

**K123476 MEGA 5.5 SPINE SYSTEM**Jan 8, 2013  
56 days to decisionK123476 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k123476/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Nov 13, 2012
Decision date	Jan 8, 2013
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lsk Biopartners, Inc.</b>
Location	Salt Lake City, UT, US
Contact	SHIN KUK YOO
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123476/> 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