FDA 510(k) Premarket Notification

K192054 Endoskeleton TAS Plate

CLEARED

Aug 29, 2019
29 days to decision

K192054 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k192054/

SUBMISSION DETAILS

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

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