

K243955 Precision AI Surgical Planning System (PAI-SPS)Jan 21, 2025
29 days to decisionK243955 · Product code: **QHE** · Orthopedic
Source: <https://www.510kdatabase.net/k243955/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Dec 23, 2024
Decision date	Jan 21, 2025
Days to decision	29 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

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