

K233725 Spine Navigation SystemJul 26, 2024
248 days to decisionK233725 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k233725/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 21, 2023
Decision date	Jul 26, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medivis, Inc.
Location	Brooklyn, NY, US
Contact	Amy Lynn
510(k) history	3 submissions · 3 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233725/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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