FDA 510(k) Premarket Notification

CLEARED

K231516 INHANCE™ Shoulder System, Sterile Single Use Instrumentation

Jul 21, 2023
57 days to decision

K231516 · Product code: **MBF** · Orthopedic
Source: https://www.510kdatabase.net/k231516/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF)
Date received	May 25, 2023
Decision date	Jul 21, 2023
Days to decision	57 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