

K251558 Precision AI Surgical Planning System (PAI-SPS)Jan 12, 2026
236 days to decisionK251558 · Product code: **QHE** · Orthopedic
Source: <https://www.510kdatabase.net/k251558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	May 21, 2025
Decision date	Jan 12, 2026
Days to decision	236 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision AI Pty, Ltd.
Location	Fortitude Valley, AU
Contact	Sara Baniadam
510(k) history	3 submissions · 3 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	Stefanie Michele Auf Der Mauer Asmuss
Contact	Stefanie Auf der Mauer

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

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