

**K132925 SAVANNAH-T, REDUCTION, SAVANNAH-T, HIGH-TOP,
SAVANNAH-T, MONOAXIAL MID-TOP, SAVANNAH-T, LOW-
TOP, SAVANNAH-LINK**Feb 11, 2014
146 days to decisionK132925 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k132925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 18, 2013
Decision date	Feb 11, 2014
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amendia, Inc.
Location	Apple Valley, MN, US
Contact	JOHN KAPITAN
510(k) history	16 submissions · 16 cleared · 2009-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132925/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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