

**K241644 SPINEART Navigation Instrument System**Aug 7, 2024  
61 days to decisionK241644 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k241644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 7, 2024
Decision date	Aug 7, 2024
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spineart SA</b>
Location	Plan-Les-Ouates, CH
Contact	Estelle Lefevre
Website	<a href="https://www.spineart.com">https://www.spineart.com</a>
510(k) history	11 submissions · 11 cleared · 2019-2026

Spineart SA is a Swiss-based orthopedic medical device company founded in 2005. Headquartered in Geneva with a manufacturing facility in Plan-Les-Ouates, Switzerland, the company specializes in innovative spine surgery solutions. Their portfolio includes motion preservation technologies, posterior fixation systems, interbody fusion devices, and enabling surgical technologies. Spineart has received FDA 510(k) clearances from total submissions since 2019. The company focuses exclusively on orthopedic devices, with a strong emphasis on minimally invasive spine surgery instru...