December 19, 2023

DePuy Ireland UC
Nicola Keedy
Regulatory Affairs Director
Loughbeg, Ringaskiddy
Co. Cork
Ireland

Re: K231526
Trade/Device Name: CORAIL Cemented Femoral Stem
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY, KWL, LZO
Dated: May 26, 2023
Received: December 8, 2023

Dear Nicola Keedy:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K231526

Device Name

CORAIL Cemented Femoral Stem

Indications for Use *(Describe)*

The use of CORAIL Cemented Femoral Stems is indicated in Total and Hemi hip replacements.

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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Partial hip 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. Avascular necrosis of the femoral head.
3. Non-union of femoral neck fractures.
4. Certain high subcapital and femoral neck fractures in the elderly.
5. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
6. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hip hemiarthroplasty.

The DePuy CORAIL Cemented Femoral Stems are indicated only for use with bone cement.

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

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork, IRELAND
Establishment Registration Number	3015516266
Name of contact person	Amy Joyce
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Alternative contact person	Nicola Keedy
e-mail address	NKeedy@its.jnj.com
Work mobile	+44 7824320636 (UK time zone)
Date prepared	26th May 2023
Name of device	
Trade or proprietary name	CORAIL Cemented Femoral Stem
Common or usual name	Hip Stem
Classification name	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3390, 888.3360, 888.3353
Product Code(s)	KWY, KWL, LZO
Legally marketed device(s) to which equivalence is claimed	Primary predicate - DePuy CORAIL AMT Hip Prosthesis K123991, cleared September 16, 2013 Secondary predicate – C-STEM AMT LE Prosthesis K220216, cleared July 22, 2022
Reason for 510(k) submission	The purpose of this 510K submission is to obtain market clearance for the CORAIL Cemented Femoral Stem
Device description	The CORAIL Cemented Femoral Stem is manufactured from wrought high nitrogen stainless steel, and is designed to be used as one component of a

	system of prostheses in hip arthroplasty. The stems are compatible with both unipolar and bipolar femoral heads intended for hemi-hip arthroplasty and with modular metal and ceramic femoral heads intended for total hip arthroplasty. The CORAIL Cemented Femoral Stem implants are uncoated with a polished finish, intended for use with bone cement. The stem consists of a wide range of stem neck designs and sizes allowing an accurate anatomical match for a wide range of patients. The CORAIL Cemented Femoral Stem is designed to provide a cemented version of the primary predicate DePuy CORAIL AMT Hip Prosthesis stem (cleared under 510(k) K123991).
Intended use of the device	Total hip arthroplasty and hemi-hip arthroplasty
Indications for use	The use of CORAIL Cemented Femoral Stems is indicated in Total and Hemi hip replacements. 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, hemiarthroplasty, 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. Avascular necrosis of the femoral head. 3. Non-union of femoral neck fractures. 4. Certain high subcapital and femoral neck fractures in the elderly. 5. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 6. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hip hemiarthroplasty. The CORAIL Cemented Femoral Stems are indicated only for use with bone cement.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES			
Characteristics	**Subject Device: CORAIL Cemented Femoral Stem**	**Primary Predicate Device: DePuy CORAIL AMT Hip Prosthesis K123991**	**Secondary Predicate Device: C-STEM AMT LE Prosthesis K220216**
Intended Use and Indications for Use	The subject device has the same intended use as primary predicate K123991. The subject device is indicated for total and hemi hip arthroplasty, same as primary predicate K123991, and indicated for cemented use, same as secondary predicate K220216.	Intended for use in total hip arthroplasty and hemi-hip arthroplasty. 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 arthroplasty 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. Avascular necrosis of the femoral head. 3. Non-union of femoral neck fractures. 4. Certain high subcapital and femoral neck fractures in the elderly. 5. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 6. 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.	Intended for use in total hip arthroplasty. 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. The C-STEM AMT Hip Prosthesis is indicated for cemented use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES			
Characteristics	**Subject Device: CORAIL Cemented Femoral Stem**	**Primary Predicate Device: DePuy CORAIL AMT Hip Prosthesis K123991**	**Secondary Predicate Device: C-STEM AMT LE Prosthesis K220216**
Material	The subject device uses the same materials to secondary predicate devices K220216	Forged titanium alloy Ti-6Al-4V, plasma-sprayed with a biocompatible hydroxyapatite (HA) coating for bone fixation	Wrought high nitrogen stainless steel, conforming to ISO 5832-9.
Fixation	The subject device uses the same method of fixation as the secondary predicate devices K220216	Press Fit; Cementless	Cemented
Stem Size	The subject device has an identical size range to a sub-set of the size range of primary predicate K123991 devices	Cementless Collared 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20 Cementless Collarless 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20 Cementless LAT Collared 9, 10, 11, 12, 13, 14, 15, 16, 18, 20 Cementless HO Collarless 9, 10, 11, 12, 13, 14, 15, 16, 18, 20	CDH (“00”), 1A, 2A, 3A, 2 Long SO, 2 Long HO, 3 Long SO, 3 Long HO, 3XL205, 3 XL240
Stem Offset	The subject device has the same stem offset options as the primary predicate K123991	Standard, High	Same as primary predicate

