

K090648 VIPER 2 SYSTEMJun 10, 2009
91 days to decisionK090648 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k090648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 11, 2009
Decision date	Jun 10, 2009
Days to decision	91 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/k090648/> 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 June 19, 2026