January 6, 2022

DePuy Orthopaedics Inc.
% Paul Shin
Project Lead, Regulatory Affairs
DePuy (Ireland)
Loughbeg, Ringaskiddy
Cork, Cork P43ED82
Ireland

Re: K213839
Trade/Device Name: DePuy Corail AMT Hip Prosthesis
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, KWL, KWY
Dated: December 8, 2021
Received: December 9, 2021

Dear Paul Shin:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213839

Device Name

DePuy Corail AMT Hip Prosthesis

Indications for Use *(Describe)*

Total hip replacement or hip arthroplasty 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 ankyloses.

Partial hip replacement or hip hemi-arthroplasty is indicated in the following conditions:
1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head.
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hip hemiarthroplasty.

HA coated stems of the Corail Hip system are indicated for cementless use only.

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

Submitter Information	
Name	DePuy Orthopaedics, Inc.
Address	700 Orthopaedic Drive Warsaw, IN 46852
Phone number	(574) 404-8348
Fax number	N/A
Establishment Registration Number	1818910
Name of contact person	Paul Shin
Date prepared	December 7, 2021
Name of device	
Trade or proprietary name	DePuy Corail AMT Hip Prosthesis
Common or usual name	Uncemented hip prosthesis
Classification name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3353, 888.3360, 888.3390
Product Code(s)	LZO, MEH, KWL, KWY
Legally marketed device(s) to which equivalence is claimed	DePuy Corail AMT Hip Prosthesis (K042992, K093736, K190344, K192946, K203167).
Reason for 510(k) submission	The purpose of this submission is to implement the following: • Addition of DePuy Ireland as a hydroxyapatite (HA) coating site. • Increase in the shelf life of **specific product codes** of Corail AMT Hip stems from 5 years to 10 years. • Addition of an alternate manufacturing process flow.
Device description	The DePuy Corail AMT hip stem family are manufactured from forged titanium alloy (Ti6Al4V) and plasma-sprayed with a hydroxyapatite (HA) coating for

	bone fixation. The stem consists of a wide range of stem neck designs and sizes allowing an accurate anatomical match for each patient. Corail AMT stems are available with or without a collar, with various neck angles, and with various neck offsets.
Intended use of the device	Total hip arthroplasty and hemi-hip arthroplasty
Indications for use	**Total hip replacement or hip arthroplasty 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. **Partial hip replacement or hip hemi-arthroplasty is indicated in the following conditions:** 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hip hemi-arthroplasty. HA coated stems of the Corail Hip system are indicated for cementless use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE				
Characteristics	**Subject Device** **DePuy Corail AMT Hip Prosthesis** **DePuy Corail Revision Hip Prosthesis**	**Primary Predicate** **DePuy Corail AMT Hip Prosthesis (K042992)**	**Additional Predicates** **DePuy Corail AMT Hip Prosthesis (K203167, K190344)**	**Additional Predicates** **DePuy Corail Revision Hip Prosthesis (K203167, K192946, K093736)**
Intended Use	Total Hip Arthroplasty	Total Hip Arthroplasty	Total Hip Arthroplasty	Total Hip Arthroplasty
Material	Titanium Alloy (Ti6Al4V) with plasma sprayed HA coating	Titanium Alloy (Ti6Al4V) with plasma sprayed HA coating	Titanium Alloy (Ti6Al4V) with plasma sprayed HA coating	Titanium Alloy (Ti6Al4V) with plasma sprayed HA coating
Fixation	Uncemented	Uncemented	Uncemented	Uncemented
Sterilization Method	Gamma	Same	Same	Same
Packaging	Nylon Inner Pouch and outer PETG blister with Tyvek peel lid	Same	Same	Same
Shelf life	10 Years	5 Years	10 Years	10 Years
PERFORMANCE DATA				
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE				

The following tests were performed on the subject devices to demonstrate substantial equivalence of safety and effectiveness with the predicate devices:

- HA coating characterization supporting addition of alternate HA coating site
  - Completed the full suite of HA coating characterization and testing per FDA Guidance 510(k) *Information Needed for Hydroxyapatite Coated Orthopedic Implant*s 1997
- Conformational design verification testing supporting addition of alternate HA coating site
  - Body fatigue testing per ISO 7206-4
  - Neck fatigue testing per ISO 7206-6
- Packaging stability testing supporting increase in shelf life
  - Visual inspection per ASTM F1886-16: Standard test method for determining integrity of seals for flexible packaging by visual inspection
  - Dye Leak per ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye penetration
  - Seal strength per ASTM F88/F88M-15: Standard test method for seal strength of flexible barrier materials
- HA coating testing on shelf-aged product per
  - ISO-13779-2: Implants for surgery – Hydroxyapatite Part 2: Thermally Sprayed coatings of Hydroxyapatite
  - ISO-13779-3: Implants for surgery – Hydroxyapatite Part 3: Chemical analysis and characterization of crystallinity and phase purity.
  - ASTM F1854 – Standard test method for stereological evaluation of porous coatings on medical implants.
  - ASTM E2109 – Standard test methods for determining area percentage porosity in thermal sprayed coatings.

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 DePuy Corail AMT Hip Prosthesis devices are substantially equivalent to the predicate devices (K042992, K093736, K190344, K192946, K203167).