

K252516 N22 EZ GlenosphereJan 15, 2026
157 days to decisionK252516 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k252516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Aug 11, 2025
Decision date	Jan 15, 2026
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252516/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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