

**K241863 Erisma® Lp Spinal Fixation System**Jul 24, 2024  
27 days to decisionK241863 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k241863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 27, 2024
Decision date	Jul 24, 2024
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Erisma® LP MIS

**APPLICANT**

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Company	<b>Clariance</b>
Location	Cumming, GA, US
Contact	Magalie Hennequin
510(k) history	10 submissions · 10 cleared · 2012-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Clariance, Inc.</b>
Contact	Magalie Hennequin

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

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