

**K223043 The Integrity Spine Core System**Mar 20, 2023  
179 days to decisionK223043 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k223043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 22, 2022
Decision date	Mar 20, 2023
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integrity Spine</b>
Location	Austin, TX, US
Contact	Timothy Leak
510(k) history	2 submissions · 2 cleared · 2013-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Jalex Medical, LLC</b>
Contact	Jennifer Palinchik

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223043/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026