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

November 1, 2019

Re: K191622
Trade/Device Name: Delta Multihole TT Pro 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
Dated: October 9, 2019
Received: October 11, 2019

Dear Stephen 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FOR Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K191622

Device Name
Delta Multihole TT Pro Acetabular System

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;
• Revision of previously failed total hip arthroplasty (Delta Multihole TT Pro only).

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.

Summary of Safety and Effectiveness

Date: September 12, 2019

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

U.S. Contact Person:
Dr. Stephen J. Peoples
Principal Consultant
Phone: 260-645-0327
Email: SPeoplesVMD@gmail.com

Product	Product Code	Regulation and Classification Name
Delta Multihole TT Pro Pro Acetabular System	LPH, MBL	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358

Common name:
Acetabular Cup System

Description:
The Delta Multihole TT Pro Acetabular System consists of a Delta Multihole TT Pro cup, an acetabular liner and a modular femoral head. Bone screws can also be used to provide additional stability of the cup.

The Delta Multihole TT Pro cup is manufactured from titanium alloy; the Delta Multihole TT Pro liners are manufactured from cross-linked UHMWPE with Vitamin E and the femoral heads made of Biolox Delta ceramic or Cobalt Chrome Molybdenum alloy.

The design of shell is similar to the Delta TT Pro Acetabular System (K182099) and the G7 Acetabular System (Biomet, Inc., K140669) devices. The acetabular liners, the Biolox Delta heads, the CoCrMo heads and the bone screws are the same as those cleared in K182099. The Multihole TT Pro cup has a hemispherical design and provides holes in cranial and caudal aspects of the cup to provide additional cup stability by means of fixation screws. The Multihole TT Pro cup is coupled with a Delta TT Pro acetabular liner that is available in neutral, protruded and high wall versions.

Intended Use/Indications:
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;
- Revision of previously failed total hip arthroplasty (Delta Multihole TT Pro only).

The Delta Acetabular System is intended for cementless use.

Predicate Devices:
The LimaCorporate Delta Multihole TT Pro Acetabular System is similar to the following cleared devices in regards to design features, indications, and materials:

- Delta TT Pro Acetabular System (LimaCorporate, K182099), primary predicate
- G7 Acetabular System (Biomet, Inc., K140669)

Summary of technology comparison:
The intended use, design, and materials of the Delta Multihole TT Pro Acetabular System are substantially equivalent to the intended use, design, and materials of the predicate devices. Design Control Activities have been completed and the results indicated that the subject device is safe and effective.

Non-clinical testing
Mechanical testing had demonstrated the device's ability to perform in a substantially equivalent manner to the predicate devices in terms of:

- Push-out, lever-out and torque-out test according to ASTM F1820-13
- Stiffness test according to ISO 7206-12:2016
- Unsupported anatomical fatigue deformation

Clinical testing
Clinical testing was not necessary to demonstrate substantial equivalence of the Delta Multihole TT Pro Acetabular System to the predicate devices.