

K231229 S-COMP Reform® POCT Navigation InstrumentsMay 25, 2023
27 days to decisionK231229 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k231229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 28, 2023
Decision date	May 25, 2023
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Spine, Inc.
Location	Pear, MS, US
Contact	Michael Dawson
510(k) history	24 submissions · 24 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
Contact	Nathan Wright

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

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