



Food and Drug Administration  
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August 22, 2016

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

Re: K160011

Trade/Device Name: H-MAX S 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: MEH, JDI, KWY  
Dated: July 18, 2016  
Received: July 21, 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 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,

Vincent J. Devlin -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)

K160011

Device Name

H-MAX S stem

Indications for Use (Describe)

The H-Max S stems are indicated for use in total and partial hip arthroplasty and are intended for press-fit (uncemented) use. The H-Max S Stem are intended for use with CoCrMo femoral heads or BioloX Delta femoral heads and Limacorporate cemented acetabular cups or cementless Delta TT acetabular cups. In partial Hip arthroplasty H-Max S stem is intended for use with Limacorporate 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.

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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## Summary of Safety and Effectiveness

Date: December 14, 2015

Manufacturer:

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

US Contact Person:

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Product	Product Code	Regulation and Classification Name
<b>H-MAX S Stems</b>  Class II medical devices	MEH	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

**Description:**

The H-MAX S femoral system consists of the H-MAX S femoral stem, a femoral head and an acetabular cup. In total hip arthroplasty, the H-MAX S stems are intended for use with modular CoCrMo femoral heads or Bioloz Delta ceramic femoral heads and a compatible Limacorporate Cemented Cup or uncemented Delta TT acetabular cup. When used in partial hip arthroplasty, H-MAX S stems are intended for use with Limacorporate Lock Bipolar Heads.

The H-MAX S femoral stem is a monolithic cementless stem made from Ti6Al4V (ISO 5832-3, ASTM F1472). The external surface has a macro-roughened surface. A layer of hydroxyapatite is applied along the length of the stem. The H-MAX S stem is manufactured in 11 sizes for each of two configurations (conventional and lateralizing) that vary in the CCD angle.

**Intended Use:**

The H-MAX S stems are indicated for use in total and partial hip arthroplasty and are intended for pres-fit (uncemented) use. The H-MAS S stems are intended for use with CoCrMo femoral heads or BioloX Delta femoral heads and Limacorporate cemented acetabular cups or cementless Delta TT acetabular cups. In partial hip arthroplasty, H-MAX S stems are intended for use with Limacorporate 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:**

- H-MAX S Femoral Hip System – H-MAX S stem (Limacorporate, K112091 and K150855)
- POLARSTEM Standard and Lateral Femoral Stems with Ti/HA (Smith and Nephew, Inc. K130728)

**Comparable Features to Predicate Device(s):**

H-MAX S Stems are exactly the same devices already cleared via K112091 and K150855. The only changes involve:

- Introduction of a new supplier for the HA coating (the subject device is substantially equivalent to the H-MAX S Stems already cleared);
- Introduction of the indication for partial hip arthroplasty (the subject device is substantially equivalent to the POLARSTEM).

**Non-Clinical Testing:**

The materials, design, femoral head sizes and acetabular components remain the same as described in previously cleared submissions. All non-clinical testing performed for the previous submissions of H-MAX S Stems remain applicable. The changes of this submission were evaluated through:

- Validation of the HA coating in accordance with FDA Guidance “510(k) Information needed for hydroxyapatite coated orthopedic implants”;
- Analysis of the Range of Motion for the H-MAX S Stem coupled with Lock Bipolar Heads for the indication of partial hip arthroplasty.

The testing results demonstrated the system’s ability to perform substantially equivalent to the predicate devices considered.

**Clinical Testing:**

Clinical testing was not necessary to demonstrate substantial equivalence of the H-MAX S Stems to the predicate devices.