FDA 510(k) Premarket Notification

CLEARED

K242253 JARVIS Glenoid Reverse Shoulder Prosthesis

Nov 25, 2024
117 days to decision

K242253 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k242253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jul 31, 2024
Decision date	Nov 25, 2024
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**FH Industrie**
Location	Quimper Finistere, FR
Contact	Naoual Rahimi
510(k) history	9 submissions · 9 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**MRC Global**
Contact	Christine Scifert

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