FDA 510(k) Premarket Notification

K100888 MODIFICATION TO LANX POSTERIOR CERVICOTHORACIC SPINAL FIXATION SYSTEM

CLEARED

Nov 15, 2010
230 days to decision

K100888 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k100888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Mar 30, 2010
Decision date	Nov 15, 2010
Days to decision	230 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