

K120646 CAPSURE(R) PS SYSTEMJun 7, 2012
97 days to decisionK120646 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k120646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Mar 2, 2012
Decision date	Jun 7, 2012
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spine Wave, Inc.
Location	Shelton, CT, US
Contact	ROAIDA RIZKALLAH
510(k) history	57 submissions · 57 cleared · 2004-2025

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