

**K242900 VADER® Pedicle System and VADER®one Pedicle System**Feb 27, 2025  
157 days to decisionK242900 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k242900/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 23, 2024
Decision date	Feb 27, 2025
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Icotec AG</b>
Location	Altstaetten, SE
Contact	Vanessa Faessler
510(k) history	16 submissions · 16 cleared · 2016-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>MRCA, LLC</b>
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242900/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026