

**K243258 Paradigm System**Feb 21, 2025  
129 days to decisionK243258 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243258/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 15, 2024
Decision date	Feb 21, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Proprio, Inc.</b>
Location	Seattle, WA, US
Contact	Shannon Eubanks
510(k) history	4 submissions · 4 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243258/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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