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

August 6, 2014

Limacorporate S.p.A.
% Stephen Peoples, VMD
Peoples and Associates Consulting LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K141327
Trade/Device Name: Minima S 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: LZO, JDI, KWY, KWZ, LPH, MBL
Dated: June 11, 2014
Received: June 13, 2014

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,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K141327
Device Name: Minima S System
Indications for Use:

Minima S System
Indications for Use

The Minima S System is indicated for use in partial or total hip arthroplasty and is intended for press-fit (uncemented) use. When used in total hip arthroplasty, the Minima S Stems are intended for use with compatible femoral heads and acetabular components. When used in partial hip arthroplasty, the Minima S 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)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Summary of Safety and Effectiveness

Date: July 16, 2014

Manufacturer:
Limacorporate S.p.A.
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Product	Common Name	Product Code	Regulation and Classification Name
Minima S System	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	Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310
		LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358
		MBL	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358

Description:

The Minima S System is intended for partial or total hip arthroplasty in cementless use. It is a monolithic collarless stem available in 9 sizes (#4-#12) in standard and lateralized versions.
When used in total hip arthroplasty Minima S stems are coupled to:

- Biolox Delta femoral heads (object of this submission) or Limacorporate Femoral Heads (K112158) articulating with Limacorporate Cemented Cups (K112158) or
- Biolox Delta heads (object of this submission) or Limacorporate Femoral Heads (K112158) articulating with Delta TT Acetabular System (K112898).

When used in partial hip arthroplasty the Minima S femoral stem is coupled to Lock Bipolar Heads (Limacorporate K112158).

The Minima S stem is made of Ti6Al4V and it has a plasma sprayed titanium coating in the proximal area (ASTM F1472 – ISO 5832-3). The stem is characterized by a 12/14 conical taper to be coupled to Limacorporate Femoral Heads, Biolox Delta femoral heads or Lock Bipolar Heads. In addition necks are lowered to reduce accidental contact between stem and acetabular cups and they are mirror-polished to reduce abrasion of the UHMWPE cups in case of abnormal contact. The stem has a rectangular section and is characterized by a "V" shaped A-P profile to improve adaptability to the most common bone morphologies and to facilitate insertion of the stem in the canal.

The Minima S System stems is available in standard and lateralized versions with different CCD angles (131° and 134°), offsets and stem lengths.

Biolox Delta Heads devices are used by surgeons to replace the head of the femur during total or partial hip surgery. They are characterized by a spherical shape and are coupled with the acetabular cup (K112158, K112898) inserted in the acetabulum, in total hip replacement, or with Lock Bipolar Heads (K112158) in partial hip replacement.

Biolox Delta heads are coupled with the Minima S stems by means of a 12/14 Morse taper. Biolox Delta heads are made of Biolox Delta ceramic and are available with 28, 32 and 36 mm of diameters and in sizes (offsets) S, M, L and XL (XL size available only for head size 36).

Intended Use:

The Minima S System 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 Minima S Stems are intended for use with compatible femoral heads and acetabular components. When used in partial hip arthroplasty, the Minima S 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:

For the Minima S Stem:

- H-MAX S stems (Limacorporate, K112091):
- Encore Linear Hip (DJO, K972791 and K991325);
- Modulus Femoral Hip System (Limacorporate, K112158);
- Taperloc 12/14 Taper Femoral Component (BIOMET, K043537).

For the Biolox Delta Heads:

- Femoral Heads (Limacorporate, K112158):
- Articul/eze (DJO, K883460 and K980513);
- Biolox Delta Ceramic Femoral Heads (Zimmer, K130899);
- Biolox Delta Ceramic Femoral Heads (Smith & Nephew, K100412, K083762).

Comparable Features to Predicate Device(s):

The Minima S stems are similar to the predicate devices in terms of intended use, indications, design and materials. The Minima S stems can be used in total hip arthroplasty as all predicates and they can be used also in partial hip arthroplasty as the Modulus Femoral Hip System (K112158). All stems are intended for cementless use.

The Minima S stems has a design which is similar to predicates with the exception that Modulus stems are made of 2-pieces coupled through conical taper. Like predicates, the subject device is available in standard and lateralized versions, with different CCD angles, offsets and sizes.

The components of the Minima S stems are manufactured from the same materials as the predicate devices.

The same considerations can be done for the Biolox Delta Heads which are similar for intended use, design and materials to predicates

Non-Clinical Testing:

The Minima S System was tested for fatigue resistance. Mechanical tests were performed on worst case components or constructs. The following tests were performed to demonstrate substancial equivalency of the Minima S System to predicate devices:

- Fatigue Test according to ISO 7206-6;
- Fatigue Tests according to ISO 7206-4 (at the end of the test the pull-out force for ceramic heads has been evaluated).

The tests results demonstrated the device's ability to perform under expected clinical conditions.
In addition the Titanium Plasma Spray coating has been characterized to verify the conformity to FDA guideline and referenced standards.

Biolox Delta heads have been tested for burst strength, fatigue and post-fatigue evaluation in accord to FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems. The tests results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Minima S System to the predicate devices.