

K223211 INHANCETM Shoulder System – Humeral Stems and StemlessDec 2, 2022
46 days to decisionK223211 · Product code: PHX · Orthopedic
Source: <https://www.510kdatabase.net/k223211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Oct 17, 2022
Decision date	Dec 2, 2022
Days to decision	46 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	Ignite Orthopedics, LLC
Contact	Russ Parrott

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.netDevice record: <https://www.510kdatabase.net/k223211/>; Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026