

K232628 VADER® Pedicle SystemFeb 26, 2024
181 days to decisionK232628 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k232628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 29, 2023
Decision date	Feb 26, 2024
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Icotec AG
Location	Altstaetten, SE
Contact	Marina Hess
510(k) history	16 submissions · 16 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
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.netDevice record: <https://www.510kdatabase.net/k232628/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026