DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 21, 2015

Limacorporate S.P.A.
Stephen Peoples
Principal Consultant
Via Nazionale 52
33038 Villanova Di San Daniele
Udine-Italy

Re: K150855
Trade/Device Name: H-MAX S Femoral Hip System
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, LPH
Dated: September 15, 2015
Received: September 22, 2015

Dear Mr. 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" (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,

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 K150855

H-MAX S Femoral Hip System
Indications for Use

The H-MAX S Femoral Hip System consists of the H-MAX S femoral stem, a modular 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 Biolox Delta ceramic femoral heads and a compatible Limacorporate Cemented Cup or uncemented Delta TT acetabular cup.

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;
- osteoarthritis after femoral heads fractures;
- revisions in cases of good remaining femoral bone stock.

The Limacorporate Cemented Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs reconstruction. The Limacorporate Delta TT Cup is intended for uncemented use.

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: October 19, 2015

Manufacturer:
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Product	Product Code	Regulation and Classification Name
H-Max S femoral hip system	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
	LPH	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented per 21 CFR 888.3358

Description

The H-MAX S Femoral Hip System consists of the H-MAX S femoral stem, a modular 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 Biolox Delta ceramic femoral heads and a compatible Limacorporate Cemented Cup or uncemented Delta TT acetabular cup.

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 and 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, standard and lateralizing, that vary in the CCD angle.

The **Biolox Delta ceramic head** is a modular femoral ceramic head with a female 12/14 taper for coupling to the male 12/14 taper of the H-Max S 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.

The **Delta TT Cup** is a hemi-spherical, 2-piece modular acetabular cup consisting of a metal shell and a polyethylene liner. The metal shell is manufactured using an EBM (Electron Beam Melting) process with titanium alloy powder (Ti6Al4V, ASTM F1472 – ISO 5832-3) producing a non-porous bulk interior surface with a Trabecular Titanium porous structure on the external surface. A polar threaded hole is used for attachment of an introducer instrument; the hole mates with the polar peg of the polyethylene liner when the liner is inserted into the cup. Three threaded holes in lateral positions allow additional fixation of the cup using bone screws; polyethylene plugs are used to fill the holes when bone screws are not required. The Delta TT Cup metal shell is coupled with a liner made of either conventional or cross-linked ultra high molecular weight polyethylene (UHMWPE) by means of a taper coupling. The Delta TT Cup metal shell is available in external diameters of 44, 46 and 48 mm, for use with Small liners; 50 and 52 mm, for use with Medium liners; and 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74 and 76mm mm for use with Large liners. The polyethylene liners are available in three (3) sizes, Small, Medium and Large, with inner diameters of 28, 32, and 36mm.

CoCrMo Femoral heads

Femoral head devices are used by surgeons to replace the head of the femur during total hip surgery. They are characterized by a spherical shape and are coupled with the acetabular cup inserted in the acetabulum.
The femoral heads are coupled with the H-Max S stems by means of a 12/14 Morse taper. Modular heads are made of CoCrMo (ASTM F1537) and are available in diameters of 28, 32 and 36 mm and in S, M, L and XL offsets.

Cemented cups

Cemented cups are used to completely replace the acetabular cavity, using cement as the fixation agent. Cemented acetabular cups are manufactured entirely from UHMWPE (ASTM F648, ISO 5834-2). An AISI 316-L stainless steel ring is inserted in the equatorial region to allow the evaluation of the device position through radiography.

The acetabular cups are available in two different versions:

- standard
- protruded

The **standard** version is completely hemispherical and is designed for use in deep acetabula. The **protruded** version has a lateral portion which provides greater coverage of the femoral head to resist dislocation. The cemented cups are available with articular diameters of 28 and 32 mm.

The following table shows the availability of the cemented cups diameters for each type of cup.

Cup Type	Inner diameter	Range of Outer Diameter
Standard Cups	28 mm	44-58 mm with increments of 2 mm
	32 mm	46-58 mm with increments of 2 mm
Protruded Cups	28 mm	44-58 mm with increments of 2 mm
	32 mm	46-58 mm with increments of 2 mm

Intended Use/Indications

The H-MAX S Femoral Hip System consists of the H-MAX S femoral stem, a modular 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 Biolox Delta ceramic femoral heads and a compatible Limacorporate Cemented Cup or uncemented Delta TT acetabular cup.

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;
- osteoarthritis after femoral heads fractures;
- revisions in cases of good remaining femoral bone stock.

The Limacorporate Cemented Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs reconstruction. The Limacorporate Delta TT Cup is intended for uncemented use.

Predicate Devices

- H-MAX S Femoral Hip System (Limacorporate, K112091)
- Minima S System (Limacorporate, K141327)
- Master SL Femoral Stem (Limacorporate, K143509)
- Modulus Femoral Stem (Limacorporate, K112158)
- Delta TT Acetabular System (Limacorporate, K112898, K141395).

