

**K233513 Remex Spine Surgery Navigation System II**May 1, 2024  
182 days to decisionK233513 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k233513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 1, 2023
Decision date	May 1, 2024
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233513/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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