FDA 510(k) Premarket Notification

K141953 ENDOSKELETON

CLEARED

Oct 27, 2014
101 days to decision

K141953 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k141953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 18, 2014
Decision date	Oct 27, 2014
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary
Other names	TA IBD AND VBR, TO AND TT, TAS, TC, TL

APPLICANT

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