FDA 510(k) Premarket Notification

K133340 SPINEWORKS ANTERIOR LUMBAR DEVICE

CLEARED

Apr 11, 2014
163 days to decision

K133340 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k133340/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 30, 2013
Decision date	Apr 11, 2014
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineworks, LLC**
Location	Washington, DC, US
Contact	ROBERT POGGIE, PHD
510(k) history	4 submissions · 4 cleared · 2005-2014