FDA 510(k) Premarket Notification

K261205 SPINEART Navigation Instrument System

CLEARED

Jul 29, 2026
107 days to decision

K261205 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k261205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 13, 2026
Decision date	Jul 29, 2026
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineart SA**
Location	Plan-Les-Ouates, CH
Contact	Estelle Godeau
Website	https://www.spineart.com
510(k) history	12 submissions · 12 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...