May 7, 2020

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

Re: K200653
Trade/Device Name: AMF Revision TT Cones
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, MBH
Dated: January 31, 2020
Received: March 12, 2020

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, Ph.D., R.A.C.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200653

Device Name
AMF Revision TT Cones

Indications for Use *(Describe)*
Physica 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.
In patients with preserved and well functioning collateral ligaments, Physica PS components are also 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. Tibial and femoral cones are intended for uncemented fixation to the bone and are fixed to the femoral and tibial implants using bone cement.

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: April 30, 2020

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

U.S. Contact Person:
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Product	Common Name	Product Code	Regulation and Classification Name
AMF Revision TT Cones	Total Knee System	JWH	Knee joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis per 21 CFR 888.3560
		MBH	Knee joint Patellofemorotibial metal/polymer porous-coated uncemented prosthesis per 21 CFR 888.3565

Description

The AMF Revision TT Cones are intended to be used as an optional accessory component in Total Knee Arthroplasty in combinations with the Physica tibial plate (K141934, K151266 and K152008) and Physica PS femoral component (K152008).
The AMF Revision TT Cones are one-piece devices, conically shaped with cannulation all the way through the cone.

Indications for use

Physica 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
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Predicate Devices

Company	Device name	Cleared via
ZIMMER	Trabecular Metal Knee System Augments	K053340, K102896 and K103517
STRYKER	Triathlon Tritanium Cone Augments	K143393.

Summary of technology comparison

The intended use, principles of operation, design, materials, sterility and methods of fixation of AMF Revision TT Cones are substantially equivalent to the ones of the predicate devices. Design Control Activities have been successfully completed.

Non-clinical testing

The following test were performed on AMF Revision TT Cones:

- Fatigue resistance of the Physica System with AMF Revision TT Tibial Cones (Internal protocol derived from ASTM F1800).

Clinical testing

Clinical testing was not necessary to demonstrate substantial equivalence of the new AMF Revision TT Cones to the predicate devices.

Conclusion

Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the AMF Revision TT Cones are substantially equivalent to the predicate devices identified in this premarket notification.