

**K243693 NEO Pedicle Screw System™**Dec 23, 2024  
24 days to decisionK243693 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k243693/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 29, 2024
Decision date	Dec 23, 2024
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neo Medical SA</b>
Location	Villette (Lavaux), CH
Contact	Larsson Jonas
510(k) history	6 submissions · 6 cleared · 2017-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Meditec Consulting GmbH</b>
Contact	Dawn Balazs-Metz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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