CLEARED

Aug 16, 2019
18 days to decision

K192018 Endoskeleton TA Interbody Fusion Device, Endoskeleton TAS and TAS Hyperlordotic 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

K192018 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k192018/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 29, 2019
Decision date	Aug 16, 2019
Days to decision	18 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