

K254003 JARVIS Metaphyseal StemJan 9, 2026
25 days to decisionK254003 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k254003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 15, 2025
Decision date	Jan 9, 2026
Days to decision	25 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, LLC
Contact	Jen McBride

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

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