

**K193423 VADER®one Pedicle System MIS and LightMore®
Pedicle System 6.0**May 22, 2020
165 days to decisionK193423 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k193423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 9, 2019
Decision date	May 22, 2020
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193423/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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