August 29, 2025

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

Re: K251718
Trade/Device Name: ArTT Augments and Buttresses and Bone Screws
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, OQG
Dated: May 15, 2025
Received: June 4, 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,

Limin Sun -S

Limin Sun, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251718

Device Name
ArTT Augments and Buttresses and Bone Screws

Indications for Use *(Describe)*
ArTT Augments and Buttresses are indicated to be used, in combination with EMPOWR Acetabular Cup System, as an alternative to structural allograft in skeletally mature patients in cases of segmental acetabular deficiencies.
ArTT Augments and Buttresses are indicated for cementless use to the bone interface; and are affixed to the mating acetabular cup 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.

510(k) Summary

Date Prepared: August 28th, 2025

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

Contact Person:
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Product	Product Code	Regulation and Classification Name
ArTT Augments and Buttresses and Bone Screws	LPH, OQG	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358

Common name: Acetabular Bone Augments, Bone Screws

Description:
This 510(k) submission aims at introducing new device components, the **ArTT Augments and Buttresses** and **Bone Screws** (Revision Bone Screws (Dia. 6.5mm), Locking Bone Screws (Dia. 6.5mm), Locking Bone Screws (Dia. 4mm), Bone Screws (Dia. 4mm)) to be used in combination with the EMPOWR Acetabular Cup System (K190057) manufactured by Encore Medical, L.P.
ArTT Augments and Buttresses are manufactured from Ti6Al4V 3D printed (ISO 5832-3) and are indicated for cementless use to the bone interface; they are affixed to the mating acetabular cup using bone cement. ArTT Augments are available in 9 diameters (Dia. 50mm to 66mm) and 3 eccentricities (Ecc. 10mm, Ecc. 15mm, Ecc. 20mm), while ArTT Buttresses are available in 3 diameters (Dia.50mm, Dia.56mm, Dia.62mm), 3 heights (H. 15mm, H. 30mm, H. 60mm) and 3 configurations (Neutral, Left, Right).
Bone Screws are manufactured from Ti6Al4V (ISO 5832-3 - ASTM F1472); they are intended for cancellous or cortical bone and are available in several lengths.

Indications for Use:

ArTT Augments and Buttresses are indicated to be used, in combination with EMPOWR Acetabular Cup System, as an alternative to structural allograft in skeletally mature patients in cases of segmental acetabular deficiencies.
ArTT Augments and Buttresses are indicated for cementless use to the bone interface; and are affixed to the mating acetabular cup using bone cement.

Predicate Devices:

No.	Company	Device name	Cleared via
1 (Primary predicate)	Zimmer Trabecular Metal Technology, Inc. (Z-TMT)	Trabecular Metal Acetabular Augments	K061067
2 (Additional predicate)	DePuy Orthopaedics, Inc.	DePuy Gription TF 5.5mm Sterile Locking Screws	K123924

Summary of technology comparison:
The subject ArTT Augments and Buttresses share extensive similarities with the Trabecular Metal Acetabular Augments cleared via K061067: they share the same fixation method (uncemented), the same fixation to the cup (cemented), the same principle of operation and equivalent performance features. ArTT Augments and Buttresses and Trabecular Metal Acetabular Augments are available in a similar range of sizes and are provided sterile to the user.
The ArTT Augments and Buttresses are manufactured from Ti6Al4V, whereas the Trabecular Metal Acetabular Augments are made of Tantalum. Similarly, the DePuy Gription TF Acetabular Augment System (K123924) features augments and buttresses made of Pure Ti.
The ArTT Augment and Buttresses can be used in combination with locking bone screws. Similarly, the DePuy Gription TF Acetabular Augment System (K123924) can be used in combination with locking bone screws.

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:

- Fretting fatigue testing of the ArTT Augments and Buttresses with Bone screws (Internal protocol);
- Torsional properties, driving torque and pull-out load of Bone Screws (ASTM F543).

Other performance requirements were fulfilled through rationales and comparisons with previously cleared components (K210717, latest 510(k) approval).

Conclusion
Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the subject ArTT Augments and Buttresses and Bone Screws are substantially equivalent to the predicate devices identified in this premarket notification.