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

June 24, 2016

Limacorporate S.p.A.
% Dr. Stephen J. Peoples
President
Peoples & Associates
411 Auditorium Blvd.
Winona Lake, Indiana 46590

Re: K161476
Trade/Device Name: SMR Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, HSD
Dated: May 20, 2016
Received: May 27, 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,

Lori A. Wiggins -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): __K161476___

# 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).

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 |

| System | | Components | Material | Use | |
|---|---|---|---|---|---|
| A | R | | | Cem | Not Cem |
| • | | 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 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) | | | | | |

***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.**
- **The SMR TT Metal Back is indicated for primary implant in anatomic or reverse total shoulder arthroplasty with poor glenoid bone quality or in revision case with consistent bone loss on the glenoid side. The implant is suitable for implantation with or without bone graft. These indications are not yet approved in the US.**
- **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.**
- **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)**

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

CONTINUE ON ANOTHER PAGE IF NEEDED

# 510(k) Summary

Date: May 20, 2016

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 Shoulder System<br><br>-Variable Height Humeral Heads<br><br>-6mm eccentricity adaptor tapers | HSD | Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per 21 CFR 888.3690 |
| | KWT | Shoulder joint metal/polymer non-constrained cemented prosthesis per 21 CFR 888.3650 |

## Description

The SMR Shoulder System in Anatomic configuration usually consists of a humeral stem, a humeral body, an adaptor taper, a humeral head and a glenoid component. Components are offered for hemi or total shoulder joint arthroplasty, in primary trauma surgery. SMR Shoulder System components are provided in different designs and are intended for cemented or cementless use.

Humeral stems are connected with humeral bodies trough taper coupling. The humeral body is then coupled with the humeral heads, directly (only for some sizes of the heads) or through adaptor tapers. Adaptor tapers are made of Ti6Al4V. They are neutral or with eccentricities and in different offsets to allow the adjustment of the centre of rotation of the joint, to provide the required offset to the humeral head and to achieve the correct balancing to the soft tissues, optimizing joint stability. The humeral heads are made of CoCrMo. They are intended to articulate with the glenoid bone in hemi-arthroplasty or with the glenoid component in total shoulder arthroplasty.

The current submission is for the extension of the available heights for each diameter of the humeral heads and for the introduction of a new eccentricity (+6 mm) for the adaptor tapers.

## Intended Use/Indications

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).

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 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 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* |

| System | | Components | Material | Use | |
|---|---|---|---|---|---|
| A | R | | | Cem | Not Cem |
| • * | • | 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) | | | | | |

***NOTE :**

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- **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.**
- **The SMR TT Metal Back is indicated for primary implant in anatomic or reverse total shoulder arthroplasty with poor glenoid bone quality or in revision case with consistent bone loss on the glenoid side. The implant is suitable for implantation with or without bone graft. These indications are not yet approved in the US.**
- **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.**
- **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 Shoulder System (Limacorporate, K100858).

## Comparable Features to Predicate Device(s)

The new heights of the Humeral Heads and the new Adaptor Taper of the SMR Shoulder System are identical to the Humeral Heads and Adaptor Tapers cleared via K100858 for design diameters, material, intended use, indications for use.

The indications for use for the devices submitted are the same of the heads and adaptor tapers of the SMR Shoulder System used in anatomic configuration cleared via previous 510(k)s. The combinations allowed for the new heights of the Humeral Heads and the new Adaptor Tapers of the SMR Shoulder System are identical to those allowed with Humeral Heads and Adaptor Tapers already cleared via K100858.

## Non-Clinical Testing:

The Variable-Height Humeral Heads and 6mm Eccentricity Adaptor Tapers do not represent worst cases for mechanical testing. Therefore, the results of the tests performed on the SMR Shoulder System in K100858 are applicable to the Variable-Height Humeral Heads and the 6mm Eccentricity Adaptor Tapers and no additional testing was required to demonstrate substantial equivalency of the Variable-Height Humeral Heads and additional adaptor tapers.

**Clinical Testing:**
Clinical testing was not necessary to demonstrate substantial equivalence of the Variable-Height Humeral Heads and the 6 mm Eccnetricity Adaptor Tapers to the humeral heads and adaptor tapers cleared for the SMR Shoulder System in K100858.