October 11, 2023

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

Re: K233233
Trade/Device Name: EMPHASYS Femoral Stems
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, KWL, KWY, MEH
Dated: September 27, 2023
Received: September 28, 2023

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 (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)*

K233233

Device Name

EMPHASYS Femoral Stems

Indications for Use *(Describe)*

EMPHASYS Femoral Stems are intended for use in total and partial hip arthroplasty. The stems are intended only for uncemented use.

Total hip arthroplasty is 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.

Partial hip arthroplasty (hip hemiarthroplasty) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem.

EMPHASYS Femoral Stems are intended for single use only.

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.

Partial hip replacement 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.

The EMPHASYS Femoral Stems 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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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	Elaine Pears
e-mail address	epears@its.jnj.com
Work mobile	**+44 7876 217532**
Date prepared	11 October 2023
Name of device	
Trade or proprietary name	EMPHASYS Femoral Stem
Common or usual name	Total or Hemi-Hip Arthroplasty Prosthesis
Classification name	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate Prosthesis, Hip, Hemi-, Femoral, Metal Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented
Class	II
Classification panel	87 Orthopedics
Regulation	**21 CFR 888.3353** 21 CFR 888.3360 21 CFR 888.3390
Product Code(s)	**LZO**, MEH, KWL, KWY
Legally marketed device(s) to which equivalence is claimed	Primary Predicate: - EMPHASYS Femoral Stems (K211657), cleared August 5, 2021 Secondary Predicate: - DePuy CORAIL AMT Hip Prosthesis (K203167), cleared November 19, 2020
Reason for 510(k) submission	The purpose of this submission is to extend the currently approved shelf life of EMPHASYS Femoral Stems (K211657) from 5 years to 10 years.
Device description	The EMPHASYS Femoral Stems include HA-coated femoral stems in standard and high offsets and in collared and collarless configurations.

	The stems are manufactured from titanium alloy forgings per ASTM F620-20 and coated with a layer of plasma-sprayed HA per ASTM F1185-14 and ISO 13779-6: 2015.
Intended use of the device	Total and Partial Hip Arthroplasty
Indications for use	EMPHASYS Femoral Stems are intended for use in total and partial hip arthroplasty. The stems are intended only for uncemented use. Total hip arthroplasty is 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. Partial hip arthroplasty (hip hemiarthroplasty) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem. EMPHASYS Femoral Stems are intended for single use only. 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 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. The EMPHASYS Femoral Stems are indicated for cementless use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristics	**Subject Device: EMPHASYS Femoral Stems**	**Predicate Device: EMPHASYS Femoral Stems (K211657)**	**Predicate Device: DePuy CORAIL AMT Prosthesis (K203167)**
Intended Use	Total and Hemi-Hip Arthroplasty	Total and Hemi-Hip Arthroplasty	Total and Hemi-Hip Arthroplasty
Material	Titanium Alloy (Ti_6Al_4V) with HA coating	Titanium Alloy (Ti_6Al_4V) with HA coating	Titanium Alloy (Ti_6Al_4V) HA coating
Fixation	Uncemented	Uncemented	Uncemented
Sterile Method	Gamma	Gamma	Gamma
Packaging	Nylon inner and outer pouch	Nylon inner and outer pouch	Nylon Inner Pouch and outer PETG blister with Tyvek peel lid
Shelf life	10 Years	5 Years	10 Years

PERFORMANCE DATA
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE
The subject HA coated EMPHASYS Femoral Stems are manufactured to the same production specifications as the predicate devices (K211657 and K203167). As the subject devices have been validated to be manufactured to the same specifications and utilize the same materials, the shelf life extension will not impact the fit, form or function of these components. Therefore, the non-clinical tests reviewed as part of K211657 and K203167 remain current. Packaging shelf-life validation has been carried out to confirm a shelf-life of 10 years. HA coating properties on aged products were tested as per ISO-13779-3 (Crystallinity, Foreign Phases and CaP ratio), ASTM F1854 (Thickness) and ASTM E2109 (Porosity) to confirm a shelf-life of 10 years.
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 device EMPHASYS Femoral Stems is equivalent to the predicates EMPHASYS Femoral Stems (K211657) and DePuy CORAIL AMT Prosthesis (K203167). There have been no modifications made to the intended use, design, biocompatibility, materials, sterilization or packaging of the existing EMPHASYS Femoral Stems. .