FDA 510(k) Premarket Notification

K150206 InFill Interbody Fusion Devices

CLEARED

Apr 3, 2015
64 days to decision

K150206 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k150206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 29, 2015
Decision date	Apr 3, 2015
Days to decision	64 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