

**K191581 Endoskeleton TL Interbody Fusion Device,  
Endoskeleton TL Hyperlordotic Interbody Fusion Device**Jan 8, 2020  
208 days to decisionK191581 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k191581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jun 14, 2019
Decision date	Jan 8, 2020
Days to decision	208 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Titan Spine, Inc.</b>
Location	Mequon, WI, US
Contact	Kelly McDonnell
510(k) history	5 submissions · 5 cleared · 2019-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mrc/X, LLC</b>
Contact	Christine Scifert

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191581/> 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 June 28, 2026