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

May 9, 2019

Re: K181491
Trade/Device Name: Delta Dual Mobility 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, LPH, MBL
Dated: April 16, 2019
Received: April 19, 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/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,

For CAPT Raquel Peat
Director
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)*
K181491

Device Name
Delta Dual Mobility System

Indications for Use *(Describe)*

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.

Delta TT cup is intended for cementless use.
The Delta Dual Mobility System is intended to be used with Delta TT Acetabular System.

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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Summary of Safety and Effectiveness

Date: May 5th, 2019

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

U.S. Contact Person:
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Product	Common Name	Product Code	Regulation and Classification Name
Delta Dual Mobility System	Total Hip Prosthesis	LZO	Hip joint, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented prosthesis, per 21CFR 888.3353
		LPH, MBL	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, per 21 CFR 888.3358

Description:

The subject Delta Dual Mobility System represents a dual mobility option for Delta TT acetabular system.

The Delta Dual Mobility System is intended for cementless use in total hip arthroplasty. The system is composed of an acetabular cup shell (previously cleared in K112898, K141395), a fixed liner, a mobile liner and a femoral head (previously cleared in K112158, K141327, K143509). Only femoral heads with offset S, M and L are intended to be used with Delta Dual Mobility System. The femoral head can be coupled with the previously cleared femoral stems. Bone screws that can optionally be used for additional fixation were cleared in K112898, K141395 and K172456.

The previously cleared acetabular cup shells are manufactured in titanium alloy: 14 cup shell sizes are intended to be used with dual mobility option. The CoCrMo fixed liners and the UHMWPE mobile liners are both available in 2 sizes. The previously cleared femoral heads are available in CoCrMo and Biolox Delta versions. Bone screws are provided for optional use to provide further primary fixation.

Intended Use:
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.

Delta TT cup is intended for cementless use.
The Delta Dual Mobility System is intended to be used with Delta TT Acetabular System.

Predicate Devices:

- G7 Dual Mobility System (Zimmer Biomet, K150522, K161190);
- MDM X3 (Stryker/Howmedica, K103233, K112556);
- Delta-TT acetabular System (Limacorporate, K112898, K141395);
- Polarcup Dual Mobility System (Smith&Nephew, K070278, K110135, K122244).
- Regenerex RingLoc + Modular acetabular shell and ArComXL polyethylene liners (Biomet, K023357, K032396, K042051, K070369).

Comparable Features to Predicate Device(s):
The intended use and indications of the Delta Dual Mobility System are the same as those of the previously cleared Delta TT Acetabular System. The Delta Dual Mobility System components are similar to the predicate devices components in terms of technical characteristics, materials, sizes, device usage, sterility and expiration / shelf life.

Non-Clinical Testing:
Results from mechanical tests and engineering analysis demonstrate the proposed Delta Dual Mobility System is substantially equivalent to the predicate devices.

Mechanical tests were performed on worst case components or constructs. The following tests were performed:

- Pull-out and Lever-out of mobile liner;
- Fixed liner push-out, lever-out and torque-out;
- Fatigue-fretting off-axis;
- Fatigue rim impingement;
- Wear.

A simulation of Range of Motion has been performed to ensure the device design does not overly limit range of motion.

The tests results demonstrated the device's ability to perform under expected clinical conditions. LAL testing has been performed to establish that the subject device meets the specified 20EU/device limit.

Clinical Testing:
Clinical testing was not necessary to demonstrate substantial equivalence of the Delta Dual Mobility System to the predicate devices.