FDA 510(k) Premarket Notification

K112592 AXLE PEEK INTERSPINOUS FUSION SYSTEM

CLEARED

Dec 5, 2011
89 days to decision

K112592 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k112592/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Sep 7, 2011
Decision date	Dec 5, 2011
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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