Limacorporate S.p.A.
Roberto Gabetta
Regulatory Manager
via Nazionale 52
Villanova di San Daniele, 33038 It

December 26, 2018

Re: K182099
Trade/Device Name: Delta TT Pro
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
Dated: November 23, 2018
Received: November 30, 2018

Dear Roberto Gabetta:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.12.26 15:34:29 -05'00'

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182099

Device Name
Delta TT Pro

Indications for Use *(Describe)*

The Delta 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 Acetabular System is intended for cementless use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 7 – 510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number K_____

I. Applicant Information

Applicant:

Limacorporate S.p.A.
Via Nazionale, 52
Villanova di San Daniele
Udine 33038
Italy

Contact Person: Roberto Gabetta
Regulatory Affairs Manager
Tel: +39 0432945511
Fax: +39 0432945512
e-mail: roberto.gabetta@limacorporate.com

Application Correspondent: Same as Applicant.

Date Prepared: **August 3, 2018**

II. Device Identification

Proprietary Name:	**Delta TT Pro**
Common/Usual Name:	Total Hip Prosthesis
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulation Number:	21 CFR 888.3358
Product Codes:	LPH, MBL
Classification:	Class II
Classification Panel:	Orthopedic Devices

III. Predicate Devices

The **Delta TT Pro** device is substantially equivalent to the following FDA cleared predicate devices with regard to indications for use, performance and technological characteristics:

510(k) Number: **K112898**, **K141395**

Trade Name:	Delta TT Acetabular System
Manufacturer:	Limacorporate S.p.A.
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Common/Usual Name:	Total Hip Prosthesis
Regulation Number:	21 CFR 888.3358
Product Code:	LPH, MBL, JDI, LZO
Classification:	Class II

510(k) Number:	**K140669**
Trade Name:	G7 Acetabular System
Manufacturer:	Biomet Manufacturing Corp.
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Common/Usual Name:	Total Hip Prosthesis
Regulation Number:	21 CFR 888.3358
Product Code:	LPH, LZO, OQG, KWZ, JDI, OQH, OQI, PBI
Classification:	Class II

IV. Device Description

The **Delta TT Pro** is an acetabular system, intended for total hip replacement in cementless applications. The system consists of a Delta TT Pro acetabular cup (Ti6Al4V) and LimaVit liners (cross-linked UHMWPE with Vitamin E), available in three different design: neutral, protruded and high-wall. The LimaVit liners articulate with the Biolox®Delta and CoCrMo femoral heads, which are coupled to LimaCorporate femoral stems. Bone screws may be used to give further stability to the cup.

V. Indications for Use Statement

The Delta 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 Acetabular System is intended for cementless use.

VI. Summary of the Technical Characteristics

The intended use, design, and materials of the **Delta TT Pro** are substantially equivalent to the intended use, design, and materials of the predicate devices. All required design control activities have been completed and the results indicated that the subject device is substantially equivalent to the predicate devices, in terms of safety and effectiveness.

Lima Corporate
Orthopaedic motion

Predicate Device Comparison Table

Device Name	Subject Device: Delta TT Pro	Predicate Device: (K112898,K141395) Delta TT Acetabular System	Predicate Device: (K140669) G7 Acetabular System (OsseoTi acetabular shell with E1 acetabular liner)	Significant Differences
Product Code	LPH, MBL	LPH, MBL, JDI, LZO	LPH, LZO, OQG, KWZ, JDI, OQH, OQI, PBI	**No significant differences.** The subject device is classified as Product Code LPH and MBL under regulation 888.3358, whereas the predicate devices are classified under regulation 888.3358 with Product Codes LPH, MBL, JDI, LZO (Delta TT) and LPH, LZO, OQG, KWZ, JDI, OQH, OQI, PBI (G7 Acetabular System). However, the three products present substantially equivalent features as well as substantially equivalent safety and effectiveness characteristics.
Regulation #	888.3358	888.3358	888.3358	
Class	II	II	II	**No difference.**

Device Name	Subject Device: Delta TT Pro	Predicate Device: (K112898,K141395) Delta TT Acetabular System	Predicate Device: (K140669) G7 Acetabular System (OsseoTi acetabular shell with E1 acetabular liner)	Significant Differences
Indications for Use	• 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. Intended for cementless use.	• 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. Intended for cementless use.	• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis. • Rheumatoid arthritis. • Correction of functional deformity. • Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. • Revision of previously failed total hip arthroplasty. Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non coated or polyethylene components may be used with	**No significant differences.** The subject and predicate devices have essentially identical Indications for Use, with the minor exception that the G7 Acetabular System is also indicated in cases of non-union and trochanteric fractures (see parts in yellow).

Device Name	Subject Device: Delta TT Pro	Predicate Device: (K112898,K141395) Delta TT Acetabular System	Predicate Device: (K140669) G7 Acetabular System (OsseoTi acetabular shell with E1 acetabular liner)	Significant Differences
			mating components that are indicated for either cemented or uncemented use.	
Environment of Use	Clinical/Hospital Environment.	Clinical/Hospital Environment.	Clinical/Hospital Environment.	**No difference.**

VII. Summary of Performance Data

Limacorporate has conducted extensive verification and validation testing of the **Delta TT Pro** as a Hip Prosthesis intended for use in total hip arthroplasty. All verification and validation testing confirms that the product specifications are met, in support of the substantial equivalence of the intended use and technological characteristic as the predicate devices.

The **Delta TT Pro** has been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate according to its intended use and in a manner substantially equivalent to the predicate devices.

The main groups of tests performed include:

- Push out, lever out and torque out disassembly test
- Stiffness test
- Impingement test
- Wear test

VIII. Substantial Equivalence Conclusions

Based on the comparison of intended use, principles of operation and technological characteristics, the **Delta TT Pro** device is deemed to be substantially equivalent to the Delta TT Acetabular System, manufactured by Limacorporate S.p.A. (K112898, K141395) and the G7 Acetabular System, manufactured by Biomet Manufacturing Corp. (K140669).

The minor differences identified between the **Delta TT Pro** and its predicate devices raise no new issues of safety or effectiveness. The performance and validation data demonstrate that the **Delta TT Pro** is as safe and effective as the predicate devices.