

**K221636 EMPHASYS Acetabular System**Sep 6, 2022  
92 days to decisionK221636 · Product code: **LPH** · Orthopedic  
Source: <https://www.510kdatabase.net/k221636/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jun 6, 2022
Decision date	Sep 6, 2022
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Depuy Ireland UC</b>
Location	Ringaskiddy, IE
Contact	Elaine Pears
510(k) history	47 submissions · 47 cleared · 2018-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Hollace Saas Rhodes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221636/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026