



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Limacorporate S.p.A.  
% Dr. Stephen Peoples  
President  
People & Associates Consulting LLC  
5010 Lodge Pole Lane  
Fort Wayne, Indiana 46814

October 6, 2015

Re: K151266  
Trade/Device Name: Physica CR 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  
Dated: September 8, 2015  
Received: September 9, 2015

Dear Dr. Peoples:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
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: January 31, 2017  
See PRA Statement below.

510(k) Number (if known)  
K151266

Device Name  
Physica CR Knee System

### Indications for Use (Describe)

Physica CR 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.

Physica CR knee system is intended for cemented fixation.

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.

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## Summary of Safety and Effectiveness

Date: October 10, 2015

Manufacturer:

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33038 – Villanova di San Daniele  
Udine - Italy

U.S. Contact Person:

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Product	Common Name	Product Code	Regulation and Classification Name
Physica CR knee system	Total Knee System	JWH	Knee joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis per 21 CFR 888.3560

### Description

The Physica CR Knee Replacement System is a total knee replacement system consisting of a femoral component, a UHMWPE tibial liner, a tibial plate, and an all polyethylene patellar component. Modular tibial stems are provide for optional use as needed. The Physica CR knee system devices are intended to be used with bone cement.

The femoral components are made of CoCrMo (ISO 5832-4 / ASTM F75). The articulating surface is polished and with symmetrical condyles. Conformity between the inner surface of the components and the resected bone of the distal femur and two fixation pegs provide stability. Ten (10) sizes in left and right versions are available.

Liners are made of standard UHMWPE (ISO 5834-2 / ASTM F648). They are characterized by a concave medial and lateral hemi-plateau. The liner is attached to the tibial plate through a snap-fit mechanism. The anterior aspect of the liner is shaped to accommodate the patellar tendon during flexion-extension movements of the knee. Ten (10) sizes, correspondently to the tibial plate sizes, in six (6) thicknesses, are available in a symmetrical version for left and right knees.

The tibial plates and all polyethylene patellar components are the same as the tibial plates and patellar components used for the Physica KR Knee Replacement System (K141934).

Traditional 510(k) – Physica CR knee system

Tibial stems can be optionally used and are the same as those cleared for the Physica KR knee system in K141934.

### **Intended Use**

Physica CR 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.

All components of the Physica CR knee system are intended for cemented fixation.

### **Predicate Devices**

- Physica KR (Limacorporate, K141934);
- Vanguard (Biomet, K113550);
- Scorpio (Stryker, K974556).

### **Basis of Substantial Equivalency**

The Physica CR knee system components share the same materials, intended use and basic design features as those of the predicate devices. Non-clinical testing demonstrates that the subject components perform at least as well as the cited predicates.

### **Non-Clinical Testing**

The following tests were performed on Physica CR knee system devices:

- Contact areas and pressures at tibio-femoral and patello-femoral interfaces;
- Wear testing;
- Constraint tests at tibio-femoral and patello-femoral interfaces.

Fatigue tests on the tibial plate, fatigue resistance of the tibial plate-tibial stem coupling, test on the locking strength between the tibial plate and the tibial liner and static shear test on the patella were performed for the Physica KR system and are applicable to Physica CR knee system.

Mechanical testing was performed on worst case components or constructs. The testing results demonstrated the device's ability to perform under expected clinical conditions.

### **Clinical Testing:**

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