DePuy (Ireland)
% Melissa Cook
Regulatory Affairs Specialist III
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

November 1, 2019

Re: K190344
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: October 3, 2019
Received: October 4, 2019

Dear Melissa Cook:

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,

FOR Vesa Vuniqi
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)*

K190344

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 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.

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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K190344

510(K) SUMMARY

(As required by 21 CFR 807.92)

Submitter Information	
Name	DePuy (Ireland)
Address	Loughbeg Ringaskiddy Co. Cork, Ireland
Phone number	574-371-4906
Establishment Registration Number	9616671
Name of contact person	Melissa Cook
Date prepared	February 12, 2019
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 (K173960, cleared September 21, 2018) DePuy Corail AMT Hip Prosthesis (K123991, cleared September 16, 2013)
Reason for 510(k) submission	Line extension – The subject devices represent hip stems with additional sizes to allow surgeons more flexibility in the choice of stem sizes, neck angles, and neck offsets. The subject devices incorporate minor modifications to the plasma spray coating process and a labeling change.
Device description	The DePuy Corail AMT hip stems 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. The stems are compatible with both unipolar and bipolar heads intended for hip hemi-arthroplasty and with modular femoral heads intended for total hip arthroplasty.
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 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 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**	**Predicate Device: DePuy Corail AMT Hip Prosthesis (K173960)**	**Predicate Device: DePuy Corail AMT Hip Prosthesis (K123991)**
Intended Use	Total Hip Arthroplasty, Hemi-Hip Arthroplasty	Same	Same
Material	Ti6Al4V with plasma sprayed HA coating	Same	Same
Fixation	Uncemented	Same	Same
Stem Size	8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20	Same	Same
Neck Angle	125° and 135°	Same	Same
Neck Offset	Low, Standard, High	Same	Standard, High
Collar	Collared, Collarless	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			
• Neck fatigue testing in accordance with ISO 7206-6:1992 • Distal fatigue testing in accordance with ISO 7206-4:2010 • Taper compatibility test • Range of motion in accordance with ISO 21535:2009 • Reamer verification test • Pyrogenicity testing using the Bacterial Endotoxin Testing (BET) method as specified in ANSI/AAMI ST72:2011 • Hydroxyapatite coating process validations			

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 stems are substantially equivalent to the predicate DePuy Corail AMT hip stems.