

K242084 EMPHASYS Acetabular Shell with RapiTite HAOct 7, 2024
83 days to decisionK242084 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k242084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jul 16, 2024
Decision date	Oct 7, 2024
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242084/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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