

**K160208 NILE Alternative Fixation Spinal System**Mar 18, 2016  
50 days to decisionK160208 · Product code: **OWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k160208/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Jan 28, 2016
Decision date	Mar 18, 2016
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>K2m, Inc.</b>
Location	Leesburg, VA, US
Contact	NANCY GIEZEN
510(k) history	100 submissions · 97 cleared · 2007-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160208/> 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