LimaCorporate S.p.A.
Stephen J. Peoples
Principal Consultant
Via Nazionale, 52
33038 Villanova di San Daniele del Friuli
Udine, Italy

January 4, 2018

Re: K172456
Trade/Device Name: Bone Screws 6.5mm
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, MBL, PHX, LZO, MBF
Dated: December 1, 2017
Received: December 5, 2017

Dear Stephen 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K172456

SMR Shoulder System
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 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 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
•	•	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 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 Reverse Baseplate. The SMR Hybrid 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).

Delta TT Acetabular System

Indications for Use

The Delta TT Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- Rheumatoid arthritis;
- Post-traumatic arthritis,
- Correction of functional deformity;
- Fractures, dislocation of the hip and unsuccessful cup arthroplasty.

Revisions in cases of good remaining bone stock.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Date: September 06, 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
Bone Screws 6.5mm	LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358. Device Class: II
	MBL	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358. Device Class: II
	LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353. Device Class: II
	PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660. Device Class: II
	MBF	Shoulder joint metal/polymer/metal non constrained or semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3670. Device Class: II

Description

Bone screws are used to provide further stability to the Delta TT acetabular cups and to the metal back glenoid of the SMR Shoulder System in reverse shoulder configuration.

The Delta TT acetabular cups (K112898, K141395) are acetabular components intended for uncemented fixation; screw holes present in the Delta TT cups allow optional additional fixation of the cup to the bone using 6.5mm diameter bone screws.

The SMR Shoulder System metal back glenoids (K110598, K113254, K133349, K161120, K163397) are components intended to be implanted into a hole drilled in the glenoid cavity. The metal back glenoid can be used in both anatomic and reverse shoulder configuration; when used in reverse shoulder configuration, the metal back glenoid are intended for uncemented use and are fixed to the glenoid bone through the use of 6.5mm bone screws.

The current submission is for additional lengths of 6.5mm diameter bone screws:

- the proposed range of bone screws used in combination with the SMR Shoulder System is 20mm to 55mm in length;
- the proposed range of bone screws used in combination with the Delta TT Acetabular System is 15mm to 90mm in length.

Design, material, manufacturing process and intended use of the new 6.5mm diameter bone screws are the same as those for the 6.5mm bone screws cleared in the previous 510(k)s.

Intended Use/Indications: the additional lengths of 6.5mm bone screws have the same indication for use as the joint replacement system with which they are used. Indications for use of the Delta TT Acetabular System (K112898, K141395) and the indications for use of the SMR Shoulder System (K110598, K113254, K133349, K161120, K163397) are provided below.

Indications for use Delta Acetabular System (K112898, K141395)
The Delta TT Acetabular System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: x Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia; x Rheumatoid arthritis; x Post-traumatic arthritis, x Correction of functional deformity; x Fractures, dislocation of the hip and unsuccessful cup arthroplasty. x Revisions in cases of good remaining bone stock.

Indications for use SMR Shoulder System (K110598, K113254, K133349, K161120, K163397)
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: x non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; x inflammatory degenerative joint disease such as rheumatoid arthritis; x treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods; x revision of a failed primary implant; x cuff tear arthropathy (CTA Heads only); x 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 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.
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System		Components	Material	Use	
A	R			Cem	Not Cem
x	x	SMR Stems (Cemented, Cemented Revision)	Ti6Al4V	X	
x	x	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X
x		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X
x	x	SMR Reverse Humeral Body	Ti6Al4V	X	X
x	x	Humeral Extension	Ti6Al4V	X	X
x		SMR Humeral Heads (Standard, CTA)	CoCrMo	X	X
x		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X
x		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X
	x	SMR Glenospheres	CoCrMo		X
	x	SMR Connectors	Ti6Al4V		X
	x	Reverse Liners	UHMWPE	X	X
x		SMR Cemented Glenoids	UHMWPE	X	
x		SMR 3 Pegs Cemented Glenoids	UHMWPE	X	
x	x *	SMR Hybrid Glenoid	UHMWPE+Ti6Al4V+Ta	X	X
	x	SMR Hybrid Reverse Baseplate + Screw	Ti6Al4V		X
x	x	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*
x	x	SMR TT Metal Back Baseplate	Ti6Al4V	X*	X*
x	x	SMR TT Metal Back Peg	Ti6Al4V	X	X
x		SMR Metal Back Liner	UHMWPE	X*	X*
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 :**

- x **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.**
- x **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.**
- x **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.**
- x **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 Reverse Baseplate. The SMR Hybrid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.

x **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

Delta TT Acetabular System (Limacorporate, K112898, K141395)

SMR Shoulder System (Limacorporate, K110598, K113254, K133349, K161120, K163397)

Continuum Acetabular System (Zimmer, K091508)

Comprehensive Reverse Shoulder System (Biomet, K080642, K113121)

Aequalis PerFORM Reversed (Tornier, K161742)

ReUnion RSA Shoulder System (Stryker, K161863)

Comparable Features to Predicate Device(s)

The new lengths of 6.5mm bone screws are identical in design, diameter, material, manufacturing process, packaging, sterilization, intended use, and indications for use to the 6.5mm bone screws cleared in K112898, K141395, K110598, K113254, K133349, K161120 and K163397; the only difference is that the new bone screws provide shorter and longer lengths.

The indications for use for the additional lengths of 6.5mm bone screws are the same as the indications for use the previously cleared 6.5mm bone screws and the same as those of the systems with which they are used, either the Delta TT Acetabular System or SMR Shoulder System.

Non-Clinical Testing:

The additional lengths of 6.5mm bone screws use the same fundamental scientific technology and device design concepts, are made from the same materials utilizing the same manufacturing processes, utilize the same packaging and sterilization processes, and have the same indications for use as the predicate devices; the new lengths of 6.5mm diameter bone screws therefore do not require any testing to determine substantial equivalency.
LAL testing is performed, according to Limacorporate sampling and testing program, to establish that the subject device meets the pyrogen limit specification of 20EU/device.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the new sizes of bone screws to the predicate devices.