

K123451 POLARIS SPINAL SYSTEM - BALLISTA II RODSDec 3, 2012
24 days to decisionK123451 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k123451/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 9, 2012
Decision date	Dec 3, 2012
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Spine (Aka Ebi, LLC)
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY MS, RAC
510(k) history	13 submissions · 13 cleared · 2010-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123451/> 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