

K100851 RANGE SPINAL SYSTEMAug 2, 2010
129 days to decisionK100851 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k100851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Mar 26, 2010
Decision date	Aug 2, 2010
Days to decision	129 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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