

**K190545 VADER® one Pedicle System MIS and LightMore®
Pedicle System 6.0**Jun 20, 2019
108 days to decisionK190545 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k190545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 4, 2019
Decision date	Jun 20, 2019
Days to decision	108 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/k190545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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