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

February 21, 2017

Re: K161120
Trade/Device Name: SMR TT Metal Back Glenoid, Bone Graft Instruments
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
Dated: January 12, 2017
Received: January 17, 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.

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 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161120

Device Name
SMR TT Metal Back Glenoid, Bone Graft Instruments

Indications for Use *(Describe)*
The SMR TT Metal Back Glenoid is intended for use in total primary or revision shoulder joint replacement with either the SMR Anatomic Shoulder System or the SMR Reverse Shoulder system.
The SMR Anatomic Shoulder System is indicated for 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);
When used as part of the SMR Anatomic Shoulder System, the SMR TT Metal Back Glenoid is intended for use with bone cement and should be used without bone screws.
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 (disabling 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.
When used as part of the SMR Reverse Shoulder System, the SMR TT Metal Back Glenoid 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.

Summary of Safety and Effectiveness

Date: January 25, 2017

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

U.S. Contact Person:
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Principal Consultant
Phone: 260-645-0327
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Product	Common Name	Product Code	Regulation and Classification Name
SMR TT Metal Back Glenoid, Bone Graft Instruments	Total or Hemi Shoulder Prosthesis	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per CFR 888.3660
		KWT	Shoulder joint metal/polymer non-constrained cemented prosthesis per CFR 888.3650
		PHX	Shoulder joint metal/polymer semi-constrained cemented prosthesis per CFR 888.3660

Description

SMR TT Metal Back device described in this submission is identical to the device described in K133349. This submission includes an alternative surgical technique and surgical instruments to be used in combination with SMR TT Metal Back device, instruments and surgical technique described in K133349 in Reverse SMR Shoulder System configuration.

Intended Use

The SMR TT Metal Back Glenoid is intended for use in total primary or revision shoulder joint replacement with either the SMR Anatomic Shoulder System or the SMR Reverse Shoulder system.

The SMR Anatomic Shoulder System is indicated for 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;

Traditional 510(k) – SMR TT Metal Back Glenoid

- Revision of a failed primary implant;
- Cuff tear arthropathy (CTA Heads);

When used as part of the SMR Anatomic Shoulder System, the SMR TT Metal Back Glenoid is intended for use with bone cement and should be used without bone screw.

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 (disabling 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.
When used as part of the SMR Reverse Shoulder System, the SMR TT Metal Back Glenoid is intended for uncemented use with the addition of screws for fixation.

Predicate Device

SMR TT Metal Back Glenoid (K133349).

Comparable Features to Predicate Device(s)

SMR TT Metal Back device described in this submission is identical to the device described in K133349. This submission includes an alternative surgical technique and surgical instruments to be used in combination with SMR TT Metal Back device in SMR Reverse configuration, instruments and surgical technique described in K133349.

Non-Clinical Testing

Non-clinical testing was not necessary to support the equivalence of the subject SMR TT Metal Back Glenoid to the device cleared in K133349.
LAL testing has been performed to establish the non-pyrogenicity of Limacorporate products.

Clinical Testing

Clinical testing was not necessary to support the equivalence of the SMR TT Metal Back Glenoid to the device cleared in K133349.