FDA 510(k) Premarket Notification

K083714 ENDOSKELETON TT INTERBODY FUSION DEVICE (IBD)

CLEARED

Apr 15, 2009
121 days to decision

K083714 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k083714/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 15, 2008
Decision date	Apr 15, 2009
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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