

K183630 SPINEART Navigation Instrument SystemJun 10, 2019
166 days to decisionK183630 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k183630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 26, 2018
Decision date	Jun 10, 2019
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spineart SA
Location	Plan-Les-Ouates, CH
Contact	Franck Pennesi
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...

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