

K092825 APEX SPINE SYSTEM 5.50 MM TITANIUM ROD & POLYAXIAL SCREW WASHERMar 16, 2010
186 days to decisionK092825 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k092825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Sep 11, 2009
Decision date	Mar 16, 2010
Days to decision	186 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092825/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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