

**K243560 Remex Spine Surgery Navigation Instrument**Dec 13, 2024  
25 days to decisionK243560 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243560/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 18, 2024
Decision date	Dec 13, 2024
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Remex Medical Corp.</b>
Location	Taichung City, TW
Contact	Cheng-Hsiung Wang
510(k) history	5 submissions · 5 cleared · 2023-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243560/> 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 14, 2026