September 6, 2022

DePuy Ireland UC
% Hollace Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th street, NW, 3rd Floor
Washington, District of Columbia 20001

Re: K221636
Trade/Device Name: EMPHASYS Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO
Dated: June 27, 2022
Received: June 27, 2022

Dear Hollace Rhodes:

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, 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)*
K221636

Device Name
EMPHASYS Acetabular System

Indications for Use *(Describe)*

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.

EMPHASYS Acetabular Cups 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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Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Phone number	574-372-7211
Fax number	574- 371-4987
Establishment Registration Number	3015516266
Submission Prepared by	MCRA
Address	803 7th Street NW, 3rd Floor Washington, DC 20001, USA
Phone number	202-552-5800
Name of contact person	Ms Hollace S Rhodes
Date prepared	1 June 2022
Name of device	
Trade or proprietary name	EMPHASYS Acetabular System
Common or usual name	Total Hip Arthroplasty Prosthesis
Classification name	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Class	II
Classification panel	87 Orthopedics
Regulation	888.3358; 888.3353
Product Codes	LPH; LZO
Legally marketed devices to which equivalence is claimed	See nested table below

	Predicate	**Reference Device**
EMPHASYS Shell	DePuy Pinnacle Gription Acetabular Cups (K071784, K093646)	Stryker Trident System PSL shell (K983382)
EMPHASYS Liner	DePuy Pinnacle ALTRX Acetabular Liners (K132959) DePuy Pinnacle Marathon Acetabular Liners (K033273)	Stryker Trident System X3 Polyethylene Liner (K062419) DePuy ATTUNE All Poly Tibia (K193057)

Reason for 510(k) submission	The purpose of this 510(k) submission is to obtain market clearance for the DePuy EMPHASYS Acetabular System
Device description	The EMPHASYS Acetabular System includes porous-coated acetabular shells in three configurations (No-Hole, 3-Hole and Multi-Hole) and AOX polyethylene liners in three configurations (Neutral, +4 Neutral and ELV).
Intended use of the device	The system is intended for use with a compatible DePuy femoral stem and modular head as a total hip prosthesis.
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. EMPHASYS Acetabular Cups are indicated for cementless use only.
Performance Testing	The EMPHASYS Acetabular System was tested to demonstrate its substantial equivalence to the identified predicate devices. Testing and analyses included: • Range of motion per ISO 21535:2007 • Analysis of shell and liner thickness • Impingement per ASTM F2582-14 • Deformation per ISO 7206-12:2016 • Clearance between femoral head and liner • Interconnection strength of shell and liner per ASTM F1820-13 and ASTM F3090-20 • Wear of aged and non-aged polyethylene per ISO 14242-1:2014, ISO 14242-2:2016 and ISO 14242-4:2018 • Friction per ASTM F3143-20 • Coating characterization per ASTM-F1160-14 and ASTM-F1147-05 and FDA's "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surface Apposing Bone or Bone Cement" • Polyethylene characterization per ASTM D638-14, ASTM F2625-10, ASTM F648-14, ASTM F2381-19, ASTM F2003-02, ASTM F2102-17, ASTM D1505-18, ASTM D2765, ASTM E647-95a, ASTM F648-14and FDA's guidance, "Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices"

	• MRI Safety per ASTM F2503-20, ASTM F2182 -19, ASTM F2052-15, ASTM F2213-17 and ASTM F2119-07 • Bacterial endotoxins per ANSI/AAMI ST 72:2019
Substantial Equivalence	The EMPHASYS Acetabular System 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 EMPHASYS Acetabular System performs as well as the predicate devices.