

**K233228 Spine Navigation and Robotic-Assistance Device**Jun 14, 2024  
260 days to decisionK233228 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k233228/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 28, 2023
Decision date	Jun 14, 2024
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ecential Robotics</b>
Location	Gieres, FR
Contact	Amanie Yazidi
510(k) history	6 submissions · 6 cleared · 2022-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233228/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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