

K241817 InSet Total Shoulder SystemFeb 11, 2025
232 days to decisionK241817 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k241817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Jun 24, 2024
Decision date	Feb 11, 2025
Days to decision	232 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

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