

K111136 EXPEDIUM SPINE SYSTEM, VIPER SYSTEM, VIPER 2 SYSTEMJun 14, 2012
419 days to decisionK111136 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k111136/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 22, 2011
Decision date	Jun 14, 2012
Days to decision	419 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Depuy Spine, Inc.
Location	Raynham, MA, US
Contact	FRANK JURCZAK
510(k) history	68 submissions · 67 cleared · 2004-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111136/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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