

K242933 SPINEART Navigation Instrument SystemJun 18, 2025
266 days to decisionK242933 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k242933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 25, 2024
Decision date	Jun 18, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spineart SA
Location	Plan-Les-Ouates, CH
Contact	Estelle Lefevre
Website	https://www.spineart.com
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...