FDA 510(k) Premarket Notification

K163269 Endoskeleton(R) TAS Interbody Fusion Device / Endoskeleton(R) TAS Hyperlordotic Interbody Fusion Device

CLEARED

Apr 13, 2017
143 days to decision

K163269 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k163269/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Nov 21, 2016
Decision date	Apr 13, 2017
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Titan Spine, LLC**
Location	Mequon, WI, US
Contact	JANE RODD
510(k) history	14 submissions · 14 cleared · 2008-2018