FDA 510(k) Premarket Notification

CLEARED

K151184 InFill Interbody Fusion Devices

Jul 14, 2015
71 days to decision

K151184 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151184/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 4, 2015
Decision date	Jul 14, 2015
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pinnacle Spine Group, LLC**
Location	Dallas, TX, US
Contact	REBECCA K PINE
510(k) history	12 submissions · 12 cleared · 2011-2017