

**K113138 ALEUTIAN SYSTEM**Jan 10, 2012  
77 days to decisionK113138 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k113138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 25, 2011
Decision date	Jan 10, 2012
Days to decision	77 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/k113138/> 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 18, 2026