

**K183557 Endoskeleton® TA Interbody Fusion Device, Endoskeleton® TAS Interbody Fusion Device, Endoskeleton® TO Interbody Fusion Device, Endoskeleton® TT Interbody Fusion Device, Endoskeleton® TC Interbody Fusion Device, Endoskeleton® TCS Interbody Fusion Device, Endoskeleton® TL Interbody Fusion Device, Endoskeleton® TA Vertebral Body Replacement (VBR) Device**Feb 11, 2019  
53 days to decisionK183557 · Product code: ODP · Orthopedic  
Source: <https://www.510kdatabase.net/k183557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 20, 2018
Decision date	Feb 11, 2019
Days to decision	53 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	Jane Rodd
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

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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