February 15, 2024

DePuy Ireland UC
Farah Valli
Project lead Regulatory Affairs
Loughbeg, Ringaskiddy
Co. Cork
Ireland

Re: K231522
Trade/Device Name: EMPHASYS™ Dual Mobility 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: January 19, 2024
Received: January 19, 2024

Dear Farah Valli:

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)*

K231522

Device Name

EMPHASYS™ Dual Mobility System

Indications for Use *(Describe)*

Total hip replacement is indicated in the following conditions:
1. A severely painful and/or disabled joint (typically due to non-inflammatory degenerative joint disease).
2. Failed previous hip surgery.
3. Dislocation risks.

EMPHASYS Dual Mobility Liners and Mobile Bearing Heads are intended for cementless applications.

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.

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510(K) SUMMARY

(As required by 21 CFR 807.87(h))

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork, IRELAND
Phone number	574-372-7211
Fax number	574- 371-4987
Establishment Registration Number	3015516266
Name of contact person	Farah Valli
Date prepared	15 Feb 2024
Name of device	
Trade or proprietary name	EMPHASYS™ Dual Mobility 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 Code(s)	LPH; LZO

<table>
<tr><td rowspan="2">Legally marketed device(s) to which equivalence is claimed</td><td>Subject Device:
EMPHASYS Dual Mobility Liners</td><td>Predicate Device:
DePuy PINNACLE Dual Mobility Liners (K200854)</td><td>Reference Devices:
Stryker MDM Acetabular System (K103233)
Zimmer Biomet G7 Dual Mobility (K150522)
DePuy SUMMIT Porocoat Hip Prosthesis – MR Conditional, DePuy SUMMIT DuoFix Hip Prosthesis – MR Conditional, DePuy SUMMIT Cemented Hip Prosthesis – MR Conditional, DePuy SUMMIT FX Cemented Hip Prosthesis – MR Conditional, DePuy SUMMIT Basic Press-Fit Hip Prosthesis – MR Conditional (K231873)</td></tr>
<tr><td>Subject Device:
EMPHASYS Mobile Bearing Heads</td><td>Predicate Device:
BI-MENTUM Dual Mobility System (K181744)</td><td>Reference Devices:
EMPHASYS Acetabular AOX Liners (K221636)
Zimmer Biomet G7 Dual Mobility (K150522)
Smith & Nephew OR3O (K232667)
DePuy SUMMIT Porocoat Hip Prosthesis – MR Conditional, DePuy SUMMIT DuoFix Hip Prosthesis – MR Conditional, DePuy SUMMIT Cemented Hip Prosthesis – MR Conditional, DePuy SUMMIT FX Cemented Hip Prosthesis – MR Conditional, DePuy SUMMIT Basic Press-Fit Hip Prosthesis – MR Conditional (K231873)</td></tr>
<tr><td>Reason for 510(k) submission</td><td colspan="3">The purpose of this 510(k) submission is to obtain market clearance for the DePuy EMPHASYS Dual Mobility System.</td></tr>
<tr><td>Device description</td><td colspan="3">The EMPHASYS Dual Mobility System includes Co-Cr-Mo Dual Mobility Liners and AOX Polyethylene Mobile Bearing Heads as well as other previously cleared compatible components.</td></tr>
<tr><td>Intended use of the device</td><td colspan="3">The EMPHASYS Dual Mobility System is designed to provide additional stability where there is an unstable joint and is for use in total hip arthroplasty, which 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.</td></tr>
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Indications for use	Total hip replacement is indicated in the following conditions: • A severely painful and/or disabled joint (typically due to non-inflammatory degenerative joint disease). • Failed previous hip surgery. • Dislocation risks. EMPHASYS Dual Mobility Liners and EMPHASYS Mobile Bearing Heads are intended for cementless applications.
Comparison of Technological Characteristics	The EMPHASYS Dual Mobility System proposes no new applications, intended use, or indications relative to the predicate devices. The material of construction of the EMPHASYS Dual Mobility Liners is identical to that of the predicate (Cobalt-chromium-molybdenum alloy (CoCrMo) conforming to ASTM F1537). The EMPHASYS Mobile Bearing Heads are manufactured from AOX Polyethylene, identical to the reference device (EMPHASYS Acetabular AOX Liners (K221636)). While there are minor differences in design between the subject devices and the predicate/reference devices, DePuy has provided comparative testing to demonstrate equivalence with existing products.
Performance Testing	The EMPHASYS Dual Mobility System was tested to demonstrate its substantial equivalence to the identified predicate devices. Testing and analyses included: • EMPHASYS Mobile Bearing Head Thickness Assessment • EMPHASYS Dual Mobility Liner Thickness Assessment • Range of Motion Analysis- ISO 21535:2007 • EMPHASYS Mobile Bearing Head Impingement-ASTM F2582-20 • EMPHASYS Dual Mobility Impingement Testing to ASTM F2582-20 • EMPHASYS Dual Mobility Liner Push-Out- ASTM F1820-22 • EMPHASYS Dual Mobility Liner Offset Pull-Out- ASTM F1820-22 • EMPHASYS Dual Mobility Liner Torque-Out- ASTM F1820-22 • EMPHASYS Mobile Bearing Head Lever-Out • EMPHASYS Dual Mobility ASTM F1875 Method I Test • EMPHASYS Dual Mobility Non-Aged Standard Walking Wear Test- ISO 14242-1:2014 and ISO 14242-2:2016. • EMPHASYS Dual Mobility Standard Walking with Mode 3 Third Body Abrasive Wear Test - ISO 14242-1:2014, ISO 14242-1 AMD 1:2018, ISO 14242-2:2016 and ISO 14242-4:2018.

	• EMPHASYS Dual Mobility High Angle Standard Walking Wear Test- ISO 14242-1:2014, ISO 14242-2:2016 and ISO 14242-4:2018. • EMPHASYS Dual Mobility Worst Case Outer Bearing Wear of EMSYS DM under Standard Walking Wear- ISO 14242-1:2014 and ISO 14242-2:2016 • EMPHASYS Dual Mobility Friction Test- ASTM F3143-20 • MRI Safety Evaluation Testing of Total Hip Systems- ASTM F2503-23, ASTM F2182 -19^{e2}, ASTM F2052-21, ASTM F2213-17, and ASTM F2119-07
Substantial Equivalence	The EMPHASYS Dual Mobility System is substantially equivalent to the identified predicates with respect to intended use, indications, materials, geometry, and method of fixation. Results of performance testing and analyses demonstrate that the EMPHASYS Dual Mobility System performs as well as the predicate devices.