

**K241082 INNOVERSE Navigation Instruments**Jun 14, 2024  
56 days to decisionK241082 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k241082/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 19, 2024
Decision date	Jun 14, 2024
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innosys Co., Ltd.</b>
Location	Uijeongbu-Si, KR
Contact	Hye-Kyung Lee
510(k) history	4 submissions · 4 cleared · 2023-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Technologies</b>
Contact	Nathan Wright

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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