FDA 510(k) Premarket Notification

K121316 LANX SPINAL FIZATION SYSTEM

CLEARED

Sep 10, 2012
131 days to decision

K121316 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k121316/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 2, 2012
Decision date	Sep 10, 2012
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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