June 20, 2023

implantcast Gmbh
% Dave McGurl
Vice President, Regulatory Affairs - Orthopedics
MCRA, LLC.
803 7th Street NW
Third Floor
Washington, District of Columbia 20001

Re: K223103
Trade/Device Name: BethaLoc® stem cementless HA
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: May 19, 2023
Received: May 19, 2023

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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)*

K223103

Device Name
BethaLoc® stem cementless HA

Indications for Use *(Describe)*

The EcoFit®, implaFit® and BethaLoc® hip stems are indicated for use 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®, implaFit® and BethaLoc® hip stems, when used in conjunction with the ic-Bipolar Heads, are intended 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.

The EcoFit® hip stems, the implaFit® hip stems cementless and the BethaLoc® hip stems are intended for uncemented, press-fit fixation.
The implaFit® hip stems cemented are intended for cemented fixation.
The ic-Bipolar Head System is intended for uncemented use in hemiarthroplasty, where the femoral head requires replacement but the acetabulum does not, in conjunction with the BethaLoc® hip stems and EcoFit® Hip 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.**

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."*

# 510(K) SUMMARY

| | |
|---|---|
| **Manufacturer:** | implantcast GmbH<br>Lueneburger Schanze 26<br>21614 Buxtehude<br>Germany |
| **Contact:** | Ms. Juliane Höppner<br>Phone: +49 4161 744-135<br>Fax: +49 4161 744-200<br>j.hoeppner@implantcast.de |
| **Prepared By:** | Mr. Dave McGurl<br>MCRA, LLC<br>803 7th St NW, Floor 3<br>Washington, DC 20001<br>dmcgurl@mcra.com |
| **Date Prepared:** | June 15, 2023 |
| **Device Trade Name:** | BethaLoc® stem cementless HA |
| **Device Class and Common Name:** | Class II, Total Hip Replacement |
| **Classification:** | 21 CFR 888.3353: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis<br>21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis |
| **Product Codes:** | LZO, KWY, OQI |
| **Indications for Use:** | The EcoFit®, implaFit® and BethaLoc® hip stems are indicated for use in cases of:<br>• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;<br>• 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®, implaFit® and BethaLoc® hip stems, when used in conjunction with the ic-Bipolar Heads, are intended 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.

The EcoFit® hip stems, the implaFit® hip stems cementless and the BethaLoc® hip stems are intended for uncemented, press-fit fixation.
The implaFit® hip stems cemented are intended for cemented fixation.

The ic-Bipolar Head System is intended for uncemented use in hemiarthroplasty, where the femoral head requires replacement but the acetabulum does not, in conjunction with the BethaLoc® hip stems and EcoFit® Hip 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.

**Device Description:** The purpose of this Traditional 510(k) is introduce into interstate commerce in the United States the BethaLoc® hip stems. The BethaLoc® hip stems are femoral stems for total or hemi hip arthroplasty. The BethaLoc® hip stems are available in standard and lateralized offset configurations.

The BethaLoc® hip stems are monoblock, tapered straight stems made from titanium alloy with a partial coating of hydroxyapatite (HA). They are fixed by press-fitting.

The BethaLoc® hip stems are intended to be used with previously cleared EcoFit® Hip components.

**Predicate Devices:**

Primary Predicate:

- EcoFit® Hip System (K203420 K163577, K180263, and K191569)

Reference Devices:

- Smith & Nephew, Inc. SL-PLUS™ MIA Femoral Stem with Ti/HA and SL-PLUS™ Femoral Stem with Ti/HA (K122296 and K143096)
- Encore Medical TaperFill™ Femoral Hip Stem (K130099)

**Substantial Equivalence:**

The BethaLoc® hip stems are substantially equivalent to the hip stems of the legally marketed predicate device systems, the implantcast EcoFit® Hip System, the Smith & Nephew, Inc. SL-PLUS™ MIA Femoral Stem with Ti/HA and SL-PLUS™ Femoral Stem with Ti/HA, and the Encore Medical TaperFill™ Femoral Hip Stem with respect to intended use and design. There are some differences in stem geometry and dimensions of the BethaLoc® hip stems as compared to the EcoFit® Hip System predicate. These differences include cross-sectional geometry, head/neck angle, stem length, neck length, and offset length. These differences do not raise new questions of safety and effectiveness.

**Performance Testing:**

All necessary testing has been performed for the "worst-case" components of the BethaLoc® hip stems 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 or worst-case compared to the finished device. The following evaluations were conducted to characterize the devices:

- Fatigue Testing (ISO 7206-4 and ISO 7206-6)
- Impingement Testing (ASTM F2582-14)

- Taper Disassembly Testing (ASTM F2009)
- Range of Motion (ROM) Evaluation (ISO 21535)
- Coating Characterization (ASTM F1980, ASTM F1609, ASTM F1185, ASTM F1044, ASTM F1147, ASTM F1926, ASTM F1160, ASTM F2024, ISO 13779)
- Corrosion and Fretting Fatigue Rationale
- Biocompatibility (ISO 10993-1)
  - Cytotoxicity (ISO 10993-5)
  - Sensitization (ISO 10993-10)
  - Irritation (ISO 10993-10)
  - Material-Mediated Pyrogenicity (ISO 10993-11)
  - Genotoxicity (ISO 10993-3)
  - Chemical Characterization (ISO 10993-18)
  - Toxicological Risk Assessment (ISO 10993-17)

**Conclusions:** The BethaLoc® hip stems subject to this submission possess the same intended use as and similar technological characteristics to the predicate device system components. All performance testing conducted for the BethaLoc® hip systems met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the BethaLoc® hip stems components are substantially equivalent to the predicate devices for the intended use.