



Food and Drug Administration
10903 New Hampshire Avenue
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Limacorporate S.p.A.
% Dr. Stephen Peoples
President
Peoples & Associates Consulting, LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

April 6, 2016

Re: K153722

Trade/Device Name: SMR 3-Pegs Glenoids
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: March 3, 2016
Received: March 9, 2016

Dear Dr. 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 Parts 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" (21CFR 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 yours,

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

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K153722

Device Name

SMR 3-Pegs Glenoids

Indications for Use (Describe)

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).

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 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 or a metal back assembled with a liner while the Reverse glenoid construct consists of the metal back, the connector and the glenosphere. On the glenoid side, the fixation of the all polyethylene glenoid 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 Glenspheres	CoCrMo		X
	•	SMR Connectors	Ti6Al4V		X
	•	Reverse Liners	UHMWPE	X	X
•		SMR Cemented Glenoids	UHMWPE	X	
•		SMR 3 Pegs Cemented Glenoids	UHMWPE	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)					

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 Glenoid 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.

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: April 5th, 2016

Manufacturer:
Limacorporate S.p.A.
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Udine - Italy

U.S. Contact Person:
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Product	Product Code	Regulation and Classification Name
SMR 3-Pegs Glenoids	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description

The SMR 3-Pegs Glenoids are made from conventional UHMWPE. They are intended for cemented fixation only.

The SMR 3-Pegs Glenoids are available in four sizes; size Small and Standard have been previously cleared for market via premarket notification K130642. The only difference between the subject SMR 3-Pegs Glenoids and those cleared via K130642 is the size offering: the subject device is offered in size Extra-Small and Large.

The SMR 3-Pegs Glenoids are characterized by an articulating surface with a radius of curvature greater than the corresponding humeral head. This mismatch allows for translation of the head in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has three pegs for fixation in the glenoid.

The SMR 3-Pegs Glenoids are designed to articulate with the Limacorporate SMR humeral heads indicated for use in total shoulder replacement.

Intended Use

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).

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 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 or a metal back assembled with a liner while the Reverse glenoid construct consists of the metal back, the connector and the glenosphere. On the glenoid side, the fixation of the all polyethylene glenoid 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 Glenspheres	CoCrMo		X
	•	SMR Connectors	Ti6Al4V		X
	•	Reverse Liners	UHMWPE	X	X
•		SMR Cemented Glenoids	UHMWPE	X	
•		SMR 3 Pegs Cemented Glenoids	UHMWPE	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)					

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.**

Traditional 510(k) – SMR 3-Pegs Glenoids
April 5th, 2016

- **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 Glenoid 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.**

Predicate Devices

- SMR 3-Pegs Glenoids (Limacorporate, K130642);
- SMR Cemented Glenoids (Limacorporate, K100858 / K101263 / K110847 / K111212);
- SMR Liners L1 for Metal Back Glenoids (Limacorporate, K113254).

Comparable Features to Predicate Device(s):

The intended use, design, and materials of the SMR 3-Pegs Glenoids 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);
- Range of motion (ASTM F1378).

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of the new sizes of SMR 3-Pegs Glenoids to the predicate devices.