

**K100438 POLARIS SPINAL SYSTEM, POLARIS/SYNERGY
STRUCTURE ANTERIOR FIXATION SYSTEM**Jun 23, 2010
126 days to decisionK100438 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k100438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 17, 2010
Decision date	Jun 23, 2010
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ebi, L.P.
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY
510(k) history	95 submissions · 94 cleared · 1997-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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