

K191565 Endoskeleton TCS Interbody Fusion DeviceAug 6, 2019
54 days to decisionK191565 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k191565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 13, 2019
Decision date	Aug 6, 2019
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Mrc/X, LLC
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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