

K061342 MALIBU SPINAL SYSTEMOct 25, 2006
193 days to decisionK061342 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k061342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 15, 2006
Decision date	Oct 25, 2006
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seaspine, Inc.
Location	Vista, CA, US
Contact	DIANA SMITH
510(k) history	27 submissions · 27 cleared · 2005-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061342/> 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