FDA 510(k) Premarket Notification

K254158 SPINEART Navigation Instrument System

CLEARED

Apr 9, 2026
108 days to decision

K254158 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k254158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 22, 2025
Decision date	Apr 9, 2026
Days to decision	108 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 Lefeuvre
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...