

K220348 Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S and SNS-spine2-VJul 14, 2022
157 days to decisionK220348 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k220348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 7, 2022
Decision date	Jul 14, 2022
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Remex Medical Corporation
Location	Taichung, TW
Contact	Chuang Shih-Chang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Jin Services Co.
Contact	Sandy Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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