March 12, 2026

implantcast GmbH
% Ryan Sexton
Manager, Regulatory Affairs
MCRA, LLC
803 7th Street, NW, 4th Floor
Washington, District of Columbia 20001

Re: K252401
Trade/Device Name: implaFit® short 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: January 29, 2026
Received: January 29, 2026

Dear Ryan Sexton:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252401

Please provide the device trade name(s).

implaFit® short stems

Please provide your Indications for Use below.

The implaFit® short 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 implaFit® short stems are intended for uncemented, press-fit fixation.

The implaFit® short 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Device Trade Name:	implaFit® short stems
Manufacturer:	implantcast GmbH Lüneburger Schanze 26, Buxtehude 21614 Germany
Primary Contact:	Mr. Ryan Sexton MCRA, LLC Manager, Regulatory Affairs rsexton@mcra.com
Secondary Contact:	Ms. Juliane Höppner implantcast GmbH Director Regulatory & Clinical & Biological Affairs j.hoeppner@implantcast.de
Prepared by:	MCRA, LLC 803 7th Street, NW, 4th Floor Washington, DC 20001 Office: (732) 770-7662
Date Prepared:	March 11, 2026
Classifications:	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
Class:	II
Product Codes:	LZO, MEH, KWY
Primary Predicate:	implaFit® hip stem (K210678)
Additional Predicate:	DePuy Actis DuoFix Hip Prosthesis (K150862)

Indications For Use:
The implaFit® short 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 implaFit® short stems are intended for uncemented, press-fit fixation.

The implaFit® short 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 implantcast's implaFit® Short Stems. The components introduced with this submission are intended to mate with other previously cleared components to make a complete prosthesis. The implaFit® short stem with collar cementless are offered in standard and lateralized offset versions. The components included in this submission consist of titanium alloy femoral hip stems, used in total and hemi hip arthroplasty and are intended for uncemented press fit application.

Predicate Device:
implantcast submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the implaFit® Short Stems are substantially equivalent to the following predicate devices:

Primary Predicate: implaFit® hip stem (K210678)
Reference Device: DePuy Actis DuoFix Hip Prosthesis (K150862)

Performance Testing Summary:
All testing was performed on test units representative of the finished device. The following testing was conducted to characterize the devices:

- Fatigue Strength Testing (ISO 7206-4 & ISO 7206-6)
- Range of Motion (ROM) Evaluation (ISO 21535)
- Impingement Evaluation (ASTM F2582)
- Taper Disassembly Evaluation (ASTM F2009 & ISO 7206-13)
- Fretting Corrosion Evaluation
- Wear of Total Hip-Joint Prostheses Evaluation
- Burst evaluation, fatigue evaluation, post-fatigue burst evaluation, and femoral head impact evaluation

- Coating Characterization (ASTM F2024, ASTM F1854, ASTM F1160, ASTM F1147, ASTM F1044, ASTM F1978, ASTM F1185, ASTM F1609, ASTM F1926, ISO 13179-1, ISO 13779-2, ISO 13779-3, ISO 13779-6)

All performance testing conducted for the implaFit® Short Stems met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the implaFit® Short Stems are substantially equivalent to the stems of the predicate devices for the intended use.

Substantial Equivalence:
The subject implantcast implaFit® short stem and the implaFit® hip stem predicate are straight, monoblock, tapered femoral hip stem designs. The key design features of the subject device are equivalent to those of the implaFit® hip stems cementless. Although there are minor differences in stem shape, dimensions and coating, the performance testing supports that the two devices are substantially equivalent.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.