# 510(k) Summary

JUN 3 0 2014

Date: June 25, 2014

Manufacturer:
Limacorporate S.p.A.
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U.S. Contact Person:
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| Product | Common Name | Product Code | Regulation and Classification Name |
|---|---|---|---|
| Delta TT Acetabular System | Total Hip Prosthesis | LPH, MBL, JDI, LZO | Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358 |

**Description:**

The Delta TT Acetabular System consists of a Delta TT cup, a liner and a modular metal femoral head. Bone screws can also be used as additional fixation for the cup.

The Delta TT cup is manufactured using an EBM (Electron Beam Melting) process with titanium alloy powder (Ti6Al4V, ASTM F1472 – ISO 5832-3). The Delta TT cup consists of a non porous bulk interior surface and a Trabecular Titanium structure on the external surface.

The Delta TT cup has an external hemi-spherical shape. A polar threaded hole is used for introduction of the cup and mates with the polar peg of the liner when the two components are assembled. Three (3) threaded holes in lateral positions allow additional fixation of the cup using bone screws; polyethylene plugs are inserted into these holes when bone screws are not required. The Delta TT cup is designed to be coupled with ultra high molecular weight polyethylene (UHMWPE) liners by means of a taper coupling.

Delta TT cups are available with external diameters of 44, 46 and 48 mm (for Small liners), 50 and 52 mm (for Medium liners) and 54, 56, 58, 60, 62 and 64 mm (for Large liners). The new sizes of the Delta TT Cups, the Delta TT Jumbo Cups, are Delta TT Cups with external diameters of 66, 68, 70, 72, 74 and 76mm and they are all intended to be used with Large Delta TT cup liners that were cleared in K112898. The liners are manufactured from standard UHMWPE (ASTM F648 – ISO 5834-2) or from cross-linked UHMWPE (X-Lima).

Liners are coupled with the Delta TT cup by means of a taper coupling. Two features are intended to give stability to the coupling, a peripheral ring and a polar peg. The peripheral ring is manufactured from Ti6Al4V (ASTM F1472 – ISO 5832-3) and surrounds the taper of the liner circumferentially, enhancing the rotational stability of the coupling. The polar peg fits into the polar hole of the cup, increasing the lever-out stability of the liner. The top of the peg is resurfaced by a Ti6Al4V (ASTM F1472 – ISO 5832-3) plug to avoid direct contact between polyethylene and bone.

The polyethylene liners are available in two (2) versions: neutral and protruded. The protruded design provides greater coverage of the femoral head and is intended to reduce the risk of dislocation. For both the designs, the following sizes are available:

- Cross-linked UHMWPE liners: Small (for femoral heads Ø 28 mm), Medium (for femoral heads Ø 28 and 32 mm) and Large (for femoral heads Ø 28, 32 and 36 mm).
- Standard UHMWPE liners: Small, Medium and Large liners for femoral heads Ø 28 mm.

Bone screws are manufactured from Ti6Al4V (ASTM F1472 – ISO 5832-3) and can be used to provide additional initial stability to the cup. Bone screws have a diameter of 6.5 mm and are available in lengths of 20, 25, 30, 35, 40, 45, 50, 55 and 60 mm.

**Intended Use/Indications:**

The Delta TT Acetabular System is indicated for use in total hip arthroplasty 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;
- Post-traumatic arthritis,
- Correction of functional deformity;
- Fractures, dislocation of the hip and unsuccessful cup arthroplasty;
- Revisions in cases of good remaining bone stock.

The Delta TT cup is intended for cementless use.

**Predicate Devices:**

- Delta TT Acetabular System (Limacorporate, K112898)
- Continuum Acetabular System (Zimmer, K091508)

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

The new sizes of the Delta TT Acetabular Cups are identical to the intended use and indications for use, the design and the materials of the Delta TT Acetabular Cups cleared via K112898. The subject devices are also of similar design to the Zimmer Continuum Acetabular shells and are available in outer diameter sizes that are identical to the outer diameter sizes of the largest Zimmer Continuum Acetabular System shells.

**Non-Clinical Testing:**

The new sizes of the Delta TT Cups do not represent worst case for mechanical testing. Therefore, the results of the tests performed on the Delta TT Cups cleared via K112898 are applicable also to Delta TT Jumbo Cups object of this submission.

With the Delta TT Acetabular System submission the following tests were provided:

- Wear test
- Push-out, Lever-out, Axial torque

- Cup deformation
- Fatigue/Fretting test

**Clinical Testing:** Clinical testing was not necessary to demonstrate substantial equivalence of the Delta TT Jumbo Cups to the Delta TT Acetabular System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

Limacorporate S.p.A.
% Stephen Peoples, VMD
President
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5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K141395
Trade/Device Name: Delta TT Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MBL, JDI, LZO
Dated: June 4, 2014
Received: June 5, 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

**Indications for Use Statement**

510(k) Number (if known): K141395

## Delta TT Acetabular System
## Indications for Use

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth E Frank -S

Division of Orthopedic Devices