

K112037 RANGE SPINAL SYSTEM (MESA AND DENALI)Oct 6, 2011
80 days to decisionK112037 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k112037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jul 18, 2011
Decision date	Oct 6, 2011
Days to decision	80 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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