

K230087 “POINT” Kinguide Agile Hybrid Navigation SystemJul 17, 2023
186 days to decisionK230087 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k230087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 12, 2023
Decision date	Jul 17, 2023
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Point Robotics MedTech, Inc.
Location	New Taipei City, TW
Contact	Sandy Lin
510(k) history	5 submissions · 5 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230087/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026