FDA 510(k) Premarket Notification

K130438 AXLE INTERSPINOUS FUSION SYSTEM

CLEARED

Jun 27, 2013
126 days to decision

K130438 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k130438/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Feb 21, 2013
Decision date	Jun 27, 2013
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**X-Spine Systems, Inc.**
Location	Centerville, OH, US
Contact	DAVID KIRSCHMAN, M.D.
510(k) history	34 submissions · 34 cleared · 2005-2018