

K111913 CAPSURE(R) PS SYSTEMAug 31, 2011
56 days to decisionK111913 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k111913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jul 6, 2011
Decision date	Aug 31, 2011
Days to decision	56 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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