

K042635 DENALI SPINE SYSTEMJan 10, 2005
105 days to decisionK042635 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k042635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Sep 27, 2004
Decision date	Jan 10, 2005
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K2m, LLC
Location	Leesburg, VA, US
Contact	RICHARD W WOODS
510(k) history	8 submissions · 8 cleared · 2005-2018

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