

**K100409 POLARIS SPINAL SYSTEM, POLARIS/SYNERGY
STRUCTUE ANTERIOR FIXATION SYSTEM**Jun 23, 2010
127 days to decisionK100409 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k100409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 16, 2010
Decision date	Jun 23, 2010
Days to decision	127 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

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