

K254128 InSet Reverse Total Shoulder SystemApr 13, 2026
112 days to decisionK254128 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k254128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Dec 22, 2025
Decision date	Apr 13, 2026
Days to decision	112 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 D. Hanes
510(k) history	8 submissions · 8 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254128/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026