April 6, 2021

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

Re: K210554
Trade/Device Name: Physica system
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, HRY
Dated: January 15, 2021
Received: February 25, 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,

Ting Song -S

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)*
K210554

Device Name
Physica 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)*

☒ 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.

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Summary of Safety and Effectiveness

Date: January 15th, 2021

Manufacturer:
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Udine - Italy

U.S. Contact Person:
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Trade name: Physica system
Common Name: Knee prosthesis

Classification Name:

Product Code	Regulation and Classification Name
MBH	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis per 21 CFR 888.3565
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:
The Physica system is a total knee replacement system consisting of a Femoral component, a Tibial plate, a Tibial liner, a Tibial stem and a Patella component; the Tibial stem and the Patella component are optional to be used as required for each individual patient and as allowed in the Instructions for Use.
The Physica Porous Femoral components are made of CoCrMo alloy and the internal surface is PoroTi coated; they are intended to be used without bone cement; the components to be used in combination with (Tibial plate, TT Tibial plate, Tibial liner, Tibial stem, Patella) were previously cleared (K141934, K152008, K190911, K201084).

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.

Predicate Devices:

No.	Company	Device name	Cleared via
1 (primary predicate)	LIMACORPORATE	Physica system	Main reference: K201084 Other references: K141934, K152008, K190911
2	ZIMMERBIOMET	Vanguard Knee System	K033489, K050222, K060303, K113550

Summary of technology comparison:
The intended use, design, and materials of the subject Physica Porous Femoral components (part of Physica system) are substantially equivalent to those of the predicate devices. Design Control Activities have been successfully completed.

Non-clinical testing
Mechanical safety of the subject cementless Physica Porous Femoral components were confirmed through a comparison with previously cleared (K141934, K152008, K190911, K201084) cemented Physica Femoral components.
The analyses (e.g. drawings overlap and testing provided) demonstrated that device performance fulfill the intended use and are substantially equivalent to the predicate devices. The PoroTi coating of subject Porous Femoral components fulfills the conformity to the FDA guidelines and referenced standards and the analysis was performed on worst case components or constructs.

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of the new Physica Porous Femoral components to the predicate devices.

Conclusion

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the Physica systems (including subject Physica Porous Femoral components) are substantially equivalent to the predicate devices identified in this premarket notification.