

K100605 MIS SYSTEMJun 4, 2010
93 days to decisionK100605 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k100605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 3, 2010
Decision date	Jun 4, 2010
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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