April 24, 2026

Implantcast GmbH
℅ Sarah Pleaugh
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K252451
Trade/Device Name: EPORE® XO cup system
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: OQI, OQG
Dated: August 4, 2025
Received: August 4, 2025

Dear Sarah Pleaugh:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

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.	K252451

Please provide the device trade name(s).

EPORE® XO cup system

Please provide your Indications for Use below.

The EPORE® XO cup system is intended for hip joint arthroplasty in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
- Revision of previously failed hip arthroplasty.

The EPORE® XO acetabular cups are intended for uncemented biological fixation.

The EPORE® XO cup system acetabular cups and cup inserts are intended to be used with mating femoral heads.

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

Device Trade Name: EPORE® XO cup system

Manufacturer:
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Lüneburger Schanze 26
21614 Buxtehude
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Prepared by:
MCRA, LLC
803 7th Street, NW
Washington, DC 20001
Office: 202.552.5800

Date Prepared: April 23, 2026

Classifications:
21 CFR §888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
21 CFR §888.3358, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Common Name: Hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented

Device Class: Class II

Product Codes: OQI, OQG

Primary Predicate: EcoFit® Hip System (K180263/ K203420/ K163577)

Reference Device: G7® Acetabular System (K190660)

Device Description:
The subject EPORE® XO cup system includes additively manufactured acetabular cups with a porous outer surface ("EPORE®") in Ø42 through 72mm diameters in two configurations (three

hole and multi-hole), polyethylene cup inserts in three configurations (neutral, 10 degree and +5mm 10 degree), optional bone screws, and femoral heads to facilitate total hip arthroplasty.

Indications For Use:
The EPORE® XO cup system is intended for hip joint arthroplasty in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable by other techniques; and
- Revision of previously failed hip arthroplasty.

The EPORE® XO acetabular cups are intended for uncemented biological fixation.

The EPORE® XO cup system acetabular cups and cup inserts are intended to be used with mating femoral heads.

Technological Comparison:
The subject and primary predicate devices all have the same or similar:

- Indications for use, intended for total hip joint arthroplasty
- Fundamental technology, including:
    - Same basic hip replacement construct consisting of a metallic acetabular cup, polyethylene insert, with ceramic/metallic femoral head and associated stem/taper components
    - Same use for uncemented biological fixation
    - Similar designs (sizes, configurations, etc.)
- Materials
- Performance, meeting pre-defined acceptance criteria for total hip arthroplasty devices

Any differences between the subject and primary predicate device are supported by the regulatory precedence set by the reference device, which is an additively manufactured acetabular cup for uncemented use. Further, the minor differences do not raise significant risks of safety or effectiveness, based on the battery of biological safety testing, performance testing, and other scientific evidence provided in this submission.

Performance Testing Summary:
All necessary testing has been performed for the worst-case configuration of the EPORE® XO cup system to assure substantial equivalence to its predicates and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of finished devices.

The performance of the EPORE® XO cup system was characterized through the following testing:

- Thickness Evaluation
- Acetabular Cup Deformation

- Acetabular Cup Deformation
- Acetabular Cup Unsupported Fatigue Test
- Modular Disassembly (Cup-Inay)
- EPORE® Characterization
- Burst Test, Fatigue Test, Post-Fatigue Burst Test, Femoral Head Impact
- Taper Disassembly (Axial Disassembly of Head-Stem)
- Range of Motion
- Impingement Testing
- Wear Testing
- Validation Testing for Additively Manufactured Components

Substantial Equivalence:
The EPORE® XO cup system is substantially equivalent in materials, indications, function, and/or performance to the predicate implantcast GmbH EcoFit® Hip System (K180263/ K203420/ K163577.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above. The EPORE® XO cup system is as safe, as effective, and performs as well as, or better, than the predicate devices.