FDA 510(k) Premarket Notification

K083353 CAPSURE(R) PS SYSTEM

CLEARED

Dec 11, 2008
28 days to decision

K083353 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k083353/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Nov 13, 2008
Decision date	Dec 11, 2008
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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k083353/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026