FDA 510(k) Premarket Notification

K253345 JARVIS Diaphyseal Stem Standard

CLEARED

Oct 29, 2025
29 days to decision

K253345 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k253345/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 30, 2025
Decision date	Oct 29, 2025
Days to decision	29 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