

K253624 INHANCE™ Reverse Shoulder SystemMar 11, 2026
113 days to decisionK253624 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k253624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Nov 18, 2025
Decision date	Mar 11, 2026
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	DePuy Orthopaedics, Inc.
Contact	Yayoi Fujimaki

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253624/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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