January 31, 2020

Limacorporate S.p.A
% Lacey Harbour
Regulatory Manager
Lima USA Inc.
2001 NE Green Oaks Blvd., Ste. 100
Arlington, Texas 76006

Re: K193284
Trade/Device Name: Physica LMC Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, HRY
Dated: November 15, 2019
Received: November 27, 2019

Dear Lacey Harbour:

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,

Ting Song
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)*
K193284

Device Name
Physica LMC knee system

Indications for Use *(Describe)*
Physica total knee system is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:
• Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
• Inflammatory degenerative joint disease including rheumatoid arthritis;
• Correction of functional deformity;
• Revision procedures where other treatments or devices have failed; and
• Treatment of fractures that are unmanageable using other techniques.

Additional indications for Physica LMC component are:
• Moderate varus, valgus, or flexion deformities

Additional indications for Physica PS components are:
• ligamentous instability requiring implant bearing surface geometries with increased constraint (preserved and well functioning collateral ligaments are required);
• absent or not-functioning posterior cruciate ligament.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Summary of Safety and Effectiveness

Date: January 27, 2020

Manufacturer:
Limacorporate S.p.A.
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Udine - Italy

U.S. Contact Person:
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Product	Product Code	Regulation and Classification Name
Physica LMC knee System	JWH	Knee joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis per 21 CFR 888.3560
	HRY	Knee joint Femorotibial Metal/Polymer Semi-Constrained Cemented Prosthesis per 21 CFR 888.3530

Description:
Physica LMC knee system is a modular knee system which consists of a Physica LMC tibial liner used in combination with the Physica CR femoral components (K151266) and the Physica tibial plate (K141934); the Physica patellar component and the Physica tibial stem, cleared in K141934, can optionally be used with the Physica LMC knee system. The Physica LMC knee system components are intended to be used with bone cement.

Intended Use:
Physica total knee system is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Inflammatory degenerative joint disease including rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

Additional indications for Physica LMC component are:

- Moderate varus, valgus, or flexion deformities

Additional indications for Physica PS components are:

- ligamentous instability requiring implant bearing surface geometries with increased constraint (preserved and well functioning collateral ligaments are required);
- absent or not-functioning posterior cruciate ligament.

Predicate Devices:

Company	Device name	Cleared via
LIMACORPORATE	Physica Knee System	K151266, K141934, K152008
ZIMMER	VANGUARD®	K050222, K113550
ZIMMER	PERSONA®	K150090

Summary of technology comparison:

The intended use, design, and materials of Physica LMC knee system are substantially equivalent to the ones of the predicate devices. Design Control Activities have been successfully completed.

Non-clinical testing:

Mechanical testing had demonstrated the device's ability to perform substantially equivalent to the predicate devices in:

- Contact area / pressure at the femoral component and tibial liner coupling (FDA guideline, ASTM F2083)
- Wear of the articulating surfaces (ISO 14243)
- Constraint of the femoral component and tibial liner coupling (FDA guideline, ASTM F1223)

Clinical testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the new Physica LMC knee system to the predicate devices.