September 20, 2023

DePuy Ireland UC
Susan Mullane
Associate Director Regulatory Affairs
Loughbeg, Ringaskiddy
Cork, Ireland

Re: K232556
Trade/Device Name: DePuy 3D Additive TriFlange Acetabular Cup and DePuy TriFlange II Acetabular Cup System
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: August 23, 2023
Received: August 23, 2023

Dear Susan Mullane:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K232556

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 bones 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.

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)*
K232556

Device Name

DePuy TriFlange II Acetabular Cup System

Indications for Use *(Describe)*

The system is intended to be used with modular liners to resurface the acetabular socket in cementless application during total hip arthroplasty.
Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Total hip replacement is indicated in the following conditions:
1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemi-arthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.
Porous-coated TriFlange Hip Prostheses are indicated for cement-less 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.

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510(K) SUMMARY
(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Cork, IRELAND
Phone number	35 (32) 149-14000
Fax number	574- 371-4987
Establishment Registration Number	3015516266
Name of contact person	Susan Mullane
Date prepared	19th September 2023
Name of device	
Trade or proprietary name	DePuy 3D Additive TriFlange Acetabular Cup DePuy TriFlange II Acetabular Cup System
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 3D Additive TriFlange Acetabular Cup (K201348) DePuy TriFlange II Acetabular Cup System (K040383) (Primary Predicate)

Reason for 510(k) submission	The only change for this submission is that the HA coating process will be conducted at an alternate facility. All other process remain the same and within the same approved facility.
Device description	The 3D Additive TriFlange Acetabular Cup and TriFlange II Acetabular Cup System is an acetabular cup system designed and manufactured to match the individual patient's anatomy. The system consists of a porous coated acetabular cup (Pinnacle cup) with three patients specific illial, ischial and pubic flanges added to reinforce weak acetabula. The device may be fixed in place with titanium bone screws of various lengths through a variety of screw holes in the flanges. The 3D Additive TriFlange Acetabular Cup is manufactured via additive manufacturing technology using Ti6Al4V ELI powder, followed by traditional finishing operations. TriFlange II Acetabular Cup System is following traditional CNC machining manufacturing process. The cups are intended for cementless use only. The proposed changes apply to product codes with hydroxyapatite (HA) coating.
Intended use of the device	Total hip arthroplasty
Indications for use	**DePuy 3D Additive TriFlange Acetabular Cup (K201348):** 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 bones loss is present in the acetabular region 2. Pelvic discontinuities Porous-coated TriFlange Hip Prostheses are indicated for cementless applications.

	DePuy TriFlange II Acetabular Cup System (K040383): The system is intended to be used with modular liners to resurface the acetabular socket in cementless application during total hip arthroplasty. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemi-arthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. Porous-coated TriFlange Hip Prostheses are indicated for cement-less applications.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	**Subject Device: Triflange**	**Predicate Device: DePuy 3D Additive TriFlange Acetabular Cup (K201348)**	**Predicate Device: DePuy TriFlange II Acetabular Cup System (K040383)**
Intended Use	Total Hip Arthroplasty	Same	Same
Material	The Triflange acetabular shells, subject of this submission, are manufactured from titanium alloy (Ti6Al4V) for surgical implant applications and are coated with beaded porous coating and plasma sprayed with hydroxyapatite (HA), which are identical materials to the predicate devices. The HA Coating process will be completed in an alternate site.	Ti6Al4V with Porocoat, with and without plasma sprayed HA coating	Same
Fixation	Uncemented	Same	Same
Cup Sizes	48mm OD to 66mm OD	Same	Same
Flange Sizes	Patient specific	Same	Same
Sterile Method	Gamma	Same	Same

Packaging	Double PETG blister with Tyvek peel lid	Same	Same
Shelf Life	5 years	Same	Same

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

- HA Powder characterization to ISO 13779-6, ISO 13779-2 ISO 13779-3 and ASTM F1185.
- HA Coating thickness per ASTM F1854.
- HA Coating characterization to ISO 13779-6, ISO 13779-2 ISO 13779-3 and ASTM F1185.
- Tensile Adhesion testing per ASTM F1147-05.
- Shear Adhesion testing per ASTM F1044-05.
- Rotating Beam Fatigue per ASTM F1160.
- Solubility of HA particles before and after HA coating
- Dissolution of HA particles before and after HA coating per ASTM F1926-10
- FTIR analysis of HA powder before and after HA coating.

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 devices are substantially equivalent to the predicate DePuy 3D Additive TriFlange Acetabular Cup (K201348) and DePuy TriFlange II Acetabular Cup System (K040383).