LimaCorporate S.p.A
% Lacey Harbour
Regulatory Manager
Lima USA Inc.
2001 NE Green
Arlington, Texas 76006

November 19, 2020

Re: K200171
Trade/Device Name: SMR TT Augmented 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, KWT, MBF
Dated: October 15, 2020
Received: October 20, 2020

Dear Lacey Harbour:

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,

For Michael Owens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200171

Device Name
SMR TT Augmented 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 Stems (Cemented, Cemented Revision)	Ti6Al4V	X	
●	●	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X
●	●	SMR Short Stems (Cementless Finned)	Ti6Al4V		X
●		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X
●	●	SMR Reverse Humeral Body	Ti6Al4V	X	X
●	●	Humeral Extension	Ti6Al4V	X	X
●		SMR Humeral Heads (Standard*, CTA)	CoCrMo	X	X
●		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X
●		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X
	●	SMR Glenospheres	CoCrMo		X
	●	SMR Connectors*	Ti6Al4V		X
	●	Reverse Liners	UHMWPE	X	X

●		SMR Cemented Glenoids	UHMWPE	X	
●		SMR 3 Pegs Cemented Glenoids	UHMWPE	X	
●	● *	SMR TT Hybrid Glenoid	UHMWPE+Ti6Al4V+Ta	X	X
	●	SMR TT Hybrid Glenoid Reverse Baseplate + Screw	Ti6Al4V		X
●	●	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*
●	●	SMR TT Baseplate	Ti6Al4V	X*	X*
	●	SMR TT Augmented 360 Baseplate	Ti6Al4V		X
●	●	SMR TT Glenoid Peg	Ti6Al4V	X	X
●		SMR Metal Back Liner	UHMWPE	X*	X*
● *	●	SMR Bone screws	Ti6Al4V		X

Material Standards

Ti6Al4V (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **UHMWPE** (ISO 5834-2 - ASTM F648) - **PoroTi Titanium Coating** (ASTM F1580) - **Ta** (ISO13782 - ASTM F560)

A= Anatomic / R=Reverse

***NOTE:**

- **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).**

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.

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510(k) Summary

Date: November 19, 2020

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

U.S. Contact Person:
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Device Trade Name	Product Code	Regulation and Classification Name
SMR TT Augmented Glenoid System	MBF	Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3670
	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
	PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Common device name: glenoid shoulder prosthesis.

Description:
The SMR TT Augmented Glenoid System is a modular shoulder system intended to be used in combination with previously cleared components of the SMR Reverse Shoulder System. The system consists of a modular glenoid component to be used in total shoulder replacement in a reverse shoulder configuration. The glenoid component consists of a metal back glenoid (named SMR TT Augmented 360 Baseplate) made of Ti6Al4V, coupled to a peg made of Trabecular Titanium; the metal back glenoid is fixed to the glenoid bone by means of bone screws made of Ti6Al4V. The glenoid component is intended for uncemented use. With this 510(k) new sizes of the SMR TT Augmented 360 Baseplate (7°X, 10°X, 15°X, 19°X, 19°) and bone screws (dia. 4,5mm and length ranging between 16 to 24 mm) are introduced.

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;
- 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 the 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 Stems (Cemented, Cemented Revision)	Ti6Al4V	X	
•	•	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X
•	•	SMR Short Stems (Cementless Finned)	Ti6Al4V		X
•		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X
•	•	SMR Reverse Humeral Body	Ti6Al4V	X	X
•	•	Humeral Extension	Ti6Al4V	X	X
•		SMR Humeral Heads (Standard*, CTA)	CoCrMo	X	X
•		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X
•		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X

System		Components	Material	Use	
A	R			Cem	Not Cem
	•	SMR Glenospheres	CoCrMo		X
	•	SMR Connectors*	Ti6Al4V		X
	•	Reverse Liners	UHMWPE	X	X
•		SMR Cemented Glenoids	UHMWPE	X	
•		SMR 3 Pegs Cemented Glenoids	UHMWPE	X	
•	• *	SMR TT Hybrid Glenoid	UHMWPE+Ti6Al4V+Ta	X	X
	•	SMR TT Hybrid Glenoid Reverse Baseplate + Screw	Ti6Al4V		X
•	•	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*
•	•	SMR TT Baseplate	Ti6Al4V	X*	X*
	•	SMR TT Augmented 360 Baseplate	Ti6Al4V		X
•	•	SMR TT Glenoid Peg	Ti6Al4V	X	X
•		SMR Metal Back Liner	UHMWPE	X*	X*
• *	•	SMR Bone screws	Ti6Al4V		X
Material Standards					
Ti6Al4V (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **UHMWPE** (ISO 5834-2 - ASTM F648) - **PoroTi Titanium Coating** (ASTM F1580) - **Ta** (ISO13782 - ASTM F560)					

A= Anatomic / R=Reverse

***NOTE:**

- **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).**

Predicate Devices:

- SMR TT Augmented Glenoid System (Limacorporate, K191746) – Primary Predicate
- SMR Short Finned Stem (Limacorporate, K191963)
- Aequalis PerFORM and PerFORM+ Reversed Glenoids (Tornier Inc., K161742)
- Comprehensive Augmented Glenoid (Biomet Manufacturing Corp, K172502)

Summary of technology comparison:

The SMR TT Augmented Glenoid System has the same intended use and the same fundamental scientific technology as the predicate devices.

The SMR TT Augmented Glenoid System has the same indications for use, design, principle of operation and materials of the devices of the Limacorporate devices approved in K191746 and K191963. Additionally, indications for use and principle of operation of the SMR TT Augmented Glenoid System are similar to those of the predicate devices Aequalis PerFORM and PerFORM+ Reversed Glenoids and Comprehensive Augmented Glenoid. When compared to the range approved in K191746, the SMR TT Augmented Glenoid System, subject of this premarket notification, is provided in a wider range of sizes, like the predicate device Aequalis PerFORM and PerFORM+ Reversed Glenoids.

The design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness. Design Control Activities have been completed and the results indicated that the subject device is safe and effective.

Non-clinical testing:

Mechanical testing had demonstrated the device's ability to perform substantially equivalent to the predicate devices in:

- Pull-out test for bone screws (ASTM F543);
- Dynamic Evaluation of the Glenoid Loosening or Disassociation (ASTM F2028);
- Fatigue Fretting test on Glenoid Baseplate in reverse shoulder configuration.

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of the SMR TT Augmented Glenoid System to the predicate devices.

Conclusion

The SMR TT Augmented Glenoid System (Subject Device System) described in this section has an equivalent intended use and same functional technology as previously cleared component of the SMR Reverse Shoulder System, primarily the SMR TT Augmented Glenoid System (K191746). Based on the testing data provided and description of the differences between the subject and predicated devices, LimaCorporate concludes that the subject device is substantially equivalent to the predicate device.