CLEARED

K230831 INHANCE Shoulder System Convertible Glenoid Inserts, INHANCE Convertible Glenoid

Nov 13, 2023
231 days to decision

K230831 · Product code: **MBF** · Orthopedic
Source: https://www.510kdatabase.net/k230831/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF)
Date received	Mar 27, 2023
Decision date	Nov 13, 2023
Days to decision	231 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