July 13, 2021

LimaCorporate
% Lacey Harbour
US Regulatory Manager
Lima USA Inc.
2001 NE Green Oaks Blvd. Ste.100
Arlington, Texas 76006

Re: K211938
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: June 7, 2021
Received: June 23, 2021

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,

For Ting Song, Ph.D., R.A.C.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211938

Device Name

Physica LMC Knee System

Indications for Use *(Describe)*

Physica 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, and
  - avascular necrosis (not applicable to Physica TT Tibial Plate);
- 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.

In patients with preserved and well functioning collateral ligaments, Physica PS components are also indicated for:

- Absent or not-functioning posterior cruciate ligament;
- Severe antero-posterior instability of the knee joint.

AMF Revision TT Cones are intended for use in skeletally mature patients with bone defect or poor bone quality (osteoporotic bone) or in case of sclerotic bone that requires supplemental metaphyseal fixation in the clinical judgment of the surgeon.

Femoral, tibial and patellar components of the Physica system are intended for cemented use, with the exception of Physica Porous Femoral components and Physica TT Tibial Plates that are intended for uncemented use, and tibial and femoral cones that are intended for uncemented fixation to the bone and are fixed to the femoral and tibial implants using bone cement.
Tibial liners can be used with cemented or uncemented tibial or femoral components.

Type of Use *(Select one or both, as applicable)*

Special 510(k) Physica LMC knee system
June 7, 2021

■ Prescription Use (Part 21 CFR 801 Subpart D) □ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (6/20) PSC Publishing Services (301) 443-6740 EF

Lima Corporate
Orthopaedic motion

510(k) Summary

Date: June 7, 2021

Manufacturer:	U.S. Contact Person:
LimaCorporate S.p.A. Via Nazionale, 52 33038 – Villanova di San Daniele Udine - Italy	Dr. Lacey Harbour lacey.harbour@limacorporate.com Lima USA Inc. 2001 NE Green Oaks Blvd. Ste.100 Arlington, Texas 76006, USA www.limacorporate.com Office Phone: 817.385.0777 ext.200 Cell Phone: 432.638.6615 FAX: 817.385.0377

Device Trade Name: Physica LMC Knee System

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

Predicate Devices: Physica LMC Knee System (K193284 and K201084).

Device Description:

Physica LMC Knee System is a modular knee system which consists of Physica LMC tibial liner, made of UHMWPE or LimaVit, used in combination with a Physica CR femoral component, Physica tibial plate, cemented or uncemented versions, Physica patellar component, made of standard UHMWPE or LimaVit and Physica tibial stem, that were cleared as part of the Physica Knee System in K141934, K151266 and K201084.

The Physica LMC knee system is intended to be used in patients with or without a functioning posterior cruciate ligament.

Indications for Use:

Physica 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, and
- avascular necrosis (not applicable to Physica TT Tibial Plate);

- 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.

In patients with preserved and well functioning collateral ligaments, Physica PS components are also indicated for:

- Absent or not-functioning posterior cruciate ligament;
- Severe antero-posterior instability of the knee joint.

AMF Revision TT Cones are intended for use in skeletally mature patients with bone defect or poor bone quality (osteoporotic bone) or in case of sclerotic bone that requires supplemental metaphyseal fixation in the clinical judgment of the surgeon.

Femoral, tibial and patellar components of the Physica system are intended for cemented use, with the exception of Physica Porous Femoral components and Physica TT Tibial Plates that are intended for uncemented use, and tibial and femoral cones that are intended for uncemented fixation to the bone and are fixed to the femoral and tibial implants using bone cement.
Tibial liners can be used with cemented or uncemented tibial or femoral components.

Comparable Features to Predicate Device(s)

This Special 510(k) describes modifications made to the labeling in the information for use and surgical technique.

- replacing the statement "damaged or deficient" with the statement "with or without a functioning" in the Product Information paragraph of the IFU,
- adding notes in the surgical technique from the indications of use for the LMC, and
  - "NOTE. Physica CR and KR are intended to be used in patients with a preserved and well functioning PCL."
  - "NOTE. Physica LMC Liner is intended to be used with or without a functioning PCL."
  - "NOTE. Physica PS is intended to be used in situations where the PCL is absent or cannot be preserved."
- adding note in the surgical technique to elaborate further on the indications of use "NOTE. Without functioning PCL, the surgeon should evaluate the possibility of removing the PCL according to patient conditions while implanting the LMC liner."

Substantial Equivalence:

The Physica LMC Knee System is substantially equivalent to the predicate device cited on the previous page with respect to indications, design, function, and performance.

Non-Clinical Testing:

Non-Clinical testing was not necessary to demonstrate substantial equivalence of the Physica LMC Knee System to the predicate devices.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Physica LMC Knee System to the predicate devices.

Conclusion:

Based on the information contained within this submission, it is concluded that the Physica LMC Knee System labeling changes are substantially equivalent to the identified predicate devices.