

K253966 PERLA® TL Posterior Thoraco-lumbar Fixation System

May 1, 2026
141 days to decisionK253966 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k253966/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 11, 2025
Decision date	May 1, 2026
Days to decision	141 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...