



January 18, 2024

LimaCorporate S.p.A
% Newman Kenneth
Senior Regulatory Affairs Specialist
Lima USA Inc
2001 NE Green Oaks Blvd. Ste.100
Arlington, Texas 76006

Re: K234011

Trade/Device Name: AMF 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: December 19, 2023

Received: December 19, 2023

Dear Newman Kenneth:

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.

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

Submission Number (if known)

K234011

Device Name

AMF TT Cones

Indications for Use (Describe)

AMF 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.

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Summary of Safety and Effectiveness

Date: December 19, 2023

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 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 TT Cones are intended to be used as an optional accessory component in total knee arthroplasty. The AMF TT Cones are one-piece devices, made from Ti6Al4V alloy, conically shaped with cannulation all the way through the cone.

With this 510(k) submission, the compatibility of the AMF Revision TT Cones (K200653) with the EMPOWR Revision Knee (K230169) manufactured by Encore Medical, L.P. is introduced.

Indications for use

AMF 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.

Predicate Devices

Device name	Cleared via	Company
AMF Revision TT Cones	K200653	LimaCorporate S.p.A

Summary of technology comparison

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

Non-clinical testing

The new compatibility introduced with this 510(k) does not introduce a worst case for mechanical testing. Test results of mechanical testing submitted in K200653 are applicable. Additional testing to demonstrate substantial equivalence to predicate devices is thus not required.

Clinical testing

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

Conclusion

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