FDA 510(k) Premarket Notification

K143143 PATHWAY ELIF

CLEARED

Jul 22, 2015
261 days to decision

K143143 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k143143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 3, 2014
Decision date	Jul 22, 2015
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Custom Spine, Inc.**
Location	Conway, NH, US
Contact	Mahmoud Abdelgany
510(k) history	12 submissions · 12 cleared · 2005-2015