FDA 510(k) Premarket Notification

CLEARED

K100191 LANX POSTERIOR CERVICOTHORACIC SPINAL FIXATION SYSTEM (PCFS)

Apr 15, 2010
83 days to decision

K100191 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k100191/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Jan 22, 2010
Decision date	Apr 15, 2010
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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