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

February 3, 2023

Re: K223876
Trade/Device Name: SMR Shoulder 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, PHX, KWS, KWT, PAO
Dated: December 22, 2022
Received: December 23, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.02.03 16:35:46 -05'00'

For Victoria Lilling, M.D.
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)*

K223876

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	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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date: January 31st, 2023

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

U.S. Contact Person:
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2001 NE Green Oaks Blvd. Ste.100
Arlington, Texas 76006, USA
www.limacorporate.com
Cell Phone: 682-597-3381

Trade name: SMR Shoulder System
Common name: Glenoid Shoulder Prosthesis

Classification Name:

Product Code	Regulation and Classification Name
MBF	§ 888.3670 - Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.
PHX	§ 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis.
KWS	§ 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis.
KWT	§ 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis.
PAO	§ 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis.

Description:

The SMR Shoulder System is a complete system intended to be used in primary or revision total shoulder joint replacement in either anatomic or reverse configurations. The SMR Shoulder System was cleared via several 510(k) submission, up to the latest approval under K220792.

The new compatibilities introduced with this 510(k) are related to the system when used in reverse shoulder configuration 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 Shoulder System in reverse configuration consists of humeral stems, reverse humeral bodies, reverse liners, glenospheres, metal back glenoid components and pegs. The metal back glenoid component, when used as part of a reverse shoulder replacement, is intended for cementless fixation with bone screws.

Glenoid components of the SMR Shoulder System are cleared for use also with the humeral components of the PRIMA Humeral System (K212800). When used in combination with the PRIMA Humeral System, the device consists of a humeral stem, tray, reverse insert, glenospheres, metal back glenoid components and pegs.
With this Traditional 510(k) submission, new compatibilities between already cleared devices of the SMR Shoulder System are introduced:

- Bone Screws dia. 5.0 mm (K210717) compatible with SMR Metal Back Glenoid (K113254) and SMR TT Baseplate (K133349);
- SMR TT Hybrid Glenoid Reverse Baseplate (K163397) compatible with SMR Glenosphere dia. 42 mm (K212800).

No changes in indications for use, materials, manufacturing processes, packaging and sterilization are introduced with this 510(k) on already cleared devices.

Intended Use:

I**ndications**
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.

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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)

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***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.**
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Predicate Devices:

The predicate device is the SMR Shoulder System cleared by LimaCorporate via K220792.

Summary of technology comparison:

The subject device has the exact same principles of operation, materials, and performance characteristics of the predicate SMR Shoulder System cleared via K220792.

The only differences between the subject and the predicate device are the addition of new compatibilities between already cleared devices:

- Bone Screws dia. 5.0 mm (K210717) compatible with SMR Metal Back Glenoid (K113254) and SMR TT Baseplate (K133349)
- SMR TT Hybrid Glenoid Reverse Baseplate (K163397) compatible with SMR Glenosphere dia. 42 mm (K212800).

The indications for use of the subject SMR Shoulder System are the same as the predicate SMR Shoulder System.

Non-clinical testing

Mechanical tests demonstrated that device performance fulfilled the intended use and that the devices is substantially equivalent to the predicate devices. Dynamic Evaluation of the Glenoid Loosening or Disassociation (ASTM F2028) was performed on worst case components.

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of the SMR Shoulder System to the predicate device.

Conclusions

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, SMR Shoulder System with new compatibilities is substantially equivalent to the predicate device identified in this premarket notification.