August 5, 2021

DePuy Ireland UC
% Clare Hill
Senior Manager, Regulatory Affairs, CRQ Regulatory Affairs
DePuy Synthes, IRenc.
700 Orthopaedic Drive
Warsaw, Illinois 46582

Re: K211657
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: May 27, 2021
Received: May 28, 2021

Dear Clare Hill:

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,

Limin Sun
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211657

Device Name
EMPHASYS Femoral Stems

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.

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.

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.

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 Munster, IRELAND
Phone number	574-404-8782
Establishment Registration Number	1818910
Name of contact person	Clare Hill
Date prepared	25 May 2021
Name of device	
Trade or proprietary name	EMPHASYS Femoral Stems
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, Hemi-, Femoral, Metal Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented Prosthesis, Hip, Semi-Constrained, Uncemented, Metal / Polymer, Non-Porous, Calcium Phosphate
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3360: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR 888.3390: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Product Code(s)	LZO, KWL, KWY, MEH
Legally marketed device(s) to which equivalence is claimed	DePuy Corail AMT Hip Prosthesis (K190344) – Primary predicate Corail AMT Hip Prosthesis (K042992) DePuy Corail AMT Hip Prosthesis (K123991) DePuy Corail AMT Hip Prosthesis (K173960) DePuy Corail AMT Hip Prosthesis (K192946) Summit Hip System (K001991)

	Summit Hip System (K170339) Actis DuoFix Hip Prosthesis - Collarless (K210581)
Reason for 510(k) submission	The purpose of this submission is to obtain market clearance for the EMPHASYS Femoral Stems, one component of a system of prostheses used in hip arthroplasty.
Device description	The EMPHASYS Femoral Stems include HA-coated femoral stems in standard and high offsets and in collared and collarless configurations. The EMPHASYS Femoral Stems are designed to be used as one component of a system of prostheses in hip arthroplasty. The stems are compatible with a DePuy modular metal, dual mobility, or ceramic femoral head, and either a one-piece or a metal-backed two-piece acetabular component for use in total hip arthroplasty, and with a modular unipolar metallic femoral head or a modular bipolar head construct for hemi-hip arthroplasty.
Intended use of the device	Total and Hemi 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. 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.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The subject EMPHASYS Femoral Stems are similar to the predicate CORAIL AMT Hip Prosthesis (K042992, K123991, K173960, K190344) in intended use, indications for use, design, material, and fixation. The subject and predicate systems are intended for total or hemi hip arthroplasty and have the same indications for use. Both are forged titanium alloy, HA coated stems for uncemented use with a tapered body and 12/14 taper. Both devices have the same size tapers, and both are offered in collared and collarless, standard offset and high offset configurations. Both devices are used in a modular hip construct which includes DePuy femoral head and acetabular components. The design of the subject and predicate devices is similar in terms of shape and function, although the intraosseous geometry of the subject devices has a narrower ML profile in places and is shorter than the predicate stems. The subject devices are offered in a 130° neck angle that is in between the two angles offered by the predicate devices.

PERFORMANCE DATA

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

Testing and engineering analyses were performed on the EMPHASYS Femoral Stems 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)
- Taper equivalence

Biocompatibility evaluation was carried out to ISO 10993-1:2018 and testing was carried out to include genotoxicity to ISO 10993-3:2014, cytotoxicity to ISO 10993-5:2009, sensitization and irritation to ISO 10993-10:2010, pyrogenicity to ISO 10993-11:2017 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 2119-07 (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.

Hydroxyapatite characterization data, as recommended in the FDA Guidance *510(k) Information needed for Hydroxyapatite coated Orthopedic Implants*, is provided.

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 EMPHASYS Femoral Stems are substantially equivalent to the predicate CORAIL AMT Hip Prosthesis.