FDA 510(k) Premarket Notification

K152211 PCT System

CLEARED

Dec 1, 2015
116 days to decision

K152211 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k152211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Aug 7, 2015
Decision date	Dec 1, 2015
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Centinel Spine, Inc.**
Location	West Chester, PA, US
Contact	JESSICA STAUB
510(k) history	10 submissions · 10 cleared · 2012-2018