FDA 510(k) Premarket Notification

K153786 PROW FUSION-V

CLEARED

Jul 11, 2016
193 days to decision

K153786 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k153786/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 31, 2015
Decision date	Jul 11, 2016
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nlt Spine, Ltd.**
Location	Washington, Dc, DC, US
Contact	Eti Zinger
510(k) history	8 submissions · 8 cleared · 2011-2016