FDA 510(k) Premarket Notification

K123767 LANX FUSION SYSTEM- SA

CLEARED

Mar 18, 2013
101 days to decision

K123767 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k123767/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 7, 2012
Decision date	Mar 18, 2013
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lanx, Inc.**
Location	Broomfield, CO, US
Contact	Alan Burkholder
510(k) history	23 submissions · 23 cleared · 2009-2013