Comparable Features to Predicate Device(s)

The subject H-MAX S Femoral Hip Stems are identical to the H-MAX S Femoral Hip Stems cleared in K112091. In addition:

- The subject CoCrMo modular heads (36 mm) are identical to CoCrMo modular heads (36

mm) approved for use with Master SL femoral stem (K143509) and with Minima S femoral stem (K141327) in combination with Delta TT Acetabular cups;

- The subject Biolox Delta heads (36 mm) are identical to the Biolox Delta Heads cleared in K141327 (Minima S) and K143509 (Master SL) in combination with Delta TT Acetabular cups;
- The subject CoCrMo heads (28, 32 mm) are identical to CoCrMo heads (28, 32 mm) cleared in K141327 (Minima S) and K143509 (Master SL) in combination with Delta TT Acetabular cups;
- The subject Biolox Delta heads (28, 32 mm) are identical to the Biolox Delta Heads cleared in K141327 (Minima S) and K143509 (Master SL) in combination with Cemented cups or Delta TT Acetabular cups.

Non-Clinical Testing:

The materials, design, femoral head sizes and acetabular components remain the same as described in previously cleared submissions and no new issues of safety and effectiveness are introduced by adding:

- CoCrMo Ø 36 mm modular heads coupled with Delta TT system for use with the H-MAX S Femoral Hip System;
- Biolox Delta Ø 36 mm modular heads coupled with Delta TT system for use with the H-MAX S Femoral Hip System;
- CoCrMo Ø 28, 32 mm modular heads coupled with Delta TT system for use with the H-MAX S Femoral Hip System.
- Biolox Delta Ø 28, 32 mm modular heads coupled with Delta TT system and Cemented cups for use with the H-MAX S Femoral Hip System.

The tests provided in previously cleared submissions are therefore applicable to the new couplings proposed to be used with the H-MAX S Femoral Hip Stem.

In detail:

- Coupling of H-MAX S Femoral Hip system with CoCrMo modular heads (36 mm) and Delta TT acetabular cups : the design, material, and sizes of the CoCrMo modular heads (36 mm) articulating with compatible Delta TT acetabular system are identical to the design, material, and sizes of CoCrMo modular heads (36 mm) cleared for use with the Minima S femoral stem (K141327) and the Master SL femoral stem (K143509) articulating with Delta TT acetabular system.
- Coupling of H-MAX S Femoral Hip system with Biolox Delta heads (36 mm) and Delta TT acetabular cups : the design, material, and sizes of the Biolox Delta Femoral Heads for use with the H-MAX S Femoral Hip System Stems are identical to the design, material, and

sizes of the Biolox Delta Femoral Heads cleared for use with the Minima S Hip System (K141327) and Master SL femoral stem (K143509) articulating with Delta TT acetabular system. The coupling between the Biolox Delta Head and the H-MAX S Femoral Hip Stem is achieved through the same taper used to couple the Biolox Delta ceramic head to the Minima Hip Stem (K141327) and Master SL femoral stem (K143509). The H-MAX S Femoral Hip Stem (K112091) is manufactured from the same material (Ti6Al4V alloy) as the Minima S Hip Stem and Master SL femoral stem cleared for use with Biolox Delta ceramic heads (in K141327 and K143509 respectively).

- Coupling of H-MAX S Femoral Hip system with CoCrMo heads (28, 32 mm) and Delta TT acetabular cups : CoCrMo modular heads sizes 28 and 32 in offset S, M, L, XL are identical in design, material and sizes to the ones cleared in the original 510(k) K112091, for the use with H-MAX S stem and cemented cups. These devices are coupled with cemented cups in the original submission of H-MAX S (K112091): the coupling of these heads with Delta TT cups has already been cleared with Master SL (K140975) and Minima S (K141327) stems.

- Coupling of H-MAX S Femoral Hip system with Biolox Delta heads (28, 32 mm) and Cemented cups / Delta TT acetabular cups : the design, material, and sizes of the Biolox Delta Femoral Heads for use with the H-MAX S Femoral Hip System Stems are identical to the design, material, and sizes of the Biolox Delta Femoral Heads cleared for use with the Minima S Hip System (K141327) and Master SL femoral stem (K143509) articulating with Cemented cups / Delta TT acetabular system. The coupling between the Biolox Delta Head and the H-MAX S Femoral Hip Stem is achieved through the same taper used to couple the Biolox Delta ceramic head to the Minima Hip Stem (K141327) and Master SL femoral stem (K143509). The H-MAX S Femoral Hip Stem (K112091) is manufactured from the same material (Ti6Al4V alloy) as the Minima S Hip Stem and Master SL femoral stem cleared for use with Biolox Delta ceramic heads (in K141327 and K143509 respectively).

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