May 22, 2025

Limacorporate S.p.A.
Simone De Marco
Regulatory Affairs Specialist
Via Nazionale, 52
Villanova di San Daniele, UD 33038
Italy

Re: K250980
Trade/Device Name: Physica System (Physica CR 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, JWH, HRY
Dated: March 17, 2025
Received: March 31, 2025

Dear Simone De Marco:

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,

Lixin Liu -S

Lixin Liu, Ph.D
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250980

Please provide the device trade name(s).

Physica System (Physica CR Porous Femoral components)

Please provide your Indications for Use below.

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.

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.
Tibial liners can be used with cemented or uncemented tibial or femoral components.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared: May 22th, 2025

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

Contact Person:
Simone De Marco
regulatory@enovis.com
LimaCorporate

Product	Product Code	Regulation and Classification Name
Physica System (Physica CR Porous Femoral components)	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

Common name: Total Knee Replacement

Description:
This 510(k) submission aims at introducing the Physica CR Porous Femoral components as part of the subject Physica system. The subject device components are intended to be used without cement, articulating with other components of the cleared Physica system. The Physica system (including subject Physica CR Porous Femoral components) is intended for a total knee replacement.
Physica CR Porous Femoral components are designed based on the cemented Physica CR Femoral components already cleared (K151266). They are made of CoCrMo (ISO 5832-4 / ASTM F75) and are intended to replace the condyles of the distal femur. The femoral components are available in ten sizes (left and right) and are intended to replace the condyles of the distal femur. The femoral components are available in left and right versions and have an asymmetric anterior flange (to adapt left and right knees) with symmetric condyles for the articulation with the tibial liner.

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.

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Tibial liners can be used with cemented or uncemented tibial or femoral components.

Predicate Devices:

No.	Company	Device name	Product code	Cleared via
1 (Primary predicate)	Limacorporate S.p.A	Physica Porous Femoral Components	MBH	K243615
2 (Secondary predicate)	Limacorporate S.p.A	Physica system	MBH, JWH, HRY	K210554
3 (Secondary predicate)	Limacorporate S.p.A	Physica CR Knee System	JWH	K151266

Summary of technology comparison:
The intended use, design, and materials of the subject Physica CR Porous Femoral components (part of Physica system) are substantially equivalent to the predicate device Physica system, including Physica CR Femoral components and Physica KR Porous Femoral components already cleared. Particularly, the subject Physica CR Porous Femoral components are manufactured with the same processes and materials and feature the same porous coating on the internal surfaces of the Physica Porous Femoral components. The Physica CR Porous Femoral components have the same sizes, dimensions and design features of Physica CR Femoral components, except for the

cement pockets. Design Control Activities have been successfully completed.

Non-clinical testing

Mechanical tests demonstrated that the device performance fulfilled the intended use, and that the device is substantially equivalent to the predicate device.

Mechanical testing was performed on worst case components or constructs:

- Fatigue testing of the femoral components (ASTM F3210-22e1).

Other performance requirements were fulfilled through rationales and comparisons with previously cleared components of the Physica system (K141934, K151266, K152008, K193284, K201084, K210554, K211938, K243615). The PoroTi coating of subject Physica CR Porous Femoral components fulfills the conformity to the FDA Guidelines and referenced standards.

Conclusion

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