



December 18, 2024

Limacorporate S.p.A.
Massimo Rosso
Senior Regulatory Affairs Processes Specialist
Via Nazionale, 52
Villanova di San Daniele del Friuli, UD 33038
Italy

Re: K243615

Trade/Device Name: Physica Porous Femoral Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented
Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: November 22, 2024
Received: November 22, 2024

Dear Massimo Rosso:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -
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Digitally signed by Peter G.
Allen -S
Date: 2024.12.18 09:23:27
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For Lixin Liu, PhD
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

Indications for Use

Submission Number (if known)

K243615

Device Name

Physica Porous Femoral Components

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
 - o osteoarthritis
 - o traumatic arthritis, and
 - o 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, PS Pro and HPS components are also indicated for:

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

Additional indications for Physica HPS component are:

- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate varus, valgus, or flexion deformities.

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.

Summary of Safety and Effectiveness

Date: September 27, 2024

U.S. Contact Person:

Manufacturer:

Limacorporate S.p.A.

Via Nazionale, 52

33038 – Villanova di San Daniele Udine - Italy

Sherri Melligen

sherri.melligen@enovis.com

Enovis

9800 Metric Blvd

Austin, Texas 78758, USA

Trade name: Physica Porous Femoral Components

Common Name: Total 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

Description

Physica Porous Femoral Components have been cleared via K210554 with a Porous coating performed by a supplier. With this 510(k) submission, Limacorporate intends to add an additional coating vendor for these components. No other change is introduced on the Physica Porous Femoral Components: Intended use, design, material, sterilization, packaging and principle of operation are unchanged compared to the information approved in K210554.

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
 - o osteoarthritis
 - o traumatic arthritis, and
 - o 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, PS Pro and HPS components are also indicated for:

- Absent or not-functioning posterior cruciate ligament;

- Severe antero-posterior instability of the knee joint.

Additional indications for Physica HPS component are:

- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate varus, valgus, or flexion deformities.

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

Device name	Cleared via	Company
Physica Porous Femoral Component	K210554 (last cleared in the system K213381)	LimaCorporate S.p.A

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 and morphological characteristics of the coating of the subject cementless Physica Porous Femoral components were confirmed through a comparison with previously cleared (K210554) cementless Physica Porous Femoral components. 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 system (including subject Physica Porous Femoral components) is substantially equivalent to the predicate devices identified in this premarket notification.