

**K192003 Auxein Nailing System**Jun 10, 2020  
320 days to decisionK192003 · Product code: **JDS** · Orthopedic  
Source: <https://www.510kdatabase.net/k192003/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nail, Fixation, Bone (JDS)
Date received	Jul 26, 2019
Decision date	Jun 10, 2020
Days to decision	320 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Auxein Medical Private Limited</b>
Location	Sonipat, IN
Contact	Rahul Luthra
510(k) history	12 submissions · 12 cleared · 2020-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192003/> 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 26, 2026