

**K213491 Universal Pilot Guidance Instrument System**May 12, 2022  
192 days to decisionK213491 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k213491/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 1, 2021
Decision date	May 12, 2022
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ctl Medical Corporation</b>
Location	Addison, TX, US
Contact	Sean Suh
510(k) history	14 submissions · 14 cleared · 2017-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Omni Strategic Solutions, LLC</b>
Contact	Dhaval Saraiya

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213491/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026