June 3, 2024

implantcast GmbH
℅ Dave McGurl
Vice President, Regulatory Affairs - Orthopedics
MCRA, LLC
803 7th St NW, Floor 3
Washington, District of Columbia 20001

Re: K240834
Trade/Device Name: EcoFit® short stem cementless cpTi
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: LZO, KWY, OQI
Dated: March 26, 2024
Received: March 26, 2024

Dear Dave McGurl:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240834

Device Name

EcoFit® short stem cementless cpTi

Indications for Use *(Describe)*

The EcoFit® hip stems are intended to be used in total hip arthroplasty for the following indications:
- 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 total hip arthroplasty.

The EcoFit® hip stems are intended for uncemented, press-fit fixation.

The EcoFit® hip stems are intended to be used in partial (hemi) hip arthroplasty in conjunction with the ic-Bipolar Head System for the following indications:
- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

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

Device Trade Name:	EcoFit® short stem cementless cpTi
Common Name:	Hip Stems and Associated Surgical Instruments
Manufacturer:	implantcast GmbH Lüneburger Schanze 26 21614 Buxtehude Germany
Contact:	Ms. Juliane Hoeppner Phone: +49 4146 744-135 j.hoeppner@implantcast.de
Prepared by:	Mr. Dave McGurl MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800 dmcgurl@mcra.com
Date Prepared:	May 28, 2024
Classifications:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Class:	II
Product Codes:	LZO, KWY, OQI
Predicate Devices:	EcoFit® Hip System (K163577, K203420, K191569, K180263)

Indications For Use:

The EcoFit® hip stems are intended to be used in total hip arthroplasty for the following indications:

- 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
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- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Device Description:
The purpose of this Traditional 510(k) is to expand the EcoFit® Hip System with a line extension to the existing EcoFit® short stems cementless cpTi. The new EcoFit® short stems cementless cpTi are available in two different sizes 16.25 mm and 18.75 mm and in both standard and lateralized offset versions. The new EcoFit® short stems cementless cpTi included in the subject 510(k) are intermediate sizes, as compared to the EcoFit® short stems cementless cpTi predicate devices

Substantial Equivalence:
The EcoFit® short stems cementless cpTi are substantially equivalent to the EcoFit® short stems cementless cpTi of the predicate device system, EcoFit® Hip System, cited on the previous page with respect to the intended use, design, and materials.

Performance Testing Summary:
All necessary testing has been performed for the worst-case configuration of the EcoFit® Hip System to demonstrate that no new worst-cases were introduced for the subject EcoFit® Short Stems cementless cpTi and the subject devices perform as intended. All testing was performed on test units representative of the finished device. The following testing was conducted to characterize the devices:

- Fatigue Strength Testing (ISO 7206-4 & ISO 7206-6)
- Range of Motion (ROM) Evaluation
- Impingement Testing (ASTM F2582)
- Taper Disassembly Testing (ASTM F2009)

- Fretting Corrosion Evaluation
- Coating Characterization

Conclusion:
The subject device and the EcoFit® short stems cementless cpTi of the predicate device system have the same intended use and technological characteristics.. Therefore, the EcoFit® short stems cementless cpTi are substantially equivalent to the predicate devices for the intended use.