

**K253345 JARVIS Diaphyseal Stem Standard**Oct 29, 2025  
29 days to decisionK253345 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k253345/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>MRC Global</b>
Contact	Christine Scifert

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253345/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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