

K251943 Spineology Navigation InstrumentsDec 4, 2025
163 days to decisionK251943 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k251943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 24, 2025
Decision date	Dec 4, 2025
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spineology, Inc.
Location	Stillwater, MN, US
Contact	Megan Polos
510(k) history	54 submissions · 51 cleared · 1999-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251943/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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