

K081381 RANGE SPINAL SYSTEM, LARGE DENALI SCREWSJun 13, 2008
28 days to decisionK081381 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k081381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	May 16, 2008
Decision date	Jun 13, 2008
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K2m, Inc.
Location	Leesburg, VA, US
Contact	RICHARD W WOODS
510(k) history	100 submissions · 97 cleared · 2007-2026

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