FDA 510(k) Premarket Notification

CLEARED

K080615 ENDOSKELETON TA INTERBODY FUSION DEVICE (IBD)

Jun 17, 2008
105 days to decision

K080615 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k080615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 4, 2008
Decision date	Jun 17, 2008
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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