

**K192678 Genesys Spine Binary® Lumbar Plate System**Oct 24, 2019  
28 days to decisionK192678 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k192678/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 26, 2019
Decision date	Oct 24, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genesys Spine</b>
Location	Austin, TX, US
Contact	Chloe Lance
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/k192678/> 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