

**K091411 KNEEALIGN SYSTEM**Sep 25, 2009  
135 days to decisionK091411 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k091411/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 13, 2009
Decision date	Sep 25, 2009
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthalign, Inc.</b>
Location	Newport Beach, CA, US
Contact	AMY WALTERS
510(k) history	13 submissions · 13 cleared · 2009-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091411/> 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 26, 2026