FDA 510(k) Premarket Notification

CLEARED

K212737 INHANCE™ Reverse Shoulder System

Apr 21, 2022
234 days to decision

K212737 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k212737/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Aug 30, 2021
Decision date	Apr 21, 2022
Days to decision	234 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