

**K183091 Elaris Pedicle Screw System**Aug 2, 2019  
269 days to decisionK183091 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k183091/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 6, 2018
Decision date	Aug 2, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinewelding AG</b>
Location	Schlieren, CH
Contact	Joerg Mayer
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice M. Hogan

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

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