FDA 510(k) Premarket Notification

K252411 JARVIS Glenoid Reverse Shoulder Prosthesis

CLEARED

Aug 28, 2025
27 days to decision

K252411 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k252411/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Aug 1, 2025
Decision date	Aug 28, 2025
Days to decision	27 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