

**K230861 VADER® Pedicle System Navigated Instruments**Jun 27, 2023  
90 days to decisionK230861 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k230861/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 29, 2023
Decision date	Jun 27, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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

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

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