

**K181295 Genesys Spine AIS-C Cervical Stand-Alone System**Aug 29, 2018  
105 days to decisionK181295 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k181295/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 16, 2018
Decision date	Aug 29, 2018
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genesys Spine</b>
Location	Austin, TX, US
Contact	Benjamin V. Keller
510(k) history	31 submissions · 31 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181295/> 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 15, 2026