

K143248 Reform Pedicle Screw SystemDec 19, 2014
37 days to decisionK143248 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k143248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 12, 2014
Decision date	Dec 19, 2014
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Precision Spine, Inc.
Location	Pear, MS, US
Contact	MICHAEL C. DAWSON
510(k) history	24 submissions · 24 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143248/> 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