

**K192054 Endoskeleton TAS Plate**Aug 29, 2019  
29 days to decisionK192054 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k192054/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 31, 2019
Decision date	Aug 29, 2019
Days to decision	29 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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192054/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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