

K100122 MODIFICATION TO CAPSURE PS SYSTEMFeb 12, 2010
28 days to decisionK100122 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k100122/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jan 15, 2010
Decision date	Feb 12, 2010
Days to decision	28 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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