DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Limacorporate S.p.A.
% Stephen Peoples
President
Peoples & Associates Consulting LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

June 29, 2017

Re: k163397
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, PHX, KWS, KWT
Dated: May 29, 2017
Received: June 02, 2017

Dear Mr. Peoples:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163397

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 replace¬ment 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 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 neces¬sary to use the device.
The 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 hu¬meral 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 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 Hybrid Glenoid	UHMWPE+Ti6Al4V +Ta	X	X
	•	SMR Hybrid Glenoid Reverse Baseplate + Screw	Ti6Al4V		X
•	•	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*
•	•	SMR TT Metal Back Baseplate	Ti6Al4V	X*	X*
•	•	SMR TT Metal Back 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.

• 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 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 Hybrid Glenoid Reverse Baseplate. The SMR Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.

• The Dia. 50, 52 and 54 mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).

The Dia. 52 and 54 mm 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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Summary of Safety and Effectiveness

Date: June 29, 2017

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

U.S. Contact Person:
Dr. Stephen J. Peoples
Principal Consultant
Phone: 260-645-0327
FAX: +39 0432945512

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
	PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR Hybrid Glenoid System 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 glenoid component (SMR Hybrid Glenoid) 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.

Intended 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 arthroplasty (CTA Heads only);
- Glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR 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 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 Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X

System		Components	Material	Use	
A	R			Cem	Not Cem
●	●	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 Hybrid Glenoid	UHMWPE+Ti6Al4V+Ta	X	X
	●	SMR Hybrid Glenoid Baseplate + Screw	Ti6Al4V		X
●	●	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*
●	●	SMR TT Metal Back Baseplate	Ti6Al4V	X*	X*
●	●	SMR TT Metal Back 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) - **Tantalum** (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.**
- **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 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 Hybrid Glenoid Reverse Baseplate. The SMR Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.**
- **The Dia. 50, 52 and 54 mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric). The Dia. 52 and 54 mm Humeral Heads with + 2mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).**

Predicate Devices:

- SMR 3-Pegs Glenoid, Limacorporate (K130642, K153722)
- Comprehensive Modular Hybrid Glenoid, Biomet Orthopedics, Inc. (K060694)
- Trabecular Metal Glenoid, Zimmer (K071090)
- SMR TT Metal Back, Limacorporate (K133349)
- SMR Glenospheres with connector and Screw, Limacorporate (K110598, K142139)
- Bio-Modular Shoulder System, Biomet Orthopedics, Inc. (K030710)

Summary of technology comparison:

The intended use, design, and materials of the SMR Hybrid Glenoid System are substantially equivalent to the ones of the predicate devices. 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:

- Static Evaluation of the Glenoid Locking Mechanism in Shear (ASTM F1829);
- Dynamic Evaluation of the Glenoid Loosening or Disassociation (ASTM F2028);
- Fatigue Fretting test on Glenoid Baseplate in reverse shoulder configuration;
- Range of motion (ASTM F1378).

LAL testing was performed to establish that the subject device meets pyrogen limit specification of 20EU/device.

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of the new sizes of SMR Hybrid Glenoid System to the predicate devices.