

**K030369 OPUS SPINAL SYSTEM**Aug 8, 2003  
185 days to decisionK030369 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k030369/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 4, 2003
Decision date	Aug 8, 2003
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Howmedica Osteonics Corp.</b>
Location	Allendale, NJ, US
Contact	KAREN ARIEMMA
510(k) history	288 submissions · 288 cleared · 1999-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030369/> 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 15, 2026