

**K111942 TSRH SPINAL SYSTEMS**Aug 30, 2011  
53 days to decisionK111942 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k111942/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 8, 2011
Decision date	Aug 30, 2011
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	LILA JOE
510(k) history	170 submissions · 159 cleared · 2000-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111942/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026