DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 27, 2015

Limacorporate S.p.A
% Dr. Stephen J. Peoples, VMD, MS
Principal Consultant
Peoples & Associates Consulting, LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K143509
Trade/Device Name: Master^{SL} 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, JDI, KWY, KWZ, LPH
Dated: January 12, 2015
Received: January 13, 2015

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 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

Indications for Use Statement

510(k) Number (if known): K143509

Master^{SL} Femoral Stem
Indications for Use

The Master^{SL} stems are indicated for use in partial or total hip arthroplasty and are intended for press-fit (uncemented) use. When used in total hip arthroplasty, the Master^{SL} Stems are intended for use with Co-Cr-Mo or ceramic femoral heads and cemented cups, or with Co-Cr-Mo or ceramic femoral heads and Delta TT Acetabular System. When used in partial hip arthroplasty, the Master^{SL} stems are intended for use with Lock Bipolar Heads.

Hip arthroplasty is intended 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;
- treatment of femoral head and neck fractures;
- revisions in cases of good remaining femoral 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: November 20, 2014

Manufacturer:
Limacorporate S.p.A.
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33038 – Villanova di San Daniele
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Product	Common Name	Product Code	Regulation and Classification Name
MasterSL femoral stem	Total or Hemi Hip Prosthesis	LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
		JDI	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350
		KWY	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis per 21 CFR 888.3390
		KWZ	Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer per 21 CFR 888.3310
		LPH	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemente per 21 CFR 888.3358

Description:

The Master^{SL} femoral stem is a monolithic, collarless, tapered wedge shaped stem intended for press-fit uncemented partial or total hip arthroplasty. When used in total hip arthroplasty the stem is coupled to a Limacorporate CoCrMo alloy femoral heads (K112158) or Biolox Delta ceramic femoral heads and with either a Limacorporate Cemented Cups or Limacorporate Delta TT Acetabular System cup. When used in partial hip arthroplasty the Master^{SL} femoral stem is used with a Limacorporate CoCrMo alloy femoral heads coupled with a Lock Bipolar Head (Limacorporate K112158).

The Master^{SL} femoral stem is made of Ti6Al4V conforming to ASTM F1472 – ISO 5832-3. The proximal 1/2 of the stem has a plasma sprayed coating of titanium alloy (ASTM F1472 – ISO 5832-3). The stem has a tapered rectangular section and the distal anterior and posterior surfaces

have a vertical groove for rotational stability. The stem provides a neck with a 12/14 conical taper to couple to Limacorporate CoCrMo alloy or Biolox Delta ceramic femoral heads and the necks are mirror-polished and lowered to reduce accidental abrasion and contact between the stem neck and the acetabular cup. The Master^{SL} stem is available 13 sizes in both standard and lateralized versions with different CCD angles.

The Biolox Delta ceramic head is a femoral ceramic head with a female 12/14 taper for coupling to the male 12/14 taper of the femoral stem. The Biolox Delta ceramic heads are available in diameters of 28, 32, and 36 mm in three (3) neck lengths (S, M, L); the 36 mm diameter head is also available with a XL neck length.

Intended Use/Indications:

The Master^{SL} stems are indicated for use in partial or total hip arthroplasty and are intended for press-fit (uncemented) use. When used in total hip arthroplasty, the Master^{SL} Stems are intended for use with Co-Cr-Mo or ceramic femoral heads and cemented cups, or with Co-Cr-Mo or ceramic femoral heads and Delta TT Acetabular System. When used in partial hip arthroplasty, the Master^{SL} stems are intended for use with Lock Bipolar Heads.

Hip arthroplasty is intended 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;
- treatment of femoral head and neck fractures;
- revisions in cases of good remaining femoral bone stock.

Predicate Devices:

- Master^{SL} Femoral Stems (Limacorporate, K140975);
- Minima S Hip Stem (Limacorporate, K141327)

Comparable Features to Predicate Device(s):

The Master^{SL} Femoral Stems and the Biolox Delta Heads are identical to the Master^{SL} Femoral Stems cleared in K140975 and the Biolox Delta Heads cleared in K141327.

Non-Clinical Testing:

The design, material, and sizes of the Biolox Delta Femoral Heads for use with the Master^{SL} Femoral Stem are identical to the design, material, and sizes of the Biolox Delta Femoral Heads cleared for use with the Minima S Hip (K141327). The conical taper used to couple to the Biolox Delta Head to the Master^{SL} Femoral Stem is achieved through the same conical taper used to

couple the Bilox Delta ceramic head to the Minima Hip Stem (K141327) and the Master^{SL} Femoral Stem (K140975) is manufactured from the same material (Ti6Al4V alloy) as the Minima S Hip cleared for use with Biolox Delta ceramic heads (K141327). The Master^{SL} Femoral Stem with Biolox Delta ceramic heads is intended to be used with the same acetabular cups as cleared for the Minima S Hip and Biolox Delta ceramic heads (K141327). Since the materials, design, femoral head sizes and acetabular components remain the same as described in K140975 and K141327, no new issues of safety and effectiveness are introduced by adding the Biolox Delta ceramic head for use with the Master^{SL} Femoral Stem and the tests provided in K140975 and K141327 are therefore applicable to use of the Biolox Delta ceramic head with the Master^{SL} Femoral Stem.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence.