July 22, 2022

DePuy Ireland UC
Sarah Matamisa
Regulatory Affairs Specialist
Loughbeg, Ringaskiddy
Co. Cork, IRELAND

Re: K220216
Trade/Device Name: C-Stem AMT LE Prosthesis
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, LZO
Dated: June 17, 2022
Received: June 21, 2022

Dear Sarah Matamisa:

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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220216

Device Name
C-STEM AMT LE Hip Prosthesis

Indications for Use *(Describe)*

INDICATIONS

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 LE Hip Prosthesis is indicated for cemented 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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510(K) SUMMARY

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork, IRELAND
Establishment Registration Number	3015516266
Name of contact person	Sarah Matamisa
e-mail address	smatamis@its.jnj.com and DePuySynthesJointsRegulatoryAffairs@its.jnj.com
Alternative contact person	Clare Hill
e-mail address	nkeedy@its.jnj.com
Work mobile	+44 7824320636 (UK time zone)
Date prepared	19 January 2022
Name of device	
Trade or proprietary name	C-Stem AMT LE Hip Prosthesis
Common or usual name	Total Hip Joint Replacement Prosthesis
Classification name	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3350 21 CFR 888.3353
Product Code(s)	JDI, LZO
Legally marketed device(s) to which equivalence is claimed	Primary predicate: DePuy C-Stem AMT Hip Prosthesis K042959, cleared December 22, 2004 Additional predicates: DePuy C-Stem AMT K082239, cleared August 29, 2008 DePuy C-STEM System K982918, cleared October 5, 1998
Reason for 510(k) submission	The purpose of this 510K submission is to obtain market clearance for C-Stem AMT LE Hip Prosthesis.
Device description	The C-Stem AMT LE Hip Prosthesis is a collarless, triple-tapered, cemented femoral stem designed to be used as one component of a system of prostheses in hip arthroplasty. It is manufactured from wrought stainless steel conforming to ISO 5832-9 (Ortron-90®) and is polished overall. It is designed to be used with commercially

	available modular femoral heads, either metal or ceramic. The subject device is compatible with DePuy acetabular shells and liners. The C-Stem AMT LE Hip Prosthesis is a line extension of the predicate C-Stem AMT Hip Prosthesis cleared under 510(k) numbers K042959 and K082239. The subject C-Stem AMT LE Hip Prosthesis and the predicate C-Stem AMT Hip Prosthesis are comprised of identical materials and share common design features, including a polished full-length triple tapered intramedullary geometry, 12/14 Articul/EZE Mini Taper and a raised lateral shoulder.
Intended use of the device	Total hip arthroplasty
Indications for use	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 LE Hip Prosthesis is indicated for cemented use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES				
Characteristics	**Subject Device: C-Stem AMT LE Hip Prosthesis**	**Predicate Device #1: DePuy C-Stem AMT Hip Prosthesis K042959**	**Predicate Device #2: DePuy C-Stem AMT K082239**	**Predicate Device #3: DePuy C-Stem System K982918**
Intended Use and Indications for Use	Same as predicate #1	Total Hip Arthroplasty 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, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. The DePuy® C-Stem AMT Hip Stem is indicated for cemented use only.	Total Hip Arthroplasty The DePuy C-Stem AMT is indicated for cemented use in the treatment of: 1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis. 2. Avascular necrosis of the femoral head; 3. Acute traumatic failure of the femoral head or neck; 4. Failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and 5. Certain cases of ankylosis.	Total Hip Arthroplasty Indicated for cemented use as the femoral component in total hip arthroplasty for replacing the hip joint of a patient with severely painful and/ or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previously surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement; and certain cases of ankylosis.
Properties				

Material	Same as predicate #1	Wrought Stainless Steel "Ortron 90®" conforming to ISO 5832-9	Same as predicate #1	Same as predicate #1
Fixation	Same as predicate #1	Cemented	Same as predicate #1	Same as predicate #1
Design Features				
Surface Finish	Same as predicate #1	Uncoated/ Brightly polished	Same as predicate #1	Same as predicate #1
Standard Offset Sizes	CDH ("00"), 1A, 2A, 3A, 2 Long, 3 Long, 3 XL205, 3 XL240	2, 3, 4, 5, 6, 7, 8	1	CDH, 1, 2, 3, 4, 5, 6, 7, 8 Revision (200mm and 240mm) 4, 6, 8
High Offset Sizes	2 Long, 3 Long	2, 3, 4, 5, 6, 7, 8	1	3, 4, 5
Stem length **(Smallest size)**	123.8mm	138.7mm	132.5mm	123.8mm
Stem Length **(Largest Size)**	240mm	175.4mm	132.5mm	273mm
Stem Offsets	Standard and High	Standard and High	Standard and High	Standard and High
Restriction on femoral head length to be used in combination with device	No greater than +12	No restriction	No restriction	Head offsets for Predicate #3 are limited to +6 by design. This is approximately equivalent to +12 when an Articul/EZE mini taper is used
Trunnion Design	Same as predicate #1	12/14 Articul/EZE Mini Taper (AMT)	Same as predicate #1	9/10 taper
Stem Geometry	Same as predicate #1	Full triple taper	Same as predicate #1	Standard length: Full triple taper

Packaging Description				
Component	Same as predicate #1	Double Sterile Barrier Pack | INNER: Nylon Pouch | OUTER: PETG Blister, Tyvek Lid	Same as predicate #1	Same as predicate #1
Sterility				
Sterile Method	Same as predicate #1	Gamma irradiation	Same as predicate #1	Same as predicate #1
Sterility Assurance Level	Same as predicate #1	10^{-6}	Same as predicate #1	Same as predicate #1
Claimed Shelf Life	Same as predicate #1	5 years	Same as predicate #1	Same as predicate #1

The subject C-Stem AMT LE Hip Prosthesis devices are identical to the predicates C-Stem AMT Hip Prosthesis (K042959, K082239) and C-Stem System (K982918), in intended use, indications for use, material, and fixation. The subject and predicate systems are intended for total hip arthroplasty and have the same indications for use. All devices are wrought stainless steel, uncoated stems for cemented use. The subject and predicate devices are offered in standard offset and high offset configurations. Method of sterilization, Sterility Assurance Level (SAL), packaging materials and shelf-life are the same across the subject and predicate devices. Trunnion design is identical for the subject device and predicate #1 and #2. Stem length for the subject devices falls within the range of stem lengths available for predicate #3 (K982918).

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

Testing and engineering analyses were performed on the C-Stem AMT LE Hip Prosthesis to demonstrate substantial equivalence of safety and efficacy with the predicate device, addressing:

- Neck Fatigue (to ISO 7206-6: 2013)
- Distal Stem Fatigue (to ISO 7206-4: 2010)
- Range of Motion (to BS EN ISO 21535: 2009)

Biocompatibility evaluation was carried out to ISO 10993-1:2018 and testing was carried out to include cytotoxicity to ISO 10993-5:2009 and chemical characterization to ISO 10993-18:2020.

The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.

Magnetic Resonance Imaging safety evaluation testing was performed following ASTM F2503-13, and the tests evaluated the worst-case components and constructs for magnetically induced force (ASTM F2052-15), torque (ASTM F2213-17), image artefact (ASTM F2119-07 (reapproved 2013)) and RF heating (ASTM F2182-19). The testing concluded that there are no safety issues related to magnetic field interactions under specific conditions identified in the labelling.

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 C-Stem AMT LE Hip Prosthesis devices are substantially equivalent to the predicate DePuy C-Stem AMT Hip Prostheses (K042959, K082239) and DePuy C-Stem System Hip Prostheses (K982918).