CLEARED

Feb 11, 2019
53 days to decision

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

K183557 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k183557/

SUBMISSION DETAILS

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

Company	**Titan Spine, Inc.**
Location	Mequon, WI, US
Contact	Jane Rodd
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