

K163011 PHA S1 Spinal SystemJun 29, 2017
244 days to decisionK163011 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k163011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 28, 2016
Decision date	Jun 29, 2017
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phamedica, Inc.
Location	Plainview, NY, US
Contact	Henry Fam
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163011/> 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 16, 2026