July 20, 2018

implantcast Gmbh
% Dave Mcgurl
Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K180263
Trade/Device Name: EcoFit Vit E Acetabular 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: LZO, OQI
Dated: June 21, 2018
Received: June 22, 2018

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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180263

Device Name
EcoFit® Vit E Acetabular System

Indications for Use *(Describe)*
The EcoFit® Hip System is indicated for use as a total hip replacement 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 total hip arthroplasty.

The EcoFit® Hip Stem and EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

Device Trade Name:	EcoFit® Vit E Acetabular System
Manufacturer:	implantcast GmbH Lueneburger Schanze 26 21614 Buxtehude Germany
Contact:	Ms. Juliane Höppner Phone: +49 4161 744-135 Fax: +49 4161 744-200 j.hoeppner@implantcast.de
Prepared by:	Mr. Dave McGurl Director, Regulatory Affairs Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: 202.552.5797 Fax: 202.552.5798 dmcgurl@mcra.com
Date Prepared:	July 12, 2018
Classification:	21 CFR 888.3353
Class:	II
Product Codes:	LZO, OQI
Primary Predicate Device:	implantcast GmbH EcoFit® Hip System (K163577)
Additional Predicates:	Zimmer, Inc. Continuum and Trilogy Cups (K091508) Aesculap, Inc. Acetabular Cups Plasmacup® SC (K042344) Aesculap, Inc. Plasmacup® NSC (K061699) Total Joint Orthopedics, Inc. Klassic HD Acetabular Insert With E-Link Poly (K141972) MicroPort Orthopedics, Inc. PROCOTYL® PRIME E-CLASS™ XLPE Liner (K171181) MicroPort Orthopedics, Inc. PROCOTYL® L-O Acetabular System (K142119) Zimmer GmbH Avenir Muller Stem (K123392)

Indications for Use:
The EcoFit® Hip System is indicated for use as a total hip replacement 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 total hip arthroplasty.

The EcoFit® Hip Stem and EcoFit® Acetabular Cup is intended for uncemented, press-fit fixation.

Device Description:
The EcoFit® Vit E Acetabular System is a line extension of EcoFit® Hip System, a modular hip replacement system offering various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient. The EcoFit® Vit E Acetabular System adds additional liners, CoCr femoral heads, and Biolox® delta heads to the currently cleared system. Additionally, Vit E liners are added as compatible components in the system.

Performance Testing:
All necessary testing has been performed for the worst-case configuration of the EcoFit® Vit E Acetabular 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 EcoFit® Acetabular System was characterized through the following tests:

- Modular Disassembly
- Normal Wear
- Abrasive Wear
- Impingement
- Range of Motion
- UHMWPE Particle Analysis
- UHMWPE Characterization
- Ceramic Burst
- Ceramic Axial Fatigue

Substantial Equivalence:
The EcoFit Vit E Acetabular System is substantially equivalent in materials, indications, function and/or performance to the predicate devices (K163577, K091508, K042344, K061699, K141972, K171181, K142119, and K123392).