FDA 510(k) Premarket Notification

K181837 Spinal Elements Ti-Bond coated devices

CLEARED

Nov 2, 2018
115 days to decision

K181837 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181837/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 10, 2018
Decision date	Nov 2, 2018
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Elements, Inc.**
Location	Carlsbad, CA, US
Contact	Julie Lamothe
Website	https://www.spinalelements.com
510(k) history	48 submissions · 48 cleared · 2007-2026