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES			
Characteristics	**Subject Device: CORAIL Cemented Femoral Stem**	**Primary Predicate Device: DePuy CORAIL AMT Hip Prosthesis K123991**	**Secondary Predicate Device: C-STEM AMT LE Prosthesis K220216**
Collar	The subject device is collarless, same as secondary predicate devices K220216, and a subset of the primary predicate devices K123991	Collared & Collarless	Collarless
Sterile Method	The subject device has the same sterile method as both primary predicate K123991, and secondary predicate K220216.	Gamma irradiation	Same as primary predicate
SAL	The subject device has the same SAL as primary predicate K123991, and secondary predicate K220216.	10^{-6}	Same as primary predicate
Packaging	The subject has the same packaging format as both primary predicate K123991, and secondary predicate K220216.	Double Sterile Barrier Pack INNER: Nylon Pouch OUTER: PETG Blister, Tyvek Lid	Same as primary predicate

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES			
Characteristics	**Subject Device: CORAIL Cemented Femoral Stem**	**Primary Predicate Device: DePuy CORAIL AMT Hip Prosthesis K123991**	**Secondary Predicate Device: C-STEM AMT LE Prosthesis K220216**
Shelf Life	The subject device has the same shelf-life as both primary predicate K123991, and secondary predicate K220216.	5 years	5 years

The subject device [CORAIL Cemented Femoral Stem] has the same form as the collarless subset of the primary predicate device [DePuy CORAIL AMT Hip Prosthesis (K123991)] and in common with the secondary predicate [C-STEM AMT LE Prosthesis (K220216)], the surface finish is uncoated and brightly polished, and the material of construction is wrought Stainless Steel.

The subject device has the same intended use as the primary predicate devices. The method of sterilization, Sterility Assurance Level (SAL) and claimed shelf-life are the same across the subject and both predicate devices. The packaging materials are the same as for the secondary predicate device.

The subject device is indicated for total and hemi hip arthroplasty, same as the primary predicate, and is indicated for cemented use, same as the secondary predicate. The range of stem sizes and neck offsets available are identical for the subject device and a subset of the primary predicate.

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

The CORAIL Cemented Femoral Stem was tested to demonstrate its substantial equivalence of safety and effectiveness to the identified predicate devices. Testing and analyses included:

- Distal fatigue and neck fatigue per ISO 7206-4:2010, ISO 7206-6:1992, ISO 7206:2013 and ASTM F2068-3
- Range of motion per EN ISO 21535:2009+A1:2016
- MRI Safety per ASTM F2503-23, ASTM F2182 -19^{e2}, ASTM F2052-21, ASTM F2213-17 and ASTM F2119-07
- Biocompatibility testing per EN ISO 10993-1:2009, ISO 10993:1-2018, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2010, ISO 10993-11:2017, ISO 10993-12:2012, ISO 10993-18:2020, BS EN ISO 22442-1:2015 and ISO 10993-17:2002
- Bacterial endotoxins per ANSI/AAMI ST 72:2019

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 CORAIL Cemented Femoral Stem is substantially equivalent to the identified predicates with respect to intended use, indications, materials, geometry, range of sizes, and method of fixation. Results of performance testing and analyses demonstrate that the CORAIL Cemented Femoral Stem performs as well as the predicate devices DePuy CORAIL AMT Hip Prosthesis and C-STEM AMT LE Prosthesis (K123991 and K220216).