

K140010 FORTRESS PEDICLE SCREW SYSTEMApr 23, 2014
111 days to decisionK140010 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k140010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 2, 2014
Decision date	Apr 23, 2014
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spineology, Inc.
Location	Stillwater, MN, US
Contact	Karen Roche
510(k) history	54 submissions · 51 cleared · 1999-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140010/> 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 17, 2026