

K121016 RANGE SPINAL SYSTEM (MESA AND DENALI)Jun 27, 2012
84 days to decisionK121016 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k121016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Apr 4, 2012
Decision date	Jun 27, 2012
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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