August 17, 2022

implantcast, GmbH
% Dave McGurl
Vice President, Regulatory Affairs – Orthopedics
MCRA, LLC.
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K210678
Trade/Device Name: implaFit® 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, KWY, JDI
Dated: July 20, 2022
Received: July 21, 2022

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210678

Device Name
implaFit® hip stems

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

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510(K) SUMMARY

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Phone: 202.552.5797
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Date Prepared: August 15, 2022

Device Trade Name: implaFit® hip stems

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

21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis.

21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

Product Codes: LZO, KWY, JDI

Indications for Use: The indications for use for the proposed implaFit® hip stems are as follows:

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

Device Description:

The purpose of this Traditional 510(k) is introduce into interstate commerce in the United States the implaFit® hip stems. The implaFit® hip stems are femoral stems for total or hemi hip arthroplasty. The implaFit® hip stems include cementless and cemented configurations (i.e., the implaFit® hip stems cementless and the implaFit® hip stems cemented).

The implaFit® hip stems cementless are monoblock, collarless tapered straight stems made from titanium alloy with a partial coating of commercially pure titanium (cpTi). They are fixed by press-fitting.

The implaFit® hip stems cemented are monoblock, collared, tapered straight stems made from cobalt chromium (CoCrMo). They are fixed using cement.

Predicate Devices:

Primary Predicate:

- EcoFit® Hip System (K163577)

Reference Devices:

- EcoFit® Hip System (K180263, K191569)
- DePuy Orthopaedics, Inc. Summit DuoFix Hip (K193398)
- Summit Cemented Hip Prosthesis (K013352)

Substantial Equivalence:

The implaFit® hip stems cementless are similar to components previously cleared with the EcoFit® Hip System

(K191569). Both are cementless femoral hip stems that are monoblock, collarless, tapered (12/14), and made from titanium alloy. In addition, both have a commercially pure titanium (cpTi) coating on the proximal end side of the stem, starting at the upper shoulder.

There are some differences in stem material, geometry, and dimensions implaFit® hip stems as compared to the EcoFit® Hip System predicate. These differences include the material, cross-sectional geometry, head/neck angle, stem length (lower shoulder to tip), neck length, and offset length.

The implaFit® hip stems are substantially equivalent to the hip stems of the legally marketed predicate device systems, the implantcast EcoFit® Hip System, the DePuy Orthopaedics, Inc. Summit Cemented Hip Prosthesis, and the DePuy Orthopaedics, Inc. Summit DuoFix Hip with respect to intended use and design.

Performance Testing: All necessary testing has been performed for the "worst-case" components of the implaFit® 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 F1820)
- Range of Motion (ROM) Evaluation (ISO 21535)
- Coating Testing (ASTM F1147, F1044, F1978, F1854, F1160)
- Wear / Corrosion Evaluation

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