

K251315 Anatase Spine Surgery Navigation System and Remex Spine Surgery Navigation System II

May 29, 2025
30 days to decisionK251315 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k251315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 29, 2025
Decision date	May 29, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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