® Laser Cage Glenoid	K212356

Summary of technology comparison:

The intended use, design, and materials of the SMR Hybrid Glenoid System with SLM manufactured central TT peg is identical to the ones of the Hybrid Glenoid System (K223876).

Non-clinical testing

Performance testing of SMR Hybrid Glenoid System with SLM manufactured central TT peg was conducted according to the following test standards:

- ASTM E8: Tensile test;
- ASTM F1044: Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings;
- ASTM F1147: Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings;
- ASTM F1160: Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings;
- ASTM F1978: Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser;
- Fatigue Fretting test on Hybrid glenoid used in reverse.

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of SMR Hybrid Glenoid System with SLM manufactured central TT peg to the predicate devices.

Conclusion

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the Hybrid TT peg made from SLM manufacturing is substantially equivalent to the predicate device.