October 19, 2023

implantcast, GmbH
% Juliane Hoppner
Regulatory Affairs Manager
Implantcast GmbH
Luneburger Schanze 26
Buxtehude, Germany

Re: K232371
Trade/Device Name: Actinia® hip stems
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, MEH, KWY
Dated: August 8, 2023
Received: August 8, 2023

Dear Juliane Hoppner:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232371

Device Name
Actinia® hip stems

Indications for Use *(Describe)*
The Actinia® 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 Actinia® hip stems cementless are intended for uncemented, press-fit fixation.

The Actinia® 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

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:	Ms. Hannah Irwin MCRA, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: 202.552.5820 hirwin@mcra.com
Date Prepared:	October 17, 2023
Device Trade Name:	Actinia® hip stems
Device Class and Common Name:	Class II, Uncemented Hip Prothesis
Classification:	21 CFR 888.3353: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Product Codes:	LZO, MEH, KWY
Indications for Use:	The Actinia® 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 Actinia® hip stems cementless are intended for uncemented, press-fit fixation.

The Actinia® 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.

Device Description:

The purpose of this Traditional 510(k) is to introduce into interstate commerce in the United States the Actinia® hip stems. The Actinia® hip stems are femoral stems for total or hemi hip arthroplasty. The Actinia® hip stems include collared and collarless variants in both standard and lateralized offset configurations. Additionally, the scope includes the coxa vara hip stem variant in a standard offset configuration.

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

The Actinia® hip stems are to be used alongside other previously cleared components to make a complete prosthesis. Specifically, Actinia® hip stems are compatible with legally marketed heads used with the implantcast EcoFit® Hip System (K163577, K180263 and K191569) and the implantcast ic-Bipolar Head System (K191569).

Predicate Devices:

- implaFit® hip stems (K210678)

Reference Devices:

- DePuy Orthopaedics, Inc. Corail AMT Hip Prosthesis (K203167)
- EcoFit® Hip System (K163577, K180263, K191569 and K203420)

Substantial Equivalence:

The Actinia® hip stems are similar to components previously cleared with the implaFit® hip stems (K210678). Both feature cementless femoral hip stems that are monoblock, tapered (12/14) and made from titanium alloy. The indications for the

subject and predicate devices are identical, with the exception of the implaFit® hip stems also include hip stems for cemented use, as well as cementless; equivalence is only claimed for the cementless indications.

There are some differences in stem material, geometry, and dimensions for the Actinia® hip stems as compared to the implaFit® hip stems predicate. These differences include stem coating, collarless design, cross-sectional geometry, stem length (shoulder to tip and lower shoulder to tip), neck length, and offset length.

The Actinia® hip stems are substantially equivalent to the hip stems of the legally marketed predicate and reference device systems, the implaFit® him stems, DePuy Orthopaedics, Inc. Corail AMT Hip Prothesis and EcoFit® Hip System, with respect to design and intended use.

Performance Testing: All necessary testing has been performed for the "worst-case" components of the Actinia® hip stems to assure substantial equivalence to its predicate and reference devices 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 F1609, ASTM F1926, ASTM F2024, and ISO 13779)
- Corrosion and Fretting Performance Rationale

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