

K230583 Tryptik TiMar 22, 2023
20 days to decisionK230583 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k230583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Mar 2, 2023
Decision date	Mar 22, 2023
Days to decision	20 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...
