October 7, 2024

DePuy Ireland UC
Elaine Pears
Regulatory Affairs Manager
Loughbeg, Ringaskiddy
Cork, Ireland

Re: K242084
Trade/Device Name: EMPHASYS Acetabular Shell with RapiTite HA
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: July 16, 2024
Received: September 12, 2024

Dear Elaine Pears:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*

K242084

Device Name

EMPHASYS Acetabular Shell with RapiTite HA

Indications for Use *(Describe)*

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.

The EMPHASYS Acetabular Shell with RapiTite HA is 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.

EMPHASYS Acetabular Shell with RapiTite HA is 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.

510(K) SUMMARY – EMPHASYS ACETABULAR SHELL WITH RAPITITE HA

(As required by 21 CFR 807.87(h))

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork, IRELAND
Establishment Registration Number	3015516266
Submission Prepared by	Elaine Pears
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Alternative Contact Person	Clare Hill
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Work mobile	+44 7795 389956
Date prepared	16 July 2024
Name of device	
Trade or proprietary name	EMPHASYS Acetabular Shell with RapiTite HA
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	21 CFR 888.3358; 21 CFR 888.3353
Product Codes	LPH; LZO

<table>
<tr><td>Legally marketed devices to which equivalence is claimed</td><td>
<table>
<tr><th>Predicate Devices</th><th>Reference Device</th></tr>
<tr><td>DePuy EMPHASYS Acetabular System (K221636/K231873) (primary predicate)

DePuy Pinnacle Duofix HA Acetabular Cup (K031495)

DePuy Pinnacle with Gription Acetabular Cups (K090998/K093646)</td><td>Stryker Tritanium® Peri-Apatite™ Acetabular Shell System (K101072)</td></tr>
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</td></tr>
<tr><td>Reason for 510(k) submission</td><td>The purpose of this 510(k) submission is to obtain market clearance for the DePuy EMPHASYS Acetabular Shell with RapiTite HA.</td></tr>
<tr><td>Device description</td><td>The EMPHASYS Acetabular Shell with RapiTite HA is a modular cementless porous-coated acetabular shell, with a hydroxyapatite (HA) coating applied conformally throughout the porous coating, offered in three configurations (No-Hole, 3-Hole, and Multi-Hole).</td></tr>
<tr><td>Intended use of the device</td><td>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.

The EMPHASYS Acetabular Shell with RapiTite HA is intended for single use only.</td></tr>
<tr><td>Indications for use</td><td>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 Shells with RapiTite HA are indicated for cementless use only.</td></tr>
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Comparison of Technological Characteristics with predicate devices	The EMPHASYS Acetabular Shell with RapiTite HA is identical to the acetabular shells in the primary predicate EMPHASYS Acetabular System in terms of intended use, indications, design and materials of construction, with the only exception being that the subject devices have an additional layer of HA coating. The HA coating is equivalent in structure and composition to that used in the secondary predicate (DePuy Pinnacle Duofix HA Acetabular Cup), and is applied in a way similar to that used for the reference device (Stryker Tritanium® Peri-Apatite™ Acetabular Shell System).
Animal & Performance Testing	The EMPHASYS Acetabular Shell with RapiTite HA was tested to demonstrate its substantial equivalence to the identified predicate devices. Testing and analyses included: • Chemical Analysis (per ASTM F1609-08(2014) & ISO 13779-3:2018) • Dissolution (per ASTM F1926-14) • Solubility (per ISO 13779-6:2015) • SEM Morphological Characterization • Abraded Particle Characterization • FTIR Analysis • XRD Analysis (per ISO 13779-3:2018) • Static interfacial shear strength (per ASTM F1044-05(2017)e1 • Static interfacial tensile strength (per ASTM F1147-05(2017)e1) • Interfacial shear fatigue (per ASTM F1160-14 (2017)e1) • Stereological evaluation (per ASTM F1854-15) • Static friction testing (per ASTM D4518-91) • Fatigue testing (per ASTM F3090-20) • Biocompatibility (per ISO 10993-1:2018) • Bone Ingrowth Animal Study • Characterization of the Physical and Mechanical Properties of the HA coated porous surface per FDA guidance documents "*Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement"* (Apr. 1994) and *"510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants* (Feb 1997)*"* • MRI Safety Evaluation Testing of Total Hip Systems - ASTM F2503-23, ASTM F2182 -19e2, ASTM F2052-21, ASTM F2213-17, and ASTM F2119-07

Substantial Equivalence	The EMPHASYS Acetabular Shell with RapiTite HA is substantially equivalent to the identified predicate devices with respect to intended use, indications, materials of construction, geometry, range of sizes, and method of fixation. Results of animal and performance testing and analyses demonstrate that the EMPHASYS Acetabular Shell with RapiTite HA performs as well as the predicate devices.