FDA 510(k) Premarket Notification

K062513 APEX SPINE SYSTEM

CLEARED

Dec 22, 2006
116 days to decision

K062513 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k062513/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Aug 28, 2006
Decision date	Dec 22, 2006
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinecraft, Inc.**
Location	Westchester, IL, US
Contact	AMI AKALLAL-ASAAD
510(k) history	3 submissions · 3 cleared · 2006-2010