

**K250182 Innovasis Navigation Instruments**Mar 24, 2025  
61 days to decisionK250182 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k250182/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 22, 2025
Decision date	Mar 24, 2025
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovasis, Inc.</b>
Location	Salt Lake City, UT, US
Contact	Michael Thomas
510(k) history	33 submissions · 32 cleared · 2004-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Technologies</b>
Contact	Hannah Taggart

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250182/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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