



January 21, 2025

DePuy Ireland UC
Amy Joyce
Senior Regulatory Affairs Associate
Loughbeg
Ringaskiddy
Co. Cork,
Ireland

Re: K243977

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: December 19, 2024

Received: December 23, 2024

Dear Amy Joyce:

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

Indications for Use

Submission Number (if known)

K243977

Device Name

EMPHASYS Acetabular System

Indications for Use (Describe)

The EMPHASYS Acetabular System is indicated for use in total hip replacement procedures.

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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510(k) Summary

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork, IRELAND
Establishment Registration Number	3015516266
Name of contact person	Amy Joyce
e-mail address	AJoyce1@its.jnj.com DePuySynthesJointsRegulatoryAffairs@its.jnj.com
Alternative contact person	Elaine Pears
e-mail address	EPears@its.jnj.com
Work mobile	+44 7876217532 (UK time zone)
Date prepared	19 th December 2024
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	21 CFR 888.3358; 888.3353
Product Code(s)	LPH; LZO
Legally marketed device(s) to which equivalence is claimed	Primary predicate – EMPHASYS Acetabular System K221636 Secondary predicate – DePuy PINNACLE with Gription Acetabular Cups K071784 Secondary predicate – PINNACLE Marathon Liners (DePuy Hip Portfolio – MR Conditional) K231873
Reason for 510(k) submission	The purpose of this 510(k) submission is to expand the scope of the legally marketed DePuy Synthes EMPHASYS Acetabular System to include additional sizes.

Device description	The subject devices in this line extension to the EMPHASYS Acetabular System (previously cleared through Primary Predicate 510(k) K221636) include three additional porous-coated titanium alloy Acetabular Shells in a multi-hole configuration and ten corresponding AOX polyethylene Acetabular 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 femoral 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 subject devices were compared to the predicate devices and assessed for worst-case, only those situations where a new worst-case was identified were testing conducted. No new worst-case was identified for the following: • Range of motion • Deformation • Impingement • Unsupported Shell Fatigue • Analysis of shell and liner thickness • Articular clearance • Wear • Friction • MRI Safety The EMPHASYS Acetabular System subject devices were tested to demonstrate substantial equivalence to the identified predicate devices. Testing and analyses included: • Interconnection strength of shell and liner per ASTM F1820-22
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 demonstrates that the EMPHASYS Acetabular System performs as well as the predicate devices.