September 21, 2018

DePuy France S.A.S.
% Melissa Cook
Regulatory Affairs Specialist
DePuy Orthopaedics, Inc.
700 Orthopaedic Dr.
Warsaw, Indiana 46582

Re: K173960
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: August 23, 2018
Received: August 24, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2018.09.21 12:01:54 -04'00'

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173960

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 (Ireland)
Address	Loughberg Ringaskiddy Cork, Ireland
Phone number	353 21 491 400
Fax number	
Establishment Registration Number	9616671
Name of contact person	Melissa Cook
Date prepared	23 August 2018
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 (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.
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 (K123991)**	**Reference Device: DePuy Corail Hip System, Revision Stem (K093736)**
Intended Use	Total Hip Arthroplasty, Hemi-Hip Arthroplasty	Same	Total Hip Arthroplasty
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	10, 11, 12, 13, 14, 15, 16, 18, 20
Neck Angle	125° and 135°	Same	135°
Neck Offset	Low, Standard, High	Standard, High	Standard, High
Collar	Collared, Collarless	Same	Collared
Sterile Method	Gamma	Same	Same
Packaging	Double PETG blister with Tyvek peel lid	Same	Same
Shelf Life	10 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
- Validation of taper dimension
- Validation of taper to head and neck to head dimension
- Range of motion in accordance with ISO 21535:2007
- Pyrogenicity testing using the Bacterial Endotoxin Testing (BET) method as specified in ANSI/AAMI ST72:2011
- Hydroxyapatite coating characterization, as specified by FDA Guidance *510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants*, in accordance with ASTM F1160-05:2011, ASTM F1044-05:2011, ASTM F1147-05:2011, ASTM F1926:2010 and ISO 13779-3:2008

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.