DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Septemeber 25, 2017

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

Re: K163577
Trade/Device Name: Ecofit® Hip 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
Dated: August 22, 2017
Received: August 22, 2017

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -S

for
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163577

Device Name
EcoFit® Hip 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 are 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

510(k) SPONSOR: **implantcast GmbH**
Lueneburger Schanze 26
21614 Buxtehude
Germany

Contact: Juliane Höppner
Email: j.hoeppner@implantcast.de
Telephone: +49 4161 744-135
FAX: +49 4161 744-200

TRADE NAME: EcoFit® Hip System

COMMON NAME: Total Hip Replacement

Product	Regulation and Description	Description	Product Code	Device Class
EcoFit® Hip System	**21 CFR 888.3353**	**Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.**	**LZO**	**II**

PREDICATE DEVICES:

- Biomet Taperloc® Complete (K101086, K103755)
- Zimmer® M/L Taper Hip Prosthesis (K032726)
- Biomet Taperloc® Complete Size 4mm and XR 123° (K120030)
- Biomet Taperloc® Complete Microplasty System (K110400)
- Zimmer Continuum™ and Trilogy® Integrated Taper (IT) Acetabular Systems (K091508)
- Aesculap Excia Total Hip System - Plasmacup SC (K042344) and Plasmacup NSC (K061699)
- Theken Companies iNSitu Total Hip System (K161184)
- Smith & Nephew REFLECTION ACETABULAR COMPONENT (K932755, K022556)
- Zimmer BIOLOX® Delta Ceramic Femoral Head (K071535, K130899)
- Zimmer VerSys® Fiber Hip Prosthesis (K061786, K964769)
- Total Joint Orthopedics Klassic HD Hip System (K143407)

DEVICE DESCRIPTION:

The EcoFit® Hip System consists of EcoFit® femoral hip stems, modular Cobalt Chrome Molybdenum alloy femoral heads, and modular metal backed acetabular cups with ultra-high molecular weight polyethylene liners.

The EcoFit® femoral stem system includes three versions: the standard length stem, the short stem and a Coxa Vara version. The EcoFit® femoral hip stem is collarless, straight, monoblock, flat tapered wedge design manufactured from $TiAl_6V_4$ alloy. The stem tapers from proximal to distal and is designed with a rectangular cross sectional geometry to provide rotational stability. A plasma sprayed coating of commercially pure titanium (cpTi) is applied to the proximal half of the stem. The modular femoral heads are manufactured from Cobalt Chrome Molybdenum alloy and attach to the femoral stem via a Morse style taper in a diameter of 32 mm in several neck lengths.

The EcoFit® Acetabular Cup is a two (2) piece modular acetabular cup consisting of a metal shell and a polyethylene liner. The metal shell is manufactured from $TiAl_6V_4$ alloy and a plasma sprayed coating of commercially pure titanium (cpTi) is applied to the back of the metal shell. The polyethylene liner is manufactured from ultra-high molecular weight polyethylene and is available with an inner diameter of 32 mm for use with 32 mm outer diameter femoral head. The metal shell has a threaded insertion hole at the apex and the shell is available in two (2) versions, one with three (3) peripheral holes for the placement of bone screws as needed for adjunctive fixation and one without screw holes. A threaded apex hole plug is provided to fill the threaded insertion hole after shell placement while bone screw hole plugs are available to fill screw holes that are not used.

The EcoFit® hip stems and EcoFit® acetabular cups are intended for uncemented press-fit application.

INTENDED USE AND 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 are intended for uncemented, press-fit fixation.

SUMMARY OF TECHNOLOGIES:

The EcoFit® Hip System is substantially equivalent to the previously cleared predicate devices based on similarities in intended use and indications, design features, materials, packaging and sterilization methods. Additionally, the EcoFit® Hip System is similar in fixation methods and comes in a similar range of sizes as the predicate devices.

NON-CLINICAL TESTING:

The following testing was performed to demonstrate substantial equivalency of the EcoFit® Hip System to the predicate devices. The results of the testing show that the EcoFit® Hip System is safe and effective for the proposed indications.

Test	Test Method	Results
Metallic Bone Screw Test (Torsional Properties, Driving Torque, Pull-Out Strength)	ASTM F 543	Acceptable
Liner Disassembly Acetabular Shell - Liner (Push-Out, Lever-Out, Torsionals Properties)	ASTM F 1820	Acceptable
Taper disassembly (Axial Disassembly Force Head – Femoral Stem)	ASTM F 2009	Acceptable
Impingement EcoFit® Cup – Stem	ASTM F 2582	Acceptable
Fatigue Strength EcoFit® Hip Stem – Distal	ISO 7206-4	Pass
Fatigue Strength EcoFit® Hip Stem – Proximal (Neck Region)	ISO 7206-6	Pass
Fretting corrosion evaluation	/	Acceptable
ROM EcoFit® Hip Stem – EcoFit® Cup	ISO 21535 Annex A	Acceptable
Biocompatibility	ISO 10993	Pass

CLINICAL TESTING:

Animal and clinical testing was not necessary to determine substantial equivalence between the EcoFit® Hip System and the predicate devices.

CONCLUSIONS:

Based on the intended use, materials, design and testing provided, the 510(k) demonstrates substantial equivalence to the predicate devices cited in this summary.