DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2017

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

Re: K161226
Trade/Device Name: Revision Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, KWY
Dated: January 16, 2017
Received: January 18, 2017

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,

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)*

K161226

Device Name

Revision Femoral Stem

Indications for Use *(Describe)*

Revision Femoral Stem is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. It is intended for cementless revision hip arthroplasty on both uncemented and cemented femoral implants.

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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510 (k) Summary of Safety and Effectiveness

Date: February 06, 2017

Manufacturer:
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Product	Common name	Product Code	Regulation and Classification Name
Revision Femoral Stem	Femoral Hip Prosthesis	LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
		LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358
		KWY	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis per 21 CFR 888.3390

Description:

The Revision Femoral Stem consists of a femoral stem and a modular neck, assembled together through a taper coupling stabilized by means of a safety screw. When used in total hip arthroplasty, the Revision Femoral Stem prosthesis is intended for use with modular femoral heads and compatible acetabular cups. When used in partial hip arthroplasty, the Revision Femoral Stem prosthesis is intended for use with a Lock Bipolar Head.

The **stem** is made of Ti6Al4V (ASTM F1472 – ISO 5832-3). The stem is straight, with a tapered profile, round finned section and a rounded tip to facilitate insertion. The external surface of the stem features a macro-roughened finishing obtained by sandblasting. Diameters ranging from 14 to 26 mm, with increases of 1 mm, for a total of 13 diameters are available. Two lengths (140 or 200 mm) for each diameter of the stem are available.

The **neck** is made of Ti6Al4V (ASTM F1472 – ISO 5832-3). The same material is also used for the safety screw, which also has a small pin made of UHMWPE (ISO 5834-2,

ASTM F648) to help prevent loosening of the safety screw. Two (2) versions of the neck are available , one with a CCD angle of 131° and another with a CCD angle of 135°. Both the neck versions are available in 7 different heights. Distally, the external surface of the neck component features a macro-roughened finishing obtained by sandblasting; proximally, the surface of the neck component is polished to reduce the chance of polyethylene wear particles if the neck accidentally rubs against the polyethylene of the acetabular component.

Indication For Use:
Revision Femoral Stem is indicated for patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck or portions of the proximal femur. It is intended for cementless revision hip arthroplasty on both uncemented and cemented femoral implants.

Predicate Devices:

Revision Femoral Stem cleared via K151739-Limacorporate S.p.A.

Comparable Features to Predicate Device(s):

The Revision Femoral Stem components share the same materials, intended use and design features as those of the predicate devices. Non-clinical testing demonstrates that the subject components perform at least as well as the cited predicate.

Non-Clinical Testing:

Mechanical testing had demonstrated the device's ability to perform substantially equivalent to the predicate devices in:

- Fatigue testing (ISO 7206-4);
- Fatigue testing (ISO 7206-6);
- Fretting evaluation;
- Analysis of disassembly torque of safety screw;
- Range of motion (ISO 21535).

LAL testing has been performed to establish that the subject device meet the specified 20EU/device limit.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of Revision Femoral Stem to the predicate device.