

**K252221 Inset Reverse Total Shoulder System**Sep 26, 2025  
72 days to decisionK252221 · Product code: **PHX** · Orthopedic  
Source: <https://www.510kdatabase.net/k252221/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jul 16, 2025
Decision date	Sep 26, 2025
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shoulder Innovations, Inc.</b>
Location	Holland, MI, US
Contact	Mark Hanes
510(k) history	8 submissions · 8 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252221/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026