

**K222753 SeaSpine 7D Navigation Instruments**Dec 9, 2022  
88 days to decisionK222753 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k222753/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 12, 2022
Decision date	Dec 9, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SeaSpine Orthopedics Corporation</b>
Location	Carlsbad, CA, US
Contact	Laeitia Cousin
510(k) history	66 submissions · 66 cleared · 2016-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>7D Surgical ULC</b>
Contact	Elena Marennny

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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