June 16, 2022

DePuy International, Ltd
% Reily Inman
Regulatory Affairs Program Lead
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K201348
Trade/Device Name: DePuy 3D Additive TriFlange Acetabular Cup
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, MEH
Dated: June 9, 2022
Received: June 10, 2022

Dear Reily Inman:

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.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201348

Device Name

DePuy 3D Additive TriFlange Acetabular Cup

Indications for Use *(Describe)*

The TriFlange Hip Prosthesis is intended to be used with modular liners to resurface the acetabular socket in cementless application during total hip arthroplasty.

The TriFlange Hip Prosthesis is indicated in the following conditions:

1. Where bone loss is present in the acetabular region
2. Pelvic discontinuities

Porous-coated TriFlange Hip Prostheses are indicated for cementless applications.

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

(As required by 21 CFR 807.92)

Submitter Information	
Name	DePuy International Ltd
Address	St. Anthony's Road Leeds United Kingdom LS11 8DT
Phone number	574-453-7014
Establishment Registration Number	8010379
Name of contact person	Reily Inman
Date prepared	June 16, 2022
Name of device	
Trade or proprietary name	DePuy 3D Additive TriFlange Acetabular Cup
Common or usual name	Acetabular cup
Classification name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3358, 888.3353
Product Code(s)	LPH, MEH
Legally marketed device(s) to which equivalence is claimed	DePuy TriFlange II Acetabular Cup System (K040383)
Reason for 510(k) submission	New manufacturing method – The subject devices are manufactured by additive manufacturing
Device description	The 3D Additive TriFlange Acetabular Cup is a patient-specific cup system designed and manufactured to match the individual patient's anatomy. The system consists of a porous coated acetabular cup with three patient-specific ilial, ischial and pubic flanges. The cup is manufactured via additive manufacturing technology using Ti6Al4V ELI powder, followed by traditional finishing operations. The cups may have

	hydroxyapatite (HA) coating. The cups are intended for cementless use only.
Intended Use	Total hip arthroplasty
Indications for use	The TriFlange Hip Prosthesis is indicated in the following conditions: 1. Where bone loss is present in the acetabular region 2. Pelvic discontinuities Porous-coated TriFlange Hip Prostheses are indicated for cementless applications.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristics	**Subject Device: DePuy 3d Additive TriFlange Acetabular Cup**	**Predicate Device: DePuy TriFlange II Acetabular Cup System (K040383)**
Intended Use	Total hip arthroplasty	Same
Material	Ti6Al4V with Porocoat, with and without plasma sprayed HA coating	Same
Fixation	Uncemented	Same
Cup Sizes	66mm OD only	48mm OD to 66mm OD
Flange Sizes	Patient specific within specified limits	Same
Sterile Method	Gamma	Same
Packaging	Double PETG blister with Tyvek peel lid	Same
Shelf Life	12 months	5 years

PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE
• Drawing comparison verification • Surface finish testing in accordance with ISO 4288 • Tensile testing in accordance with BS EN ISO 6892-1: 2011 • Corrosion testing in accordance with ASTM G3-14 and ASTM G5-14 • Hardness testing in accordance with ASTM E18-16 • Functional fatigue testing • Pyrogenicity testing using the Bacterial Endotoxin Testing (BET) method as specified in ANSI/AAMI ST-72: 2011
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical tests were conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject 3D Additive TriFlange devices are substantially equivalent to the predicate DePuy TriFlange II Acetabular Cup System.