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

November 2, 2016

Limacorporate S.p.A.
% Ms. Cheryl Hastings
Hastings regulatory LLC
P.O. Box 696
Winona Lake, Indiana 46590-696

Re: K113523
Trade/Device Name: SMR Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: November 22, 2011
Received: November 29, 2011

Dear Ms. Hastings:

This letter corrects our substantially equivalent letter of December 20, 2011.

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" (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): K113523

SMR Reverse Shoulder System
Indications for Use

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.

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 SMR Reverse Shoulder System humeral bodies, cemented non-finned humeral stems and cemented revision stems are intended for cemented use. The SMR Reverse Shoulder System humeral bodies, finned humeral stems and uncemented revision stems are intended for cementless use. The SMR Reverse Shoulder System metal-backed glenoids and glenospheres are intended for uncemented press-fit use only with the addition of screws for fixation.

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)

for Mark Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113523

K113523

DEC 2 0 2011

510(k) Summary

Date: November 21, 2011

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

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Product	Product Code	Regulation and Classification Name
SMR Reverse Shoulder System	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR Reverse Shoulder System (cleared via 510(k): K110598) consists of a humeral stem, a reverse humeral body, a reverse liner, a metal-back glenoid, a glenosphere and a connector with screw. Bone screws are used for the fixation of the metal-back glenoid to the scapula. Humeral stems and reverse humeral bodies are provided for both cemented and cementless fixation. The SMR Reverse Shoulder System metal back glenoids and glenospheres are intended for uncemented press-fit use only with the addition of screws for fixation.

This submission is to add the SMR Revision Stems, cleared in K111212, as compatible humeral stem components of the SMR Reverse Shoulder System.

Intended Use / Indications:

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.

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 SMR Reverse Shoulder System humeral bodies, cemented non-finned humeral stems and cemented revision stems are intended for cemented use. The SMR Reverse Shoulder System humeral bodies, finned humeral stems and uncemented revision stems are intended for cementless use. The SMR Reverse Shoulder System metal-backed glenoids and glenospheres are intended for uncemented press-fit use only with the addition of screws for fixation.

K113523

Predicate Device:

Limacorporate SMR Reverse Shoulder System (K110598)

Summary of Technologies/Substantial Equivalence:

Based on similarities in indications, intended use, design, materials, method of manufacture and a print review to compare taper dimensions and tolerances, Limacorporate believes that the SMR Reverse Shoulder with modified labeling to include the SMR Revision Stems as compatible components is substantially equivalent to the SMR Reverse Shoulder System cleared in K110598.

Non-Clinical Testing:

A print review was conducted to compare the taper dimensions and tolerances of the SMR Revision Stems to the taper dimensions and tolerances of the SMR humeral stems cleared for use with the SMR Reverse Shoulder System in K110598. This comparison indicated that the SMR Revision Stem tapers were substantially equivalent to the SMR Humeral Stem tapers.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the SMR Reverse Shoulder System with modified labeling to the predicate device.