

**K241130 "POINT" Kinguide Agile Hybrid Navigation System  
(PSHF01-000)**Jul 24, 2024  
91 days to decisionK241130 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k241130/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 24, 2024
Decision date	Jul 24, 2024
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Point Robotics MedTech, Inc.</b>
Location	New Taipei City, TW
Contact	Wayne Kao
510(k) history	5 submissions · 5 cleared · 2022-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241130/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026