

**K201457 Auxein Brand Vertaux 5.5 mm Pedicle Screw System**Apr 6, 2021  
309 days to decisionK201457 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k201457/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 1, 2020
Decision date	Apr 6, 2021
Days to decision	309 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Auxein Medical Private Limited/71164</b>
Location	Sonipat, IN
Contact	Gaurav Luthra
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201457/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026